



# UNDERSTANDING THE LIVED EXPERIENCE OF ECZEMA

The "Voice of the Patient" Report on the Eczema Patient-Focused Drug Development Meeting

**More Than Skin Deep** is a collaboration of the following organizations:



# Atopic Dermatitis – the Most Prevalent Form of Eczema

More than 33 million Americans of all ages experience eczema, an inflammatory skin disease that results in rashes and patches of itchy, red skin that can appear anywhere on the body, but most commonly occur on the neck, face, hands, feet, and joints. Eczema can vary in severity, yet often leads to diminished quality of life and significant emotional burden in addition to pain, physical discomfort, and sleep disturbance for affected individuals. Despite the high prevalence of this condition, there are limited FDA-approved topical and systemic therapies for eczema, and few patients, especially those with moderate to severe eczema, experience total symptom relief or sustained control of the disease. Learn more about eczema and atopic dermatitis on page 11.

## THE MORE THAN SKIN DEEP “VOICE OF THE PATIENT” REPORT

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## THE MORE THAN SKIN DEEP INITIATIVE ORGANIZERS

On August 1, 2019, five organizations launched a collaborative effort, the **More Than Skin Deep** initiative, to inform treatment research and development for atopic dermatitis, the most prevalent form of eczema. For the first time ever, adults and children living with eczema and their family members were provided the opportunity to share perspectives on what it's like to live with eczema with U.S. Food and Drug Administration (FDA) regulators, drug developers, and researchers. Learn more about PFDD and the initiative on page 9.

Brief descriptions and web addresses for each of the five collaborating organizations follow in alphabetical order. The report includes a perspective on the **More Than Skin Deep** initiative from each organization.



### About the Allergy & Asthma Network

Allergy & Asthma Network is the leading nonprofit patient education and advocacy organization for people with asthma, allergies, and related conditions. Our patient-centered network unites individuals, families, healthcare professionals, industry, and government decision makers to improve health and quality of life for Americans with asthma and allergies. We specialize in making accurate medical information relevant and understandable to all while promoting evidence-based standards of care. Learn more at [allergyasthmanetwork.org](http://allergyasthmanetwork.org).



### About the Asthma and Allergy Foundation of America

Founded in 1953, the Asthma and Allergy Foundation of America (AAFA) is the oldest and largest non-profit patient organization dedicated to improving the quality of life for people with asthma, allergies, and related conditions through research, education, advocacy, and support. AAFA provides practical information and community-based services through its digital communities and network of chapters and support groups. AAFA is a member of the National Health Council. Learn more at [aafa.org](http://aafa.org).



### About Global Parents for Eczema Research

Global Parents for Eczema Research (GPER) is a grassroots, parent-led nonprofit organization focused on improving our knowledge of how to treat and manage eczema through research and innovation. GPER's mission is to improve quality of life for children living with moderate to severe eczema. GPER achieves its goals by influencing research, conducting research, engaging in public policy, and disseminating research to patients and families. Learn more at [parentsforeczemaresearch.org](http://parentsforeczemaresearch.org)



### About the International Topical Steroid Awareness Network

The International Topical Steroid Awareness Network (ITSAN) is a US-based nonprofit formed in 2012 to provide support and raise awareness about a condition called Topical Steroid Withdrawal Syndrome (TSW Syndrome), also known as Topical Steroid Addiction or Red Skin Syndrome. ITSAN has grown into a global support network and educational resource for individuals, caregivers, and healthcare providers. Its main goals are prevention, early detection, accurate diagnosis, and proper treatment for all TSW Syndrome patients worldwide. Learn more at [itsan.org](http://itsan.org).



### About the National Eczema Association

Founded in 1988, the National Eczema Association (NEA) works to improve the health and quality of life for individuals with eczema through research, support, and education. Specifically, NEA seeks to break through negative stereotypes to promote understanding of eczema and reduce burden of disease; equip medical practices for a new era in eczema care; promote new models of care; support high-value/high-yield research projects; and, advocate for accessible and affordable treatments for all eczema patients. Learn more at [nationaleczema.org](http://nationaleczema.org).

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An online version of this report is available at [bit.ly/eczema-report](https://bit.ly/eczema-report)





The burden of itch went far beyond a simple sensation. It contributes to skin damage and physical harm, shame, difficulty with mood and attention, negative effects on social and intimate relationships, poor school and work performance, negative self-image, depression, and anxiety.

# EXECUTIVE SUMMARY

Hundreds of members of the eczema community gathered in person and by live webcast to share their experiences at the **More Than Skin Deep** patient-focused drug development meeting on September 23, 2019. This meeting and a contemporaneous web-based survey was the first initiative of its kind for eczema. It was hosted by five organizations serving the eczema community (Allergy & Asthma Network, Asthma and Allergy Foundation of America, Global Parents for Eczema Research, International Topical Steroid Awareness Network, and National Eczema Association) in collaboration with the U.S. Food and Drug Administration (FDA). (See page 9 for more details.)

The meeting and survey addressed the burdens of symptoms and impacts of eczema, as well as ways in which individuals were treating and managing eczema. This report compiles the learnings from both sources, drawing heavily on survey and live polling data and direct quotations from adults and teens with eczema, parents of children with eczema, and spouses and other family caregivers. It reflects a broad range of experiences offered by the 160 participants who attended in person, hundreds more who contributed via the live webcast, and 1,508 individuals from the U.S. and 57 other countries who completed the 32-item survey.

## GREATEST BURDENS

Across all methods of gathering perspectives, itch was identified as the most problematic symptom; 79% of survey respondents placed it in their top three; it received more than twice the number of votes in live polling compared to the second-place symptom, “red, inflamed skin.” The torturous effects of itch echoed throughout the meeting, appearing 143 times in the transcript; itch was mentioned 629 times in open text survey responses. The burden of itch went far beyond a simple sensation. It was described as contributing to skin damage and physical harm, shame, difficulty with mood and attention, negative effects on social and intimate relationships, poor school and work performance, negative self-image, depression, and anxiety, as depicted on page 17.

The effect of eczema on the condition and appearance of the skin was the second-most burdensome symptom, also leading to numerous negative impacts on daily life including discomfort and pain, low mood, poor self-image, and lack of confidence. Each of the panelists who spoke at the meeting displayed photos documenting severe damage caused by eczema to the body’s largest organ; many of those photos are included in the pages of this report.

Sleep was badly disrupted among children and adults with eczema, as well as parents of children with eczema. Depression, frequent infections, and co-occurring atopic conditions were other burdensome aspects of eczema that levied heavy physical, mental, emotional, social, and financial impacts.

One of the clear findings emerging from this initiative is the extent to which parents of children with eczema are personally affected by their child’s condition and the care it requires. Personal accounts offered at the meeting illustrated their intertwined experiences and survey data provided quantified evidence. Results to a question about the global impact of eczema over the past month from adult eczema patients and caregivers of children showed an identical response pattern, as seen on page 73. Extreme feelings of helplessness, guilt, anxiety, and depression; strains on marital, family, and interpersonal relationships; and negative influences on work performance, career attainment, and family dynamics were among the many ways in which parents reported their own lives were affected by eczema.

## TREATING AND MANAGING ECZEMA

The burdens of treating eczema were almost as great as the burdens associated with the disease itself. Although there are numerous approaches to treating eczema, the most widely used treatment was topical corticosteroids as measured by live polling and with 97% of survey respondents reporting current (55%) or past (42%) use. Oral corticosteroids (such as prednisone) was the next-most-often reported treatment, with 54% reporting past use and 4% currently taking this medication (generally prescribed for short-term use only). There was relatively limited use of other systemic treatments; the first biologic therapy approved for use in treating eczema, dupilumab (or Dupixent), was reported to be used currently by 10% of survey respondents – the most of any systemic therapy (aside from prednisone). There were a wide variety of adjunctive or complementary approaches pursued, with lifestyle and dietary modifications each reported as currently used by 55% of survey respondents.

At the meeting, two sets of panelists shared their approaches to treatment, describing the array of treatments considered, tried, and sometimes stopped. They spoke to difficult benefit-risk assessments they make and time-consuming regimens they follow. Panelists also reported on harms they experienced, including from use of and the process of withdrawing from topical steroids. A wide-ranging list of downsides to current therapies generated through the meeting testimony appears on page 49. In spite of these challenges, some people reported achieving benefits from single therapies including dupilumab; from a compounded formulation of corticosteroids, antibiotics, and moisturizer known as the “Aron Regimen”; phototherapy; and/or complex customized protocols painstakingly calibrated over time through trial and error and with persistent care and attention. These accounts were built on by other participants, some offering similar experiences and others adding new information. Overall, a vast majority of meeting participants and survey respondents — 89% — reported limited treatment effectiveness and/or harms from current therapies. Survey results show a correlation between the level of control achieved with current therapies and self-assessed disease severity; more severe patients reported less satisfactory control. (See page 76.)

## LOOKING AHEAD

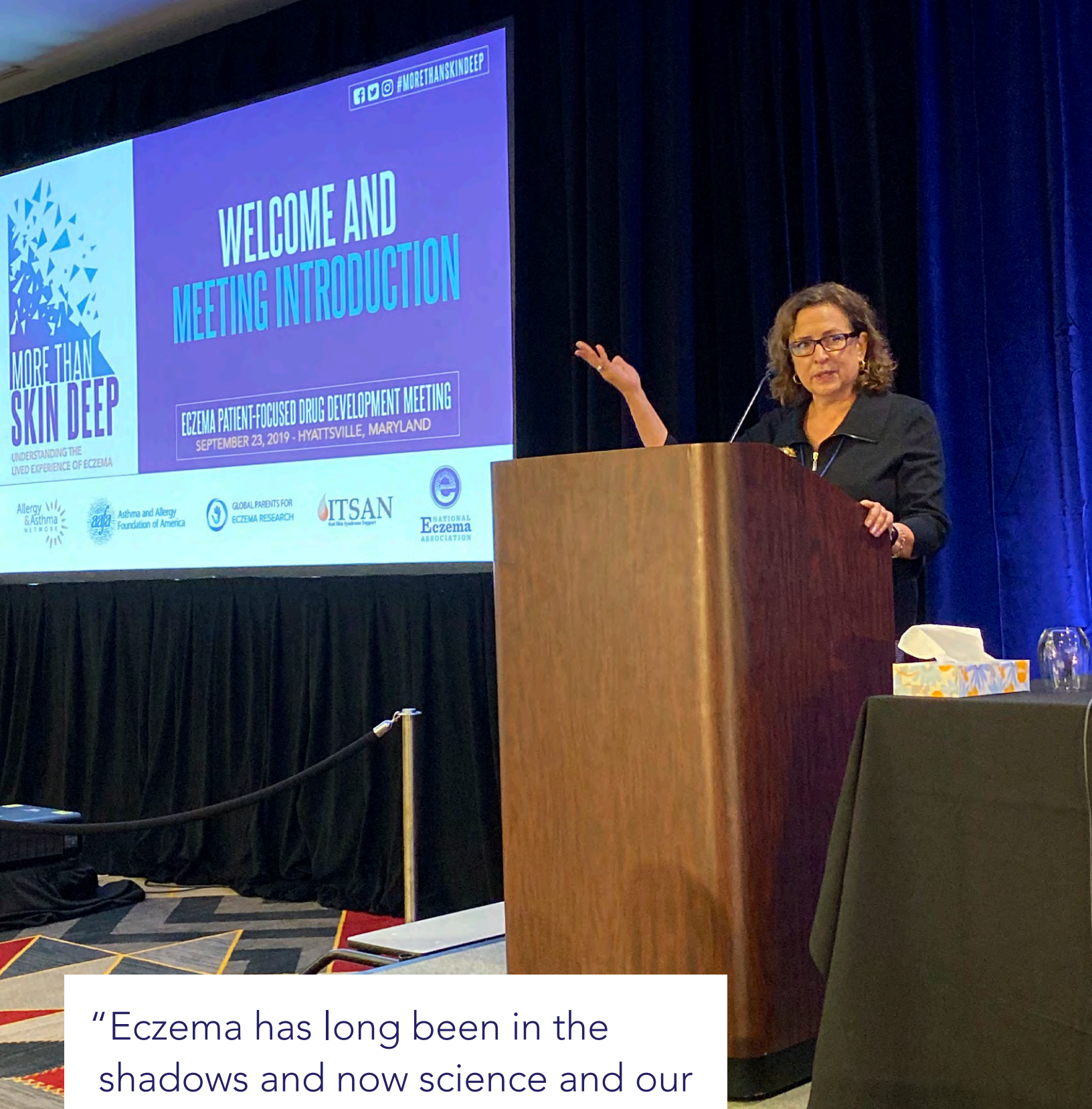
The meeting and survey underscored the large number of unmet medical needs among people affected by eczema, and both concluded with questions about attributes of the ideal therapy and experience with clinical trials. When asked about the ideal treatment benefit, “immediate and sustained relief from itch” received the greatest number of responses by polling and was selected by 51% of survey respondents. The second most-widely endorsed treatment benefit was, “increased ability to go about daily life,” with 15% of survey respondents selecting it.

At the meeting, many people expressed a desire for more targeted approaches to therapy based on biomarkers, clinical features, and/or treatment goals and a need for more evidence to inform treatment decisions, especially for children. Recognizing the key to more effective and safer therapies is research and clinical trials, there is great opportunity to engage more patients in these endeavors. Two-thirds of those who participated in the survey reported never having been asked to participate in a clinical trial; just 8% had participated in the past or were currently enrolled in a clinical trial.

The five host organizations offer their perspectives on the meeting and how they’ll incorporate the learnings in future mission-based efforts in a “Reflections” article beginning on page 57. This report will be submitted to the FDA as an evergreen resource for agency staff, life science companies, the eczema community, and the public.

Meeting participants described the array of treatments considered, tried, and sometimes stopped. They spoke to difficult benefit-risk assessments they make, time-consuming regimens they follow, and harms they have experienced.





“Eczema has long been in the shadows and now science and our incredible eczema community are shining a spotlight on this long under-served disease.”

– Julie Block, President and CEO of the National Eczema Association (NEA)

# INTRODUCTION

Offering a warm welcome to participants who had gathered in the large ballroom and those watching via the live webcast, the **National Eczema Association's** chief executive officer, **Julie Block**, proclaimed, "With science advancing at a rapid rate and new treatments making their way through the drug development process, this is our time! Eczema has long been in the shadows and now science and our incredible eczema community are shining a spotlight on this long under-served disease."

Julie's welcome was followed by introductory remarks from **Korey Capozza**, a co-founder of **Global Parents for Eczema Research**. Korey had applied to the U.S. Food and Drug Administration's (FDA's) Patient-Focused Drug Development (PFDD) program (see Inset 1, page 9) to create this opportunity for people living with eczema, family caregivers, care partners, and other loved ones to share their experiences. Speaking as an advocate and a parent of a young child with eczema, she identified four primary reasons to bring the lived experience of eczema to FDA, medical product sponsors, and others through this special program:

- Eczema is profoundly underappreciated and misunderstood;
- The true burden is far-reaching, but hidden from view;
- There is a large unmet need for better treatments; and,
- Patient and caregiver perspectives have been missing from the treatment development and approval process.







## MORE THAN SKIN DEEP BY THE NUMBERS

**5** partner organizations

**9** corporate sponsors

**160** in-person meeting participants with lived experience – 55% of whom were people with eczema; 40% were parents of children with eczema; and 5% were other family members/loved ones

**200** total participants attending in person

**1,508** responses to the **More Than Skin Deep** web survey

**1,839** live views of the webcast during the meeting

**3,750+** total views of the meeting recording (as of February 19, 2020)

**164,992** words in open text survey responses



Korey Capozza, MPH  
Founder, Global  
Parents for Eczema  
Research (GPER)

Korey explained, “Today’s meeting is important because when people don’t understand the true impact of eczema, there is less attention for it. There is less research funding, investment, and progress on new treatment. There are fewer resources and supports to help patients and families. We need to tell the story of what living with eczema is actually like. I invite you to speak openly and honestly today.” She urged those in active listening mode, including FDA staff and representatives from life science companies developing new treatments for eczema, “Please incorporate patient priorities in your programs so new treatments meet the needs of those they intend to serve. It’s a gift to be listened to, so thank you for being here and supporting this meeting.”

### PROVIDING CONTEXT FOR THE MEETING

Presentations followed from **Dr. Jill Lindstrom**, Deputy Director of the Division of Dermatology and Dental Products at the FDA’s Center for Drug Evaluation and Research, and **Dr. Jonathan Silverberg**, Associate Professor of Dermatology, Medical Social Sciences and Preventative Medicine at the Feinberg School of Medicine, Northwestern University.\*

Dr. Lindstrom provided an overview of FDA and the drug development process. “It’s a long process, often taking 10 to 17 years. It’s a difficult process. Only 10-12% of drug candidates tested in phase one studies make it through to FDA approval. It’s also an expensive process, costing \$1.5-\$2.5 billion to develop a drug product.” She continued, “While FDA doesn’t decide which compounds to test or conduct clinical trials, FDA does offer technical support, where we can, across the drug development life cycle to assist sponsors in their very challenging effort to develop drug candidates.” Dr. Lindstrom described how FDA uses information from PFDD meetings to inform its review and

\*As of October 1, 2019, Dr. Silverberg began a new appointment as Director of Clinical Research at The George Washington University School of Medicine and Health Sciences.

CONTINUED ON PAGE 10



# FDA'S PATIENT FOCUSED DRUG DEVELOPMENT (PFDD) INITIATIVE

The PFDD initiative is part of a larger set of programmatic commitments passed into law in 2012 as part of the Food and Drug Administration Safety and Innovation Act. It began as a series of 20 disease-specific meetings to enable FDA to hear directly from patients and caregivers about burdens of their condition and its treatment.

FDA's learnings from the PFDD meetings<sup>1</sup> recognize that:

- Patients with chronic and other serious diseases are experts on what it's like to live with their condition
- Patients' "chief complaints" may not be factored explicitly into drug development plans, including measures of drug benefit planned in trials

Due to its success and popularity, the meeting series was expanded to include an opportunity for patient organizations to host PFDD meetings in collaboration with FDA. To date, a total of nearly 60 PFDD meetings have been held on a wide range of rare and prevalent medical conditions.

FDA now has a variety of patient-focused programs that inform decision-making across the agency. A series of regulatory guidances is helping to articulate the agency's expectations for patient-focused medical product development and is generating more interest in patient perspectives from life science companies. For more information, please visit <http://bit.ly/FDA-PFDDinfo>.



Jill Lindstrom, MD – Deputy Director, Division of Dermatology and Dental Products, FDA

## THE MORE THAN SKIN DEEP INITIATIVE

In 2018, the eczema community was approved to hold a PFDD meeting and five organizations serving the eczema community joined forces to host the More Than Skin Deep initiative: Allergy & Asthma Network (AAN), Asthma and Allergy Foundation of America (AAFA), Global Parents for Eczema Research (GPER), International Topical Steroid Awareness Network (ITSAN), and the National Eczema Association (NEA). This is the largest coalition of organizations to collaborate for a PFDD initiative. See the inside front cover for a description of and contact information for each of these organizations.

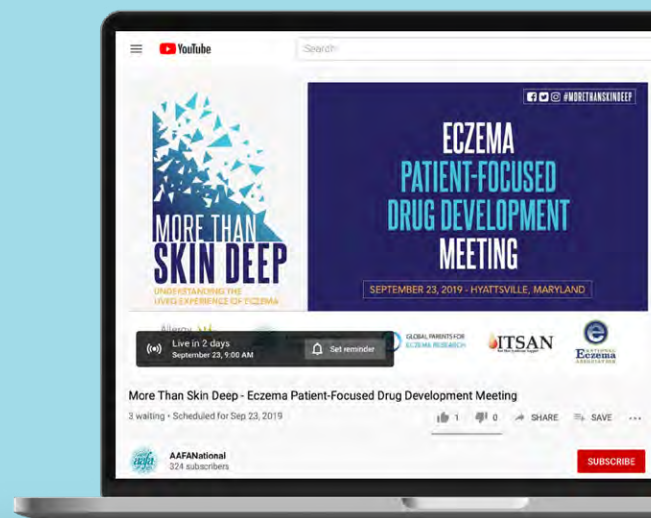
The name, "More Than Skin Deep," was chosen to reflect the fact that eczema is often considered to be "just a skin condition." The initiative was designed to reveal the full range of experiences with eczema and to illustrate that its impacts go well beyond what's seen on the surface of the skin.

In addition to planning and hosting the More Than Skin Deep meeting, organizers fielded a web-based survey to collect data from patients and caregivers. The 32-item survey attracted responses from 1,508 individuals, including comments submitted in open text fields that total nearly 165,000 words. Survey results are summarized in Section 3 of this report and the survey instrument is provided in the Appendix.

Support from nine corporate sponsors helped to defray meeting costs, offset travel expenses

for most patient and caregiver participants, and cover other direct costs. Organizers worked with the conference hotel staff to ensure the comfort of patient-participants, from planning a food-allergy-aware menu, to advising on detergents and cleaning products, to arranging for rooms with bath tubs for participants who follow specific bathing routines as part of their self-care regimen for eczema. On the day of the meeting, an art-themed "kid's camp" was offered at no cost to families traveling with young children.

This report is the primary record of the day's dialogue and the survey results. It will be submitted to FDA as an enduring resource and widely distributed by the host organizations. Preliminary learnings have been shared at research meetings and other presentations and publications are planned. Each of the hosting organizations has the opportunity to incorporate learnings into its mission-centered strategies and programs. See "Reflections" from host organization leaders on page 56.



<sup>1</sup> Mullin, Theresa. <https://www.nationalhealthcouncil.org/sites/default/files/MullinFDA.pdf>, accessed November 16, 2019

"I was born with eczema. I am having a traumatic experience just sitting in this room today. Listening to your stories brings back a lot of emotions and a lot of terror. Sometimes you think you're over it, but you're really not. But I stand here today, having lived almost 50 years with eczema, victorious."

– Danielle Alexander

decision-making processes. "Understanding and measuring outcomes that matter to patients can help us guide sponsors in the design of studies. Patient perspectives can improve recruitment and retention in studies by minimizing the burden of participating in trials. Meetings like this one help regulators to integrate the patient's assessment of risks and benefits as we make a regulatory decision. They can also help us communicate the most important information about medicines to healthcare providers and patients so that they can make better decisions to improve their health."

Dr. Lindstrom concluded her presentation on a personal note, "I am a mother of a child with eczema. I'm the sibling of an adult with eczema. I cared for patients with eczema when I was in practice. Those are limited experiences, but they inform my thinking. We have a great number of people with experiences of their own to share today, so my thinking can be expanded as I hear from you. So again, thank you."

**Dr. Silverberg**, a practicing physician and researcher who specializes in atopic dermatitis, spoke from his professional experience which is also informed by his personal experience as the father of a child with eczema. "I'm going to take off my parent/caregiver hat and focus on evidence to describe what eczema is, how to establish the diagnosis, to debunk some of the myths that have developed in clinical practice, and to treat the condition," he stated. In a fast-moving 20-minute presentation, he did just that, also speaking to the significant personal, public health, and economic burden of eczema. (See Inset 2, page 11)

He began with a simple description of eczema as a chronic, inflammatory skin disease characterized by itch and eczematous lesions – scaly, rough, red rash. Importantly, in the setting of this meeting where 71% of participants in a live poll reported having moderate-to-severe eczema, Dr. Silverberg emphasized the difference between mild eczema and moderate-to-severe eczema. "Among patients with mild disease, the most burdensome symptom is itch. It drives these patients crazy and it's what they want treated. But when you look at the moderate to severe patient population, the top burden is still itch, but now there's a lot more going on. There is more complexity, blistering, a lot more sleep problems, a lot more pain, open sores, etc. So, moderate-to-severe atopic dermatitis is not just a more intense form of a mild disease, it's an entirely different condition because it brings with it many other symptoms that may not occur in mild patients."

These opening remarks, invitations, and presentations set the stage for a day of candid, intimate portrayals of the challenges faced by patients and caregivers alike that were frequently punctuated with raw emotion. As participant **Danielle Alexander** stated near the end of the morning session, "I was born with eczema. I am having a traumatic experience just sitting in this room today. Listening to your stories brings back a lot of emotions and a lot of terror. Sometimes you think you're over it, but you're really not. But I stand here today, having lived almost 50 years with eczema, victorious." That expression of resilience in the face of tremendous suffering echoed throughout the day.



Danielle Alexander, Participant

# REVEALING TRUTH: EVIDENCE OF ECZEMA'S DEEP AND WIDE IMPACT

Dr. Jonathan Silverberg's presentation early in the meeting drew on data to debunk myths that have developed in clinical practice and general knowledge about eczema. Throughout the day, participants spoke to the barriers these and other myths create in terms of accessing appropriate care and building social support.



Jonathan Silverberg, MD, PhD, MPH

## MYTH 1: Eczema is a trivial condition

Truth: "A study commissioned by the National Eczema Association<sup>2</sup> estimates the economic burden of eczema to be \$5.3 billion a year, representing both direct costs (for medical care including physician and emergency room visits, in-patient hospital care, prescriptions, and non-prescription treatments) and indirect costs for things like lost productivity and reduced quality of life. Of that total, \$619 million of lost productivity comes from patients who can't work or who have to take off from work to care for children with eczema."

## MYTH 2: Eczema starts in early childhood and is gone by adulthood

Truth: "Rates of eczema peak in childhood, with about 10% of children experiencing eczema. Roughly 20-50% of these children will have persistent eczema eight years later. Rates drop in the teen years to 7% (for reasons we don't yet understand) and remain there through adulthood. Depending on the study, 10-50% of adults report onset of eczema during adulthood. This is clearly not 'just' a childhood disease."

## MYTH 3: Eczema is mostly a mild condition

Truth: "When you look at the data, while the rates of eczema fall across the population over time, the proportion of people who have moderate to severe disease actually increases with age. Among children ages 3 and under, less than 25% are moderate or severe. When you move into the adolescent population, the proportion of moderate to severe increases to 37%. The highest rates are

in the adult population where you have almost 50% of patients with atopic dermatitis reporting moderate to severe disease.<sup>3</sup>"

## MYTH 4: Eczema is just a skin condition

Truth: "Across pretty much every study out there, there is an incredibly strong anxiety signal and a very consistent depression signal as well. A recent study shows that eczema is associated with significantly higher depression scale scores, parental depression, antidepressant use, and suicidality.<sup>4</sup> If you treat the skin disease adequately, in many patients these mental health symptoms go away, suggesting they are a manifestation of the eczema itself. Also, the diagnostic criteria reflect that people with eczema have frequent skin infections, which can lead to hospitalization, emergency care, major pain, flares, etc. In fact, some of my patients are covered head to toe with staph infections. It was also recently reported in a meta-analysis of several studies that patients also had higher rates of systemic infections including ear infections, strep throat, urinary tract infections, endocarditis, meningitis, encephalitis, bone and joint infections, and sepsis.<sup>5</sup> We are also finding evidence that eczema is associated with increased risk of cardiac diseases (including heart attack, stroke, and heart failure)<sup>6</sup>, diabetes, and high blood pressure. So this is hardly a condition of the skin alone."

