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Improving Management of Atopic Dermatitis in Children and Adults with Novel Therapies

Announcer:
Welcome to CME on ReachMD. This activity, titled “Improving Management of Atopic Dermatitis in Children and Adults, with Novel Therapies,” is provided by Clinical Care Options, LLC, and the Partners for Advancing Clinical Education (PACE) and is supported by educational grants from Insight and Sanofi, and Regeneron Pharmaceutical. Prior to beginning the activity, please be sure to review the faculty and commercial support disclosure statements, as well as the learning objectives.

Ms. Garcia-Albea:
My name is Victoria Garcia-Albea. I go by Tori. I’m a nurse practitioner at Lahey Dermatology in Burlington, Massachusetts. Today’s talk is entitled, “Improving Management of Atopic Dermatitis in Children and Adults – Novel Therapies, Transition of Care and Healthcare Disparities.” I am so happy to be joined by Dr. Benjamin Ungar, Assistant Professor in the Department of Dermatology at the Icahn School of Medicine at Mount Sinai in New York City. Here are the disclosures. We have one learning objective – to identify patients who may benefit from new and emerging therapies for atopic dermatitis, based on patient factors and drug safety and efficacy. So, just a little background on atopic dermatitis. It affects about 11-25% of children. The most common onset is between 3-6 months of age. Of those diagnosed with atopic dermatitis, 60% develop it by 1 year of age, 90% by age 5 years. It does affect about 10% of adults. 10-30% of pediatric cases persist into adulthood, and 1 in 4 adults with atopic dermatitis report adult onset of symptoms. Black, Asian and Hispanic individuals are more likely to have atopic dermatitis than non-Hispanic whites.

And the clinical presentation is variable based on age. Infants tend to have it more focused on their cheeks, their forehead and scalp, because they can’t really move their bodies that much, so they kind of scratch against their car seat and whatever they’re leaning up against. They sometimes have it on their extensor extremities – their arms and legs, flexural creases. As they get a little bit older, they’re able to move more and control their body. They can scratch, so they have it more localized, so it’s in the flexural creases, dorsal hands and feet, and the cheeks. Adolescents are starting to look a little bit more like the adult presentation, where it’s, again, more focused. Palms and soles, face and neck. And then adults – flexural creases, dorsal hands and feet.

We wanted to put in this slide here, just reminding you that when you have a patient with darker skin, the erythema is going to be harder to appreciate. It’s going to look more violaceous. You’re going to look for lichenification, again that violaceous rather than like that bright red color, but it will have the same distribution.

And, as we know with psoriasis, there are several comorbidities that affect atopic dermatitis. So we, of course, know about the atopic tetrad atopy, asthma, food allergies, allergic rhinitis, conjunctivitis, eosinophilic esophagitis. There’s immune-mediated conditions, like alopecia areata and urticaria, that our atopic derm patients are more at risk of getting. There’s mental health and substance use concerns – depression, anxiety, self-harm, substance use, ADHD and autism spectrum disorders. We’re now learning, scarily enough, that there are cardiovascular disease comorbidities, so hypertension, coronary and peripheral artery disease, congestive heart failure, thromboembo – thromboembolic diseases. And then, metabolic disorders – obesity, dyslipidemia. Bone health – osteoporosis and fractures, and skin infections.

So we’re going to get into the treatment and management of this common disease. So we’re going to start with a case study. It’s an 11-year-old girl, who comes in with her mother. She was diagnosed with atopic dermatitis at age 4, and she’s had cyclical atopic dermatitis

control after nonpharmacological and topical therapies were insufficient. We're going to hear from an actual patient and her mother, who are describing the burdens of atopic dermatitis, and significant impact of effective treatment when they were able to get it. So let's listen now.

Patient:
Eczema has really affected my life. Whenever people usually ask about it, I get really shy and I get – I don't really talk to them that much, so usually I'm really shy. Again, I don't really talk about it a lot in front of my friends. And most of the people at the school that I go to don't really know that I have it, so… A few years ago, I wasn't able to sleep with it a whole bunch, so I didn't really get sleep that often. So I got really tired, and I couldn't do a lot of stuff in school, so…

Parent:
Scratching while she's asleep has – she's done that since she was a baby. And sometimes scratching until she's bleeding, and then blood on her sheets or her pajamas. It has not been something that's been unusual. Missing school for medical appointments has been something that's come up, or trying to explain what's going on to her teachers, or if she needs special stuff – special hand sanitizer. Her doctor told me that she needed to try something systemic, and at that time there really wasn't – there wasn't anything on the market that was approved for her age group, so we had to use an oral medication that was not approved for eczema.

It's a oral chemotherapy agent, and they require blood draws, have a lot of risks, not a long-term option. The biologics, we were able to eventually get about 6 months later, because we had a doctor that worked with us. Then we went through FDA compassionate care.

Patient:
For like, injections, like, I'd do it if it helps even a little bit. My eczema gets a lot better, and I don't itch as much afterwards. I am getting up to my fourth year with shots, and so I also use lotion daily. It really helps, like, I used to have rashes all over my face and now I really don't, and there are a lot of things that have been helping me.

Dr. Ungar:
So, I'll get started on treatment options, and the approach to, you know, care for atopic dermatitis. And the idea of approaching this treatment of this disease spans the whole spectrum, from mild to severe disease, which we'll get into. But the basic idea is this kind of step-care management approach, where there are nonpharmacologic approaches, topical treatments and then systemic treatments, depending on the disease severity and response to the treatments. And so this is an overview, but we're going to go into the details of all of these, with the idea of trying to treat flares, and then continue with maintenance therapy with the goal of reducing or hopefully eliminating flares.

And so, the first, you know, key is to identify the AD disease severity, and if it's in the mild to moderate range, there may be a little bit of a different approach initially, as opposed to the moderate to severe range, although the whole spectrum and the kind of approach from start to finish can be applied, again based on the response to treatment, and how well patients are doing.

And so in this mild to moderate range for AD, nonpharmacologic therapy is crucial and can be a very, very big impact, in terms of preventing disease flares. And then once patients are clear, to keep them clear as well. And so, part of it may be identifying triggers that lead to flares. Sometimes that can mean allergy testing, when patients have sensitivities to different external allergens, such as fragrances and so on. Baths or showers – you know, bathing habits can have a big impact. Frequent and long, hot baths or showers can lead to drying out of the skin. Harsh soaps or cleansers can also contribute to that. Often, use of periodic bleach baths can help prevent flares as well, and so depending on the age of the patient, you can use a different amount of bleach, you know, 2-3 times a week and that can be very effective in helping to prevent flares. And then, very crucially is very frequent and liberal application of moisturizers, to keep the skin moist, because the dry skin is a very important contributing factor to flares and disease recurrence.