## MYTH 5: You must have flexural involvement (at the knees, elbows, or other joints) to have eczema

Truth: "The gold standard diagnostic criteria described

by Hanifin and Rajka<sup>7</sup> require 3 of 4 major criteria, of which flexural involvement is one, plus 3 of 4 minor criteria. Therefore flexural involvement at the joints is neither necessary nor sufficient for a diagnosis of eczema. In fact, across studies of eczema in several countries, we found only 58% of patients had signs at the joints.<sup>8,9</sup> It's more common among adults with childhood onset of eczema and less common in children and among adults with adult onset of symptoms."

## MYTH 6: Only infants have head and neck involvement

Truth: "When you compare studies that looked at children and adults, the presence of eczema on the head, face, and neck is virtually identical.<sup>10</sup> It may be more common in adult onset eczema compared to adults with childhood onset. Rash and lesions on the face, head, and neck can be very concerning and stubborn to treat."

## MYTH 7: People of color can't have eczema

Truth: "I have patients with darker skin who were told they were crazy and that their itch was all in their mind. In reality, they were covered head to toe, but their pattern was a more purplish color, masking the skin's pigment. It can be very challenging to see where it starts and stops. It's essential that we update our clinical materials to reflect the different presentation of eczema on skin of color."

<sup>2</sup> Drucker AM, Wang AR, Li WQ, Severson E, Block JK, Qureshi AA. The Burden of Atopic Dermatitis: Summary of a Report for the National Eczema Association. *J Invest Dermatol.* 2017 Jan;137(1):26-30.

<sup>3</sup> Silverberg JI, Chiesa Fuxench ZC, Gelfand JM, Margolis DJ, Boguniewicz M, Fonacier L, Grayson MH, Simpson EL, Ong PY. Content and construct validity, predictors, and distribution of self-reported atopic dermatitis severity in US adults. *Ann Allergy Asthma Immunol.* 2018 Dec;121(6):729-734.

<sup>4</sup> Patel KR, Immaneni S, Singam V, Rastogi S, Silverberg JI. Association between atopic dermatitis, depression, and suicidal ideation: A systematic review and meta-analysis. *J Am Acad Dermatol.* 2019 Feb;80(2):402-410.

<sup>5</sup> Serrano L, Patel KR, Silverberg JI. Association between atopic dermatitis and extra-cutaneous bacterial and mycobacterial infections: A systematic review and meta-analysis. *J Am Acad Dermatol.* 2018 Nov 21. pii: S0190-9622(18)32954-2. doi: 10.1016/j.jaad.2018.11.028

<sup>6</sup> Ascott A, Mulick A, Yu AM, Prieto-Merino D, Schmidt M, Abuabara K, Smeeth L, Roberts A, Langan SM. Atopic eczema and major cardiovascular outcomes: A systematic review and meta-analysis of population-based studies. *J Allergy Clin Immunol.* 2018 Dec 18. pii: S0091-6749(18)32728-3. doi: 10.1016/j.jaci.2018.11.030.

<sup>7</sup> Correale CE, Walker C, Murphy L. Atopic Dermatitis: A Review of Diagnosis and Treatment. *Am Fam Physician.* 1999 Sep 15;60(4):1191-1198.

<sup>8</sup> Yew YW, Thyssen JP, Silverberg JI. A systematic review and meta-analysis of the regional and age-related differences of atopic dermatitis clinical characteristics. *J Am Acad Dermatol.* 2019;80(2):390-401.

<sup>9</sup> Lee HH, Patel K, Singam V, Rastogi S, Silverberg JI. A systematic review and meta-analysis of the prevalence and phenotype of adult-onset atopic dermatitis. *J Am Acad Dermatol.* 2018. doi: 10.1016/j.jaad.2018.05.1241. [Epub ahead of print].

<sup>10</sup> Yew, op. cit.





"I went to school to become a registered dietitian thinking I was going to become an expert. Today we all got badges that identify us as experts. So I didn't realize before today that I didn't need my credentials. I've been an expert all along!"

– Rahki Roy

## SECTION 1

# SYMPTOMS AND IMPACTS OF ECZEMA

“This day has been long in coming. Before we even started this morning I had tears in my eyes. Seeing familiar faces, we don’t even have to have to say a word. We look in each other’s eyes and there are tears. It’s so exciting to be here to share our experiences and help move better treatments along.”

These were the words of **Kelly Barta**, patient, advocate, and President and CEO of the **International Topical Steroid Awareness Network (ITSAN)**, one of the host organizations. Kelly’s greeting helped transition the focus from professional experts like Drs. Lindstrom and Silverberg to the lived experience and expertise of people with eczema and parents, spouses, and other family caregivers and care partners of children and adults with eczema.

Kelly introduced moderator **James Valentine**, an associate with Hyman, Phelps & McNamara who previously worked in FDA’s Office of Health and Constituent Affairs. James reviewed the agenda for the rest of the day, structured around two topics. “First we’ll spend time digging into the different disease symptoms and the daily impacts they have on your lives and your loved ones’ lives. This afternoon we’ll talk more specifically about treatments – all the things you’re doing to manage eczema, how well treatments are working for you, and the downsides of those treatments.” He explained, “For both topics, we will use three methods to hear from you: panels of patients and caregivers selected to reflect a range of experiences, live polling questions for those here and participating by webcast, and then a facilitated discussion where you’ll have the chance to share your experiences.” Following some initial polling questions, the first panel took the stage and shared gut-wrenching accounts of their lives with eczema.



Kelly Barta, (then) President & CEO, International Topical Steroid Awareness Network





INSET 3

## PANELISTS

**Kelly Barta** of Atlanta, Georgia

**Tyler Berryman** of Sunnyvale, California

**Raelle Brown** of Philadelphia, Pennsylvania

**Lisa Choy** of Corte Madre, California

**Brianna Cox** of Memphis, Michigan

**Joseph Cutaran** of Fort Worth, Texas, speaking on behalf of his 4-year-old son, Drew

**Lynelle Doyle** of Pontiac, Michigan, speaking on behalf of her 13-year-old son, Bryson

**Ashley Ellis** of Olive Branch, Mississippi, speaking on behalf of her 8-year-old daughter, Hadley

**Angela Fox** of New Braunfels, Texas, speaking on behalf of her 6-year-old son, Cooper

**Pamela Friedman** of Orinda, California

**Stephen Gawron** of Long Island, New York

**Keri Kelley** of Yukon, Oklahoma, speaking on behalf of her 7-year-old son, Callen

**Sarah Pry** of Crossville, Tennessee, speaking on behalf of her 11-year-old son, Aiden

**Heather Sullivan** of Spokane, Washington, speaking on behalf of her children, Hazel and Sawyer

**Lindsay Swire Jones** of Chicago, Illinois

**Kathryn Tullos, R.N.** of Houston, Texas, speaking on behalf of her son



## MOST PROBLEMATIC SYMPTOMS

### ITCH

**Brianna Cox**, the youngest of all the panelists, paused several times during her remarks to choke back tears. "I'm 14 and I've had eczema my whole life. From infancy on, severe itching, sleep loss, and the constant burning on my skin has taken a toll on me. My dry, flaky, split, oozing skin would make kids in elementary school not want to hold my hand or touch me for fear of catching what I have. Invitations to sleepovers were rare because I would randomly itch, bleed, and sometimes cry uncontrollably. Most people couldn't handle the burden of it and I'd be forced to go home early. I felt rejected. At night I was covered in wraps of slimy, greasy medication with Papa's long socks covering my arms and legs. I'd wake every few hours, bloody and in tears because I had ripped everything off in my sleep because my skin felt like it was on fire. It burned and itched and the only thing I could do for relief was to scratch and claw at it, rub it feverishly on anything I could reach. I put holes and rips in furniture, in my clothes, and several mattresses. It was like I was possessed. I left a trail of blood, skin, and tears. My family tried to stop



me, but I couldn't control it," Brianna said, shaking her head. Concluding her remarks, she expressed this simple wish: "I want to do what my friends do with no fear of having intense pain and itch, simply because I had fun. That would be life-changing."

This description – among the first of many heard throughout the day – drove home the profound impact this cardinal symptom has on the life of the person with eczema. As another panelist, **Stephen Gawron**, said later in the day, "I am a 50-year-old, lifelong sufferer. Most of you know the clinical definition of eczema, but please allow me to give you my personal definition of the disease. I call it torture. I endure endless bouts of itchy, torn open, bleeding, oozing, red, flaky skin from head to toe." These descriptions of itch also reveal how this symptom contributes to other symptoms and is intertwined with the impacts on their lives, as depicted in Inset 4, on page 17.

The dominance of itch as the chief complaint was clear. In polling, it was selected as the symptom with the greatest impact by 50% more people than the next most frequently identified symptom (red, inflamed skin). Among respondents to the **More Than Skin Deep** survey, it was selected by 79% of respondents as one of their three most problematic symptoms. Number two in the survey was also red, inflamed skin, which was selected by 49% of respondents. The words "itch" and "itchy" appear a total of 143 times in the meeting transcript and 629 times in open text comments submitted by survey respondents. In his opening presentation, Dr. Silverberg cited the prominence of itch in other studies, as well.

Brianna's use of the word "claw" and the phrase "couldn't control it," to describe intense actions taken in response to itch, came up several times throughout the day.

*"I still wake up unconsciously clawing at my skin. When I itch during the day I can find a distraction or I can try and control it, but there's no control over scratching in my sleep."* – **Lindsay Swire Jones**

*"He would carpet-burn the skin off the tops of his feet, rubbing them on the carpet. Once we had to drive straight to the urgent care clinic after he made a bloody mess in the car seat while we were sitting in the bank drive-through."* – **Keri Kelley**, speaking on behalf of her son, Callen

*"Cooper clawed at these areas until they reopened and created wounds on top of his eczema."* – **Angela Fox**

*"When I hit my 40s it was on my face. I would have itching so bad I would be on the porch at 2 a.m. in a snowstorm to cool down my skin and stop the itch."* – **Rene Green**, participating by webcast

*"My partner will have itching/scratching fits that she cannot control, and the helplessness we both feel is both scary and devastating as it can undo a 'good skin day' in a matter of minutes."* – **Andrew Kubicz**, webcast participant

*"I remember taking turns with my wife, lying awake at night, holding Drew's arms down so he wouldn't scratch and peel the skin off his face and throwing away his bloodstained clothes because we just didn't want to wash them."* – **Joseph Cutaran**

Several people described ways in which they attempted to create barriers between their skin and fingers, hands, and other objects to prevent direct contact and scratching, most of which failed or created other problems. Its relentless, damaging nature is certainly belied by the small, insignificant word "itch" most people associate with an insect bite or a mild, fleeting sensation.





## CONDITION AND APPEARANCE OF THE SKIN

As stated above, the symptom of second greatest impact as rated in the both the polling and the survey relates to the condition and appearance of skin itself: red, inflamed skin. Nearly all the other condition/appearance-related symptoms tied for fourth place. Panelist **Raelle Brown** described a morning in her lifelong experience with eczema. "A year ago, at age 26, I had the worst flare of my life. I became unrecognizable, being covered from my scalp to my legs, with all my hair falling out as well. During this time I would wake up in the morning with instant anxiety. 'What do I look like?' I have no idea. 'Can I bear a shower?' Probably not because it burns too bad. I'll take a soothing bath because it's the only way to add any form of moisture or to calm the oozing skin. I have to care for my scalp. Then there's moisturizer that only lasts for a second. Finally, slowly putting on loose, ugly clothes that are just going to irritate my skin and be messed up by the end of the day from shedding skin and pus."

"I became unrecognizable, being covered from my scalp to my legs, with all my hair falling out as well."

– Raelle Brown

Each of the panelists showed photographs taken of themselves or their child that made shocking impressions. Their descriptions of the condition of skin demonstrated the difficulty of focusing on a single feature. Many of their comments incorporated multiple descriptors of how the skin looked and felt. Pain and burning sensations were mentioned frequently in connection to the rash, flaky texture, and/or rough, crusty patches. Swelling, oozing skin was a particular problem noted by several participants.

*"Sawyer's skin has been obviously and consistently irritated since his first week of life, though it morphs from red to flaky, from swollen to oozing. The faces of eczema are so diverse and nonlinear, the treatment is inevitably hindered."* – **Heather Sullivan**

*"One of the symptoms that bothered me most was large areas of oozing open skin."* – **Pamela Friedman**

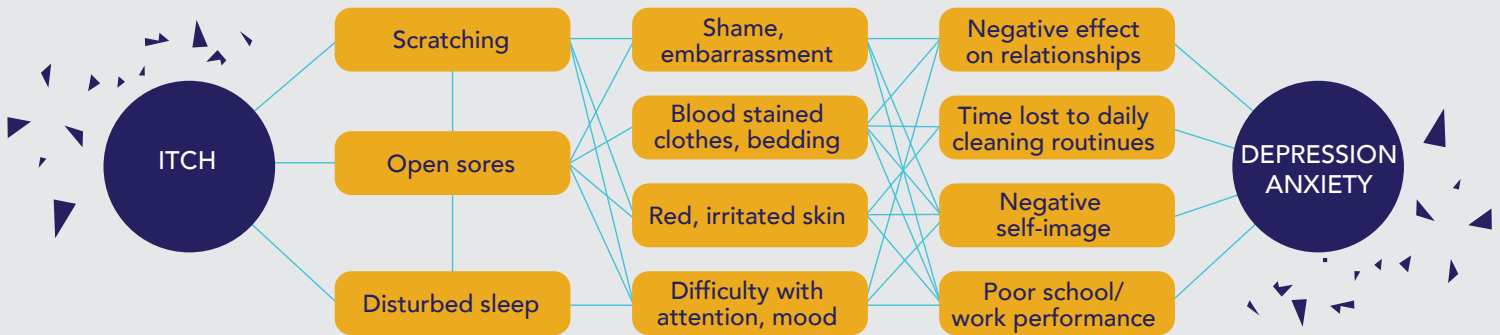
*"I'm a freshman college student. When I was younger, between two months to 13 years old, I had a low to moderate severity of eczema. I had it around my neck and on my arms and my legs. It was somewhat uncomfortable. However, when I turned 14 it turned up to what felt like max. I had it all over my face, even more on my legs and arms. Waking up sucks now. I don't want to move in the mornings because my entire face and arms are caked in dead skin cells and pus that has risen at night."* – **Alex Lumsden**, webcast participant

**Angela Fox** also described the spreading skin involvement from one part of her son's body to another. "Cooper was diagnosed at 10 months of age when his baby acne and an infected spot on his chin continued to spread. As he grew, new patches appeared around his body, typically centered on his face, hands, feet, and lower legs. When he was four, Cooper's eczema literally exploded all over his body and covered him from head to toe. His face and body had a steady look of sunburn that would crack and ooze, especially on his forehead and eyelids. Cooper got to a point there where he could not move his neck because of the pain and the crusting and oozing. Each time we tried to decrease his number of treatments, the angry red bumps, the sunburnt-looking skin, and his infected crevices returned."



# EFFECTS OF ITCH ON OTHER SYMPTOMS AND LIFE IMPACTS

(for illustrative purposes only)



Like itch, the condition of the skin's surface was tightly connected to other symptoms, including pain, and their impacts. The effect on the individual's self-image, confidence, and mood were tightly connected to these visible signs of eczema. Feeling embarrassed and ashamed of both their appearance and flaking or oozing skin was a common sentiment expressed by participants. Several people said that involvement of the face, hands, and fingers was especially tough.

*"I got eczema when I was 22. I used to be covered head to toe, but I feel like when your head, face, and neck are broken out, it's the most exhausting and stressful. It's what everyone sees and there is not a lot you can do to treat it."* – **Rachel Bronstein**

*"[As a teenager] it changed from being on his arms and legs to covering his whole face. His hands got worse. It was concentrated on all the visible spots that you wish he could have hidden because then he might go outside. But he couldn't hide anything."* – **Jenn Johnson**, speaking on behalf of her teenage son

*"Some of you mentioned flaky skin in the morning. The moment I open my eyes, I can't even move. I have to count to three to get my entire body up to drag myself out of bed to clean my bed sheets."* – **Hanna Kim**

*"I'm a high school freshman and the worst part for me would be all the itchy, dry skin that flakes off and gets on everything. I'll go to the locker room to change, and I'll pull off my pants to put on my shorts, and it'll just rain down everywhere. It gets all over my stuff and sometimes gets on my friend's stuff too. And at the black science tables, if I itch my forehead, it gets all over there."* – **Kylie Bogar**

*"As a kid, my rash used to be all over my arms and legs mostly. I learned how to cope and deal with it pretty well. You can always cover it up with pants or sweatshirts. However, as an adult, my eczema has transitioned to mostly my face. It's really tough having to go to work every day with eczema on your face and everyone has to see it. It's really upsetting for me."* – **Kristina Howell**, webcast participant







**"From 2014 to 2018 he missed enough school to equal a full school year and was homebound multiple times."**

–Sarah Pry, speaking on behalf of son Aiden, 11 years old

## SLEEP DISTURBANCE

As the participant quotations about symptoms of itch and the condition of the skin itself have already shown, sleep is badly disrupted and disturbed – both among people with eczema and those caring for them, a topic explored in greater depth later in this section. In responses to polling and the survey, sleep ranked third among the top three most problematic symptoms, with more caregivers of children with eczema rating the symptom of sleep disturbance among the top three (48%) compared to adults with eczema (22%). As webcast participant **Andrew Kubicz** stated, "My partner is at the conference, but the one issue I believe she plays down the most is sleep loss and sleep anxiety. She cannot work. The mentality/mood that comes with it carries on through the night and next day. The anxiety just compounds." **Keri Kelley** described the desperation she feels when her son can't sleep. "Living with eczema means calling the pediatrician at 3:00 a.m., begging for a sedative just to let Callen get a little bit of sleep."

Participants' remarks make it hard to tease apart cause-and-effect relationships between these top three symptoms, but their collective impact is stark and long-lived on many aspects of life including school, work, and relationships, as these participants' experiences illustrate:

*"Aiden is in much pain when he wakes up hurting or itching. Sometimes he has no sleep or slept so badly that we have to debate whether school is an option that day. We have been back in school less than two months this school year; he has already missed almost a week and has been tardy at least twice due to his eczema. From 2014 to 2018 he missed enough school to equal a full school year and was homebound multiple times. The school would send a teacher for his lessons as he was in too much pain and sleep-deprived to fully attend the normal schedule."* – **Sarah Pry**

*"Sleep deprivation has severe impact on students with eczema. Homeschooling and online classes are options we have taken. It's still challenging."* – **Ganesa McIntosh**, webcast participant

*"I can't even get my undergrad degree; I'm doing so poorly and failing courses because of sleep deprivation. I'm still pushing through because I believe in myself and I really, really want to become a health professional."* – **Hanna Kim**

*"We talk about sleep deprivation. It's real, right? You can't concentrate, you're anxious. You're just sitting there not sleeping. You're scratching. So when you're scratching, you're bleeding. When you're bleeding, it's on the sheets. Everyone here knows – you've looked down at your bed sheet. It's covered in blood. And then, if you lift it up to itch the skin, it just showers skin on you, so you don't. If you had photos of the sheets of eczema sufferers and what they do to themselves overnight, it would help people to better understand sleep deprivation and the loss of intimacy with partners."* – **Elizabeth Hoff**

For people at any age, long-term sleep deprivation has negative effects on attention, performance, productivity, and mood swings. It is associated with higher rates of anxiety, depression, and hyperactivity. For children, the long-term impact of deprivation of sleep's building and restorative functions can also be seen in growth and development delays. Adults may suffer problems with judgement and other executive brain functions, as well as putting them at increased risk for obesity, cardiovascular problems, and other serious health issues. These factors were mentioned by participants across the day, although often not directly in connection with sleep problems.

## ANXIETY AND DEPRESSION

Throughout the meeting, participants expressed mental health concerns, predominantly anxiety and depression. Panelist **Ashley Ellis** described her daughter's struggle.

"Hadley's anxiety increased. She stopped eating at school. She had headaches; she was diagnosed with situational anxiety disorder and began counseling. Her eczema was not controlled at all. At school, she was expected to perform academically and she struggled. Her anxiety kept progressing, and it progressed to full panic attacks." **Angela Fox** reported a similar experience with her 6-year-old son, "Next month, we'll add a counselor in an effort to help Cooper with the overwhelming anxiety he feels and the emotions he experiences as a result of this disease."

Several people courageously shared the extreme impact of these symptoms on their lives. **Greg Clark** recalled his dark days, "I got depressed. I was suicidal. I couldn't look at myself in the mirror because I didn't control who I was. [Eczema] was controlling me." **Akilah Evans-Pigford**, who had eczema through her teenage years, spoke about her son's emotional battle as a preteen before they found effective therapy. "After a while it got to the point where my son was extremely depressed. Much like the young lady who spoke on the panel, he said things like, 'Why is God doing this to me?' 'I hate myself.' 'I don't want to be here anymore.'"



## INFECTIONS

As Dr. Silverberg indicated in his clinical overview, people with eczema experience frequent infections. These have profound effects on the individual and factor into the tremendous economic cost of the disease, owing in part to related hospitalizations.

**Brianna Cox** shared her experience during her statement on the opening panel. "I spent time in the hospital with staphylococcus and Methicillin-resistant Staphylococcus aureus (MRSA) infections, covered head to toe with hot raised lesions that hurt at the slightest touch. It made me not want to live anymore. I prayed for God to take me," she disclosed.

**Sarah Pry** described son Aiden's hospitalization from MRSA at age 9 as the most difficult time they have experienced in his 11-year journey. "He stated that he didn't want to live and wished he would die. Despite all the pain he was in, the itch was still there and he still wanted to scratch. He had teams of doctors working with him that whole week – including a dermatologist, a psychologist, and his allergist."

**Alison Piluso** reported that every time she tried to shave her legs beginning at age 12, she would get a staph infection. Between the ages of 12 and 16, she got MRSA three times. "I wasn't hospitalized, but the sores were on my muscles; it hurt and I couldn't walk," she said. **Kathryn Tullos'** son also got recurrent MRSA infections, along with other serious problems after withdrawing from topical steroid use (see page 38). "All of his lymph nodes blew up – he had golf-ball sized lymph nodes in his groin. He got recurrent MRSA infections. His heart developed a new murmur and a thickened heart wall. He dropped from 75th percentile in height to 15th percentile." Participating by webcast, **Kelly Russo** contributed her experience. "I was hospitalized from an opportunist infection in my eye. I lost nearly all of my hair and my sanity."

"I got depressed.  
I was suicidal.  
I couldn't look  
at myself in the  
mirror because  
I didn't control  
who I was.  
[Eczema] was  
controlling me."

– Greg Clark



**Kelly Barta** provided graphic detail of the infection she endured with eczema herpeticum, a herpes simplex 1 infection of the skin.



In her panel statement, **Kelly Barta** provided graphic detail of the infection she endured with eczema herpeticum, a herpes simplex 1 infection of the skin. "I was in the hospital completely immobilized because the immunity in my skin had been shot and it couldn't fight that virus. I almost died. That went full body and I can't explain to you how terrifying, how painful that was. It's like having shingles all over. It's in your nerve endings," she explained. "It took me three months to even look at those photos," Kelly said, pointing to the images on the screen.

## CO-OCCURRING CONDITIONS

In addition to the infections described above, and other health conditions mentioned in comments cited earlier, the complication of co-occurring conditions arose often. The top three reported in the survey are allergic rhinitis, asthma, and food allergy, with the order varying between children and adults with eczema, as described in Section 3 of this report. For some, including **Joseph Cutaran's** family, dealing with this trilogy forces some major changes to the living environment. "We went through a whole legal process to get out of our rental house because we found that our son was allergic to something in it. We built a house with special carpet, wood floors, and a special HVAC system that filters the air. We got rid of our dog," he lamented.

Following are some of the comments describing these and related conditions:

*"I have not just eczema, but asthma and allergic sinus rhinitis. I went to an allergist when I was in primary school and he said, 'Move from New York to Florida,' because my skin was so dry. So we moved and it did help with the dryness and my asthma. It didn't address my itching. In high school I had four years of allergy shots. That helped my environmental allergies, but not my itching. I got sinus surgery for nasal polyps that developed from hay fever. That helped my hay fever, but not my eczema."* – **Rahki Roy**

*"I have a food allergy to corn which is ubiquitous. Cornstarch is a filler in many pills."* - **GO'M H**, participating by webcast

*"I was born with eczema. I had a rash that was treated in the hospital before my parents took me home, and by age three I had been diagnosed with food allergies and asthma. At age six, I completed a month-long inpatient stay at National Jewish in Denver."* – **Lindsay Swire Jones**

*"Aiden has asthma that has slowly eased up over the years, thankfully. As a baby, he was hospitalized for bronchitis and breathing issues many times. He has multiple life-threatening food allergies and carries an EpiPen, as he has done for a majority of his life."* – **Sarah Pry**



For some who understand the common linkage between these conditions, worry precedes the advent of symptoms. **Armando de la Libertad** expressed concern for his 10-year-old daughter's future health. "There is constant anxiety about what's coming next, anticipating the 'atopic march' – the association with asthma and additional allergies. There are all these studies that show connections between eczema, heart disease, and other diseases and conditions. I worry about what impact that will have on my daughter's outlook and how best to avoid or prevent these things from developing, if possible."

## IMPACTS OF SYMPTOMS ON THE LIVES OF PEOPLE WITH ECZEMA

The direct quotations from meeting participants featured so far illustrate the tightly bound relationship between symptoms, such as itch and sleep disturbance, and impacts on many aspects of the lives of people who experience them. Here we look specifically at some of the impacts that were mentioned most often as intruding on their lives.

### PHYSICAL EFFECTS

Panelist **Sarah Pry** spoke about the ways eczema affected her son's sleep and physical condition.

"Aiden's eczema became a struggle at three months as it started to flare all over his body. Even though I was told his condition would more than likely be temporary, there have been years of nights that I've slept in the same bed as my son. I still do. I rub and scratch gently for him. If I don't, he can – and literally will – tear himself apart. At two years old he had no eyebrows from scratching his face so hard. He really didn't have any hair on his arms or legs. He has scars everywhere and is still making new ones."

Another description of the severe physical impacts was provided by **Joseph Cutaran**. "At six months old, our son Drew was admitted into the hospital for one and a half weeks because he was labeled 'failure to thrive.' Based upon the open lesions on his back, he was thought to have a rare form of cancer by the head pediatric oncologist and head rheumatologist at the children's hospital in Fort Worth. After reviewing the blood work that we demanded, he also was found to have super low sodium levels and we were told he should be in cardiac arrest or in a seizure. His body downsized back to a newborn diaper. We were following our physicians' treatment plans and Drew was eating all the time, but his body was using all its energy to fight infection and not to grow."

**Hanna Kim** described the impact of eczema on her cognitive abilities. "I'm a full-time student. There are 8:00 a.m. lectures and sometimes I'm so tired that I can't even concentrate. For a really long time I thought I was stupid. My friends always got 90% on their exams; and then there's me, looking at my 60% being like, 'Oh my God. Why can't I get this stuff?'"

"I'm a full-time student. There are 8:00 a.m. lectures and sometimes I'm so tired that I can't even concentrate."

– Hanna Kim





"I couldn't take care of my daughter the way I wanted to because I was too busy taking care of myself; I felt selfish."

— Maria Harris

Eczema brings with it food sensitivities and sometimes food allergies that complicate life and health, as **Raelle Brown** explained, "My diet completely changed. I was reacting to absolutely everything and I came to a point that I lost at least 15 pounds, leaving me barely at 100 pounds. There wasn't really a visual difference between me and a cancer patient. Exhaustion, soreness, sweat that hurt and burned just for basic movement." **Rachel Bronstein** spoke about her dietary restrictions. "I eliminated gluten and dairy to try to reduce the inflammation. And when dairy was reworked back into my diet, I became anaphylactic. So now I have a dairy allergy from eliminating it," she said.

Eczema restricts activities as well, as **Brianna Cox** told meeting participants. "Playing at recess, running in gym, using play dough, paints and chalk, and sand would make my skin erupt in red inflamed lesions. My hands and feet would split and these things would cause persistent itch.

Wearing gloves was not a solution because the heat caused sweat and it would also cause the same issues." **Kylie Bogar** had to give up a favorite activity. "I just stopped doing pointe [ballet] because the tights would rub against the backs of my legs and all the skin would come off. It would be red and itchy; it was absolutely horrible." **Hanna Kim** shared a similar experience. "In 2016, my eczema started to get really bad. I had to quit my job as a professional cheerleader for a Canadian Football League team, the BC Lions. I really loved it and just could not do it anymore. It was really hard for me. When my cheer friends asked, 'Are you coming back next year?' I lied and blamed it on school."

**Maria Harris** spoke about how eczema interfered with her ability to parent her daughter. "I couldn't take care of my daughter the way I wanted to because I was too busy taking care of myself; I felt selfish. My mobility was limited. I had to nurse her with stiffness in my neck, burning skin all the while. Sometimes I couldn't even hold her. I had to stop nursing her, wake up my husband, and tell him to take care of her. She'd cry, and that really broke my heart because I couldn't nurse her as much as I wanted to. I ended up also having eczema herpeticum. I had to tell her not to touch my face because the sores were there."

Various aspects of the environment can trigger or worsen eczema, so many individuals and families have to take strong measures to detect and avoid lots of things, as **Keri Kelley** described. "Eczema means re-homing your family dog and removing all the carpet from your house, trying to search for the triggers. It means journaling obsessively about diet, daily activities, fragrance exposure, and the weather. It means keeping photo diaries so you can assess whether things are improving or declining. It means feeling jealous as you watch the neighbor's kid sit in the grass without a care in the world." A webcast participant, **Kristina Howell**, echoed this burden. "When a bad flare happens, you have to try to remember everything that happened and possible causes, trying to quit or change certain things to see if anything helps."

**Lisa Choy** described her constant state of alert. "I try to avoid my triggers. My vigilance sometimes leans toward paranoia. For example, coming to this meeting or traveling anywhere, I think about the bedsheets and the towels at the hotel. I wonder, are they 100% cotton? I wondered if they been laundered with fragrance-free, dye-free detergent, because I know fragrances and dyes could cause my eczema to flare. Even meeting people could be hazardous, right? I don't know if you pet your dog or cuddled your cat before you shook my hand. I don't know if you put on cologne, aftershave, or perfume because those things can make me itchy. Not all the time, but it can happen."

## EMOTIONAL AND PSYCHOLOGICAL EFFECTS

Throughout the day, participants shared heart-breaking stories about how the negative reactions of the others shaped their experience of eczema, contributing to shame, isolation, low self-esteem, anxiety, depression, and more. **Andrea Lozada-Gomez** shared her experience, both as a person with eczema and as a mom of a child with eczema. "I have suffered with eczema for 15 years. My youngest child was diagnosed with eczema on the back of her knees this past March. Thankfully she has me. One of the effects that gets you at a very young age is the impact on your self-esteem. Your anxiety and depression is real. My 3-year-old told me, 'Mommy, I don't want to wear my shorts. My legs are ugly.' And I can relate so much, because at 12 years old in 7th grade with a flare-up all over my face, you feel ugly."



"My 3-year-old told me, 'Mommy, I don't want to wear my shorts. My legs are ugly.' And I can relate so much, because at 12 years old in 7th grade with the flare up all over my face, you feel ugly."

– Andrea Lozada-Gomez

**Greg Clark** talked about the added weight of the emotional burdens from eczema. "The loneliness came from the sense of the skin oozing, the skin shedding, not sleeping. When you do sleep, waking up and just seeing it there, being stuck and trapped in bed. You're already isolated physically and now it's attacking you mentally. And when it gets to you mentally, it's really cumbersome."

**Anne Marre Bautista** reflected on the impact of eczema on her childhood. "When I was a kid, the most severe eczema symptom was the itching part. Not only did it affect my sleep, but when I was younger, I would itch and itch and therefore I would get bullied at school. Other children didn't understand what I was going through. I got isolated from the group because they thought I was contagious. I would miss months of school because of bullying. So I was very vulnerable and it really affected my childhood. I'm not saying that it doesn't affect me now as an adult, but the difference is that now I am stronger as a person."



"I would get bullied at school. They thought I was contagious."

– Anne Marre Bautista



This resonated with webcast participant **Ganesa McIntosh**, who added, “Bullying from adult educators and children who do not understand can sometimes make isolation a welcome change from negativity in my experience. I refuse to let negative reactions crush my child! Children with eczema have brilliant minds with a complex condition. How do we help everyone understand? It’s hard.”

**Sarah Pry** spoke to the burden of these effects on 11-year-old Aiden. “His mental state has been completely affected. We have tried counseling and when the hard questions come, so does the scratching. His burden and mental scars are much deeper than the ones on his skin. He doesn’t like to talk about it or how it makes him feel. Our family and I are his voice, but I can’t always tell or say exactly what or how he’s feeling. I can only watch and pay attention. I can tell you he has very little self-confidence or self-worth. He’s told me that he just wants to be ‘normal.’” This yearning to be “normal” weighed heavy on many participants, as we heard often in regard to desired treatment outcomes later in the day.

Webcast participants focused in on the emotional and identity impacts on their lives:

“The anxiety of not knowing when I’ll flare up again and not being able to get it under control in time for a social event. Social isolation.”

– Devin Shaheen

*“I’m in a wedding in a couple months and I wonder how I will look in the photos and how insecure I will feel that day.” – Kristina Howell, participating by webcast*

*“The anxiety of not knowing when I’ll flare up again and not being able to get it under control in time for a social event. Social isolation.” – Devin Shaheen, participating by webcast*

*“The not knowing is super tough. You are constantly on the edge of figuring out if what you’re doing, eating, touching, experiencing that particular day will affect you. It can cause major anxiety.” – Briana Banos, participating by webcast*

*“My parents divorced just after I was born and I had eczema since I was 2 months old. I lived with my grandparents and they didn’t know how to take care of my condition. I was depressed because no one cared for me and that made my eczema worse. It was a cycle of depression and eczema for 25 years. Now I’m married and found a bit of happiness. My eczema is better but it is still an ongoing issue.” – Takeawaysc, participating by webcast*

## SOCIAL AND INTERPERSONAL RELATIONSHIP EFFECTS

The emotional impacts are intertwined with challenges interacting and maintaining relationships with friends, family, and even strangers. As **Danielle Alexander** recounted from childhood memories, “You go to school where you definitely don’t interact with people because they don’t want to interact with you. You’re scratching. You just want to scratch so badly all day – that itch is just so nightmarish. But you get through all of your classes. As soon as you get home, you go to your bedroom, which I called my ‘glass house.’ When I was there, I could look out the window but nobody could see me. I didn’t want you to see me ripping at my clothes, scratching until I was raw.”

**Raelle Brown** spoke to how eczema affected her relationships. “My social life is non-existent. Something as simple as going to my best friend’s house had to be cut because she had a cat. Every relationship has been completely transformed. Even going to the beach or the pool creates fear or simply avoidance because of the unknown effects on this disease. This can be directly correlated with its burden.”

A few people spoke about the impact on intimate relationships, including **Elizabeth Hoff**. “How could anyone love me when the bed is really not a comfort place? How do you have a deep relationship with a partner when you don’t want to be touched and the

bed is disgusting and filthy? When you have to wash your sheets every day because of the bloodstains? I think this has an impact on both the isolation and the divorce rate of patients who suffer.”

**Kelly Barta** raised this issue, too. “The topic of physical intimacy in our relationships is very personal, but it impacts us all. There are very mixed emotions – frustration, disappointment, anger – that I have to count as a cost in an area of life so many others take for granted, one that should be full of joy and freedom. With our partners, there’s a whole risk of, ‘Do I talk about this and potentially make it a worse problem, because now they feel bad?’ Or do I just have to decide what sacrifice is worth their happiness and my happiness. It’s just very complicated.”

“My husband who’s the man of the house wanted to take care of his wife. But he didn’t know how and I didn’t know how he could. It’s almost like the family circle’s broken. I couldn’t take care of my daughter; my husband couldn’t take care of me; and here I am alone having to take care of myself,” mourned **Maria Harris**.

**Stephen Gawron** related his last moments with his dad. “In my 30s I had not seen my father in over 10 years. Upon learning of his impending passing, I visited him one last time in the hospital. With his eyes closed he asked me if he had any grandchildren. I had to tell him, ‘No.’ I watched the tears roll down his face when he asked me, was this because of my skin? And I said, ‘Yes.’” Stephen questioned how his father experienced this loss, “Am I a failure because of eczema?”

**Amando de la Libertad** added to the impact on family relationships, referencing the interaction between his two children. “I have a son who’s younger than my daughter with eczema; he does not suffer from this condition. There is that interplay of managing her needs with his, figuring out how to explain to him what’s going on and why she has to go through these different routines. At some point they’re going to be older and they’re going to better understand what’s happening and the differences between their experiences.”

## FINANCIAL IMPACTS

As Dr. Silverberg described in his opening presentation, the economic burden of eczema mounts from numerous sources – direct medical expenses, both out-of-pocket expenses and those covered by other payers; costs for medical insurance coverage; travel expenses related to seeing out-of-town specialists and to participate in research (beyond what might be reimbursed); payments to counselors, tutors, and for other emotional, social service, and educational supports; costs for over-the-counter products including skin care products; additional food costs to adhere to particular dietary restrictions; relocations of or modifications to the home (as several participants addressed above); and costs for financing or carrying debt related to these and other expenses.

Days, weeks, and years of missed work or school due to symptoms and/or their impacts were a common refrain among participants, like this comment from **Stephen Gawron** and others quoted above, “My skin was so bad that I ended up in the hospital for weeks at a time with severe staph infections. That obviously caused me to miss endless days of school, and then even work further on in life.”

Participants reported the impact of eczema on educational attainment, career choice, or changes to jobs or workplaces, along with their financial consequences. Several people stated that they lost beloved careers, including **Molly Evans**. “I no longer get to work



“I have a son who’s younger than my daughter with eczema; he does not suffer from this condition. There is that interplay of managing her needs with his, figuring out how to explain to him what’s going on.”

– Amando de la Libertad



**"My son Sawyer has never experienced a day that wasn't ruled by his skin."**

– Heather Sullivan

as an elementary school principal, which was the best job in the whole world. I can't trust my skin yet to do it, but what I can do is trust myself to be strong enough to own what this skin looks like and accept that I have eczema here and here," she said pointing to several places on her body.

Another account came from **Andrea Lozada-Gomez** who lost her job at a community clinic. "Last year I had a really bad reaction to Dupixent where I was paralyzed from my neck down my shoulder, and they just wouldn't work with me on it. I am now working part-time as a librarian. On the weekends I bartend just to make ends meet. I thank God that I have my mother and my children's father to help. They are my support system. If I didn't have them in my life, I wouldn't be able to stand here with such confidence and reassurance to let you all know that we will get through this."

**Raelle Brown** was running her own business when she had the worst relapse in her lifelong battle with eczema. "I had to work much less during this period, revolving my work around how I felt because I had no ability to push through – the added stress would make my night or next day worse. This led me to rely more than desired on credit cards, my savings, and my wonderful parents. I had to do side jobs that didn't require much of any effort so that I didn't feel overworked. Although working remotely and freelance helped, I still could do only the minimum requirements rather than the above-and-beyond work I have always done."

**Shawna Wiggins**, participating by webcast, made this plea, "Let's talk about the disability process. [It was a] three-year process. [I'm] Bankrupt."

Time spent on extra self-care regimens and personal hygiene impact productivity and take hours and energy away from work or school. **Hanna Kim** talked about this drain, "I clean my bed sheets every two days. I wake up three hours before school just so I can come home to not-dirty sheets or floors."

**Tyler Berryman's** time-intensive routine rose to one of his greatest annoyances about eczema. "Every time I shower, I've got to apply the moisturizers, the creams, and any other stuff – if I'm on a more serious treatment regimen. This puts a limit on how quickly I can go do anything. When asked to add something to my schedule, I just straight up have to say, 'No, I won't be ready in time. There's no way.'"

Finally, **Raelle Brown** addressed the opportunity cost of time spent keeping up-to-date on information about eczema. "I couldn't do much else physically or thinking mentally due to the constant reminder of pain. I spent hours researching for help that my doctors could not give me."

## IMPACT OF CHRONICITY

A recurring theme through the day was the ominous, oppressive, omnipresence of eczema on people's psyche. **Heather Sullivan** put it simply, "My son Sawyer has never experienced a day that wasn't ruled by his skin." **Lindsay Swire Jones** described it this way, "I recently had a physician tell me that eczema patients are brave for being willing to try new treatments, but I don't feel brave. I feel desperate. I am exhausted all the time from battling my own body."



**Lisa Choy** expressed her constant attention to her condition. “It took me almost six months and required a monumental effort to get myself from severe to mild. Maintaining this mild state is incredibly exhausting and time-consuming. So for me, living with eczema means almost every waking moment, I am: 1) Thinking about my eczema; 2) Treating my eczema; and 3) Managing my eczema.”

**Kelly Barta** held up a Spiderman suit to illustrate this point. “Imagine you put this on and zip it up. Every piece of you is covered with this suit and now this suit can turn on at any given time. It can start itching; it can start burning. You’re hot, you’re sweaty. Now imagine, your arms and your neck are itching. Maybe it’s your face itching. Maybe it’ll last a week, maybe a month, maybe two months. You can’t make it stop. Now it’s on your legs. This is the chronic nature of eczema. You can’t control it. You can’t predict it. It’s going to do what it’s going to do. You can find some temporary relief, but it doesn’t really fix it. And now imagine, I tell you, you can never, ever, ever, ever take this suit off. You’re going to wear it for the rest of your life. You’re going to go to bed with it. You’re going to wake up with it; you’re going to take a shower with it. You’re going to go on dates with it. You’re going to go to work and give your presentation that you’ve planned for a year and you don’t know what your skin’s going to do. That’s what it’s like living with eczema. That’s what it’s like when people tell you there’s no cure.”



“When I look back at the first year of Drew’s life, I see that we were robbed of all those happy and joyous milestones that a couple should have when they have their first child.”

– Joseph Cutaran

## IMPACTS OF ECZEMA ON FAMILIES AND CAREGIVERS

Based on a live poll taken at the start of the first session, approximately 45% of meeting participants were there to speak on behalf of a loved one who has eczema – they were mostly parents, but also spouses, partners, and other family care partners. What was made clear through their comments is that the impacts of eczema relate not just to the person diagnosed with the condition, but to the people who live with them, provide care for them, and love them. This was borne out in the survey responses as well, which will be explored in Section 3 of this report.

The first speaker on the morning panel, **Joseph Cutaran**, described the impact on his family in piercing terms. “This panel is about burden. I don’t know if I like that word for our situation because being a father – doing anything to keep my child safe and healthy – is not a burden. It’s my job. But when I look back at the first year of Drew’s life, I see that we were robbed of all those happy and joyous milestones that a couple should



"Caring for a child with eczema means long-term sleep deprivation and the anxiety that follows. You aren't able to sleep even when you have the opportunity because you're always on edge."

– Keri Kelley

have when they have their first child. You understand what I'm talking about – all those milestones that everybody posts on Facebook and Instagram at one month, two months, etc. I don't remember any of that. I don't remember having the joy of seeing Drew learn to crawl when we were expecting him to crawl. My wife, Christine, and I didn't have the joy of people commenting, 'Wow, your son is growing so fast.' I don't remember hearing Drew laugh when he recognized that his dad had just come home from work. Nope. Instead, I remember hearing the pain in my wife's voice when we couldn't figure out why my few months old baby boy had sores and open lesions spreading across his body. I remember the blank stares that Drew would give me, wondering to myself, 'Why does my child not smile?' It turns out the blank stares were that of constant itch, pain, and infection, and that was his normal. That's all he knew."

**Lynell Doyle** shared a similar feeling of helplessness in caring for her son with eczema. "Imagine perpetually having a dried lump in your throat every time you look at your child's battered body from his war with eczema. Feel the heaviness of having tear-stained eyes whenever you hear your child's pained cries for relief from yet another bout of nightly scratching. You are his mom or dad and it's your job to take care of him and to make everything all right, but this time you can't. You've tried and tried and there's little to nothing you can do because you simply don't have access to a cure or even a worthwhile patch that can make it all better right now. What a sad, helpless, and hopeless feeling. This is a sad, helpless, and hopeless feeling that I personally have felt many times."

This helpless feeling was compounded for **Ashley Ellis**, an experienced health professional. "I have been a pharmacist with a passion for patient care for the past 13 years. As we progressed along with Hadley's treatment, a deep sense of guilt started to creep in because as Hadley's eczema got worse, I realized that no matter what I did, she was not controlled at all. I could help patients every single day and see results with them, but I wasn't able to help my own daughter."

Feelings of guilt at not being able to do more or take away their child's pain and suffering were expressed by many of the parents who participated, including **Sarah Pry**. "Aiden has not had, and possibly never will have, the childhood that I'd wished for him. I've been looking into his face for 11 years. They look back at you with all of their pain and all they can do is cry. They ask you why all this pain is happening to them. Why can't Mommy, the person that is supposed to be able to cure anything, make it stop? I can tell you Mommy's kisses do not fix this. Imagine, if you can, the guilt and anger we feel as parents and patients because we can't fix it. Because even when we have done everything we've been taught to do, the itch still gets to him and he hurts all over again." **Shawna Wiggins**, participating by webcast, contributed that her 80-year-old mother feels guilty that she can't provide relief for her child.

The endlessness of the experience is a source of constant worry, anxiety, and sleeplessness, as several parents related. **Keri Kelley** was among them. "Caring for a child with eczema means that you shamefully wish for an end, any end to the torment and you consider whether you'd trade places with someone dealing with cancer. Severe eczema feels endless and it's not living life. It's just existing and coping and hoping for an end of suffering. It means wondering how your child will ever survive in this world if their skin is failing them at keeping the bad out and keeping the good in. I even started wondering what my son's funeral would be like. It means long-term sleep

deprivation and the anxiety that follows. You aren't able to sleep even when you have the opportunity because you're always on edge. You're always anticipating when your child's next scratching fit is going to start. You always have a hand on them all through the night, scrolling the internet looking for a miracle."

For some, the feelings of guilt extended to wondering what role they had as the source of their child's eczema. **Joseph Cutaran** mentioned this about his wife, Christine.

"One of the worst things was watching Christine blame herself for this. Since she was breastfeeding, she thought she was the cause. She went on a total elimination diet and at one point ate only 'benign foods,' being literally ice cubes and water." Motioning to Christine, he continued, "She is about five feet tall on a good day and maybe 100 pounds soaking wet. But when she went through that elimination diet, she just looked sick. There's no any other way to put it. It was hard seeing her that way, and this was not how we envisioned life as new parents."

Several panelist-parents shared the impact that their child's eczema had on their marriage and other family relationships. **Jason Tullos**, participating by webcast, wrote in to support his wife, Kathryn, a panelist and member of the More Than Skin Deep project team. Cheering her on, he said, "Kathryn is one of the strongest and smartest people I've ever met! Our son is better because of her strength and proper treatment." Others noted the strain on marriages and families.

*"As we watch our son suffer, our marital conversations often revolve around treatment, symptoms, and triggers. We don't always agree on what should be done to help Cooper. Our ideas don't mesh, causing tension in our home. The never-ending search for normalcy is mentally and physically exhausting for everyone."* – **Angela Fox**

*"Date nights or even quiet dinners at home for just the two of us were nonexistent. When my husband and I would catch a few moments of downtime, we spent it sobbing together."* – **Keri Kelley**

*"Drew's condition strained my marriage. My wife and I are just now learning how to be a couple again, because the past few years we've just been tag-team caregivers."* – **Joseph Cutaran**

*"My daughter, Hazel, was diagnosed with severe eczema at just a few months old. But when her brother, Sawyer, was born a couple years later, the term 'severe' took on a whole new and frightening meaning. It feels unavoidable that my daughter's eczema treatment took a back seat to the ever-consuming task of getting Sawyer through each day."* – **Heather Sullivan**

The challenge of working outside the home was raised often. **Joseph Cutaran** mentioned the necessity of one parent staying home to provide the level of care needed for the child with eczema. He also admitted feeling bad that his wife would be at home, while he had an outlet. "I had extreme guilt waking up in the morning knowing that I got to go to work. People say things like, 'Dang. I don't want to go to work.' But I was so guilty because I got to get away from the house for eight hours. I got to go out for lunch, hang out with coworkers. After lunch my thought was, 'Oh shoot, I've got to get back to the routine again. I've got to go back to the itchy son who's going to rip his skin off.'" **Keri Kelley** reported her husband had a similar feeling, "He told me that he would dread coming home from the office because he knew the real work was about to begin."

Several parents referenced long and/or repeated family trips to take their children to see experts. "Sawyer has been all over this country to visit specialists, and his medical files have traveled to many continents in our desperation to get answers," **Heather Sullivan** stated. She went on to explain that one treatment approach required monthly blood

**"Our marital conversations often revolve around treatment, symptoms, and triggers. We don't always agree on what should be done"**

– Angela Fox

**"This was not how we envisioned life as new parents."**

– Joseph Cutaran





"The cruel irony of my situation is I understand complex biology; I understand genetics. So I carry great guilt that I may have given this to my daughter."

– Sean Scott

draws and nearly 40 trips to the prescribing university 300 miles from their home. **Keri Kelley** shared one experience, "By age two, Callen's eczema was out of control. He was accepted into the program at National Jewish Health around the same time I gave birth to my second child. We were so desperate to get help that at two weeks postpartum I drove all night from Oklahoma to Colorado with my newborn while my husband and Callen flew to Denver because driving with my son seemed impossible at the time. We spent our baby moon living at a Ronald McDonald house doing skin tests, blood draws, food challenges, and learning the messy art of wet wrapping." These expeditions take time, cost money, and take a huge emotional toll on the family.

Late in the day, another parent spoke for the first time, **Sean Scott**. He put his motivation for participating in the meeting into terms that drew head nods from around the room. "I have expertise in genetics and genomic technologies and most of my career has been spent in research and diagnostics to help detect rare diseases and provide hospital systems with better solutions for identifying treatment and trial options for their patients. My daughter, Jemma, is 12 years old. She was diagnosed with eczema at birth and has severe atopic dermatitis. The cruel irony of my situation is I understand complex biology; I understand genetics. So I carry great guilt that I may have given this to my daughter. And so that drives great sorrow. But I've been able to harness that emotion into wanting to contribute and influence positive change. And that's in part why I'm here today."

Finally, **Lynell Doyle** shared a conversation she had with her son about the meeting. "As I was writing my panel statement, my son asked if I was nervous. I had to think about it for a minute. Yes, I am nervous. I'm nervous that treatments for my son and all our children will not be as effective and/or even available to them. I'm nervous that without continued drug research and approval, a cure for this awful life-stripping disease will not come soon enough, or at all."

## SESSION 1 WRAP-UP

"It's my honor to close out this morning and what a morning it has been," said **Tonya Winders**, CEO of the **Allergy & Asthma Network**, another of the five collaborating hosts of the **More Than Skin Deep** initiative. "We have spent the last couple of hours focused on symptoms and the daily impact of this disease. I am the mother of five teens. My 16-year-old daughter, Katelyn, lives with moderate atopic dermatitis and I heard her voice in so many things that were said today. 'Why am I not the pretty sister?' 'Please don't touch me mom.' 'It hurts.' 'Will anyone ever love me?' I cannot say thank you enough to those of you who are bravely here, sharing your stories, raising the fact that this disease is truly 'more than skin deep.'"

"I cannot say thank you enough to those of you who are bravely here, sharing your stories, raising the fact that this disease is truly 'more than skin deep.'"

– Tonya Winders, President & CEO,  
Allergy & Asthma Network









"Throughout his short life, Cooper has been on 10 topical steroids, 2 topical antibiotics, 2 nonsteroidal creams, 10 different allergy and asthma medications, multiple eye creams and drops, allergy immunotherapy via shots and drops, oral steroids, multiple oral antibiotics, several bath additives, multiple rounds of allergy testing, and various creams, supplements, probiotics, and vitamins. And that is just what we can remember. He has seen numerous dermatologists, allergists, immunologists, pediatricians, and alternative medicine doctors."