Once nonpharmacologic interventions are not sufficient to prevent the disease from flaring or progressing, then traditional topical therapies may be used as well. And there are a few different classes available. So, certainly the most commonly used and in some respects, the most versatile, are topical corticosteroids, considered first-line treatments in patients who don't respond to those skin care routines – emollient use and so on. And, typically these are applied, you know, 1-2 times a day – probably more commonly 2 times a day. And one of the major issues with them is addressing patient attitudes towards steroids – many patients have steroid phobias. And then, the flip side of that is to make sure that they're appropriately educated and aware of the risk of side effects with long term use, and so have an appropriate plan and clear instructions on the frequency and duration of use.

Alternatives or second-line treatments may include topical calcineurin inhibitors, like tacrolimus ointment or pimecrolimus cream. These can be used in the short term. You know, sometimes it can be used for a little longer, given, you know, less of a risk of the kind of long term side effects that are associated with topical steroid use. It's important to counsel patients that for the first few applications, there may be burning or stinging, which sometimes can be pretty significant, so that it's important to make sure they're aware so they don't

stop after the first treatment. And then, another option is Crisaborole, phosphodiesterase 4 inhibitor. It's an ointment that's safe for use in infants and older, and again, there can be significant burning, discomfort and pain with application, so it's very important that patients are aware of that, and they can factor that into the use.

Okay, and so, that's kind of the initial treatment approach for mild to moderate AD. Sometimes that's not sufficient, and sometimes the disease is more widespread and more significant, and if, you know, nonpharmacologic treatments and topical options are insufficient, when optimized of course, then it's very important to consider and, you know, not have a very, very high barrier to use of a systemic treatment.

And so, traditional systemic therapies have been used, you know, until relatively recently very commonly. The goal, of course, is to try to use the minimal effective dose, once there is a treatment response – and a sustained treatment response – and then go to the minimal dose effective, to again keep patients clear or doing well. Adjunctive therapies, both nonpharmacologic and topicals, are important as well. And, you know, it's very, very important to remember to try to avoid systemic corticosteroids, if at all possible. There's a very significant risk of a rebound flare, after taper completion, even if tapered slowly, and this can be even more difficult to treat often. There are some scenarios for very acute, severe exacerbations, used as a bridge therapy to other systemic treatments where it may be appropriate.

Some of the traditional systemic treatments that are used include cyclosporine, azathioprine and methotrexate mycophenolate. Cyclosporine tends to work the most quickly of all of these, and, you know, the rest of them can be effective with time as well.

And so we mentioned, you know, the kind of traditional systemic treatments – the traditional systemic, immunosuppressive treatments, and one reason they're used less frequently now, and you know, certainly should be used with caution, is that they are all associated with very significant, you know, side effects and risks. All of these vary, from treatment to treatment, and so when, you know, considering the use, it's very important to really remind yourself and be aware of the different risks. That includes appropriate screening bloodwork, and monitoring as well. And, you know, some patients may not be candidates for some versus others – you know, for example, someone with significant renal impairment may not be the most appropriate candidate for cyclosporine. These systemic treatments, you know, the kind of traditional ones are certainly associated with all those side effects, and so fortunately, now we're in an age where there are safe – much safer, and you know, typically more effective systemic treatment options that can be used as well.

And so, the first of these that was approved now, a little more than 5 years ago, is dupilumab, indicated for moderate to severe AD going down all the way to 6 months of age and older. More recently – within the last year – another biologic, you know, cytokine targeting therapy – tralokinumab, which – and I forgot to mention, you know, dupilumab blocks the IL-4 alpha receptor, which inhibits both IL-4 and IL-13 signaling. Tralokinumab, which is newer now, approved about 9 months ago inhibits IL-13 for adults. There's a new topical JAK inhibitor – a new topical, nonsteroidal, anti-inflammatory option, approved just about a year ago. It's indicated for mild to moderate AD patients, 12 years and up, and can be used twice daily. And then, lastly, and most recently, at the beginning of this year, 2 oral systemic JAK inhibitors, that both inhibit the JAK-1 signaling, are approved for moderate to severe AD. So, abrocitinib in adults, upadacitinib in adolescents 12 years and adults as well. Both are taken orally, and once daily.

So, when considering dupilumab – so again, you know, this has been approved now for the last 5 years, most recently earlier this year approved for 6 months and older. So, for patients older than 6, there's a loading dose of 2 injections. For those younger, there's no loading dose necessary. And then after that, there's a continued treatment for every 2 weeks typically, and sometimes that can be stretched out, depending on the agents, so on to every 4 weeks. Typically, it's very well tolerated, but there are some common adverse events to be aware of.

So most commonly, injection site reactions, which can be – lead to, you know, erythema, and some pain at the area of infection. Conjunctivitis, often itchy red eyes that can certainly play a role fairly commonly. And then, there are some more significant adverse events that are much less common, but should be aware of – rather, both you and the patient should be aware of – urticaria, angioedema, more significant reactions like erythema multiforme, facial erythema which is a rash that is accompanied with treatment, looks different than the atopic dermatitis that would normally be there. And then, not common exactly but also importantly, ocular symptoms that extend beyond conjunctivitis – blepharitis, keratitis, and so on. Keep ophthalmologists in mind if patients develop those symptoms.

Okay, so the dupilumab treatment is based on some significant clinical trials, which showed that moderate to severe AD patients responded very well, with every week or every other week, and ultimately it was approved for every other week, versus placebo. And importantly here is the orange parts of the graph which is that every other week dosing that was improved. It's important to know that patients in this study were able to use topical corticosteroids or topical calcineurin inhibitors, which from the perspective of the clinical trial itself, may, you know, muddy the waters a little bit, but the reality is that in real world practice, as we know, it's important to use adjunctive treatments when necessary, such as topical steroids or topical calcineurin inhibitors, or potentially some other options that

we've discussed as well. And so the IGA score – the investigator global assessment response – was pretty significant. EASI75 responses, which essentially are 75% improvement in disease severity, and you can see here at week 16, there's almost 70% of patients achieving that result, and then that was maintained with continued treatment for 52 weeks – a year. And now we have data that extends beyond that, showing continued response for many patients.

It's very important also, that we consider the patient experience with these treatments. You know, it's – I think many of us have the perspective of having the patient in front of us, and looking, and examining them, and saying okay I see some erythema, I see some eczematous lesions. But ultimately, it's very, very important to remember the patient treatment perspective, which is that they want to feel better. They want to have the improved quality of life. And so, when we look at a dupilumab, you know, patient-oriented eczema measures, we can again see that there are very significant responses here. And so, the number of days here with itchy skin in the past week – and you can see over there on the right, the responses with treatment. So even at 16 weeks, 4 months of treatment, you know, a nontrivial percent of patients had no days of itching at all. Another large block had 1-2 days of itching, you know, and so on. So definitely a significant improvement and can be very effective.

So more recently, tralokinumab. Again, IL-13 inhibitor, approved several months ago. And so, the initial dose maybe is a little more onerous. There are 4 initial loading injections, and then after that it's 2 injections every 2 weeks. Important to note that on the FDA label, there is the potential to decrease to treatment every 4 weeks for patients who weigh less than 100 kilograms, and who had that response that are – they are clear or nearly clear after 16 weeks. So that is something that potentially can be considered in that patient population. Similar to dupilumab, there are injection site reactions that are associated with it. Upper respiratory type tract infections and headaches as well. Again, nothing too significant. And then, more significant but much more rare adverse events including ocular symptoms similarly. It seems – and we're still collecting data regarding this, so maybe a little less common than dupilumab, but that remains to be seen – and so, there are these kind of rare, ocular complications as well.