– Angela Fox



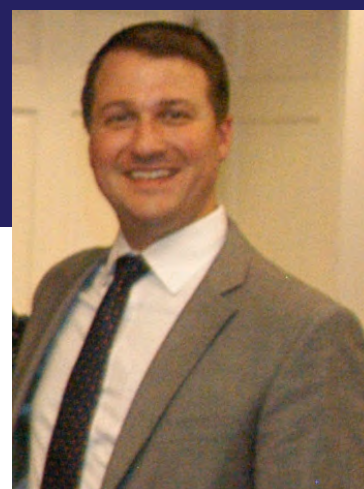


## SECTION 2

# TREATING AND MANAGING ECZEMA

Following a break for lunch, moderator **James Valentine** introduced the topic for the afternoon session. “Building on this morning, we shift our focus now to the different approaches to treatment that you employ in your daily lives. We are defining ‘treatment’ very broadly to include not just prescription drugs or biologics, but also medical procedures, anything you purchase over the counter, and modifications you make to your lifestyle, such as bathing regimens or special diets. We want to understand how well those things are working for you and what you experience as downsides. We’ll also talk about changes you’ve made over time and the reasons for those changes. Finally, looking towards the future, we’ll explore what you’d like to see from future therapies.”

**Dr. Jonathan Silverberg**’s morning presentation included a brief outline for how treatment is approached in clinical practice. He drew heavily on a step-care approach to management that he and other authors published in *Annals of Allergy, Asthma & Immunology*,<sup>11</sup> summarized in a table from the article shown in Inset 5, on the next page. Dr. Silverberg explained, “We always start with a conservative approach – with moisturizing, gentle skincare, trying to avoid triggers, first and foremost. We try to avoid medications if we can, but for so many patients this non-medicinal approach is not enough. We step up to using prescription topical corticosteroids (TCS), calcineurin inhibitors, and now we have topical phosphodiesterase-4 (PDE-4) inhibitors.” He then addressed the treatment of more moderate to severe disease. “We start stepping up into additional kinds of therapies. There are oral systemic immunosuppressing agents like cyclosporine and methotrexate. There’s narrowband ultraviolet-B (NB-UVB) phototherapy and now we have the welcome addition of dupilumab as our first biologic treatment for atopic dermatitis.”



James E. Valentine, JD, MHS,  
Hyman, Phelps & McNamara, P.C.

<sup>11</sup>Boguniewicz M, Fonacier L, Guttman-Yassky E, Ong PY, Silverberg JI, Farrar JR. Atopic dermatitis yardstick: Practical recommendations for an evolving therapeutic landscape. *Ann Allergy Asthma Immunol*. 2018. 120: 10–22.

Commenting on the tradeoffs, Dr. Silverberg continued, “If I had to rank these efficacy-wise, this cluster of dupilumab, cyclosporine, and prednisone is at the top. (See Inset 6, page 35.) Methotrexate and azathioprine are in the middle, and phototherapy a little less efficacious, in general. Other treatments like mycophenolate, antibiotics, and antihistamines are at the bottom. As for the challenges with these approaches, dupilumab is our ‘new kid on the block.’ It’s our first biologic, very effective and safe so far for long-term use. Arguably, I think it should be considered a first-line systemic treatment in patients with moderate-to-severe atopic dermatitis with inadequate response to topical therapy. There are access and cost issues that need to be navigated and we still see some non-responders, so we have to address these issues. Cyclosporine is probably the best of the available oral options, but the toxicity profile is not exactly good beyond 6-12 months use. There are a lot of side effects and a lot of required lab monitoring. Prednisone is the most commonly used systemic agent out there. It’s fast and it’s effective, but it’s also not safe for long-term use. Even with short-term use, there are studies showing safety concerns, and yet unfortunately it’s used like water in clinical practice. Nasal thiopurine, methotrexate, and many of those other therapies are a little bit slower to work, a little less robust in terms of their efficacy. Phototherapy is slower to work too, but we see robust responses when dosed appropriately. It’s likely the safest long-term option, although it does present some hassles for patients.”

Dr. Silverberg’s presentation provided context for the first-person accounts shared by meeting and webcast participants. Two panels opened the afternoon session. The first was composed of parents speaking to the experience of managing their children’s eczema. A second panel of adults shared their experiences, several of whom have been working for the majority of their lifetimes to adequately treat their disease. Following these panels, polling and moderated discussion elicited an even wider set of experiences.

## INSET 5

# STEP CARE MANAGEMENT OF ATOPIC DERMATITIS

	Non-lesional	Mild	Moderate	Severe
MAINTENANCE TREATMENT	<b>BASIC MANAGEMENT</b>  <b>Skin Care</b> <ul style="list-style-type: none"> <li>Moisturizer, liberal and frequent (choice per patient preference)</li> <li>Warm baths or showers using non-soap cleansers, usually once daily and followed by moisturizer (even on clear areas)</li> </ul> <b>Trigger Avoidance</b> <ul style="list-style-type: none"> <li>Proven allergens and common irritants (eg, soaps, wool, temperature extremes)</li> <li>Consider comorbidities</li> </ul>	<b>BASIC MANAGEMENT</b>  <b>Skin Care</b> <ul style="list-style-type: none"> <li>Moisturizer, liberal and frequent (choice per patient preference)</li> <li>Warm baths or showers using non-soap cleansers, usually once daily and followed by moisturizer (even on clear areas)</li> </ul> <b>Antiseptic Measures</b> <ul style="list-style-type: none"> <li>Dilute bleach bath (or equivalent) ≤2x/week according to severity (especially with recurrent infections)</li> <li>Antibiotics, if needed</li> </ul> <b>Trigger Avoidance</b> <ul style="list-style-type: none"> <li>Proven allergens and common irritants (eg, soaps, wool, temperature extremes)</li> <li>Consider comorbidities</li> </ul>	<b>BASIC MANAGEMENT + TOPICAL ANTI-INFLAMMATORY MEDICATION</b>  <i>Apply on areas of previous or potential symptoms (aka flare)</i> <b>Maintenance TCS</b> <ul style="list-style-type: none"> <li>Low potency 1x-2x daily (including face)</li> <li>Medium potency 1x-2x weekly (except face)</li> </ul> <b>OR Maintenance TCI (pimecrolimus, tacrolimus)</b> <ul style="list-style-type: none"> <li>1x-2x daily</li> <li>2x-3x weekly (not an indicated dosage)</li> </ul> <b>OR Crisaborole 2%</b> <ul style="list-style-type: none"> <li>2x daily</li> </ul>	<b>BASIC MANAGEMENT + REFERRAL TO AD SPECIALIST</b>  <b>Phototherapy</b> <b>Dupilumab</b> <b>Systemic Immunosuppressants</b> <ul style="list-style-type: none"> <li>Cyclosporine A</li> <li>Methotrexate</li> <li>Mycophenolate mofetil</li> <li>Azathioprine</li> <li>Corticosteroids</li> </ul> <b>Consider acute tx for some patients to help gain control</b> <ul style="list-style-type: none"> <li>Wet wrap therapy</li> <li>Short-term hospitalization</li> </ul>
ACUTE TREATMENT	<b>Apply TCS to Inflamed Skin</b> <ul style="list-style-type: none"> <li>Low to medium potency TCS 2x daily for 3-7 days beyond clearance [Consider TCI, crisaborole]</li> </ul>		<b>Apply TCS to Inflamed Skin</b> <ul style="list-style-type: none"> <li>Medium to high potency TCS 2x daily for 3-7 days beyond clearance [Consider TCI, crisaborole]</li> </ul> <b>If not resolved in 7 days consider</b>	<ul style="list-style-type: none"> <li>Non-adherence</li> <li>Infection</li> <li>Misdiagnosis</li> <li>Contact allergy to medications</li> <li>Referral</li> </ul>

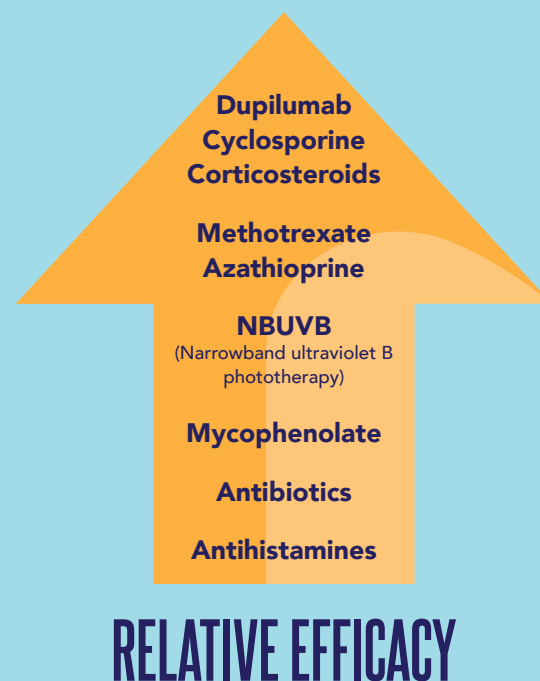
## HADLEY ELLIS' EXPERIENCE: HIGHLIGHTING CHALLENGES AND BURDENS

Pharmacist **Ashley Ellis** was the first panelist of the afternoon, speaking on behalf of her 8-year-old daughter, Hadley. Hadley's third-grade class was watching together by webcast, one of several events organized for remote group viewing of the meeting. Ashley's statement began with a theme that would echo throughout the discussion – the multi-faceted approach to management that included a wide range of treatment approaches undertaken over time and in combination in search of sustained relief and control. As Ashley stated and others were heard to say, "We've tried every single medication, compounded cream, diet modification. You name it, we've tried it."

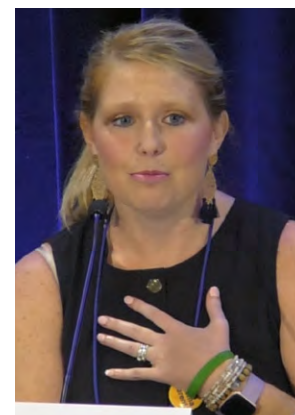
Ashley's description of their early treatment progression mirrored the step-care approach Dr. Silverberg had described, with some additions. "At one point when Hadley was a baby, she was missing so much skin on her hands that we began having to use pain medications. She had fungal scalp infections and swollen lymph nodes and required months of treatment for those." Ashley described the constant need to re-evaluate benefits and risks. "We could achieve adequate control for about two-week periods with oral cephalexin and prednisolone, both of which are unsustainable as long-term options because of the side effects and effect on her growth. So, every year of her life, we cycled through those six to eight times. Later, our allergist recommended allergy shots. Although I had given 1,000 shots my first year out of pharmacy school, I underestimated the strength of an adrenaline-fueled 8-year-old. At that time, Hadley's treatment regimen consisted of hydroxyzine four times a day for itching, moisturizing twice a day, and hydrocortisone, Protopic, and Eucrisa twice a day each, applied three hours apart." Her statement underscored the unrelenting odyssey and trial-and-error nature of much of the treatment they undertook. "A \$250 lotion that I used on Hadley's skin caused a major flare over about 80% of her arms and trunk. I stuffed it into a bag with all the other creams and lotions we had tried. That bag seems to be something each of us has."

When Hadley's overall condition worsened to include significant mental health issues (as described on page 19), their doctor recommended methotrexate. Ashley described her reaction, "My heart dropped. My entire career is built on recommending medication and explaining what we can expect in terms of benefits versus the risks. But in this situation, my heart was just breaking. I could only think like a mother. 'What are the side effects?' 'How long can she be on it?' 'Will it affect her growth?' 'Will it affect her fertility in the future?' We worked through some of those questions and I didn't want to do it. We explored treatment with Dupixent, but the clinical trials were closed, our insurance company would not cover it, and the out-of-pocket expense was just too much for us. So, I was kind of in a corner and Hadley was struggling. We had to do something. We did the blood work to start methotrexate."

Ashley described the further obstacles – the injections, her lingering doubts, and the fact that none of her colleagues said unequivocally that they would have put their child on the drug. "I was very uneasy, but we persevered. Surprisingly, the methotrexate gave her remarkable improvement." Describing the benefits, Ashley reported, "She's making straight A's in school and she doesn't scream in the bath or in the morning when we apply her lotion. She's calmer and she's braver. She has developed this precocious empathy that allows her to tune into other people's suffering. Other adults around her



*Referenced by Dr. Silverberg in his clinical overview presentation*



"A \$250 lotion that I used on Hadley's skin caused a major flare over about 80% of her arms and trunk. I stuffed it into a bag with all the other creams and lotions we had tried. That bag seems to be something each of us has."

– Ashley Ellis





Hadley Ellis

“Every eczema patient deserves excellent care and the best available treatments – and a future full of hope and innovation.”

– Ashley Ellis

The many factors that affect individuals’ treatment experiences came through in the meeting discussion.

tell me she’s kind of like a different child. She still hates the shots, but she has developed strategies through counseling to get through it.” The outcomes have extended to Ashley’s own state of health. She added, “I am no longer feeling physically depleted and exhausted the second I drop her off at school.”

In spite of the notable improvement methotrexate has contributed, Hadley’s overall treatment protocol remains burdensome. Ashley detailed it, “What it takes to control her eczema right now is: hydroxyzine four times a day; moisturizer twice a day; Eucrisa and Protopic twice a day; Triamcinolone twice a day; Singulair once a day; methotrexate and folic acid once weekly on different days; sertraline for panic attacks; biweekly counseling; and monthly allergy shots. Does that sound like a lot? It is. If I had to pay cash out of pocket it would cost \$2,000 per month. And for that, she’s okay, but not great. And she still has eczema.”

She described another challenge they would soon face. “We’re nearing the end of a safe, predetermined amount of time for Hadley to be on methotrexate. I was terrified for her to start the drug and now I’m terrified for her to stop it without another option in place. Right now, I don’t have another option.”

Ashley concluded with this call to action. “Let me be clear: Hadley is currently subsisting and that’s due to a good doctor and a relentless mother – who happens to be a pharmacist – and who won’t take ‘no’ for an answer. Average patients cannot be expected to navigate these challenges to access moderately effective care. Children and the families who love them are barely getting through the day and they’re barely living through the struggle. So, the current status quo we have right now is not good enough. Every eczema patient deserves excellent care and the best available treatments – and a future full of hope and innovation.”

## TREATMENT APPROACHES

As both Dr. Silverberg’s presentation and Ashley’s testimony illustrate, selection of a treatment approach and individual treatments within that approach are guided by many factors, including: medical history and physical examination, personal treatment goals and preferences (both of the patient and caregivers for pediatric patients), assessment of expected benefits against potential harms and/or risks, tolerance for side effects and adverse events, accessibility, costs, and convenience. The many factors that affect individuals’ treatment experiences came through in the meeting discussion, with both similarities in experiences conveyed through comments and head nodding around the room. There were points of divergence as well.

Below we review the various treatment elements that were raised in the meeting and report some of the experiences with those treatments as were shared by participants.

## DRUG TREATMENTS

**Topical Corticosteroids (TCS):** As Dr. Silverberg described in his overview of treatment, therapy for mild-moderate eczema often starts with TCS therapy. Topical corticosteroids come in a variety of strengths and formulations, from low potency creams and ointments sold over the counter to progressively higher strengths or formulations available only by prescription. Polling results from meeting participants indicate that TCS were the most-used therapy – both at present and in the past. Results from the **More Than Skin Deep** survey showed that 97% of respondents were currently using them or had used them in the past.

The composition of people attending this meeting – with live polling indicating 71% affected by moderate or severe eczema – reduced the chance that TCS therapy alone would have been sufficient, as can be the case for people with mild to moderate symptoms. Experiences shared by meeting participants – both those in the room and attending by webcast – reflected that their positive response to treatment with TCS was temporary, mixed, and/or overshadowed by harmful impacts over time. Others expressed challenges using TCS until they used them in a specially compounded formulation with antibiotics and moisturizers, known as Compounded Antibiotic-Steroid-Moisturizer (CASM), or the Aron Regimen after its originator, Dr. Richard Aron. (See Inset 8, page 40, for additional information.)

While the exposure to TCS was nearly universal, almost half of meeting participants who had tried TCS were no longer using them according to polling during the meeting. For some, this treatment was simply not effective at any strength. Panelist **Heather Sullivan** has two children with eczema; Hazel is moderately affected while son Sawyer is severe. “Both children failed to respond to topical steroids at the mild and mid-level. They were prescribed [stronger] steroids with black box warnings as infants. Hazel is fortunate to experience some intermittent relief from a few of these, but Sawyer appears not possible to respond to steroids alone.”

**Lindsay Swire Jones** described how her use of TCS changed over time. “During my 20s, I was prescribed countless tubes of topical steroids with little to no warnings about usage. My skin looked great, so I used them pretty much daily. A few years later, I saw a dermatologist who added steroid injections. Then, one winter, I had a flare so bad that the steroids didn’t even begin to touch it. My body had gone into some sort of steroid dependency mode. It was no longer reacting positively to prior dosing.” Webcast participant **Tiffany Watson** shared her son’s similar experience. She wrote, “Over the years we were prescribed topical steroids with increasing potency. That was followed by oral steroids, then shots. His body started reacting negatively to steroids. We then stopped all steroids.” Several participants referenced accumulated tolerance to steroids and the difficulty of withdrawing from them, as well as positive outcomes at the end of the arduous process, as described in Inset 7, page 38.

Several participants pointed out that the instructions for use of TCS creams often lack details that would help patients and parents better understand the risks and potential harms. **Jolene MacDonald** spoke to her 9-year-old son Max’s experience. “He was diagnosed as a baby and at three months old he was prescribed a low level topical steroid cream. We were told to use as needed twice a day on affected areas. At nine months old, he was tested for food allergies and found to have multiple allergies, so we tried to eliminate those things from his diet. At the same time, our pediatrician recommended a second topical steroid cream and it was a much higher strength, class three. At the time, we had no idea about the classes. I think the classification system is a key piece of information that parents and patients should have access to and understand, given how potentially harmful they can be for a small infant.”

Webcast participant **Andrew0099** gave voice to the challenge of weighing the tradeoffs for TCS therapy. “My son has been on and off all kinds of eczema treatments. One reason we have stopped is after a while, the treatments seem to stop working as efficiently and when the eczema returns, sometimes it’s worse. Nothing we have tried heals it completely, so you begin to weigh pros and cons. Do you take the risk of constant full-body topical steroids for only partial relief from the eczema? Or, do you go off the medications and deal with the eczema? Sometimes you’re choosing between two evils and there is no right answer.” Several other webcast participants weighed in with comments like this one from **Kelly Russo**, “Steroids are worse than the disease itself.”



“My body had gone into some sort of steroid dependency mode. It was no longer reacting positively to prior dosing.”  
– Lindsay Swire Jones

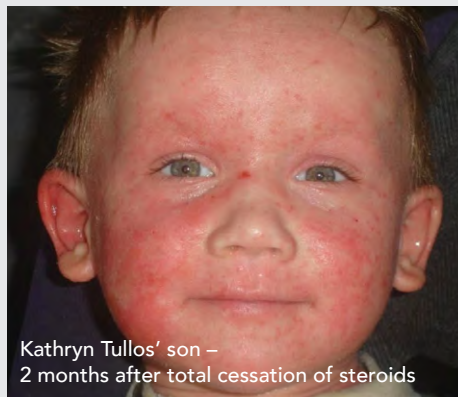
# TOPICAL STEROID ADDICTION AND WITHDRAWAL

As was heard throughout the day, the mainstay therapy for eczema, topical corticosteroids (TCS), carries a risk of serious adverse events associated with prolonged use of TCS, especially with escalating dosage, potency, and frequency of application. Many meeting participants (both in the room and participating by webcast) shared their experiences with these adverse events and the cessation of TCS products. About half of the survey respondents indicated they had withdrawn completely from steroid use. The resulting condition is known by several names, including "topical steroid addiction," "topical steroid withdrawal," and "red skin syndrome." Symptoms can arise in spite of strict adherence to prescribed TCS treatment protocols and can be mistaken for "worsening eczema." Meeting participants in which this occurred indicated their experience with decreasing potency, applying to fewer areas of the body, applying less often, or ceasing use cold turkey can all cause varying degrees of withdrawal symptoms, which can be severe and protracted – taking months to years to improve or resolve.



Jolene MacDonald

**Jolene MacDonald** reported how this unfolded for her 4-year-old son. "He started to go from classic eczema, in small patches and in the creases of his body, to uncontrollable spreading eczema throughout his body. The rashes were starting to intensify. When we stopped using the TCS creams, his skin, which was used to them, basically turned red over his whole body. Our understanding was that his blood vessels had become constricted and then they were vasodilating and 'demanding' more of the cream. So, we stopped all of it. Now we're five years off all topical steroid creams and I will say the itch can improve. He is not itchy during the day like he was, and his quality of life has improved tremendously."



Kathryn Tullos' son –  
2 months after total cessation of steroids



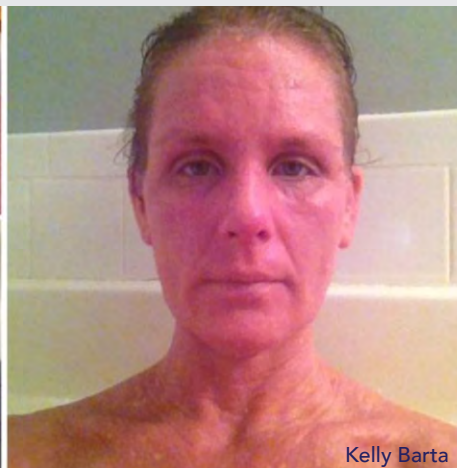
11 months after total cessation of steroids

**Kathryn Tullos's** son had a similar experience. Some of the symptoms he endured are described on page 19. She also recounted the period after they stopped TCS therapy at the recommendation of two doctors. "Topical steroid withdrawal was brutal. For months, my son was covered from his scalp to the soles of his feet with red, weeping, flaking, intensely itchy skin. Words can't explain the impact this had on my child, my family, my marriage, or my sanity, but it was hell," she said. She reports the outcome was well worth it, though. "Roughly a year after stopping steroids, my son's skin was about 85% clear. He has been completely steroid-free for six years and he has been discharged from all services of every single one of his specialists."

Several people on the webcast offered their experiences, including **Maureen Green**. "I found information about the potential impact of topical steroid addiction. I decided to try stopping the steroids and found myself in full-blown topical steroid withdrawal. I was at my worst with red, burning, itchy skin over every inch of my body, swollen lymph nodes, swollen ankles, and sleeplessness for about two years. I am now six years steroid-free with residual eczema still on my hands, arms, neck, and face. Steroids significantly impacted my life and I am so much happier steroid-free."

Like Maureen, **Kelly Barta** decided to withdraw steroid treatment after learning about steroid addiction while doing research to understand her increased sensitivities and allergies. At that time, she was using high potency TCS creams. "I thought

to myself, 'My skin's all right. I have mild to moderate eczema. I'll just use better barrier creams,' so I started doing that. It came on fast for me. Within two days of stopping steroids completely, my skin started to burn. There was this bone-deep itching and I was up all night. I started getting a splotchy rash that ended up covering me from head to toe; red, burning skin that was peeling off at alarming rates. It literally felt like someone had poured boiling water all over me. I couldn't be a real person anymore and my nervous system started to shut down. I couldn't have conversations with people; it was overwhelming. I became bedridden for a year and a half and I watched the seasons pass outside my window. I had to lie naked on towels because my skin was oozing so severely. I couldn't even turn to my side because my skin burned so badly. It took a year and a half before my body started to heal again, before I started to get back to life." Early into a very slow return to "normal," Kelly was exposed to infection with eczema herpeticum, as described on page 20. She closed her panelist testimony saying, "It was so traumatic and that scares me for our eczema community members who have been on steroids. What are we setting ourselves up for? This is something that we need to address, and we need to figure out better treatments."



Kelly Barta





**Kathryn Tullos, RN**, learned from her son's experience with TCS how "woefully insufficient the labeling for topical steroids is. There is no clear dose. There is no indication of how many 'fingertip units' is too many, how large a treatment area is too large, or how long a treatment period is too long. The phrase, 'or as directed by your doctor' gives both patient and doctor permission to ignore age-based recommendations and usage guidelines. Topical steroids are commonly used for months or years, even though the clinical trials are typically just two to three weeks in length. And there is no mention of topical steroid withdrawal syndrome as an adverse effect."

**Elizabeth Paz** emphasized that the need for better guidance applies to the lower strength TCS creams as well. She urged, "For most of my childhood, my eczema was treated with hydrocortisone that's over the counter, the 1% strength. It wasn't until I was in my late 20s to early 30s that I started getting prescriptions for stronger ones. But the 1% cream is available over the counter, so you can easily use it any time. Although I was only using it every few weeks, it has impacted my life as an adult when I'm looking for other options because even the stronger topicals, injections, and pills aren't working."

**Oral and Injectable Corticosteroids:** Several participants referred to past or present use of other forms of corticosteroids, with oral prednisone being the most commonly cited to help during a symptom flare. Dr. Silverberg mentioned the short-term nature of this treatment approach due to its safety risks over a longer term, as Ashley Ellis also described (see page 35). Participant **Hanna Kim** stated that her first experience with prednisone was very recent. "I'm actually currently on my first course of prednisone in order to come here today. I don't think I would have been able to make it here without prednisone. It was a really big decision for me, because I would prefer not to take any systemic therapies." **Erinn Schie** turned to prednisone after deciding to withdraw from topical steroids, "I ended up going on a taper of prednisone because I was crippled. I couldn't do anything for a little while."

**Pamela Friedman** described her experience with escalating use of topical and systemic corticosteroids. "My story starts with eczema as a baby, then childhood asthma and allergies that required treatment with systemic steroids. Fast-forward to my 20s and an itchy red eyelid, a visit to a dermatologist, and a prescription for a low potency steroid. Soon, I had multiple topical steroids of different potencies and formulations that I used intermittently and sparingly; applying appropriate potencies to different parts of my body only when I had flares. I was compliant, yet I kept getting worse. When topical treatment wasn't sufficient, my doctors added oral steroids. It became more and more difficult to taper without recurrence of symptoms during or immediately after the taper. Sometimes I opted for a steroid injection instead. Over time, the dosage increased and the effectiveness declined."

CONTINUED ON PAGE 41

"Over time, the [steroid] dosage increased and the effectiveness declined."

– Pamela Friedman



Pamela Friedman referenced data she has tracked for years

# ARON REGIMEN

Dr. Richard Aron, a dermatologist practicing in South Africa, was recognized by several meeting participants as being the innovator for a therapy approach responsible for providing meaningful relief to children and adults with moderate to severe eczema. **Heather Sullivan** explained Dr. Aron's approach and the rationale for "Compounded Antibiotic-Steroid-Moisturizer" (CASM) or the "Aron Regimen." "When just the right amount of these two very common medicines are professionally compounded with a moisturizer, the product is one in which, in my son's case, reduced exposure to topical steroids by nearly 80%. As the skin's biome improves, it can function more as it should by protecting the body from allergens and bacteria, enabling patients to reduce the applications of antibiotics and steroids, therefore decreasing their exposure to the side effects of these chemicals."



Jeff Kastner

The protocol often begins with multiple applications a day and tapers as the condition improves, as **Jeff Kastner** described. "Starting

out, Dr. Aron told me to put it on my son six times a day. That first night – after four years of my wife and I taking turns staying up with our son and getting a collective 2-3 hours of sleep per night – he slept through the whole night. His response kept getting better and better. We went down to five applications a day and within a year, it was down to once a day. After two years, use was very sporadic – just once or twice a week. Since then, he's never used it again. He's 11 now and is the happiest boy in the world."

Webcast participant **Heather McBride** described her experience as an adult using this approach. "The only thing that has provided me any real and long-term relief has been the Aron Regimen. The itch was reduced by 90% after the first application. I have experienced no ill effects. CASM put me into remission after 42 years of misery including 17 years of daily oral steroids and immunosuppressants." Another web participant, **Dawn Coletta**, reported the impact on itch that her infant son experienced. "We started him on Aron Regimen when he was 5 months old after a MRSA infection and seeing no end in sight for his skin getting any better. We're working down to one application per day and he rarely itches."

**Keri Kelley** found information about this therapy approach on Facebook, when they were going through a particularly desperate time in Callen's eczema odyssey. "We found immediate relief from the itch. My son is now seven. He plays baseball and goes swimming; he loves fishing, camping, and hiking. When he was younger, those things were impossible then and they felt unimaginable for his future."



Keri Kelley's son, Callen

Even among those who extolled the benefits of this therapy, there was concern. **Armando de la Libertad** shared this perspective, "The first application of the compound resulted in a full night's sleep and so for us it was kind of a miracle. That was seven years ago. My ongoing concern, which has been expressed by a number of folks, is the long-term side effects of using a topical steroid and an antibiotic. However, it's the only thing that's provided us relief. So, it has become a very important part of our daily routine," he stated.

*Note: Results from the first formal clinical trial of the Aron Regimen<sup>12</sup> have not yet been reported in the peer-reviewed literature. The compound is not available commercially in the U.S., although it can be compounded by specialty pharmacies with a doctor's prescription. The specific formulation and frequency of application depends on symptom severity and response to treatment.*

<sup>12</sup> Efficacy of combining topical antibiotic/steroid/moisturizer therapy compared to active comparator in atopic dermatitis. <https://clinicaltrials.gov/ct2/show/NCT03052348>

**Other Topical Immunosuppressants:** Three additional topical treatments were raised by meeting participants for which both polling and survey data show some broader (current and past) experience. **Ashley Ellis's** review of her daughter's extensive treatment regimen (above) included both Protopic and Eucrisa, two of the immunosuppressive ointments sometimes prescribed for moderate to severe eczema. **Angela Fox** also included Protopic among the treatments her son, Cooper, has tried.

Outlining the questions she asks herself to help determine which elements of her treatment "toolkit" she will use on a particular day, **Lisa Choy** said this: "[I ask] how many days have I used a topical steroid on exactly which area of my body, because I want to avoid extended use of topical steroids. I consider which areas have flared in the past but are not currently flaring because now I should use my non-steroid Protopic. Each situation calls for a different weapon in my toolkit and the battle never ends."

**Kelly Barta** described how her eczema was treated from the time she was diagnosed as a child until she developed difficulties years later. "I used the first-line topical steroids for 26 years; Protopic was added after 16 years because the capillaries in my face started to break."

**Tyler Berryman's** experience with Protopic began when he participated in clinical trials as a child. He referenced it in describing an experience that came up through the day relative to many treatment approaches. "As some people have already mentioned, you have to adapt as your atopic dermatitis does. One year, you find a certain cream or ointment that seems to work wonders and you think, 'I've found it. This is the miracle.' Everything's cruising along for a couple of years and then, all of the sudden, something changes and it just doesn't work. This happened to me with Protopic."

**Lindsay Swire Jones** shared the downsides she experienced. "I've used topical immunosuppressants, which worsen the itch and make my skin look 'lined' in appearance. It's hard to describe the pain of putting a topical immunosuppressant on your skin – burning and stinging that's so bad. It's like a physical reaction where I can't sit still and even days later there's an after-burn sensation under my skin." Webcast participant **Ganesa McIntosh** mentioned the need for a two-step approach when using this medication, "Thirty minutes of swim therapy in a heated chlorine pool was essential in getting the secondary infections healed enough that we could use Eucrisa, which works well but burns on inflamed, open skin spots."

Two participants described challenging benefit-risk assessments for these medications due to comorbid conditions. Reviewing the options for her son, **Kathryn Tullos** expressed this concern, "Our remaining treatment options were extremely narrow. It was suggested we try Protopic or cyclosporine, but how could I put a child covered in MRSA boils on immunosuppressants?" **Pamela Friedman's** story (page 39), continues, "In the 1990s, I was diagnosed and treated for non-Hodgkin's lymphoma and thyroid cancer. Despite the known cancer risk, I was talked into trying Elidel and Protopic. These are indicated for short-term use in non-immunocompromised patients, and besides being contraindicated for me because of my medical history, my disease was too advanced. They were too little, too late." She indicated that a more recent trial of Eucrisa, after withdrawing from steroids, led to a severe red skin reaction, so that was not an option for her either.

**Oral and Injectable Immunosuppressants:** As **Ashley Ellis'** story (above) illustrates, the decision to pursue treatment with potent immunosuppressant medications can be fraught with uncertainty and worry. **Heather Sullivan** described their family's experience. "At just 15 months old, Sawyer's treatment team felt that we'd exhausted all resources and we were introduced to an immunosuppressant known as cyclosporine, a medication first used to prevent an adult body from rejecting a transplanted organ. Of course,

"One year, you find a certain cream or ointment that seems to work wonders and you think, 'I've found it. This is the miracle.' Everything's cruising along for a couple of years and then, all of the sudden, something changes and it just doesn't work."

– Tyler Berryman





**"I started using Hibiclens as surgical sterile rinse. Now instead of using Dove bar soap, I actually wash my legs with Hibiclens."**

– Alison Piluso

eczema was off-label and use on infants was unheard of, but we were desperate. Headaches, stomach upset, diarrhea, and vomiting were common side effects to many of his medications and this added to that list significantly. Still, I defend our decision to increase our baby's risk of infections, blood clots, kidney disease, and cancer so that we could introduce him to childhood. Although his safety necessitated daily tests, monthly blood draws, and nearly 40 trips to the prescribing university 300 miles from our home, we watched our baby smile. The suppression of his immune system repeatedly landed us in hospitals with serious infections, but he also mastered crawling, sitting, standing, and walking, and we were able to teach him to communicate effectively. For the first time ever, Sawyer was able to express his feelings without scratching violently. Even then, Sawyer was never completely free of eczema symptoms and people still commented on his damaged skin. But to us, this was the nearest normal we'd ever experienced. Unfortunately, all half-good things must end, and during one of his two-week treatments at the National Jewish Hospital, treatment was ceased for safety concerns. We spent the next 6.5 years retrying every steroid and non-steroid available, but Sawyer was relegated to being unable to walk, turn his head, or smile without the piercing pain of wounds breaking open."

**Antimicrobials:** Topical and oral medicines to treat infections were noted as helpful by a few people, including **Pamela Friedman**. "Today, my treatment regimen consists of drugstore brands of moisture cream and ointment, over-the-counter

and prescription antihistamines and antibiotics, drugstore antiseptic cleansers, and miscellaneous comfort strategies." **Alison Piluso** reported on her experience with staph and MRSA infections when she began shaving her legs in her early teens. "Antibiotics were effective at treating staph and I got to the point where I knew I needed a five-day or 10-day cycle of antibiotics to wipe it out. I started using Hibiclens as surgical sterile rinse. Now instead of using Dove bar soap, I actually wash my legs with Hibiclens."

**Abigail Lewellyn** derived some benefit from taking an antifungal medication. "Currently, I'm on Diflucan, which is not prescribed for eczema, but it's the only thing that has brought relief for my facial eczema," she reported.

**Keri Kelley** referred to use of these medications in describing her young son's treatment early on. "Constant scratching episodes led to repeated oral steroids and oral antibiotics, although they never really cleared his skin." Others mentioned antimicrobials as part of a broader current or past regimen, including **Lynell Doyle** and **Kathryn Tullos**. **Angela Fox** provided this extensive list: "Over his short life, Cooper has been on 15 topical treatments, 10 allergy and asthma medications, multiple eye creams and drops, allergy immunotherapy, oral steroids and antibiotics, several bath additives, medicated wraps for wound care, and various creams, supplements, probiotics, and vitamins. And that's just what we can remember."

## BIOLOGIC THERAPY

As Dr. Silverberg described, the newest treatment approach for eczema is the advent of a biologic<sup>12</sup> drug approved for eczema, dupilumab (also referred to by the brand name, Dupixent). Panelist **Tyler Berryman**, age 25, has had eczema since he was an infant. He described his current treatment regimen. "My treatment boils down to two stages. Every day, I have to shower, apply my topical steroid ointments and then moisturizer immediately once I get out of the shower, regardless of when or where the shower

<sup>12</sup>[https://www.medicinenet.com/biologics\\_biologic\\_drug\\_class/article.htm](https://www.medicinenet.com/biologics_biologic_drug_class/article.htm)

is or what is happening afterwards. Every other week, I also take a biologic injection, dupilumab. Typically, I'll go into the bathroom at work with the little kit you have to 'take care of business.' However, to get to this stage, I've tried all sorts of treatments – as I'm sure pretty much all of you have. Things are starting to look a little better now going forward. There are a lot more options for people to choose from than when I was a little kid. I'd say overall, my treatment regimen is generally effective and like anyone else with moderate to severe eczema can tell you, there are good days and there are bad days. If it wasn't for my treatment, I doubt I could exist in society without being perpetually and literally uncomfortable in my own skin. Doing any of the things most normal people do while in a flare is quite a challenge. Getting to this stage where everything is sort of stabilized – with respect to both what the treatment regimen is and how my skin is – has been quite a journey."



"If it wasn't for my treatment, I doubt I could exist in society without being perpetually and literally uncomfortable in my own skin... getting to this stage has been quite a journey."

– Tyler Berryman

**Brianna Cox** is also benefitting from dupilumab combined with the Aron Regimen (see Inset 8, page 40). "This combination has helped my symptoms. The itch is barely there; the lesions are healing; and my skin is not burning. I am in school wearing clothes, shoes, and socks without my skin sticking to them or causing sores. And, I'm here today," Brianna said with relief in her voice. The final panelist to speak, **Stephen Gawron**, shared his experience, too. "At a very low point in my life, after almost half a century with eczema, I was finally offered something that seems to be working. I asked to get on Dupixent as soon as it was approved. It has been a life-changing experience for me. It has finally given me some relief from the never-ending symptoms, especially that constant itch. I can finally do some things that I will refer to as 'normal.' Things as simple as washing my hands, touching food, wearing shorts, going swimming, or even holding my wife's hand are now possible."

**Lindsay Swire Jones** reported that she's been taking dupilumab for 2.5 years. "It has changed the way the eczema presents on my skin. It still gets angry and red, but it no longer weeps. It will just dry up and flake off. I would say my body is about 75% clear on a good day, but I still get bad flares primarily on my face and my neck." She lamented other difficulties. "We're fighting our insurance companies for access and because of this I have missed doses. I don't think Dupixent is as effective for me as when I first started. I now have a fear that eventually it is just going to stop working for me altogether."



**Akilah Evans-Pigford** spoke to the physical improvement and the other benefits her 12-year-old son has experienced on Dupixent as part of a clinical trial for a little more than a year. “It changed my child’s life and I got my child back. I can touch his face. I can kiss his skin. It’s smooth, just like my skin. He may still have the battle scars and dark pigmentation because of his skin color, but he has smooth skin. My son went from being a hermit who was afraid to go outside. He was often late to school due to bloody sheets and oozy skin. Now he can go out and play rugby in the grass. He went from not doing very well in school to thriving. He has friends that he didn’t have before – real friends. He’s doing so well. I’m telling you, it’s like night and day.” Referring to Lindsay’s comments, Akilah added, “I know that these new medicines aren’t the be-all and end-all, but as more of these types of treatments become available, we have to think about affordable access so that people aren’t making life decisions about whether to skip medicine or something else in order to afford it.”

“Within a year of being on Dupixent, my mood had changed and my ability to think and process information had completely changed.”

– Erinn Schie

**Brittany Roche** reported her son’s improvement using dupilumab. “Peyton has severe eczema and he is in the trial in San Diego. So far, Dupixent is our best treatment at the moment. At times, 95% of his body was covered and now on good days he’s at probably 20-30%. It’s not perfect; we still have work to be done, but it is the best that it’s ever been right now.” **Ashley Ann Lora** has had eczema for 27 years and she too participated in the clinical trial. “My story is the same story as everything I’ve heard today. I have tried everything. What has changed my life started in 2015 when I got on Dupixent. I immediately saw a change because I was going through topical steroid withdrawal at that time.” She also did trauma work and learned how to better recognize triggers. “I was able to manage my eczema in a way I never have before. I stopped taking Dupixent in 2017 because my skin was doing so well,” Ashley Ann said.

Another clinical trial participant, **Erinn Schie**, shared her experience. “Within two weeks of being on Dupixent, I felt a calm throughout my body that I had never experienced before. I had a reduced amount of itch and within a month I had a full night’s rest of sleep that I had never experienced in my life. Within a year of being on Dupixent, my mood had changed and my ability to think and process information had completely changed. Growing up I was told I had a learning disability. I was put in special classes and I barely passed high school. Further education was nowhere on my horizon. I am now in my second year of college at almost 30 years old. I am now able to read and process things after feeling so stupid for so long. All through childhood, dermatologists said, ‘If we can just get the rash under control, we can help your healing.’ Well, I finally have the rash under control and I’m finally finding other ways to heal than just the medications that the dermatologist can give.”

Two people at the meeting – **Abigail Lewellyn** and **Andrea Lozada-Gomez** – mentioned they had experienced bad reactions to dupilumab. Webcast participant **Kelly Russo** shared, “Dupixent was life-saving and changing for me as well. Unfortunately, I developed severe conjunctivitis and had to stop treatment.”

Three other webcast participants contributed their experiences:

*“In my 60s I started Dupixent which changed my life. It is manageable now. I have pretty skin and I wore shorts on the beaches of Florida for the first time.”*

– **Rene Green**



*"Nonsteroid and steroid creams could never do it for my dyshydrotic eczema. Nothing worked until Dupixent. 100% clear after four weeks. Dupixent has given me my life back. I can do everyday things again. I have my independence and pride back. Even though it's not a cure, I'm thankful for it for the time being. It has been a life saver; my miracle. But we need more." – Jessie Larson*

*"Dupixent and light therapy have not helped with itch but has helped with flare ups." – Andrew Kubicz, on behalf of his wife*

## MEDICAL DEVICE THERAPY

Treatment using narrow band ultraviolet-B phototherapy was raised by several people, often as a non-medicinal approach to complement or replace pharmaceutical approaches. Some made reference to home light machines, while others' descriptions implied they were being treated in a clinic. As with medications, there were mixed reports. Webcast participant **Kelly Russo** made this observation: "I own two FDA-approved light machines. Light therapies of all kinds are very helpful to heal and regrow skin cells AFTER a flare, but I have not found them helpful with providing relief from severe inflammation."

**Andrea Lozada-Gomez** reported benefit. "I do light therapy now. I went from three times a week last December to one time a week now. Since winter is around the corner, I may go twice a week just depending how I feel, but that's what's been healing me."

**Kathryn Tullos's** son has also had a positive response. Referencing his long series of treatment failures, she said, "After all of this, we obtained a very expensive at-home narrow band UVB light unit. Our dermatologist ordered three phototherapy sessions a week. Phototherapy isn't perfect. It takes months to have any effect at all and of course there are risks, but after six months of phototherapy and 18 months steroid-free, his skin was 100% clear."

For **Angela Fox's** son, the benefit didn't last. "Beginning in late September 2018, Cooper underwent approximately 60 sessions of UV light therapy and slowly the nummular lesions began to shrink. However, his relentless itch never went away. In early 2019, like most treatments, Cooper reached a threshold where his progress stalled and we discontinued light therapy."

*"Beginning in late September 2018, Cooper underwent approximately 60 sessions of UV light therapy and slowly the nummular lesions began to shrink. However, his relentless itch never went away."*

*– Angela Fox*

## OVER-THE-COUNTER PRODUCTS

**Medical Products:** Participants included in their descriptions of treatments they were using several over-the-counter medical products, including low-dose topical steroids and antibacterial cleanser (referenced above). Also mentioned were antihistamines.

**Amanda Lewis** shared the consequences of daily use of antihistamines, as directed by her son's allergist, when he was three years old. "The biggest medication side effect we experienced is constipation. After being on a daily dose of children's Claritin and Zyrtec, going to the bathroom became torturous for him. We had to go to the hospital three times. We finally went to a natural doctor and she told us they can be very dehydrating, which led to his constipation." Antihistamines were also mentioned by **Angela Fox** and **Kathryn Tullos** as having been part of their sons' treatment regimens at one time.

**Lindsey Swire Jones** included Benadryl among her mainstays as a child with eczema and **Pamela Friedman** noted that antihistamines are part of her current care protocol.

**Ganesa McIntosh**, participating by webcast, stated an antihistamine helped her son sleep. "Hydroxyzine and melatonin helped my child to sleep soundly enough to not itch, therefore allowing his skin to heal, mind to rest, and body to grow."



**Skin Care Products:** Several participants made mention of the essential use of skin moisturizers after bathing or showering and throughout the day. As **Lisa Choy** put it, “A huge part of managing my eczema starts with bathing and moisturizing twice a day – once in the morning and then again at night before bedtime. It’s not as simple as taking a shower and applying moisturizer. It means actually employing the arsenal in my toolkit.” She described how she uses the various tools in her kit (shown at left) and noted that she carries small containers of each item everywhere she goes. **Lindsay Swire Jones** also spoke about her moisturizing practices. “The moisturizers that were

best for me are the lipid replenishing ones and the newer ones targeting bacteria. However, I find if I use the same one for too long, it doesn’t work as well. So, I rotate them.” **Amanda Lewis** expressed hope that benefits of a moisturizer from French company Bioderma would continue to benefit her son. “It has been the best product we’ve found so far to work on his skin.” Several people lamented the fleeting nature of the benefit of moisturizers in soothing their skin. Special shampoos and scalp oils were also listed by **Raelle Brown**, **Kathryn Tullos**, and **Rahki Roy** as part of self-care routines.



**Lisa Choy's Toolkit**



“A huge part of managing my eczema starts with bathing and moisturizing twice a day – once in the morning and then again at night before bedtime. It’s not as simple as taking a shower and applying moisturizer. It means actually employing the arsenal in my toolkit.”

– Lisa Choy

healed.” Another webcast participant, **jfindra5**, also found benefit with herbal remedies. “[I’ve had] eczema since I was a child and went through topical steroid withdrawal at age 24. Years later, a holistic dermatologist was the first and only person to clear my skin completely with diet changes and herbal remedies.” **Lisa Choy** included herbal remedies in her eczema toolbox over time and **Elizabeth Paz** mentioned them as one of her treatment approaches as well.

**Cannabidiol (CBD):** People participating on the webcast contributed their experience using CBD. “Sublingual CBD [lessened the rash] for me,” noted **GO’M H. Celeste Peoples** followed that comment with her experience, “CBD topical or sublingual worked briefly, but like all other treatments tried, soon were no longer effective.” **Kelly Russo** commented as well. “Yes, CBDs are helpful if you can control access to quality. We need it to be federally legal so pharma can be involved with quality control.”

## OTHER SELF-CARE PRACTICES

Participants highlighted a number of approaches they took on their own or with guidance from medical professionals to ease suffering. One of the practices most frequently noted at the meeting was withdrawal of conventional therapies, especially use of topical steroids. See Inset 7, page 38, for more on this approach.

**Avoiding Triggers/Allergens:** Numerous participants made mention of the need to – and benefit of – identifying and avoiding irritants, allergens, and other triggers that made their eczema symptoms worse. Carpets, pets, heat, humidity, grass, foods, fabrics, fragrances, dyes, and additives are among the substances that were specifically mentioned as offending triggers or harboring irritants. Webcast participant **Alex Lumsden** observed, “One thing I found out during this semester in college was that certain environments made me feel worse. I would scratch more and be irritated in certain classrooms.” Stress – both from eczema and its impacts as well as other sources

– was a trigger noted by some people. **Raelle Brown** drew attention to the importance of noticing what’s happening mentally, as well as physically, when thinking about triggers. “We get triggers. I’m big on being aware ‘within,’ because that’s important, too.”

**Kathryn Tullos** and others remarked upon the benefit of patch testing to help identify sources of exacerbation, once her son’s skin got clear enough to make it possible. “Avoiding irritants revealed by patch testing turned out to be extremely effective. I truly wish that patch testing had been the first line of treatment rather than the last,” she said. **Andrew Kubicz**, participating by webcast on behalf of his wife, reported, “She’s focusing on a low-nickel diet following a recent nickel allergy diagnosis. [We are] still unsure of many triggers as her skin is too irritated/infected to perform a proper patch test.”

**Abigail Lewellyn** found she must avoid any moisturizer, balm, or ointment that contains petroleum, including Vaseline and Chap Stick, due to an allergy. “I’m deathly allergic to petroleum. I can’t touch it or I’ll die.” This precludes her use of many mainstay therapies. **Lindsay Swire Jones** noted many changes she’s made. “I have given up wearing makeup, because it just aggravates my skin more. Humidity has always been a trigger, but I overheat more easily now. I use fans, air conditioning, and humidity gauges at work and at home.” Others mentioned these environmental triggers as well.

**Intensive Bathing and Moisturizing Regimens:** As **Raelle Brown** (see page 16), **Tyler Berryman** (page 42), and **Lisa Choy** (page 46) highlighted, their daily routines included one or more baths or showers and time-consuming application of multiple moisturizing products. Raelle noted this added an hour each to her morning and evening schedules; Tyler highlighted it as one of the most frustrating aspects of living with eczema. Lisa described how the need to shower and have time to deploy her skin care toolkit factored into her moment-to-moment accommodation of eczema. Parents, too, recounted the trying, time-consuming nature of these routines, which included the more specialized bathing-related self-care treatments – bleach baths and wet-wrapping, described below.

**Bleach Baths:** Bathing in water with a small amount of bleach added, followed quickly by an application of barrier creams and/or moisturizers is a common supportive therapy for eczema. It was mentioned by **Joseph Cutaran** and **Amanda Lewis** as being part of their sons’ care. **Rachel Bronstein** contributed, “The bleach baths really saved me and got me through some of the more severe times. It’s really hard to treat yourself with topical steroids and have them be effective if you can’t catch the infection that’s sitting on your skin.” **Ganesa McIntosh** mentioned the benefit her son derived from a similar approach – time in a heated, chlorinated pool (see page 41).

**Wet Wrapping:** Nighttime application and securing of wet, medicated dressings to clean, moisturized, and treated skin can help to rehydrate, improve absorption, and soothe. It is included in the step care chart referenced by Dr. Silverberg (see page 34) as an acute strategy for severe eczema to help gain control. It is a burdensome process, as **Angela Fox** described. “In February 2018, shortly before Cooper turned five, we traveled to National Jewish Health in Denver to receive intensive wet wrap treatment. We continued these at home 2-3 times a day and were spending 4-6 hours a day soaking, wrapping, keeping him warm, unwrapping, and then moisturizing.” **Keri Kelley**’s experience with wet wrapping her son was a similar drain for her family,



“The bleach baths really saved me and got me through some of the more severe times.”

– Rachel Bronstein







Callen Kelley in wet wraps



Molly Evans

"All I have left, my only treatment options now are eating the best diet I can, being mindful, and living an intentional life as much as I can."

– Molly Evans

"We spent our 'baby-moon' living at a Ronald McDonald House doing skin tests, blood draws, food challenges, and learning the messy art of wet wrapping. Living with severe eczema means wet wrapping a toddler, morning and night, for months on end while your newborn is crying in the next room, waiting to be taken care of too."

**Joseph Cutaran, Lindsay Swire Jones, and Fang Liu-Walsh** also mentioned wet wrapping among the management approaches used at one time or another. **Pamela Friedman** commented on a related approach, "One of the symptoms that bothered me most was large areas of oozing open skin. We had some success treating this with classic old-fashioned wet wound healing techniques."

**Ice packs/cold compresses:** **Maria Harris** described using ice packs to soothe pain and itch while nursing her daughter. "I had to figure out a way to make sure those ice packs really stayed there on my neck. Because once those ice packs really lost their coldness, I had to stop nursing her and wake up my husband to feed her." Webcast participant **Rene Green** mentioned standing outside in the cold to curb itch, as quoted on page 15.

**Burning hot showers:** **Jenn Johnson** talked about how her son's eczema changed when he became a teen, and the new challenge finding treatments he was comfortable using. "He would take burning hot showers. We heard this from so many people at the National Eczema Association's Expo – that they could make it through the day if they could have a burning hot shower which provided a little bit of relief."

**Restoring gut microbiome:** **Rahki Roy**, a registered dietician and person with eczema, mentioned her personal and professional experience paying attention to gut health by reducing exposure to food dyes and additives and using medical nutrition therapy approaches to reduce inflammation. She recognized the need for more evidence-based approaches to understand and heal the gut microbiome.

**Counseling/Psychotherapy:** Several participants indicated the positive role that counseling has played in their ability to cope with eczema and its impact on their lives. "I do not like how I had to meet my counselor, but I'm happy I did. I was put on meds for anxiety and depression. She teaches me coping skills for the mental effects of my flares, including breathing techniques and walking off the edginess and the anger that this itch instills in me. She helps me conquer the evil of eczema," asserted **Brianna Cox**, thinking back to a period of deep depression and lost hope during which she lost months from school. Panelists **Ashley Ellis, Angela Fox, Sarah Pry, and Kathryn Tullos** specifically mentioned getting counseling help for their children.