And so here are some of the efficacy data that were published in the pivotal trials for tralokinumab. And so, again here, you know, the every 2 weeks which is in blue is perhaps the most relevant for the vast majority of patients, but looking at the every 4 week dosing is relevant because that is an option for a, you know, not insignificant subset of patients on this treatment. And we can see here that, you know, using the IGA score of 0 or 1, which is clear or almost clear, and you know, these are all moderate to severe patients at enrollment, or that EASI75 response, which is a 75% improvement in treatment. We see here, you know, 50, 60% of patients, depending on, kind of which specific measure you want to use, have that – I think what would be considered to be a very good response to treatment. The numbers are a little lower overall for the every 4 week dosing, so that's something to just be mindful of, if you do decide to head in the direction of reducing the dosing frequency – just to monitor and be aware of whether the patients maintain that response, or perhaps need to be on every 2 week treatment.

And then the other class of treatments that have recently been approved and begun use in clinical practice are the systemic JAK inhibitors – 2 of them, both with the same target, JAK-1 – abrocitinib and upadacitinib. They are approved for moderate to severe AD patients who are not controlled by, or in those who cannot use, other systemic therapies including biologics. You know, this is a little bit of a vague wording, so I think, you know, whether someone's not controlled or can't use other systemic therapies is a judgment call by you and in conversation with the patient. So some of the potential benefits are that it – you know, there is not the immunogenicity concerns that may be accompanied by monoclonal antibodies that can produce potentially antibodies – the body can produce antibodies against those monoclonal antibodies. Many patients may not want to inject themselves, you know, on a ongoing basis, and so oral therapy may be preferred.

And, you know, there is a potential for flexible dosing schedules. You know, this is approved for daily use, but the reality is that because it works very quickly, and there is not these concerns for, you know, use and then stopping use and the development of antibodies, there – you know, there's the potential for shorter term use, to treat flares, active disease and then, you know, maybe have a different regimen potentially, if the disease is well-controlled with the idea in mind that, you know, down the road, you know, the dosing can be adjusted in a more, kind of nimble way than the biologics, which you know are only administered every 2 weeks or every 4 weeks or so on.

The pivotal trials for the JAK inhibitors certainly show that they're very effective. So the JADE EXTEND trial was for the abrocitinib, and you can see here again, without going into too much of the details, that the responses – and there were 2 different doses that I forgot to mention for both of these treatments. The recommendation is to start at the lower dose, and then titrate up if needed. And so, for abrocitinib that's 100 milligrams daily or 200 for the higher dosing. And so, you know, these patients were treated initially with dupilumab, washed out, and then treated with abrocitinib. And for patients who responded to dupilumab, you know, again using different metrics – IGA 0-1, EASI75 – you see, you know, 75 and 90% responses. EASI90, which is a much more stringent kind of target for response, even that 80%. The itch scale – peak pruritis itch scale – again, a large majority of patients doing very well. And as you can

see, the numbers go up with the higher dose, and so if someone's inadequately controlled on the lower dose, that's a consideration as well. Dupilumab non-responders, similarly, you know, a not insignificant proportion of them responded to abrocitinib treatment as well. As you can imagine, with one treatment not working, the numbers were not as good for a second treatment, but still shows that it can be efficacious in that population.

They also did a head-to-head study, comparing upadacitinib and dupilumab, and here you can see that the numbers favor upadacitinib, at least a bit. So this was, you know, 71% versus 61% EASI75 response, and this is after 16 weeks of treatment. They separate it out a little more at the EASI90 level, and so that's, you know, depending on whether EASI75 for an individual patient is sufficient control. You know, upadacitinib may be a consideration as well. And similarly, the decreased and worse pruritis followed along the clinical efficacy from the IGA or EASI perspective.

Now, the flip side of the JAK inhibitor use is that there are considerations, or potential concerns, for safety. There are common adverse events associated with them, the most common being acne, or kind of an acneiform eruption that develops with treatment, as well as nasopharyngitis, nausea, upper respiratory tract infections.

You know, many of the kinds of side effects we see with many of these treatments. And then, perhaps most importantly, and it's something that's very, I think, high on the minds of people who consider this treatment – is that the FDA has a black box warning for several, you know, potentially very significant side effects for use of these treatments. So, the 5 that they list are serious infections, and they – and it's required to screen for tuberculosis and hepatitis viruses prior to treatment, all-cause mortality, malignancies such as lymphoma, major cardiovascular events, cardiovascular death, heart attacks, stroke, and then thrombotic and thromboembolic events – DVT, PE, arterial thrombosis and so on. When considering JAK inhibitor, it's important to have those risks, or potential risks, in mind. So that includes, you know, appropriate – age-appropriate – cancer screening, given that potential risk of malignancy, screening for risk factors for cardiovascular and thromboembolic, potential risks, so smoking, someone with a history of a clot, and so on. And then, you know, monitoring as well. And, you know, it is, I think, important to note that so far, in terms of the clinical trials that have been done, monitoring for all these risks, there have been minimal if any of these side effects. Longer term data certainly is needed, but so far, according to the best data that we have for treatments – for these treatments in these populations, these risks don't seem to be bearing out in a very significant way. And so I think that, you know, keeping them in mind and then – as well as screening, you know, as appropriate, monitoring bloodwork and so on, these can really be excellent options for treatment.

There are also additional emerging options for AD that are in late-phase clinical trials, and show I think a lot of promise. So in the moderate to severe range, another anti-IL-13 therapy – so in addition to tralokinumab, lebrikizumab which is very promising as well. Nemolizumab which targets anti-IL-31, the "itch cytokine," and then in terms of – for the mild to moderate range, 2 additional nonsteroidal topical anti-inflammatories, so tapinarof and aryl hydrocarbon receptor modulator, which was recently approved for psoriasis. And then, similarly, another phosphodiesterase 4 inhibitors, roflumilast, which also was recently approved for psoriasis. And both of these have very promising, you know, initial results in the clinical trials thus far, and now in phase 3, hopefully these may be options for us to use in the future as well.

Ms. Garcia-Albea:
The answer is dupilumab.

Ms. Garcia-Albea:
My name is Victoria Garcia-Albea. I go by Tori. I'm a nurse practitioner at Lahey Dermatology in Burlington, Massachusetts. Today's talk is entitled, "Improving Management of Atopic Dermatitis in Children and Adults – Novel Therapies, Transition of Care and Healthcare Disparities."

I am so happy to be joined by Dr. Robert Sidbury, and Dr. Benjamin Ungar. Dr. Robert Sidbury is the Chief of the Division of Dermatology at Seattle Children's Hospital. He's a professor in the Department of Pediatrics at the University of Washington School of Medicine in Seattle. And Dr. Benjamin Ungar is an Assistant Professor in the Department of Dermatology at the Icahn School of Medicine at Mount Sinai in New York City, and they are going to help me present this talk. Here are their disclosures.