**Mindfulness and a healing mindset:** A number of participants spoke about the trauma associated with living with eczema for both the patient and their loved ones. A few shared their approaches to adopting techniques for mindfulness or other meditative practices to support healing and help manage stress. As webcast participant **Kelly Russo** noted, "Meditation and becoming a certified yoga instructor was the only way off the steroids. Learning to be still and create an environment for healing. AD is very traumatic, and we need to do the work to heal our trauma." **Molly Evans** also had to withdraw from topical steroids and other treatments after experiencing too many harms. She said, "All I have left, my only treatment options now are eating the best diet I can, being mindful, and living an intentional life as much as I can."

**Greg Clark** credits adopting a "healing mindset" as essential to his improvement. "I went to a holistic doctor who told me that to heal my body, I'd not only need to eat healthier, but also being aware of the people around me, where I am, and how I feel." He referenced a documentary titled, "Heal." "In it they say, 'the power to heal the body is the body.' A lot of times we look outside of ourselves for something, but it's in all of us. If we're worrying and we're stressing, that's not conducive to healing. We have to find

our calm. With our calm, things become more peaceful. When that happens, there is no more struggle. We're living and we begin to thrive and we can live the life that we're destined to live," Greg said.

**Ashley Ann Lora** spoke to a similar experience. "What has helped me is consistency in what I call 'healing mindset practices' – meditating daily, doing my affirmations on a daily basis, journaling, reading, and doing anything that brings me peace, love and joy. I truly believe that when I'm experiencing happiness, my eczema doesn't exist. That is not to say it doesn't exist on the physical level, it's just that I'm not thinking about it. And when I'm not thinking about my eczema, I'm not itching. I'm not going into an anxiety attack."

CONTINUED ON PAGE 50

## DOWNSIDES TO THERAPIES DESCRIBED BY MEETING PARTICIPANTS

INSET 9

- Long-term consequences (including organ damage, stunted growth, infertility)
- Ineffective symptom control (immediate or over time)
- Pain, stinging, and/or burning upon application of topicals
- Increased risk of infection
- Other intolerable side effects (physical and mental)
- Short- or long-term damage to skin condition and/or appearance
- Inconvenient
- Time spent adhering to and tracking treatment and effects
- Need for and cost and inconvenience associated with required laboratory monitoring
- Lack of education and/or clear direction for how to use topical corticosteroids
- Lack of documented evidence to guide use of individual therapies and/or combinations of therapies (especially for use in children)
- Unclear or conflicting protocols and inconsistent adoption of existing care guidelines by health care professionals adding to confusion and frustration
- For unregulated therapies, lack of quality control and evidence to guide use
- Fears and challenges associated with injections
- Family discord over treatment approach(es) and administration of treatments
- Foul smell and damage to clothing, furnishings, and bedding from ointments, creams, and other topicals
- Lack of insurance coverage/reimbursement
- Cost (both total cost to all payers (including insurers) and out-of-pocket costs incurred by patients/families)



## BURDENS OF AND DOWNSIDES TO CURRENT THERAPY APPROACHES

As **Dr. Jill Lindstrom** described at the beginning of the meeting, all drugs have both benefits and risks. Through its patient-focused drug development (PFDD) program and related initiatives, FDA seeks to understand "...how patients weigh those risks and benefits in making a decision [about treatment]. PFDD can inform how FDA regulators need to weigh those risks and benefits as they make a regulatory decision on a population basis on the approval (or non-approval) of a drug candidate for the market," she said.

Some of the downsides of individual therapeutic approaches are described above in the words of patients and caregivers participating in the meeting. Participants also gave accounts of the downsides of their current and past regimens and general challenges associated with treating eczema that are illustrated here and in the list in Inset 9 on page 49.

### LONG-TERM USE

As indicated by the live polling during the meeting and through the survey, the most frequent downside to existing therapy options among patients and caregivers is concern about long-term use. This arose in connection with first-line therapies (including over-the-counter products) along with systemic therapies generally reserved for moderate to severe eczema. **Lindsay Swire Jones** said this about one of

the mainstay therapies. "For the majority of my life, I have been encouraged to take over-the-counter allergy medication for itch. Now studies are showing these types of drugs can cause memory loss or even dementia. I've noticed issues with my short-term memory already and I fear it's the start of something that will get worse as I age." **Stephen Gawron**'s comment echoed others heard throughout the day, "I hope and pray that my organs forgive me for using oral immunosuppressants for years on end that only provided – at best – minimal temporary relief, just so I could go to work."

Concerns about long-term use of topical steroids were voiced by many, including **Kelly Barta**. "When I look back to my teens when I started this journey of topical steroids, I wonder, was it worth it? Is it worth the trade-off for a quick fix and for pretty skin as a teenager? As a 46-year-old having gone through five years of hell, I say, 'No! It was not worth it.'" Discussing the benefits her son has derived from the Aron Regimen, **Heather Sullivan** expressed concerns too. "Although we've been able to taper his applications from five times a day to just a couple, there isn't a day that I'm not concerned about the risks of such regular use of antibiotics and steroids."

### INTOLERABLE SIDE EFFECTS

There were many reports of side effects for individual medications tried, but **Jenn Johnson** summed them up well with this statement: "As a parent, I should never have to compromise one of my son's organs for another. I shouldn't have to worry that I gave him a medication, but now he can't breathe, so we're in trouble for that. Or, we got his lungs okay, but now he can't move and he's bleeding everywhere. He's in a severe flare. A lot of these medications don't even talk about the mental health issues they cause, so you're also potentially trading off mental health, too."

"As a child, my bathing treatments were so painful that they caused me to hide under the bed in fear, which only sparked fights between my parents and left me wondering what I had done wrong."

– Stephen Gawron



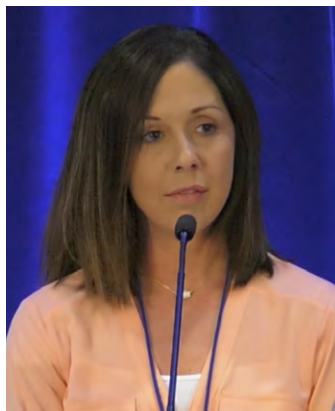


These tough tradeoffs came up over and over again throughout the day. **Stephen Gawron** added a memory from his early years, and the impact on his whole family. “As a child, my bathing treatments were so painful that they caused me to hide under the bed in fear, which only sparked fights between my parents and left me wondering what I had done wrong. More arguments arose over how much steroid medication to put on me – more, less, at what frequency? And then the fighting really began when side effects such as a moon face, weight gain, thinning of my skin, or stretch marks would show up.”

## INEFFECTIVE AT CONTROLLING SYMPTOMS

In response to a polling question, more than half of meeting participants indicated that their experience with currently available therapies was “mixed.” As **Lisa Choy** spoke about her current eczema ‘toolkit’ (see page 46), she qualified the description. “The key word here is ‘current’ because about a year and a half ago, I would say all but one of those products were not in my toolkit, meaning things have changed. I have tried every potency of TCS cream and ointments, oral steroids, Kenalog shots, topical non-steroids, as well as herbal meds, acupuncture, and photo light therapy, like most eczema patients. ... Each situation calls for a different weapon in my toolkit and the battle never ends.” **Lynell Doyle** made a similar observation, “My son has cried through 13 years of stinging, greasy, sometimes foul-smelling topical steroids and nasty antibiotics; burning, possibly toxic light therapies; and other frightening yet ineffective treatments.”

As highlighted earlier, many people shared that once-effective therapies lost their effect over time. “I find it just insane that every time I thought he was getting better, either with a new steroid or cream, ointment, I watched to see if he was letting the hair on his body grow back rather than scratching so hard it couldn’t grow. I would get very excited, but of course it was always temporary. His body would just become accustomed to whatever treatment we were doing and the eczema would flare just as vicious as it was in the beginning,” observed **Sarah Pry. Brianna Cox’s** worry went beyond a loss of efficacy. She said, “I worry and fear most that I will never fully heal, that the meds will quit working again and I will always be an outcast and that the itch will never end.”



“Why are we as parents forced to weigh the risk that we may harm our child?”

– Angela Fox

## CHALLENGE OF WEIGHING BENEFITS AND RISKS

Several parents spoke to the challenge of evaluating the potential tradeoffs for benefits against the risks especially for therapies that have a smaller evidence base for children compared with adults. As **Lynell Doyle** stated, “It takes a lot for parents to decide to give their child a brand-new drug that has not been proven effective on children. When immunosuppressants didn’t work, we made the decision [to try Dupixent] because by this time he — we — had lost to the itch, the pain, and the fear and depression seemed to have won.”

**Joseph Cutaran** offered a similar perspective. “Most of the treatments we considered were not labeled for infants and had black box labels. For some, an insurance case worker would call us before they would approve the medicine upon receiving the request from pharmacy, just to make sure this is really what we wanted to do.”

**Angela Fox** spoke with anguish about this debacle. “We are currently debating beginning the biologic medication. However, the side effects of these injections include



“My son has cried through 13 years of stinging, greasy, sometimes foul-smelling topical steroids and nasty antibiotics; burning, possibly toxic light therapies; and other frightening yet ineffective treatments.”

– Lynell Doyle



inflammation, eye irritation, and facial flares and these are things he already deals with daily. We need relief from them, not an increase in them. When investigating new medications, I ask, 'Why are we as parents forced to weigh the risk that we may harm our child's eyesight, stunt their growth, and possibly inhibit their ability to have children someday against their immediate need for the relief from the painful itching and the weeping wounds?' It is a horrible and gut-wrenching position for us to be in every day."

## GREASY, SMELLY NATURE OF TOPICALS

The impact on clothing, furnishings, and bedsheets of the messy formulation of topical medications upset many participants, as **Danielle Alexander** described. "The painfulness of knowing that when you wear white clothes to hide the flaking skin, even after washing them twice in the approved detergent, they still have this nasty, greasy film all over them. You try and pick it off, but it sticks to your fingers because it's grease."

"I want to have a medication that lets us eczema warriors live our lives fully and not just exist through the next flare."

– Brianna Cox

## INJECTIONS

As **Ashley Ellis** stated vividly, several people commented on the difficulty of getting (or giving) regular injections as the mode of administration for allergy and eczema medications. One account in particular, offered by **Lynell Doyle**, made a lasting impression. "The sight of the shot itself is nothing less than menacing. It is huge in comparison to a standard insulin syringe. The injector is clunky, loud, and it doesn't move fluidly. Each week my son would become anxious knowing the day was coming for the big, painful shot. If the pain had lasted for just a moment, that may have been tolerable, but the pain lingered for nearly half an hour each time. The visible side effects were just as awful as the eczema itself, if not worse. The very last shot that he ever took was the worst. Due to a malfunction, the needle twisted and broke off in his abdomen, sending him into excruciating pain and unparalleled panic. This drug was no longer an option for him."

## AN IDEAL TREATMENT

The final topic of the day invited participants to focus on future treatments. A polling question asked, "Assuming there is no complete cure for eczema, what is the most important result that a treatment could provide?" The result was overwhelming: 64% selected "immediate and sustained relief from itch." **Stephen Gawron** summed up the feelings of many. "Please focus on helping us reduce the itch as that's where it all starts. It has taken me a lifetime to feel comfortable in my own skin," he pleaded at the end of his panel presentation. **Lisa Choy** made a similar request, "My primary quality of life issue is itch. My appearance is not as important. It's embarrassing to have rashy

skin, but I can live with it. It's the itch that drives me crazy. If you can imagine having the itch of poison oak or poison ivy 365 days of the year, then you understand what we eczema patients endure. My wish is not to itch." **Alison Piluso** weighed in on this, too. "If I could follow a regimen with moisturizers and take a pill once a day; I don't care if it's twice a day. Morning, night, and noon – I don't care. I just want to not itch." Webcast participants made similar requests, including this one from **Ih53gp**: "We do need a cure, of course. In the meantime, we need something that actually works to quell the itch without such horrible side effects."

**Brianna Cox** stated well the second most-endorsed polling option with 15% of participants selecting it, "Increased ability to go about daily life." Brianna said simply, "I want to have a medication that lets us eczema warriors live our lives fully and not just exist through the next flare." **Heather Sullivan** stated it this way: "These children deserve a cure and a treatment. They deserve to be able to live without having to constantly worry if their skin will hold up to the next moment."

From there, discussion shifted more broadly to features that the ideal treatment would have. **Lisa Choy** qualified her request for effective itch reduction this way, "I look for efficacy, but I also want minimal side effects. Treating a known evil with an unknown one gives me pause. You know, it has taken me a lifetime to corral my eczema. If I'm asked to live with a set of side effects I have no experience with, that's more than a little scary for me." A similar request came from **Kathryn Tullos**, "We desperately need new treatment options that are both effective and safe. We need to be able to treat the problem without creating new problems and we need to be very clear about the possibility and severity of side effects, even if they are rare." **Jenn Johnson's** ideal treatment would also be safe over the long-term. She stated, "We need to find safe treatments so 20 years from now, my son doesn't come to me and say, 'We can't have kids, Mom. They say that I used X when I was two years old, and now we can't have kids.' No parent should have to choose that. No teenager should have to look at that and say, 'Okay, Mom. Let's do it.' And no adults should have to decide, 'Do I need my kidneys that bad?' just to be able to go out in public, to be able to work, or to be able to have a life."

**Tyler Berryman** asked for a more convenient, less burdensome treatment, as did other participants. "If I was to envision my ideal treatment, it would be nothing, obviously. No pills to take, no creams to apply, no injections to stick yourself with – nothing. But at the end of the day, I have to be realistic. The closest thing would be a small pill that you could take every week. For kids, that could even be a gummy so you can get them trained to start taking care of themselves and not have to worry about whether they're going to want to deal with taking their own medicine, like my parents had to do when I was young." Web participants also endorsed the ease of a pill, with a few other features, as illustrated by this comment from **Jessie Larson**: "The ideal drug: Pill form (frequency doesn't matter). Keeps my skin 100% clear. Affordable. Manages itch and pain of open sores." **Lynell Doyle** had a similar refrain, "The ideal treatment for eczema would be easy to acquire, easy to use, and effectively do no harm to the individual using it. Instead of creating a lifelong dependence on drugs that don't work, it would teach bodies with eczema to win the fight against their skin without having to give up other parts of their lives due to side effects. New drugs need to provide hope with real measurable benefits for the users."

The theme of addressing possible root causes was raised by **Lindsey Swire Jones** and others. "I'd like to see treatments that help with the facial skin sensitivity and I'd like to see more treatments that focus on the microbiome balance. We need more treatments that address the cause of what's going on in our bodies, rather than the effect of the rashes on our skin." Web participant **Shady** said, "The underlying itch is internal inflammation that is not going to go away until the root cause is sorted out." **Armando de la Libertad** suggested a focus on a particular facet. "I'd like to see more attention paid to the underlying role that staph infection is playing, whether it's causal or simply exacerbating



"We need to find safe treatments so 20 years from now, my son doesn't come to me and say, 'We can't have kids, Mom. They say that I used X when I was two years old, and now we can't have kids.' No parent should have to choose that."

– Jenn Johnson





**"We need different types of treatments because not everyone is the same."**

– Akilah Evans-Pigford

the condition. If I had a pot of funds, I would challenge researchers to engage in a competition to deal with staph."

Requests for more targeted therapy and precision approaches built on this theme. As **Akilah Evans-Pigford** stated, "We need different types of treatments because not everyone is the same." She continued, "I hate the fact that doctors think that they could give you and you and you the same thing," pointing to people sitting near her. "Not everyone is the same." **Sean Scott** drew on his recent experience to support the call for more targeted therapies. "With just two months of my daughter's experience with Dupixent, it's still early for us to see if it benefits her in terms of the inflammatory skin responses that she continues to have. But we're hopeful with the advent of new biologics that are much more targeted. They're much more precise in terms of achieving precision medicine. It's been a watershed moment for us, and we're very hopeful to see further advancements." From the web, **Kelly Russo** added, "Identify biomarkers so we can classify the sub-types of AD. It's clear this isn't just one disease and we need to understand the sub-typing."

**Pamela Friedman** pulled together this set of requests, "I'm here today to ask us to think differently about the future of eczema treatment. First, let's stop putting all eczema patients into the same treatment bucket. This creates some pretty significant gaps in the treatment continuum. Next, let's work harder to assure that the most common treatment for eczema, topical steroids, is directed towards patients who can benefit most. Finally, in a perfect world, there would be both a treatment plan to support TSW recovery as well as more low-risk non-steroidal treatment options to manage the underlying eczema."

**"Today is really the beginning, not the end, of the work ahead of us. Thank you, everyone, for coming and for sharing your stories and again to our partners. This is just the start."**

– Kenny Mendez, President and CEO of the Asthma and Allergy Foundation of America



## CLOSING COMMENTS

**Kenny Mendez**, President and CEO of the **Asthma and Allergy Foundation of America** (AAFA), was the final speaker of the day. "Today's meeting has been incredible for me. I have served as AAFA's CEO for about 18 months. Two of my kids have severe allergies and eczema. Although I've never talked about it in public before – and my staff may not even know this – I myself have eczema. I'm talking about it now because you guys have gotten me over the hump, and I also realize that we need to be talking about it more in public. Your comments drew me back to my childhood. I am Filipino and in the Philippines you get a nickname. My nickname is 'Corky' and I was the youngest of three kids. The joke in my family was that of the three kids, I was the one who was always scratching. We traveled back to the Philippines every year and they would take pictures of me, Corky, scratching in the Philippines; Corky scratching on Long Island." Joking a bit, he said, "I looked around the room today and I was pretty impressed because none of you were scratching although, myself, I definitely felt an itch."

"That brings me to recap some of the things I heard today for the FDA and our industry partners as they think about new therapies. First, the itch is uncontrollable. It's unbearable and inconsolable sometimes. No one wants to be that way. You might think it's a twitch or something like that, but it's not. And you're living with it all the time. That has an impact on your self-esteem. You deal with isolation and loneliness. All those things, I completely understand.

"Second, I heard that awareness and education are quite important for the community. That has helped me talk about my own experience today. The fact is that one out of every 10 kids has some form of eczema or atopic dermatitis, but we don't hear a lot about it in the schools. It's really important that we feel comfortable talking about this. Many of you showed your kids in school and talked about how bullying can be a major issue for them as well. I think about my youngest son who was a varsity athlete and has now graduated from college. My wife and I would talk about how his eczema was flaring and the challenge of sticking with his regimen at school, given his schedule. It worries me for the next generation – not just my kids, but his kids because eczema is in the family now. As we think about the unmet needs out there that industry partners and FDA are working on, that's really critical for the next generation, as we've all seen and heard today from what you all have gone through.

"I look at the results from the poll about your overall treatment experience and it struck me that 53% said they had a "mixed" response in terms of therapies that are out there and nearly 30% said they were harmed by existing therapy; only 2% said they were satisfied with current therapy. We definitely need some better solutions because there's tremendous unmet need.

"The final thing I want to say about this is that patient assistance and affordability are critical. I understand how expensive it is to develop these drugs and the number of years it takes, but having access and affordability is really important for all of us going forward. I encourage our industry partners to work with patient organizations to help get there."

Kenny then offered his thanks to the panelists, "It took an incredible amount of courage for many of you to come up on the stage and talk about these things." He expressed gratitude to all the participants, the other speakers, the FDA, and the sponsors, and he acknowledged the staff members from each of the five organizations whose work over the course of a year created this forum. (See "Acknowledgements" on page 87 for a listing of all whose efforts contributed to the **More Than Skin Deep** initiative.)

Closing out the meeting, Kenny made a commitment. "Today is really the beginning, not the end, of the work ahead of us. We will be communicating your experiences through the 'voice of the patient' report which will be shared with the FDA and much more broadly. Thank you, everyone, for coming and for sharing your stories and again to our partners. This is just the start."

**"Only 2% said they were satisfied with current therapy. We definitely need some better solutions because there's tremendous unmet need."**

– Kenny Mendez,  
AAFA President  
and CEO







Working on behalf of their organizations and collectively as a cohesive team, these women contributed their skills, talents, and boundless energy to planning and delivering the **More Than Skin Deep** initiative.

PICTURED left to right: Kelly Barta (ITSAN); Julie Rathjens (Hello Brand); Wendy Smith Begolka (NEA); Sanaz Eftekhari (AAFA); Korey Capozza (GPER); Keri Kelley (GPER); Cara Kraft (AAN); Tonya Winders (AAN); Kim McCleary (Kith Collective); and Lisa Butler (NEA).  
Not pictured: Kathryn Tullos, RN (ITSAN)



# MORE THAN SKIN DEEP REFLECTIONS:

## Host Organizations

The eczema community is served by five national organizations that joined forces more than a year prior to the meeting to develop and carry out the **More Than Skin Deep** initiative. (See pages 2 and 88-92 for more information on each one.) This coalition effort spans the vast areas of concern in the eczema community and is the largest formed to-date solely for the purpose of convening an externally led PFDD meeting.

Leaders of these five organizations looked back at what they have learned from this initiative and how they'll carry those learnings forward.

### "There is nothing like being together!"

These words from **Julie Block**, President & CEO of the National Eczema Association (NEA), articulate the spirit of unity that characterized months of advance planning and culminated in a very real, palpable way at the September 23, 2019 meeting. "Our organizations truly came together under the 'More Than Skin Deep' banner to empower people to bravely share their experiences and expectations," commented **Kenny Mendez**, President & CEO of the Asthma and Allergy Foundation of America (AAFA). Steady, coordinated outreach by the five organizations and a responsive team approach to supporting people's interest in participating reached a crescendo by the meeting date. **Korey Capozza**, one of the founders of Global Parents for Eczema Research (GPER), remembers the feeling when the date finally arrived: "The empathy and energy in the room was electric. It was inspiring to see patients and families united in the struggle to cope with the burdens of eczema and in their search for more and better ways to alleviate the symptoms and the suffering."

To **Kathy Tullos**, President & CEO of the International Topical Steroid Awareness Network (ITSAN), this feeling of unity helped transcend subgroups that naturally form in a community as large and diverse as the eczema community. "Patients and caregivers are often desperate for answers. When they find something that works, they often bond with those who agree and use the same approach. While this is great within those groups carved from shared interests, it can create barriers within the larger community. At the meeting, I truly felt those barriers come down by sharing our common experiences," she said. "This opportunity for our organizations to work together has definitely strengthened our community," observed **Tonya Winders**, President & CEO of the Allergy & Asthma Network (AAN).

"I truly felt barriers that form naturally within the community come down by sharing our common experiences."

– Kathy Tullos

“The experiences shared at the meeting made it so deeply personal.”

– Tonya Winders

“We must embrace new ideas and approaches so the millions of people with eczema are truly served by the drug development process and healthcare system.”

– Julie Block

## EXCRUCIATING BURDENS

Korey expressed her hope that this initiative will contribute to greater awareness of the extreme suffering eczema causes, saying, “The true burden of eczema is often hidden from view, but it is profound, wide-ranging, and long-lasting. While children and adults with eczema experience those burdens in the most direct manner, caregivers are impacted to almost the same degree as the loved ones they care for.”

“The pain, the despair, the isolation; it was so real in that room,” Julie recalled. “We heard such vivid descriptions of daily struggles as well as treatment burdens across the lifespan, including the dismissive and judgmental attitude some healthcare professionals exhibit when it comes to treating people with eczema. We must do better.”

“I agree,” Tonya said. “As much as we know these things through our collective work on behalf of the community, the experiences shared at the meeting made it so deeply personal. I had a difficult time not feeling the pain of every person, every parent through my own experience parenting a teen with moderate-to-severe eczema.”

“It was striking to me how similar the stories were,” noted Kathy. “People were initially prescribed the same treatments based on the same guidelines. They followed the treatment plans, received the same unhelpful advice, took the same dead-end roads. Either their eczema didn’t improve, or it got worse. While they may land all over the map in terms of therapeutic regimens and beliefs, they endured a lot of the same physical and emotional struggles along the way.”

## PRECISION APPROACHES TO THERAPY NEEDED

Powerful individual testimonies at the meeting and data and comments collected through the survey underscored the urgent need to go beyond “one size fits all” approaches to treating eczema. “We must continue to push the envelope to better understand the phenotypes and underlying immunology in eczema,” Tonya urged. “It is only then that we will move closer to accurate diagnosis and ensure we get the right treatment to the right patient in the most timely and effective manner.”

Julie remarked, “This initiative drives home the fact that eczema is such a heterogenous disease and can be quite complicated for the moderate to severe patient. What works for one person may not work for another. We must embrace new ideas and approaches so the millions of people with eczema are truly served by the drug development process and healthcare system. This includes working with life science companies to help develop therapies and design clinical trials that better align with patient outcomes of priority interest – most importantly, itch!”

ITSAN board member **Kelly Barta** raised the need to identify biomarkers that enable customizable care: “We also need to gain a better understanding of mechanisms of topical steroids, a mainstay therapy, so we can identify which patients may become steroid resistant or experience harms from steroid treatment that follows current guidelines.”

Korey raised the need to build a stronger evidence base to deliver customized care to children with eczema: “Parent after parent spoke to the tremendous uncertainty they face in making decisions about their child’s care and the tradeoffs they must weigh with little information to guide them. Patient priorities must inform research.”

## KICKOFF TO A NEW ERA OF HOPE AND EMPOWERMENT

Initiative organizers agreed that the **More Than Skin Deep** meeting marked an important milestone. “There is new hope in the eczema community – hope for more patient-centered research that leads to safer, more effective treatment options,”

Korey said. Julie built on that theme, “Through this initiative, patients and caregivers recognized that their voices matter. By sharing their perspectives, they can shape a brighter future. I hope all who read this report see themselves represented and gain a real, true, authentic sense of hope for a better future.”

Kenny reflected on the rising empowerment. “I loved seeing participants’ reactions to the name badges identifying them as the ‘EXPERTS.’ (See page 12.) This seemingly small detail turned the usual conference hierarchy on its head, where physicians and researchers are the identified experts and patients and caregivers are more like spectators. Meeting participants ‘owned’ that label and I believe it helped empower such broad participation in the discussion.” Kathy agreed, adding, “This whole initiative gave voice to the voiceless. Patients and caregivers are pioneers on a new frontier. Future eczema patients will have better, safer, more effective options because people shared their experiences at the meeting and through the survey.”

“Now is the time for patients to be engaged, educated, and empowered to enter into shared decision-making with their healthcare providers. It is only by understanding and appropriately considering the risks and benefits of each treatment option that a patient should comfortably commit to moving ahead,” Tonya advised.

Kelly encouraged more opportunities like this one. “A very passionate cry is beginning to emerge from the eczema community. Before now, many people have felt marginalized and hopeless as a combined result of the degree of suffering, limited understanding of eczema by the medical community, and frustration with the lack of safe and effective treatment. With new treatment on the horizon, hope is beginning to rise, but we must continue to help people engage and make their voices heard.”


## RESPONSIVE ORGANIZATIONAL PRIORITIES

Each of the leaders remarked that this meeting and the articulation of so many unmet needs helped to inform their plans and programs. A few shared details. “GPER will use the stories shared and survey responses to drive a patient-centered research agenda, improve the alignment of outcomes used in clinical trials with those that matter most to patients and caregivers, and develop programs to address patient and caregiver needs highlighted through this initiative,” Korey pledged.

Speaking on behalf of ITSAN, Kelly stated, “We hope to use the information from the meeting and survey data to promote the development of more appropriate treatment guidelines for eczema patients, especially surrounding the current mainstay treatment of topical steroid creams. With more than 25% of survey respondents and meeting participants reporting adverse events from long-term steroid use, this issue came out loud and clear, highlighting the need for changes in drug labeling, physician education, and public awareness.”

Tonya made this commitment from AAN: “We will use the key learnings from the **More Than Skin Deep** survey and meeting to better inform and direct our patient education and support services. We will continue to update and implement decision aids to ensure each person living with eczema clearly understands his/her options.”

“At NEA we will continue furthering the truth that patients are experts in their disease,” Julie vowed. “We’ll use the learnings from this initiative as building blocks to address the knowledge and research gaps necessary to improve the health and quality of life for those impacted by eczema. As always, we will work together with individuals and families, researchers and healthcare professionals, our sister organizations, and our corporate partners to vision a better future for the eczema community. We’ll do all we can to validate the experience of every person, to connect them to the support and education they need and deserve, and to convey the spirit of hope made so tangible through this initiative.”



“There is new hope in the eczema community – hope for more patient-centered research that leads to safer, more effective treatment options.”

– Korey Capozza





# MORE THAN SKIN DEEP REFLECTIONS:

## Initiative Sponsors

The hosting organizations extended an opportunity for initiative sponsors that provided unrestricted grants at Platinum and Gold levels of support the opportunity to share observations following the More Than Skin Deep meeting.



### COMMENTS RECEIVED FROM ABBVIE

Patients provided valuable insights during the “More Than Skin Deep” Eczema Patient Focused Drug Development (PFDD) meeting. In preliminary data from a web survey fielded by the organizers, 1,300 patients with eczema indicated that the top three symptoms are itch, red/inflamed skin, and sleep, with 60% of patients reporting affected sleep. These concerns were recapitulated during the meeting, with patients adding that eczema impacts on self-confidence, physical and family activities, work/school, concentration, stress, diet, and family planning. One mother of a young child with eczema summarized the disease by saying, “[The] true burden is far reaching, but often hidden from view.”

Patients emphasized a desire for more treatment options that can provide immediate and sustained itch relief, preferring oral over injectable therapies. Side effects of topical steroids and dupilumab were commonly cited, and some patients felt that “no therapy” is better than current options. The Aron Regimen, consisting of topical steroids, topical antibiotics, and moisturizer, was mentioned, underscoring patients’ willingness to try unconventional therapy in searching for relief. The risk of topical steroid withdrawal (TSW) was heavily discussed. While side effects from long-term topical steroid use are well established, the possibility of addiction and subsequent withdrawal is less understood. Efforts must be made to quantify TSW burden by appropriately coding TSW outcomes to increase understanding and prevention of TSW. Importantly, 70% of patients in the web survey reported never being asked about clinical trial enrollment. Pharmaceutical companies could partner with organizations hosting the “More Than Skin Deep” initiative to improve patient outreach regarding clinical trials, with the overall goal of realizing the ideal eczema treatment.



### COMMENTS RECEIVED FROM BOEHRINGER INGELHEIM

The More Than Skin Deep Eczema Patient-Focused Drug Development Meeting provided a forum for patients and caregivers to articulate the symptoms and issues that matter most to individuals dealing with atopic dermatitis (AD). The results of a survey, fielded in advance, complemented and enhanced the rich experiences shared by the participants during the event. Together these perspectives provided a deep appreciation of the broad and significant impact that AD has on the lives of those affected.

Participants described the relentless itch as the symptom of greatest burden, which often resulted in sleep disturbance and deprivation. The loss of identity and self-confidence was a consequence that had direct impact on quality of life and often went underappreciated. As one patient states, “Eczema has changed the entire outlook on my life.”

Participants reported experience with a myriad of topical, systemic, and alternative therapies. Results were mixed with current treatment options and participants emphasized that additional options are desperately needed. Several participants reported experiences with long-term steroid (LTS) withdrawal; highlighting a need for better guidance and education regarding the use of LTS and how to safely transition patients to other treatments if appropriate. Although there were limited examples of adequate control, when attained the impact was striking. One participant described how his son got his childhood back.

Overall, the meeting provided a platform to frame the impacts of eczema on quality of life, but also an opportunity to emphasize the dire need for advancement in research and development of novel medical treatments.



## COMMENTS RECEIVED FROM DERMIRA

Despite the knowledge and scientific discoveries that have emerged in recent years, forums such as the recent Eczema Patient Focused Drug Development (PFDD) meeting help to highlight how far we've come and remind us how much work remains in order to continue improving the lives of people living with Eczema. The information shared highlighted the desperation patients and caregivers face trying to find a therapy that works. Their perspective, particularly as it relates to the burden of itch, highlighted an unmet need which will inform years of research, clinical development, and physician treatment.

The emphasis on education and diagnosis was critical to helping construct a complete picture of the many different facets of eczema and its impact on patients. Notably, the focus on building awareness of clinical trials and emerging therapies, as well as the impact that current treatment's side effects have, was invaluable information to further enhance our understanding of eczema and pursue development of new treatments that will hopefully address the underlying cause of the disease and its associated symptoms. We firmly believe the patient perspectives shared during the meeting will play a significant role to inform therapeutic development.

Dermira was pleased to support the PFDD and thanks the organizers – Allergy & Asthma Network, Asthma & Allergy Foundation of America, Global Parents for Eczema Research, International Topical Steroid Awareness Network, and National Eczema Association – for their steadfast commitment to addressing the clinical, economic, and social needs of the millions of eczema patients around the world.



## COMMENTS RECEIVED FROM ELI LILLY AND COMPANY

### Innovation and the Need for New Therapies

One key learning from September's PFDD meeting is the need for new, innovative atopic dermatitis treatments. Patients who manage atopic dermatitis with a biologic medication expressed fear that their medication could eventually stop working. This concern is compounded by the fact that there is only one approved biologic for the treatment of atopic dermatitis. Patients also discussed the need for future innovation given the heterogenous nature of atopic dermatitis and the need for multiple mechanisms of action.

### Access and Coverage

A second key learning from September's PFDD meeting are the access and coverage barriers existing and future therapies face, including cost and insurance coverage. One patient even suggested that insurers should "be in the room [during meetings like the PFDD]" given the access limitations imposed on new therapies. As new, innovative therapies enter the market, it will be imperative to ensure that coverage and access barriers, including high cost-sharing, and utilization management techniques such as step therapy and fail first, do not limit patient access to the most medically-appropriate medication or therapy.



## COMMENTS RECEIVED FROM LEO PHARMA

LEO Pharma was honored to be in attendance and support the Patient Focused Drug Development meeting for eczema. While talking with brave patients and caregivers, hearing their stories, and listening to all the speakers, we identified the following key learnings:

- **The Burden on Caregivers:** The PFDD event shined a spotlight on the burden of the disease not only on those living with it, but on their caregivers as well. Especially for parents of children with eczema, care invokes emotions ranging from guilt to anger and fear, and leads to physical challenges such as lack of sleep.
- **The Mental Health Impact of Living with Eczema:** As with all chronic diseases, there is a mental health impact that is often overlooked. For many living with eczema, a disease on the largest and most visible organ of the body, fears of being shunned, bullied, or discriminated against can lead to depression, self-harm, and worse. Treating the disease must go beyond providing treatment options by offering holistic assistance to address the entire range of comorbidities.
- **The Non-Stop Struggle of Itch:** There are still no validated tools to measure the full impact of itch and how debilitating it can be, and the entire eczema community continues to look to the FDA for guidance on this.

This was a crucial first step to ensure the patient's voice is heard during the drug development process for eczema, but by no means the last one. LEO Pharma stands committed to working with all engaged parties to ensure all people achieve healthy skin.



## COMMENTS RECEIVED FROM PFIZER

As we listened to the deeply personal accounts at the recent meeting, we were struck by both the variety and magnitude of the unmet need, especially for the subset of patients with severe atopic dermatitis. These patients spoke of the debilitating nature of AD, which substantially impacts their day-to-day functioning. They described their multiple hospitalizations, their inability to use their hands or feet, attend school, or hold steady employment. Even patients with less severe forms of AD spoke of the devastating emotional and psychological impact of having persistent and recurring flare-ups for months and years because available therapies are not working for them. Despite treatment advances in recent years, patients are clearly still searching for more options.

Pfizer recognizes the importance of incorporating the patient's voice in drug development, having recently partnered with the National Eczema Association, whose input led to changes in our clinical protocol design. We applaud these groups and the FDA's efforts to engage patients and the patients that participate in and help guide clinical trial development. We are sincerely grateful to our clinical trial participants for engaging in this process to help advance care and guide research. They make significant contributions, and their voice in clinical trials will become more central and influential for us as Pfizer develops new medicines.



# SANOFI GENZYME

## REGENERON

### COMMENTS RECEIVED FROM SANOFI GENZYME AND REGENERON

Sanofi Genzyme and Regeneron were pleased to be able to attend and support the first ever Patient Focused Drug Development Meeting focused on atopic dermatitis. The meeting provided the opportunity for various stakeholders, including the U.S. Food and Drug Administration (FDA), to hear first-hand the heartfelt testimonials of those who are impacted by the disease daily. Several key insights were underscored:

- People with atopic dermatitis expressed that their disease is misunderstood, and that the comments they receive from people who do not live with the disease regarding the severity of symptoms such as itch, pain, bleeding, and oozing often times minimize what they are experiencing. They feel that they would appreciate greater understanding and empathy.
- People with atopic dermatitis shared that they often experience embarrassment, crippling anxiety, depression, and feelings of hopelessness. Caregivers express feeling guilty and helpless that they cannot do more to ease the disease.
- People with atopic dermatitis discussed the impact of living with the disease on a person's mental health, including self-confidence and self-perception. Parents with children with AD said that the disease impacts all aspects of their child's and a family's life. Patients and caregivers alike agreed that while AD may be a common condition, it impacts people differently and they are looking for different and more innovative treatment options to address the different needs of patients across all age groups.

Sanofi Genzyme and Regeneron are committed to the atopic dermatitis community and we look forward to continuing our work to support and empower the lives of those impacted by atopic dermatitis.



### CLOSING RECEPTION

Following the **More Than Skin Deep** meeting, a closing reception gave participants the opportunity to build on relationships formed during the day and at past conferences and meetings.





The initiative organizers wish, to thank the 1,508 individuals who generously contributed their experience to the **More Than Skin Deep** survey.

*Above are some of the social media images used to attract community members to participate in the meeting, webcast, and survey.*

## SECTION 3

# RESULTS OF THE MORE THAN SKIN DEEP SURVEY

In preparation for the **More Than Skin Deep** meeting, the five host organizations developed and fielded a web-based survey to capture a broad set of experiences from patients and caregivers. Jointly promoted by the five organizations, the 32-item survey attracted responses from 1,508 adults between the dates of August 1 and October 11, 2019. This is one of the largest surveys of the eczema community to date.

The survey was designed to address the same general PFDD topics as the meeting and had three key objectives:

1. **Inform the meeting:** Organizers used early survey responses to develop the meeting discussion guide and polling questions.
2. **Reflect experiences of a larger segment of the eczema patient and caregiver community:** The survey enabled greater participation in the **More Than Skin Deep** initiative than would have been possible to accommodate at the meeting. It also helped to expand participation to those who may not have been able to travel to the Washington, D.C. area or who preferred to remain completely anonymous.
3. **Augment the meeting program:** An interim survey analysis was included in the program distributed at the meeting and posted to the initiative website. This helped draw attention to the survey, garnering additional responses and providing an additional point of interest for those attending in person and via live webcast.

All responses to the survey were anonymous and no personal identifiers were collected. Individuals of age 18 and over were permitted to respond to the survey; there were no geographic restrictions, as evidenced below. The survey was housed by Dynata through an existing contract with the Asthma and Allergy Foundation of America. Respondents who completed the full survey were offered the option to enter a drawing through a separate web link to win 1 of 10 \$50 Amazon gift cards. The survey instrument is provided in its entirety, beginning on page 95.

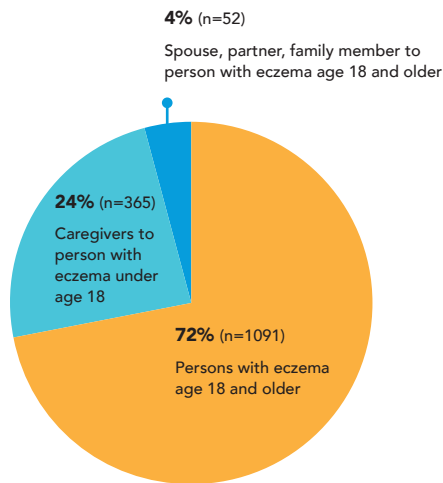
This is one of the largest surveys of the eczema community to date.



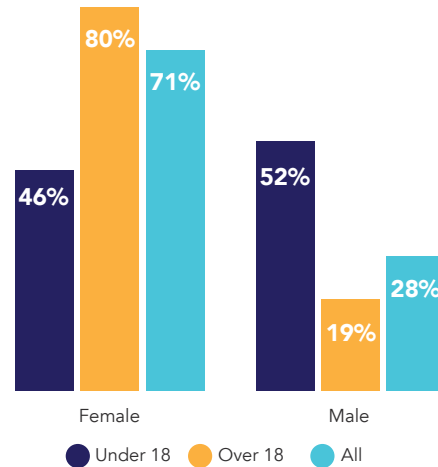
## RESPONDENT DEMOGRAPHICS

Nearly three-quarters (72%) of survey responses came from individuals speaking to their own experience with eczema (patients). A combined 28% of responses came from caregivers; 24% responded on behalf of one or more children under the age of 18 who have eczema and 4% replied on behalf of an adult child, spouse, partner, or parent with eczema. The distribution of the current age of the person with eczema is shown below, with 12% of the total sample being age 5 or younger and 13% being 65 or older.

SURVEY RESPONDENTS BY TYPE OF LIVED EXPERIENCE



DISTRIBUTION OF GENDER OF PEOPLE WITH ECZEMA REPRESENTED IN THE SURVEY

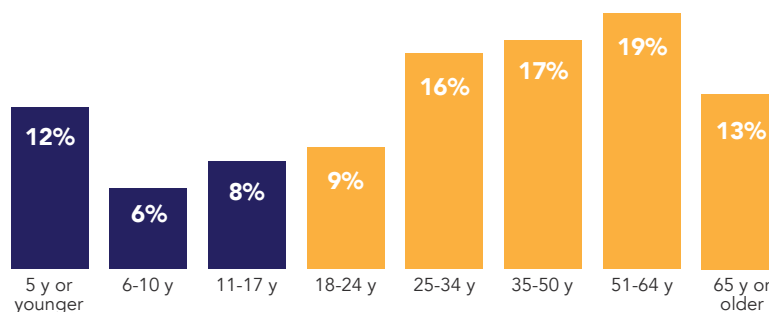


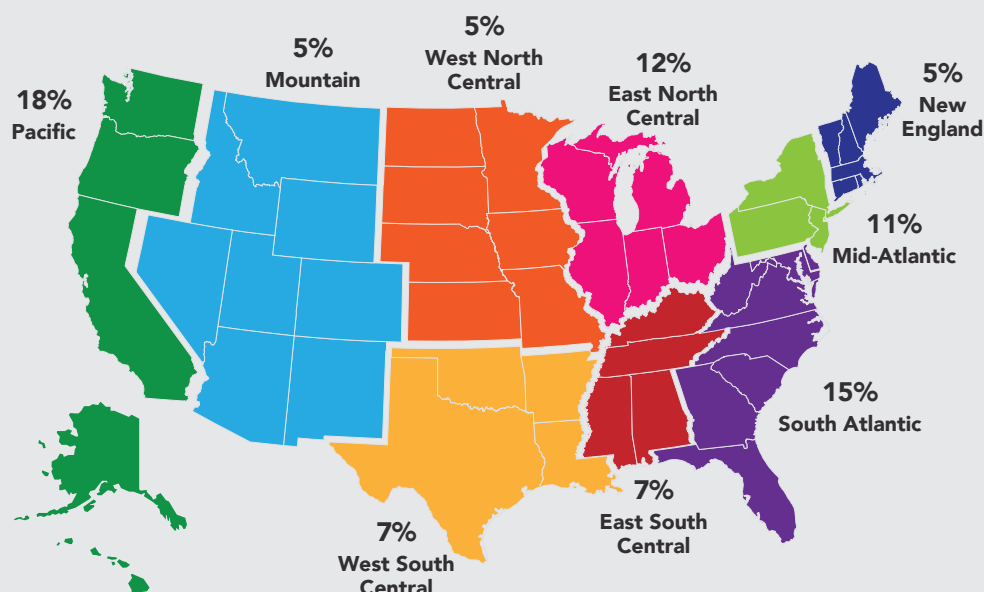
Sixty-nine percent (69%) reported having one person with eczema in the household; 22% have two affected household members and 9% have three or more people with eczema in the household.

Among all respondents, 71% indicated the person with eczema identifies as being female, although there was closer gender balance among the patients under age 18, as shown above. Health surveys in general, and PFDD-related surveys in particular, commonly receive a disproportionately high portion of responses from females.

Sixty-nine percent (69%) reported having one person with eczema in the household; 22% have two affected household members and 9% have three or more people with eczema in the household. Respondents were well distributed across the U.S., with the largest groups of respondents living in the Pacific (18%) and South Atlantic (15%) regions, as shown on next page. Twenty percent of responses (302) came from outside the U.S., with Canada and the United Kingdom providing most. However, there were one or more responses from 57 countries and six continents (see page 67).

DISTRIBUTION OF CURRENT AGE OF PEOPLE WITH ECZEMA REPRESENTED IN THE SURVEY





## COUNTRIES REPRESENTED AMONG THE SURVEY RESPONSES

**United States of America (1,206 responses)**

**Other Countries (302 responses)**

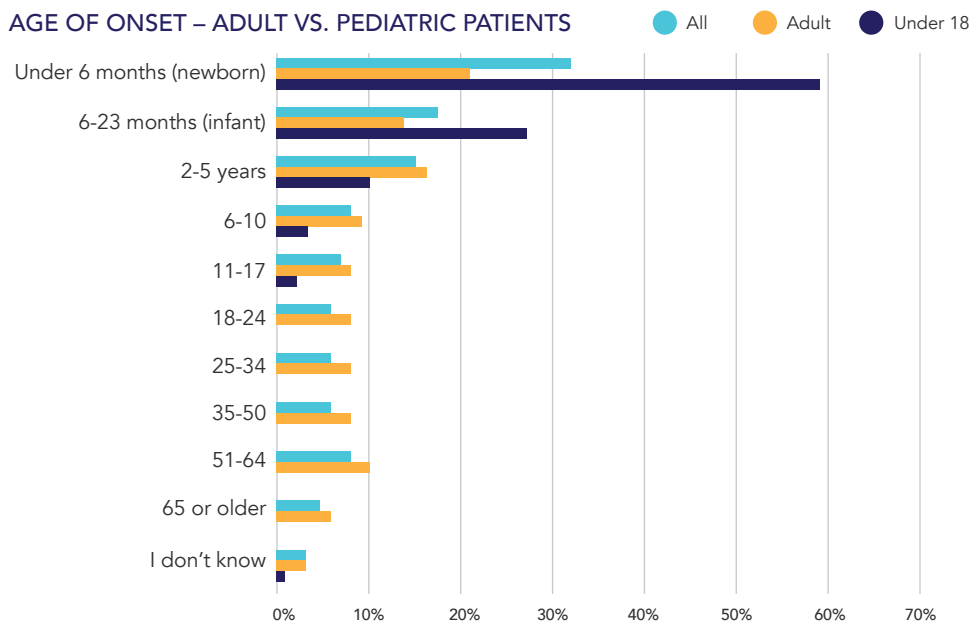
Argentina	Colombia	Grenada	Kurdistan	Pakistan	Slovakia
Australia	Croatia	Hong Kong	Lithuania	Paraguay	Slovenia
Austria	Czech Republic	Hungary	Malaysia	Philippines	South Africa
Barbados	Denmark	India	Malta	Poland	Spain
Belgium	Ecuador	Indonesia	Mauritius	Portugal	Trinidad
Bermuda	Egypt	Ireland	Mexico	Puerto Rico	United Kingdom
Bhutan	Eswatini	Israel	Mongolia	Qatar	Vietnam
Brazil	France	Italy	Netherlands	Russia	
Brunei	Germany	Japan	New Zealand	Scotland	
Canada	Greece	Kenya	Norway	Singapore	

## SYMPTOM BURDEN AND IMPACTS

### DIAGNOSIS AND SEVERITY

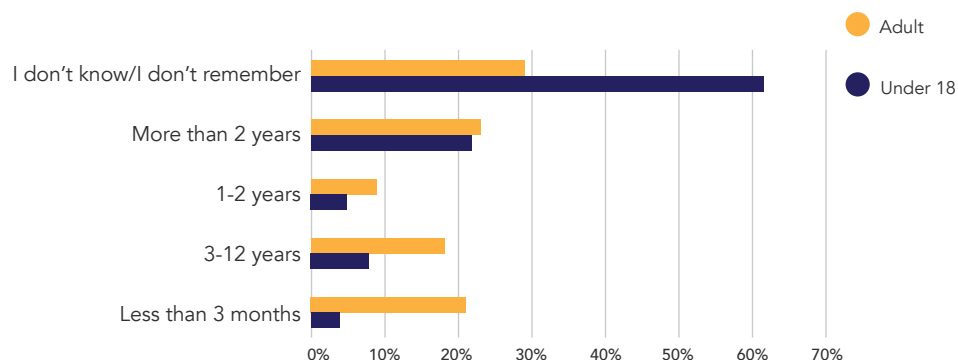
The distribution of the person's age at the time of eczema onset as reported by survey respondents is similar to reports in the literature; 72% reported onset before age 18. Nearly one-third of all respondents reported onset of the person's symptoms within the first six months of life, with another 28% reporting onset between 6 months and 5 years of age. When stratified by current age, the predominance of onset in infancy is even more pronounced, with 69% of those responding on behalf of a child reporting onset in the first 6 months of age. The peak for adult onset occurred between the years of 51 and 64 with 12% of adults reporting later-life emergence of symptoms.

## AGE OF ONSET – ADULT VS. PEDIATRIC PATIENTS



Nearly all – 99% – of respondents were diagnosed with eczema by a physician; 60% received a diagnosis within 12 months of symptom presentation. While only 16% of all respondents indicated that the diagnostic process took more than two years, an analysis by current patient age indicated that individuals with adult-onset eczema were more likely to experience delays in diagnosis. Nearly 20% of adults with eczema reported it taking more than two years, compared with less than 10% of children under 18.

## ADULT PATIENTS MORE LIKELY TO EXPERIENCE DELAYS IN DIAGNOSIS



Most of the open text comments provided in response to this question reflected a relatively straightforward diagnostic process as the data indicate. However, there were also many comments that illustrate some of the issues that contributed to a longer process for both adults and children, such as the following:

*"A diagnosis was predicted by our general practitioner (GP) but then we needed to wait several months to see a dermatologist to confirm."*

*"Diagnosis was challenging. The level of discomfort was not taken seriously. Eczema was mistaken for fungal infection and other skin issues, leading to inappropriate treatment."*

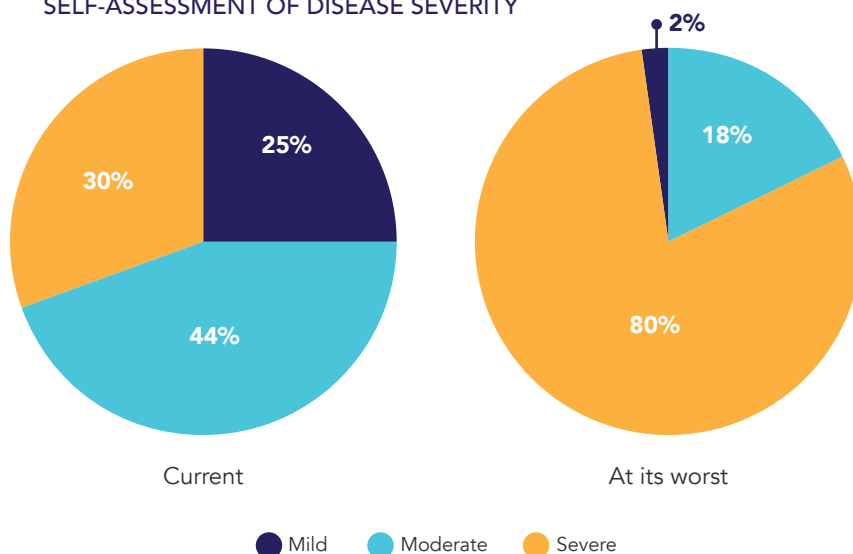
*"I had to wait until my flare-ups were extremely severe and covering more than 60% of my body to get an actual diagnosis of eczema."*

*"Around 1970 my eczema was diagnosed as poison oak. The drugs for that made my skin burn as if acid was being poured on it. I was 10 years old at the time. It wasn't until I was 18 or 19 that I was actually diagnosed with eczema. Before I had a real diagnosis, I had no treatment for my eczema. I have permanent scarring because of my eczema."*

*"At 2 months old, I was told my daughter had ringworm that she probably 'picked up from the hospital nursery.' We were given an antifungal with [a warning that read], 'Not to be used on persons under the age of 18.' No doctor in my area would even see her for allergies and no dermatologist would even look at her before she was 2. They all said she was too young and that she would grow out of it by her third birthday."*



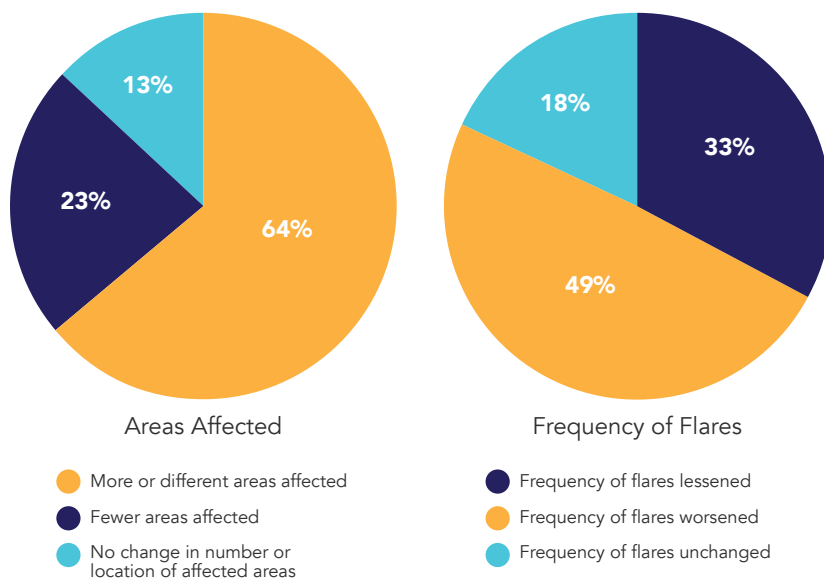
## SELF-ASSESSMENT OF DISEASE SEVERITY



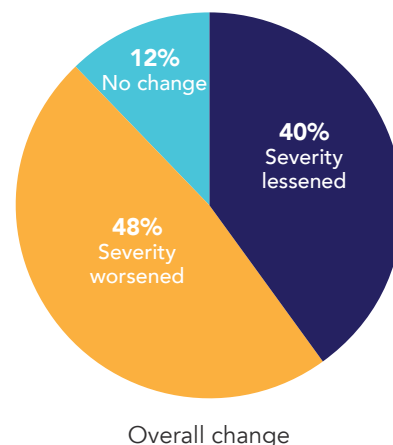
At its worst point, 80% of respondents rated their eczema as severe. At present, responses were more spread across the spectrum of severity, with 30% reporting severe symptoms, 44% reporting moderate symptoms, and 25% reporting mild symptoms. When analyzed by current age of the person with eczema, among those reporting for individuals under the age of 18, 33% indicated the child currently had severe eczema compared with 29% of those 18 and older.