We have one learning objective, which is discuss the components, goals and benefits of an effective transition from pediatric to adult atopic dermatitis care, with adolescent and young adult patients and their caregivers. So we're going to talk about healthcare transitions. I think it's something that we don't think about as much as I need to. So we have a case study. It's a 19-year-old patient, who's new to the adult atopic dermatitis care team. They were diagnosed with moderate to severe atopic dermatitis in childhood. So we're going to hear from Kyle, as a young adult describing his experience transitioning from pediatric to adult dermatology care. Here we go, take a listen.

Kyle:

Transitioning from pediatric doctors to my adult doctors now, has been quite the challenge, because it's just like you're restarting from scratch. Yes, they can get their files from before, but are they going to follow those? Are they going to look at that and say, okay they tried this, let's try this? I found that it was repetitive once I switched over to that. It was the same treatment that he wanted – that I was given. It was constantly the same until I found a different doctor, and I feel like that bond between a patient and a doctor is significant in the treatment that you receive. If you don't have that bond with your doctor, or you can't look at them and have an honest conversation about how you're feeling and the treatment that you're on, you can't truly get the best from your doctor if you don't have that personal connection.

So during the transition, I didn't notice a difference in my skin because I had my treatment that just carried over. It was hard going from that to a different doctor, having to travel because we didn't have any dermatologists near us. It was a pain because you're going from the pediatric side, where you've had that bond your whole life with them, and then you go to this new person who knows nothing about you, and it just made it hard for me because they were adamant that we try different things, that I knew weren't going to work because I'd tried them before. So, it definitely took time to adjust but once we found the doctor that fit us, it made it a lot easier. (pause)

Ms. Garcia-Albea:
So nice to hear from another patient, but I think he points out some challenges that we all can be more aware of.

Dr. Sidbury:
We'll talk about barriers to self-management now. You know, there are a lot of issues with – with barriers to self-management and transitions to care. First of all, there's lack of information and confusion about disease and treatments. Historically not a huge problem with atopic dermatitis, because we had so few, but as Tori and Dr. Ungar have nicely highlighted thus far, we have a wealth of new treatments which can lead to a wealth of confusion, and so that's something that we need to manage. We need to hear conflicting and concerning information about these treatments. Topical corticosteroid-phobia is a huge deal, and despite all the – our new treatments, topical corticosteroids are a foundation for us still, and we need to make sure patients are comfortable with them. We also need to take the time, and sort of go over the issues with both non-pharmacologic and pharmacologic therapy. We need to talk about side effects and we need to not just dismiss, but hear and address doubts about efficacy that patients may have. So all of these things are critical.

In terms of healthcare transitions from adolescent to adult care, we need to empower our patients. I've worked in a children's hospital all my life, and we frankly coddle our patients. We're very parental in that regard, and we're proud of that fact, but there's some harm to that in the sense that patients miss an appointment, we'll call them. You know, why – what's going on? Is everything okay? And then as they get older and they transition to adult care, that's not necessarily the structure they're going to be entering into, so we need to empower the child and the parents as they start to make their transition. We need to communicate with our adult providers, from our perspective. The adult providers need to communicate with us, and the parents need to be in that sort of triangulated form of care so that the patient themself is taken care of. We need to monitor and assess for progress. We need to involve the whole family, and all of this is critical to taking care of patients properly as we transition them to the adult world.

So that transition starts early. Starts at age 11-13. This is when I think we should really start talking about this. Some dermatology programs that I'm aware of, including ours, don't see patients any older than 16 any longer, so that's a fairly young age, and we need to make parents aware of that, we need to make kids aware of that, and start that process of education and empowerment earlier. And that support can last for awhile, up until 25 years of age or so, until we start to really make sure that the patient is embedded into the new system of care, and going to be taken care of in the way that we want them to be taken care of.

So, we – these are all about making sure all of this happens, and there are tools to help us. This is not something we need to reinvent the wheel here. There are track – surveys and questionnaires that you can use that are going to be made available to you, that have these sort of check lists with these knowledge and skills to assess. Is the patient ready to make this transition? We need to do motivational interviewing. We need to ask, we need to listen, we need to hear that they are not just parroting information we're saying, but actually hearing us and able to act on it.

And then we need to engage in shared decision making. And that's true with every aspect of care, but in particular this one. And that involves the components that we're also used to. You know, shared decision making for me is a concept which is very popular now. It's something we should have been doing as providers forever. We should always try to encourage trust, listen to our patients, make sure that they feel they are being heard. We have very short, quick appointments. We need to make sure that during those appointments, we are not making the patients feel like they're short, quick appointments, and that's a hard trick to do. That's part of the art of medicine.

We need to individualize our treatment. We need to make sure we're not force feeding a plan that's not really aligned with a patient's goals. We need to hear what their biggest problem is. If they've got atopic dermatitis, maybe it's the sleep loss. Maybe it's the visible appearance of the rash. What is it that they want addressed first and most? And that's where we target our therapies. And then finally, of course, we need to educate. Treatment options, all of the fears, misconceptions, all of these things we've been talking about, and written

action plans can help us there.

This is an example from the National Jewish Hospital, a wonderful mecca for allergic and atopic diseases, and it just shows you a dynamic plan for taking care of patients with atopic dermatitis. What happens when they're doing reasonably well? Well, maybe it's just bathing and moisturizing properly. When things flare a little bit, perhaps we'll have something for the face, something for the body, whether it's a topical steroid or nonsteroid, and instructions on how to use that. And when things flare, we've got a plan that's further and more aggressive to address that. So, we all know how dynamic this condition is. We need to make sure that the parents and the patient have a dynamic plan to match it.

So, that's the, sort of, pediatric perspective. As far as I'm concerned, we need to collaborate, we need to educate, we need to write these things down, and we need to make sure that there's appropriate overlap.

Dr. Unger, from your perspective, sort of receiving these pediatric patients, how does that jive with your practice?

Dr. Ungar:
Yeah, no, absolutely. I think that's so critical, and, you know, this is, unfortunately, right now a lifelong disease, and so having patients learn to manage their disease, to factor in the kind of different strategies to help them specifically improve is crucial. And, you know, inheriting patients who are aware of that, you know, it makes continued treatment that much easier and sort of aligned, in terms of goals and plans. And, you know, having them plugged in to that kind of healthcare setting, where they feel comfortable with the continued treatment is very crucial.

Ms. Garcia-Albea:

So we're going to get into our case discussion.

Dr. Sidbury:
Indeed. This is a child with moderate atopic dermatitis. Diagnosed early, at 6 months of age, which as we see is so common of these kids, developing symptoms very, very early. Just entered first grade, is having issues with sleep, focusing, irritability, teacher's just saying she's not interacting with her peers very much, and has noticed that some kids are asking about her rashes. And, so that's the story. Her physical exam shows 12% body surface area involvement, typically flexural involvement and involvement on the face. So, here the sort of thoughts we come up with when we see a patient like this – what are the different topical therapies we might use. You know, things like topical calcineurin inhibitors are nonsteroidal options – Crisaborole. Nonsteroidal options have proved down to 3 months of age now. Or is this a child you might think about with dupilumab, such as we've talked about? And so, those are sort of the issues with this case, and if you are, in fact, thinking in this particular patient of dupilumab, how do you discuss this sort of injectable therapy with the family? And so, for me, you know, these are huge issues. First of all, we have to deal with steroid phobia, so we want to address that question, because a patient with mild to moderate disease, that may be all they need. Moderate to severe, it's still probably part of their care. Nonsteroidal options like topical calcineurin inhibitors have boxed warning, which sometimes are not necessarily the greatest balm for steroid phobia, so you need to navigate through those waters as well. And then, Crisaborole – nonsteroidal, no boxed warning, but a fair number of my patients have had some application site stinging, so that can be a big barrier that you will need to work around. With regard to dupilumab, you know, it's a shot. This is a young child. How do you deal with that? These are things we need to equip our parents with, with strategies about how to make those injections more tolerable. So these are all things that I work with my patients through, and my parents through. Tori, is that something that you do as well?

Ms. Garcia-Albea:
It is, and I'm going to pop us ahead to this slide, because I think when you're trying to decide, especially in a 6-year-old, whether an injection treatment is the best method of treating them, you have to take into consideration all of these comorbidities, because the shot becomes more tolerable if it is going to reduce – you know, like we have sort of highlighted here – the distress of their disease. So, I think I present it like that to my patients and their families, like you know, I know it's going to be a big step up from using these creams, but on the other side, look at how happy your child might be, you know, in just a matter of weeks. What do you think?

Dr. Sidbury:
Totally. Totally agree with that and, you know, it's – you know, we have to make these treatments fit the patient, and it's, you know, first and foremost does the severity warrant consideration of a therapy like this, and that's where those comorbidities that you just talked about can get into that. As we know, dupilumab treats atopic dermatitis and asthma, so if patients have a certain type of asthma, that may be a treatment for both conditions with the same medication. So, I think those are probably the key issues with this first case.

Ms. Garcia-Albea:
The only other point I want to make is, similar to psoriasis, of course we use body surface area a lot in determining severity, but certain body parts bump up the severity, so you know, genitalia, face, hands, et cetera. And I think we can borrow from the psoriasis literature

to the atopic derm patient, in this case, where even if their BSA isn't that extensive – I don't think it was really commented on in this case study, but if they're very, very bothered and distressed, that increases their severity. So then, you can count it as more moderate to severe disease, because of its impact on their overall psyche.

Dr. Sidbury:
Yeah, I think that's a just absolutely wonderful point, and the other thing – sort of analogous to that is if some of the providers listening to us aren't as familiar prescribing some of these medications, you know, historically with a condition like atopic dermatitis, we just put in our chart, oh that patient's severe therefore we're going to prescribe X. Well, here I think, because of these new medications, they're more expensive, insurance companies are going to scrutinize these prescriptions more. I think it's important to become savvy with some of the metrics that they're going to look for, like the Investigator Global Assessment. If you're thinking about prescribing a medication such as dupilumab, that's indicated for moderate to severe patients, then by definition, those patients are going to need to have an Investigator Global Assessment score of 3 or 4 – moderate or severe. And then, the body surface area you mentioned is good to comment on as well, and then special body parts as well that might, sort of, amplify the significance in terms of quality of life. Absolutely a great point.

Ms. Garcia-Albea:
We have some really great questions that the audience has been sending in. Are there any lifestyle recommendations in reducing AD symptoms? Does diet have any influence on severity or recurrences?

Dr. Sidbury:
So, for sure. You know, reducing irritants, things that are known to be challenging for their skin. So, wool sweaters are never going to be good birthday presents for someone with atopic dermatitis. There are certain things that are always going to irritate the skin. Of course, you want to minimize those. If certain patients are triggered by heat, and so minimizing, and cooling environments – things like that are good. Food is a huge, huge question, because it's forever and a day been linked to atopic dermatitis – food allergies, and there are certainly patients who have food allergy-driven atopic dermatitis. But the vast majority of patients with atopic dermatitis – though they may have a food allergy, that is not the primary cause of their eczema. So certainly you want to avoid it, to minimize any symptoms of allergic rhinitis or conjunctivitis or other allergic symptoms, but just focusing on food when trying to treat atopic dermatitis oftentimes leads to minimizing or misprioritization of things that are much, much more important, like proper bathing and moisturization, and those sorts of things.

Ms. Garcia-Albea:
Alright. And I think we have time for, probably one more. At what point should a patient with atopic dermatitis be tested for an autoimmune disease, to rule out that as an underlying cause?

Dr. Ungar:
I mean, I can take that briefly. You know, there are associations with autoinflammatory and autoimmune diseases, in general. The link with AD to individual, specific ones is not super clear cut, so I personally don't do routine screening. I think, you know, it's important to be aware of certain conditions like alopecia areata which may be somewhat visible, and you know, there's a potential for, you know, easy screening for things like, you know, thyroid disease, certain questions about, you know, heat and cold intolerance, and so on that may be useful, but personally, as a general rule, you know, the AD tends to be kind of idiopathic and sort of unexplained, and I don't necessarily go down the path of looking for other conditions in the absence of, you know, clear reasons to do so.

Ms. Garcia-Albea:
I agree. If you feel the diagnosis is atopic dermatitis, I don't look for an autoimmune disease. If the diagnosis is unclear, certainly, but if it's atopic dermatitis, I don't run any labs or anything like that unless there's reason to do so.

Ms. Garcia-Albea:
My name is Victoria Garcia-Albea. I go by Tori. I'm a nurse practitioner at Lahey Dermatology in Burlington, Massachusetts. Today's talk is entitled, "Improving Management of Atopic Dermatitis in Children and Adults – Novel Therapies, Transition of Care and Healthcare Disparities." I am so happy to be joined by Dr. Robert Sidbury, and Dr. Benjamin Ungar. Dr. Robert Sidbury is the Chief of the Division of Dermatology at Seattle Children's Hospital. He's a professor in the Department of Pediatrics at the University of Washington School of Medicine in Seattle. And Dr. Benjamin Ungar is an Assistant Professor in the Department of Dermatology at the Icahn School of Medicine at Mount Sinai in New York City, and they are going to help me present this talk. Here are their disclosures.

We have one learning objective, which is apply strategies to address healthcare disparities in clinical practice, to improve the management of atopic dermatitis. So now we're going to talk about reducing healthcare disparities, which is of course a very important aspect of the care we provide. So, the final case study for this presentation is a woman, mid-30s, Latin-x female who was diagnosed with atopic dermatitis in infancy. She moved to the United States as an infant. Parents were not fluent in English. We're going to hear

what she experienced, in her own words. Take a listen.

Unknown Female Patient:
I definitely faced a lot of disparities throughout my journey living with atopic dermatitis, even starting off as a baby being diagnosed with it. My parents are immigrants from Dominican Republic, and so they didn't really know or understand what I was going through at that time. They really just trusted anything and anyone with a white coat on, as they were desperate for me to just heal. They didn't really have the knowledge and awareness to do their own research, and to ask certain questions. I feel like that really impacted my journey, as I wasn't really given any options. Really just one treatment options, which was a topical, growing up. That was very hard, because I personally didn't understand, so if my parents didn't understand what I was going through, I definitely didn't understand what I was going through. And so, it took a while for me, until I was in my mid-20s, to really ask questions to my doctor. These questions, I feel like, really stemmed from my research and advocating for myself. What are the other treatment options that exist? Or what can I do outside of treatment to manage my skin? If it weren't for my own research, I feel like those conversations wouldn't have happened, which again goes to show just the disparities and the lack of resources that currently exist for our community.

Ms. Garcia-Albea:
Again, so nice to hear from a patient, really expressing themselves.

Dr. Ungar:
This is so – such a crucial topic, and you know, it's so important to remember that we are treating patients with all the complicated aspects related to that, and not just treating a disease in a textbook. And so, you know, we can come up with the best therapy in the world, and if there are barriers to getting it, to using it, and so on – the patient doesn't understand the considerations involved, you haven't explained it entirely, then the patient's not going to get better. There are so many different aspects. It's so complicated. Certainly we don't have time to get into every single detail, but it's important to remember that if a patient can't afford the medication, or it's too onerous from that perspective, it may not work. If they don't have access to transportation to get to appointments, if there's insufficient literacy, or language barriers to understanding how to use things, what the risks are, and so on, then, you know, it's inadequate. And we can go on and on. The support systems, availability of appropriate healthcare providers, and so on. And so, the social determinants of health need to be factored in really to every patient, and to make sure that we are appropriately treating each patient as best as possible, in the context in which they live.

And so, you know, certainly some major considerations are, as an example, race and ethnicity, where there are differences in clinical presentation and outcomes associated. We have to be mindful of that when treating these patients. So, you know, in terms of clinical presentation, as an example, black patients are more likely to have eczema - atopic dermatitis – with popular, follicular eruptions, less obvious erythema, more significant component of post-inflammatory hyperpigmentation. You know, on the other hand, Asian patients with atopic dermatitis often have more clearly demarcated lesions that almost, you know, begin looking psoriasiform, more common scaling along those lines, lichenification and so on. And so, if we're not aware of these considerations, there's going to be a delay in diagnosis, and often missed diagnosis. And so, these are, you know, examples of things that are crucial to keep in mind.

And then we see, you know, the impact of these health disparities on outcomes. So, racial and ethnic minorities are more likely to have treatment-resistant disease. They are more likely to experience some of the social determinants of health that are barriers to effective treatment. Lower socioeconomic status, living in older homes or multiple homes, education level, so you know, simply being black is a risk factor for more moderate to severe disease. And so, again, you know, these are things that we need to be mindful of. Being aware of and recognizing the significant impact of social determinants of health and health disparities is crucial, and so that's a big part of it, but then the other part of it is to make sure that we're doing our part to reduce those health disparities and be aware of the factors, and address them head on.

Some of them are kind of big picture, very tough, systematic – you know, increasing education, awareness for healthcare providers, and certainly that's an ongoing effort that's greatly needed across the whole medical system, but on the individual basis, you know, working to strengthen the patient-provider relationship, increasing diversity and minority representation among healthcare providers and staff. It's crucial to make sure that clinical trials appropriately reflect the population that we're treating across, and that means increasing diversity in the clinical trials.

And then, from a practical perspective, you know, making sure that there's appropriate access to care for patients. Sometimes that can mean expanding office hours, so that it's not during the typical working hours – you know, nights, weekends. Increase appointment flexibility, telephone service available for patients when they're not able to come in and have – you know, wait, off-hour questions that can have a big impact on their life, telehealth visits, specific educational initiatives and efforts for the whole range of patients that we see. And then, you know, again that's just an ongoing issue, just continuing education, access and so on.

And so, I think now we'll kind of just go through a summary of, you know, the large amount of information that we have discussed. And so, to start with, you know, topical therapies have a very important role for many patients, but they're usually not effective and not sufficient for severe, extensive disease. And because of that, it's important to really be mindful and have systemic treatments as part of the treatment arsenal. The traditional systemic immunosuppressants, which I think many people are understandably reluctant to use, have poorer adverse event profiles, tolerability, safety consideration. But fortunately, we've now entered an age where there are many new – and frankly, soon, even more likely to be emerging therapies – that expand the options in an effective and safe way, so that way we are going to be able to tailor care for patients with different treatment options.

Healthcare providers should lead patients and their caregivers in an intentional transition plan, from the pediatric to adult care, and as we talked about, that is not an overnight process but it's important to get started early and be consistent, so that way this chronic condition is treated throughout the whole transition from pediatric to adult care. And lastly, it's important to be very mindful and cognizant, in an active way, that the healthcare team across, you know, really everyone involved, should be employing and implementing strategies to reduce healthcare disparities in – among AD patients, for optimal care.

Ms. Garcia-Albea:
Alright, so we're going to get into our case discussion. In this example, we have a 15-year-old boy with dark skin, history of asthma which is controlled, and relapsing moderate to severe AD. The symptoms of AD started at age 5, but he was initially diagnosed with contact dermatitis. Treated with over-the-counter antihistamines, without improvement. Ultimately diagnosed by dermatology with atopic dermatitis, and treated with topical corticosteroids and topical calcineurin inhibitors. They've had a recent worsening of symptoms, with itching, swelling, and thickening of the skin. On exam, there's a popular rash. You can see lichenification and erythema, with a body surface area involved of about 30%, which is very high.

So, what we were going to discuss for this case is how to approach use of the newer treatments. So, Dr. Sidbury and Dr. Ungar, I would love to hear what your approach is – like, what goes through your head. You have this 15-year-old boy with a lot of surface involved.

Dr. Sidbury:
Yeah, I mean, I guess from my perspective, this is a 15-year-old child, so this is where we're going to want to talk about some of these things that we've discussed. So first and foremost, this is an injectable medication, if we're talking about dupilumab versus on the screen here, upadacitinib as an oral medication. So, that may or may not drive things. This child's 15, so either of those are FDA-approved, age-wise. The cream listed here, ruxolitinib, is for mild to moderate. This is a kid with 30% body surface area – that's – I'm not going to be thinking about using a topical agent at this point, given the things that they've failed and the severity that they have, so I'm thinking more along the lines of these two systemic agents, and so once we've talked about systemic versus, or oral versus injectable, then we want to talk about some of the adverse effects with these medications, to help inform that. And so, if you then sort of look at these issues, those are – things like dupilumab – has this child had a history of conjunctivitis, going into the discussion or your thoughts about this medication. If they have, well, that's one of the potential side effects of dupilumab. It may make you more interested in thinking about other therapies. Upadacitinib – the JAK inhibitors – are newer. They have a relatively daunting boxed warning that Dr. Unger covered nicely earlier. If they are – really strong history in the family, or personal history of liper – lipid abnormalities, or clotting problems, or cardiovascular disease – those are things that might influence your discussion there. So for me, it's a matter of number 1, are these drugs that we can get? Do we have access to these? What's the insurance situation? Are these things that the patient's going to be able to take? If so, if a drug is an option, then you want to make sure that you go through all of the potential benefits, thinking about what things the patient wants to get better. Is it their itch? Is it the rash? Is it all of the above, which is usually the case. And then, thinking about side effects and matching that to the patient.

Ms. Garcia-Albea:
If you had this patient, and let's say very clean history, no family history of anything that would make you lean away from upadacitinib, and say you had even coverage of both – which, you know, probably isn't actually going to happen – would you lean towards dupilumab because it has been around longer, or are you more excited about an oral medicine? Like, do you have, sort of a bias towards one or the other? You know, for children, or you know, older adolescents, let's say.

Dr. Sidbury:
I do. It's a great question because that – you know, we are – pediatric providers are conservative by nature, and just – I mean, dupilumab is not old, you know, approved first in 2017, right? For adults, so it's not been around forever…

Ms. Garcia-Albea:
Feels like it's medically long ago, so…

Dr. Sidbury:
It really does, and it's – and we've – the thing about it is, it's now approved down to 6 months of age. Why? Because the side effect

profile has been so clean, and so encouraging. And you know, we could talk about the boxed warning for the JAK inhibitors, and whether or not that's really relevant, or appropriate to consider for healthy atopic dermatitis patients versus adult rheumatoid arthritis patients with many comorbidities, where that boxed warning was really generated from. But, that said, I totally agree, that in the scenario you just painted, dupilumab's been around longer, I'm more comfortable with it, that would be my preference.

Ms. Garcia-Albea:
And once you have explained everything, do you find that patients and families tend to get over the fact that it's an injectable. I mean, especially a 15-year-old, I think probably would, but you know, do you have to spend a lot of time counseling patients on the injection aspect of it, or not so much?

Dr. Sidbury:
I do, and it – oftentimes, even with the much younger patients, for whom the getting started is much, much harder, when they start seeing the benefit, that gets better. That said, I've certainly had patients who got better, but the shots just became too much. They just couldn't do it, and that's just a super individual thing, and you take that case by case, and work through it, and then that sometimes directs you towards a different therapy.

Ms. Garcia-Albea:
I want to go to our next case, but just really quick, since you are a pediatric dermatologist. Do you have any tips for our audience about needle phobia? Anything that you could summarize in like 30 seconds? Any magic? (chuckles)

Dr. Sidbury:
Oh, gosh, yeah. I mean, well, we are spoiled at children's hospitals because we have things like Childlife, where we have these specialists come who are gifted in the art of distraction, and that's something that, you know, even if you're not a Childlife specialist, distraction is huge. I tend to have patients sit up, rather than lie down. You know, typically when we inject for biopsies and things like that, we always want patients to lie down because we're worried about them vasovagaling. In general, with patients sitting up, they're more comfortable, they're more relaxed, and so I tend to have them sit up for those injections. And then just making sure that they realize that it's something that's going to be over quickly. You can even potentially ice the site a little bit beforehand. You could potentially use some Emla cream. There are lots of things that you can do to try to mitigate some of the discomfort.

Ms. Garcia-Albea:
I've been using the Buzzy Bee lately, when I do intralesional triamcinolone, and that's probably something that patients could – or parents could buy. I don't know how much they cost, but that's a little vibrating device that provides distraction.

Dr. Sidbury:
Yeah, I love it too. So you just use that little vibrating device fairly proximal and adjacent to the actual injection, and it can be a wonderful distraction.

Dr. Ungar:
This is a 65-year-old man. 5-year history of moderate AD, so kind of a relatively late onset. He did have a myocardial infarction in the past. And so his prior AD therapy history included dupilumab, which he responded to initially really excellently. But then he started to lose response to dupilumab. He was then switched to tralokinumab, with inadequate response. And he continues to have symptoms. Again, despite optimized, nonpharmacologic and topical therapies. And so the question here is, on someone who – for whom dupilumab is not working anymore, tralokinumab is not working – you know, what is the next best step in therapy?

And so, before I kind of go through it, I think the short answer is there's no easy answer. This is a challenging case, and unfortunately, it's actually all too common, and so I think it's important to consider the different options, and you know, ultimately it's going to be an individualized, specific, you know, decision plan with the patient. But some options that can be considered – so you know, systemic JAK inhibitors are, you know, certainly indicated for a patient like this, with – who has, you know, failed other systemic treatments. But with a history of MI, I think most people would say this is not an appropriate treatment.

There is at least the warning, and at this point, you know, the consideration that if someone has a history of an MI, you know, the JAK inhibitors – abrocitinib, upadacitinib – are not really appropriate. You could consider restarting dupilumab again, with the goal of using every dosing. So you know, that is off-label use, but in some cases, you know, the loss of efficacy such as he experienced may be associated with just kind of a slow decrease, and with increased frequency of dosing, sometimes people can actually recapture that. Now, it is a challenge, because insurances don't – I would say, readily – approve weekly dosing, but sometimes with appeals and so on, that can be done. And so, it's good to keep that in mind as an option. We know dupilumab's safe. It used to work for him. There is, actually, a good chance that with this increased dosing, it may work again. Similarly, you can try tralokinumab with every-week dosing. The fact that he hasn't responded, really, initially to the loading and kind of – would probably make me a little less optimistic that weekly

dosing would do the trick, but it's a consideration. The downside really, certainly isn't there from the safety perspective, so the question is how long can we go without really getting a treatment that working for him and having him continue suffering from the disease.

And then, you know, there are adjunctive therapies. So maybe we restart dupilumab or tralokinumab, and add phototherapy. You know, we didn't really discuss phototherapy too much, as kind of the – one of the traditional treatments, but for many people there's still an important role for fer – phototherapy – you know, usually narrow band UVB. It's very safe. It can be effective. In someone like this, I wouldn't necessarily be 100% confident that it would work as monotherapy, but as an adjunctive treatment to one of the biologics, certainly a consideration. You know, so important to remember that it works slowly, so it's not something that, you know, is going to get him clear in the next week or two, even with the biologics which themselves can work a little slowly. But between the two of them, you know, I think there's actually cause for optimism that it may be successful. Not everyone is able, logistically, to do phototherapy and that can be one of those barriers that's very significant, and so in the right patient, it may be an option and certainly is something to consider.

You know, the treatment with biologics – dupilumab, tralokinumab – those, you know, in clinical trials are monotherapies usually, but as we mentioned with some of the other therapies, the reality is you can use that with topical therapies. Topical corticosteroids, sometimes even the more potent ones, and then, you know, fortunately we now have these nonsteroidal options that appear to be safe, you know, for longer term use, you know, even if that becomes an off-label use.

I don't have listed here – although it is a consideration – is to now, then consider some of the, you know, older, traditional immunosuppressants, systemics.

It's not listed here because personally, from my perspective, that's something I try to avoid. There may be cases where that's an option, but you know, he has – he is 65 years old, already has a cardiac history. There is a reasonable chance that he has other comorbidities, and you know, with cyclosporine, methotrexate, and so on, you know, we are – I wouldn't say rolling the dice, but you know, you're definitely opening up to risks that are not shared by these other options, and so I really would try to exhaust all of these before going to that. But that's something to keep on the back burner also. You know, and ultimately, given the history of MI, probably would start one of those traditional therapies, even before systemic JAK inhibitor which really would be very, very last, sort of a line therapy with a long discussion of the potential risk. So, I hopefully got through some of it, but…

Ms. Garcia-Albea:
Perfect. I want to pick your brain on that, just one more second. Are you hoping that more studies come out about the oral JAKs, that prove the safety in these cardiac patients, or are those not going to be done? Like, are we basically at a dead end for our cardiac patients for JAK inhibitors?

Dr. Sidbury:
That's a great question. I think that there's going to be probably 2 stages of getting the appropriate data, so that we can be confident and be a little less speculative, although I think the speculations tend to suggest that these are actually safe medications. Step 1 is going to be getting really good data in. You know, many, many patients, tons of patient years of treatment, and then also longer term, you know, treatment. Someone who's been on it for 5 years, 10 years – you know, we're obviously several years off from that – to say, hey, you know, the risk of an MI in someone with no history is actually equivalent to the background risk, and this is not a treatment that's going to really be associated with that increased risk. Certainly in this patient population, the black box warning is associated with rheumatoid arthritis patient. You know, it's a very different population, and we can't just pigeonhole everyone into the same category.

So that's going to be step 1, and that's going to, I think, provide some reassurance in these kind of edge cases to say, okay well, for people without a history, this is probably – I mean, not probably, this appears to be really safe. Can we extrapolate that to patients who have a history of cardiac disease? And then, I think, you know, that's going to be probably more of a delay, and I don't know if that's going to first be, you know, some case series, some post-marketing surveillance considerations, but I do think that in an – you know, it's hard to project, but in the next 5 years or so, 10 years maybe – we'll probably have pretty good data that it is safe for use, even in someone with cardiac history. But until we have that, you know, caution is needed, because we just don't know, and given, you know, the – what is believed to be the considerations now, it's just not the best option for this patient.

Without that – without the cardiac history, I wouldn't hesitate, you know, for a moment to start this patient on one of the JAK inhibitors.

Ms. Garcia-Albea:
Such a great explanation. I think we're all so excited and looking forward to using those, but of course, everybody is a little bit nervous about, you know, exactly how to best do that. We have some really great questions that the audience has been sending in. Do you routinely recommend a baseline ophthalmology consult or eye exam prior to use of dupilumab? And I would turn that over to either Dr. Ungar or Dr. Sidbury.

Dr. Ungar:

Sure, I'm happy to – to get started with that. The short answer is no, I don't. You know, when you look at the data, ocular side effects from dupilumab use, we're talking roughly in the range of 20% of patients experience some eye symptoms. So, you know, we're still talking about a minority of patients, and the majority of those patients experience mild symptoms that are often alleviated with simple over-the-counter eyedrops. Sometimes I'll kind of bump it up to some, you know, antihistamine eyedrops, or even in rare cases, prescription eyedrops, but usually that's not an issue. I would say it is a very rare case where I have someone who's having such significant ocular symptoms that really requires, you know, stopping the treatment or significant ophthalmologic intervention. I think being cognizant of it, and you know, counseling the patients to be aware of changes – you know, eye symptoms and all that – is important and have them, you know, potentially, readily plugged in for an ophthalmologist if that develops is great, but I don't – I don't have routine ophthalmologic screening.

Ms. Garcia-Albea:
Thank you. This is regarding the last case, Dr. Ungar, that we just discussed. With that patient's age and recent MI, wouldn't that make you hesitant to restart dupilumab, given his risk factors? So can you clarify that a little bit?

Dr. Ungar:
Absolutely. Absolutely, so what I – my perspective with dupilumab – and this is based on my own experience, but also the data and, you know, just – it is very safe, and the significant side effects that can be experienced are very rare. I have no hesitation. I don't really see many children, but I would have no hesitation starting a young child on it. I have no hesitation starting someone in their 80s, 90s on dupilumab either, because the safety profile is so favorable. For this patient, he had an MI but I have not seen any data whatsoever to suggest that dupilumab increases the risk of that, plays a role in that. And so, you know, certainly the involvement of the cardiologist in the treatment plan would be appropriate, but I think frankly, you know, aside from maybe phototherapy, restarting dupilumab is probably the safest thing to do regarding risk of future MI's.

Ms. Garcia-Albea:
Thank you. I have a couple of questions in the chat about coverage. So, one is asking a little bit more about low income patients and biologics, and then the other one is a little bit more specific for the new – newer treatments. So, can you talk just for a minute or two about insurance coverage and how you deal with that?

Dr. Sidbury:
Sure, I can talk about that. It's something that I live – I bet you both live every day. It's just such a…

Dr. Ungar:
Absolutely.

Dr. Sidbury:
Such a chronic issue. And so, I do. I think, just picking back up on one of the things I mentioned a little bit earlier is just make sure that you document, perhaps more than you're used to documenting, with our patients with atopic dermatitis, when trying to get the medication. So document – as Tori said earlier – document their quality of life, how are they impacted by this, what are we looking to change? Document any things that have happened that might, in fact, be expensive. It's sort of a cynical way to look at it, but that's really the bottom line here for the insurance company. So have they had infections? I've had plenty of patients who have been hospitalized with their infections – those are expensive for the insurance carrier. So document all of those comorbidities, document quality of life issues, document the Investigative Global Assessment score. You've got to be a 3 or a 4 – moderate or severe – if you're going to get this drug. And then, body surface area if you can. Things like the Scorad or the EZ – the other things – those are generally things, certainly if you're savvy and familiar with them, great. That's going to help, but I don't think they're necessary. And then the next thing to say is, when you see these patients in follow-up, document them again. You can actually teach patients that, you know, 1% of their body surface area is the palm of their hand, and so they can come in ready to tell you – I've got blank percentage of my body surface area now. So if it was 15 before, and they come in telling you it's a 2 or a 3, well then you can document that as the medicine working, and that's what you need to do in follow-up, so all of those things help.

Ms. Garcia-Albea:
I think one last tiny question. If a patient doesn't have a bath for a bleach bath, is there any way they can take a bleach bath in a shower?

Dr. Ungar:
Chlorhexidine wash is an excellent substitute. Just make sure it's done from the neck down, because it can be ocular and ototoxic. But I've had a lot of success using chlorhexidine wash daily. I don't know if either of you have other tips.

Dr. Sidbury:

Oh, yeah, we just deal with this a lot with our teens, who are – they look at you like you have two heads if you say bath. So, just put a gallon bucket in the shower, and put a teaspoon of bleach in it, and then use a washcloth to sort of dab in and do little compresses, and rinse off at the end. So a little bleach shower can work, too.

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