Compared to the time of symptom onset, nearly half (48%) of all respondents indicated that at the present time, symptom severity had worsened and 12% stated there had been no change, while 40% stated that it was less severe now than at onset. This underscores the dynamic nature of the condition and the variable assessment of symptom severity at any point in time, as well as the limits of current therapy, as 60% have experienced unchanged or worse symptoms since onset. Nearly two-thirds (64%) reported that more areas or different areas are affected; 49% indicated that the frequency of flares was worse than at onset.

## CHANGES IN DISEASE THAT AFFECT SELF-ASSESSMENT OF SEVERITY



## CHANGE FROM ONSET TO PRESENT

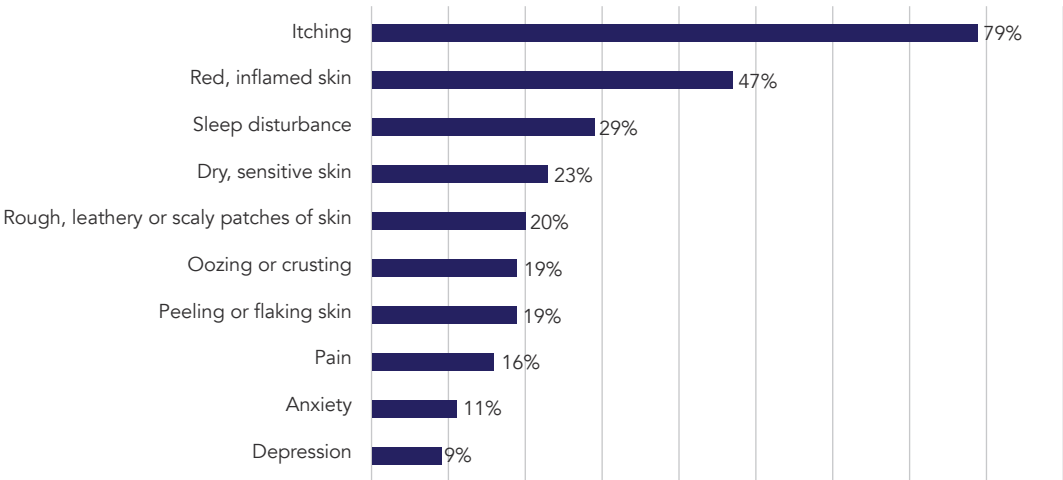


## SYMPTOMS OF GREATEST BURDEN

When asked about which three symptoms have been the most problematic for the person with eczema, the most prominent symptom was itch, with 79% of respondents selecting it. The two next most frequently selected symptoms were red, inflamed skin (47%) and sleep disturbance (29%).

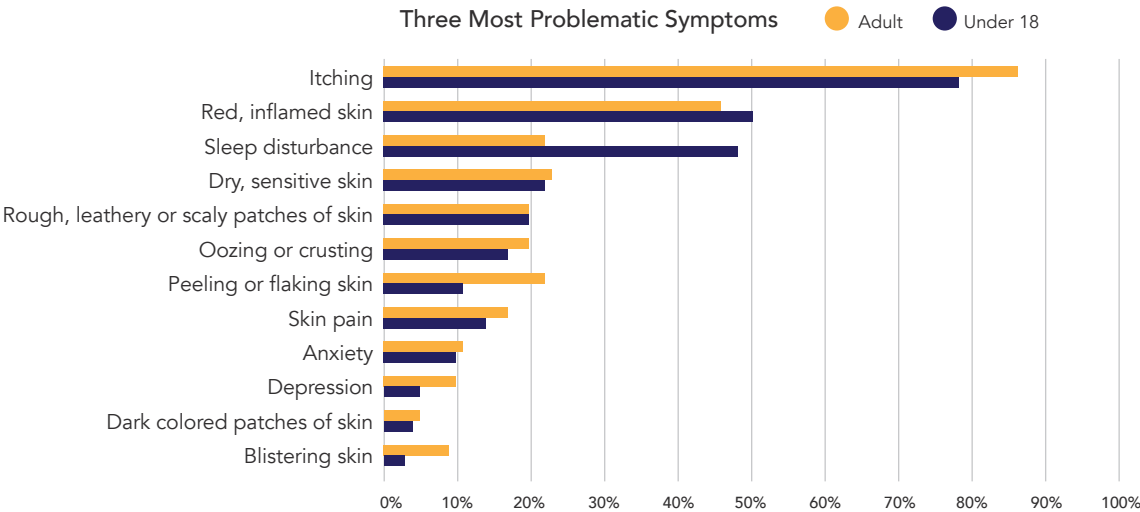
“The itch is so bad that I bruise myself from scratching. Lost sleep has really affected my well-being. I am exhausted and sometimes don’t feel mentally prepared for the day.”

### THREE MOST PROBLEMATIC ECZEMA SYMPTOMS



There was a significant difference in ratings of sleep disturbance between the two age groups. For patients under 18 years of age, sleep disturbance was selected by 48% of respondents. By comparison, 22% of adults selected it as a top-three most problematic symptom. Peeling or flaking skin and depression were selected more often by adult patients compared to those reporting for children.

### SLEEP DISTURBANCE IS MUCH MORE PROBLEMATIC FOR PEDIATRIC PATIENTS



Following are some of the many open text comments about symptoms, including how they have changed over time, from adult patients:

*“The itch is so bad that I bruise myself from scratching. Lost sleep has really affected my well-being. I am exhausted and sometimes don’t feel mentally prepared for the day.”*

*"The pain and severity of peeling and damage went deeper and deeper under my skin as time went on. It spread from just between my fingers to taking over the palms of my hands, the tips of my fingers, and underneath my nails. It also spread to the bottoms of my feet."*

*"At the most severe points of a flare up, it feels as though I've dipped my skin in acid and set it on fire. Having eczema drains my energy. I wish that in the previous screen we could rank the severity of the symptoms listed, because I know I'm not the only one who feels more than three. Social awkwardness is another eczema symptom that's not listed and should be, as well as intimacy issues."*

*"The frustration was the worst symptom, more than even anxiety, depression, or sleep disruption. There was no way out of myself. I would never consider suicide, but if I had left the earth any other way, I would have been perfectly okay with it. There was no escape."*

*"As a child, eczema only affected my sweaty spots behind the knees, elbows, and hands. As I grew into adolescence, I had very dry lips and often cold sores with my eczema, and it spread to my body. In my mid-20s, it affected my whole body and especially my face, which has been the most difficult to manage."*

*"I was diagnosed as a child with symptoms on my arms, legs, and face. I went many years unaffected only to have it resurface after having children. It has gotten considerably worse after I went through peri- and early menopause at age 48."*

A few more comments, submitted by caregivers:

*"The disease doesn't just make [my child] itchy. It causes sleepless nights, poor appetite, failure to thrive, and often leads to skin infections. It is exhausting and takes over every aspect of daily life for the entire family."*

*"When my son's eczema was the most severe, he would shed a pile of dead skin nightly. He was in so much pain even the air hurt. His skin oozed and peeled. He scratched, and it was very difficult to sleep. I would sleep with him to hold his hands down to not injure himself further."*

*"She thinks her face is ugly and her friends will start picking on her or bullying her about it. Picture day is coming up and she is terrified of having her picture taken with red eczema bumps on her face."*

*"At its worse, the skin was very painful and impacted his ability to sleep. This caused a combination of depression and shame that made him withdraw from others. As parents, we were deeply concerned about the change in personality and impact to his self-confidence."*

*"The biggest symptoms of eczema are the lack of confidence, poor body image, and sense of isolation that the child feels. These affect my son so much so that he will not go out in public without being covered from his neck to his feet, even on the hottest days. It's not because there is any outward sign of eczema (red skin or rash) but because he does not feel comfortable in his skin, so he hides it."*

**"The frustration was the worst symptom, more than even anxiety, depression, or sleep disruption. There was no way out of myself."**

**"She thinks her face is ugly and her friends will start picking on her or bullying her about it."**

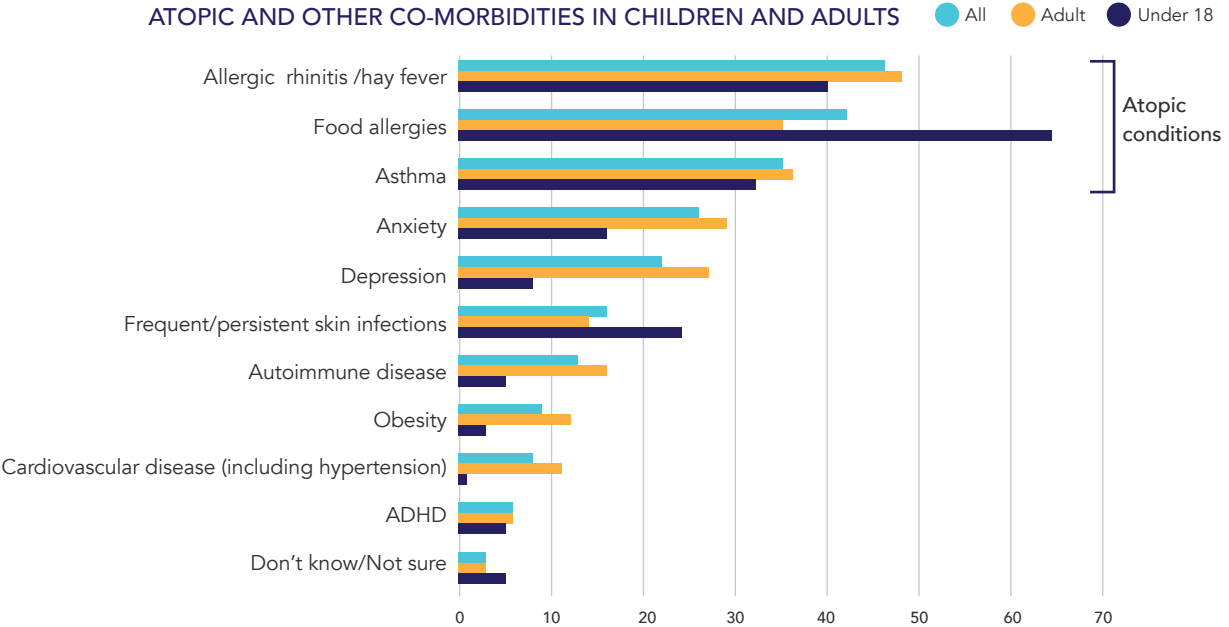


Among children, food allergy and frequent/persistent skin infections were much more common than in adults.

COMORBIDITIES

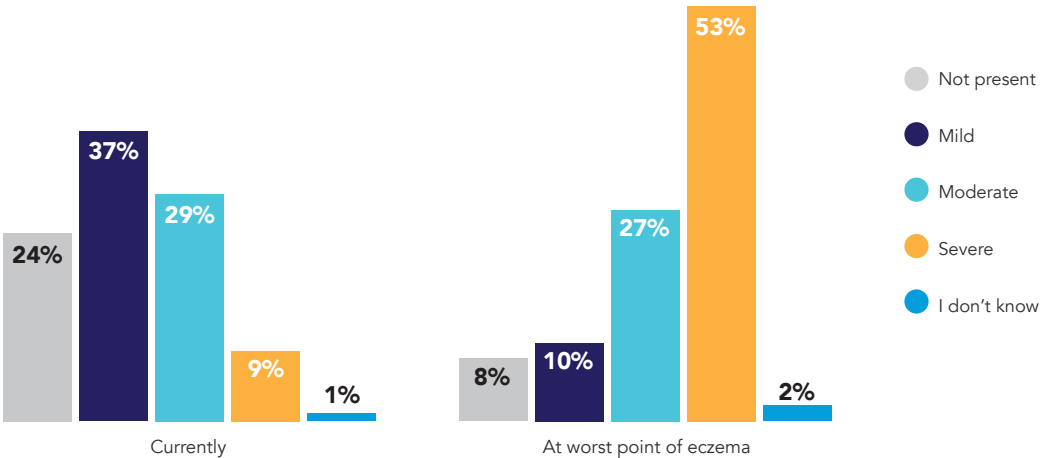
Diagnosed comorbidities were common among all respondents. One or more of these five conditions were present in more than 20% of all respondents: allergic rhinitis (46%); food allergy (42%); asthma (35%); anxiety (26%); and depression (22%). The top three comorbidities are immune-related conditions that are known to have an association with eczema as part of a progression known as the “atopic march.”<sup>13</sup> Among children, food allergy and frequent/persistent skin infections were much more common than in adults. Notably, adults reported higher rates of anxiety and depression, as well as other conditions that might be expected to occur at higher rates along the lifespan such as autoimmune and cardiovascular diseases.

ATOPIC AND OTHER CO-MORBIDITIES IN CHILDREN AND ADULTS



When asked directly about symptoms of depression (“feeling sad, empty, and/or anxious; feeling hopeless; loss of interest in hobbies or other activities; decreased energy; feeling tired more often; difficulty concentrating; restlessness, unable to sit still”), 38% of all respondents rated them as “severe” or “moderate” at present. At the worst point of their eczema, this combined figure jumped to 80%, with 53% rating these symptoms as having been “severe” and 27% rating them as “moderate.” Ratings for these symptoms were quite similar between adults and children at present; however, at the worst point, these symptoms presented a challenge for a greater share of adults, with 84% indicating severe or moderate impact, compared to 69% of those responding for children.

MOOD DISTURBANCE CORRELATES WITH ECZEMA SEVERITY

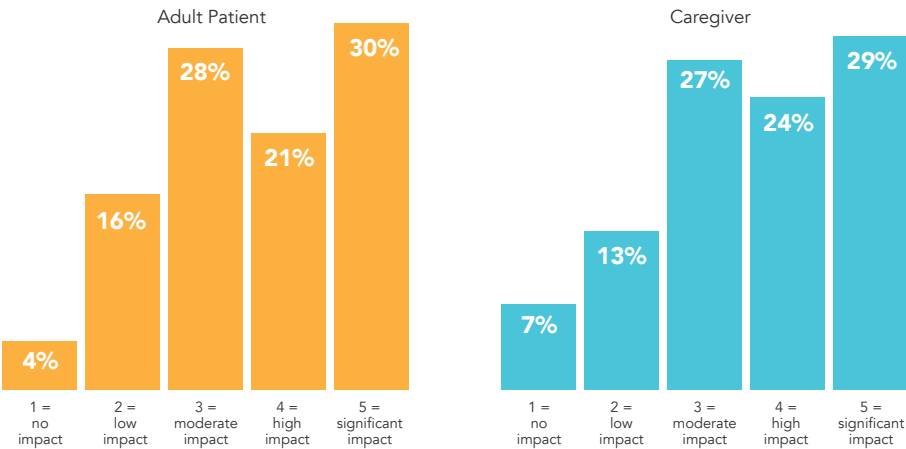


<sup>13</sup>Paller AS, Spergel JM, Mina-Osorio P, Irvine AD. The atopic march and atopic multimorbidity: Many trajectories, many pathways. *J Allergy Clin Immunol.* 2019. doi: 10.1016/j.jaci.2018.11.006.

# IMPACTS OF ECZEMA ON ADULT PATIENTS AND CAREGIVERS

Questions about the impacts of eczema were posed to be answered by the adult patient respondent for him or herself; caregivers were responding about the impacts on their own life, rather than the child or adult who has eczema. A question about the global impact of eczema over the past month reveals a nearly identical impact signature when comparing adult patients to adult caregivers.

## OVERALL ECZEMA IMPACT IN THE LAST MONTH

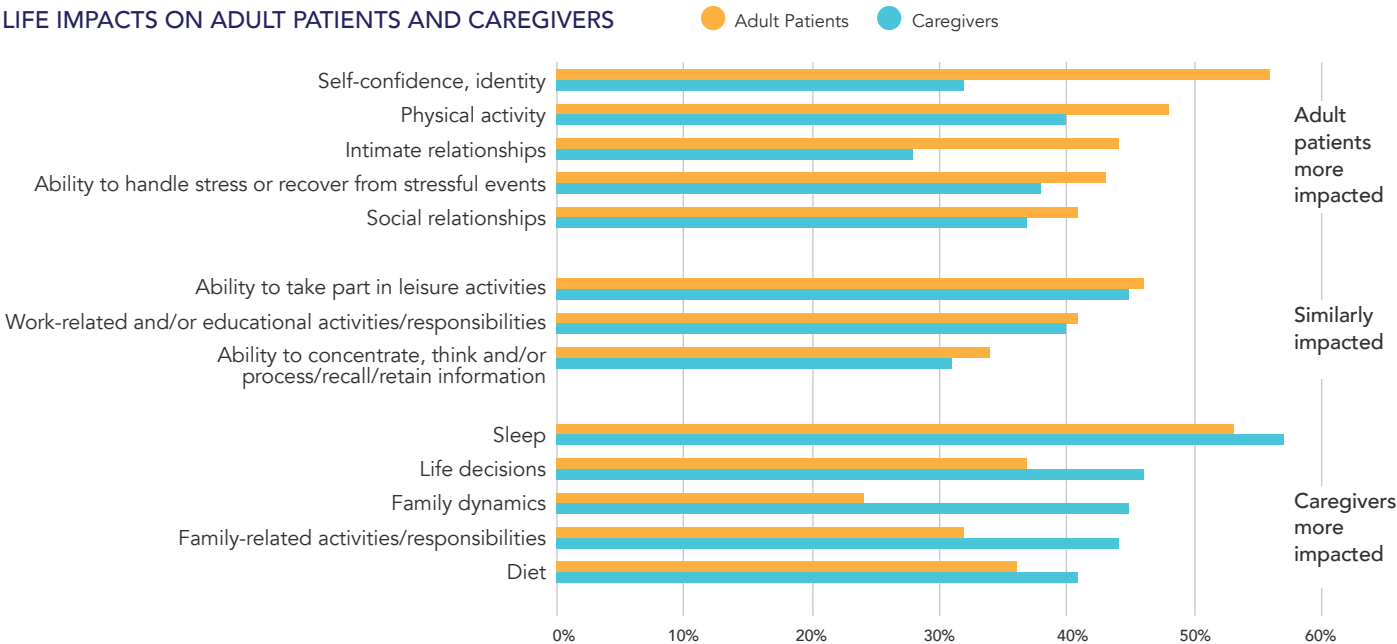


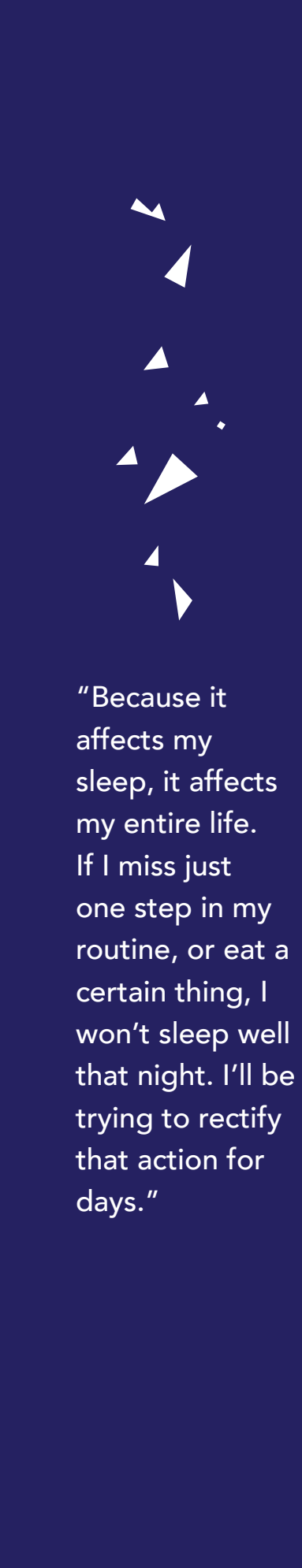
A question about the global impact of eczema over the past month reveals a nearly identical impact signature when comparing adult patients to adult caregivers.

The impact of eczema on their sleep was rated as significant (33%) or high (21%) by 54% of all respondents. The impact on identity and self-confidence ranked second overall, with 29% of all respondents indicating its impact as significant and 21% as high.

An analysis of responses to questions about specific life impacts shows that some were more often endorsed by adult patients (self-confidence and identity; physical activity; intimate relationships; and social relationships), while others were more often rated as highly impacted by adult caregivers (sleep; life decisions; family-related activities; family dynamics; and diet). Four areas were rated similarly by both groups – ability to take part in leisure activities; ability to handle stress; work-related or educational activities; and cognition.

## LIFE IMPACTS ON ADULT PATIENTS AND CAREGIVERS





"Because it affects my sleep, it affects my entire life. If I miss just one step in my routine, or eat a certain thing, I won't sleep well that night. I'll be trying to rectify that action for days."

Comments about life impacts provided by survey respondents echo similar themes from the meeting. Here is a small sampling from adult patients:

*"Eczema has changed the dynamics of my life. I have been seeking treatment for 50 years, and I am still looking for a new treatment."*

*"Because it affects my sleep, it affects my entire life. If I miss just one step in my routine, or eat a certain thing, I won't sleep well that night. I'll be trying to rectify that action for days. Sometimes I won't sleep well even if I've done everything I could. Sometimes the flares seem to come from nowhere."*

*"The symptoms compound. I itch so much that I wake up scratching. The scratching leads to raw, open wounds. All of this impacts my sleep and general health. My eczema is largely on my feet, so finding shoes that don't worsen my condition is difficult, and those shoes that seem safe are not what is expected in a professional arena, so I feel awkward and emotionally uncomfortable as well. All of this also impacts my other physical health because exercising is painful, and sleep is not restful."*

*"As a teacher, when my eczema was at its worst, appearing before my students and their parents was extremely difficult. I was embarrassed, and the constant questions became very tiring."*

*"Eczema makes me irritable and uncomfortable. I have higher anxiety when I am inflamed, which is 95% of the time. I get irritated at my daughter, family members, friends, and partners because I am itchy or in pain. My self-confidence is low at times and that affects how I socialize."*

*"Currently 95% of my thoughts are about my skin, how it makes me feel, always being aware of my skin (due to it being so itchy I can never ignore it). I am constantly reminded of feeling uncomfortable. Knowing I look in pain, my children comment on how sore my skin looks. I can't take them swimming. I can't do any exercise that makes me sweat; I can't be in the sun. It impacts every aspect of being a mother. Most of the time, I have to rise above it for the sake of my family and it's exhausting."*

Some comments about impacts from caregivers that illustrate the collateral impacts of eczema on the lives of patients and the people who care for them:

*"As a caregiver, you would probably be surprised to know that my son and I share a lot of the same struggles, even though I don't have eczema myself. Our family is centered around his eczema. He sleeps with my husband and me most nights because he can't sleep due to the itch. Therefore, we don't sleep. I'd be lying if I said our marriage hasn't struggled from it. We can't go certain places, including my father's house, due to a cat allergy which makes him flare up. We can't find childcare because no one can soothe him other than my husband and myself, so he doesn't leave our side. I work from home because it's my only option; I have to be with my son. He will begin preschool next year, however we currently do not know how that will work because of the reasons mentioned above, so we are looking into homeschooling options. If we homeschool, I will have to stop working and financially that will be a huge burden. I've become distant with my friends because they do not understand, and honestly, I don't have the energy to maintain friendships. My plate is full. We also have two other children that still need attention and care. I often feel guilty that I can't give them the same attention my son gets."*



*"As a mother of a child who suffered from severe eczema, I was desperate, scared, and sleep-deprived. My marriage suffered and eventually ended. It was the darkest and most hopeless time in my life."*

*"The sorrow that a parent feels for a chronically ill child is the most pervasive feeling that I can articulate. The frustration with the lack of knowledge of the disease causality and limited treatment options only compounds the situation. Having a child with severe atopic dermatitis not only defines the child and their perception of themselves but also impacts the broader family relative to sleep disturbances, and neglect of other siblings. My wife does not work due to my daughter's situation; I have had to turn down career opportunities and promotions and our son does not get to go on vacations, as we need to stay close to home and our caregivers."*

*"Impacts include: Bickering with my husband over treatments because we don't know what to do or how to help. Loss of sleep thinking of her having to deal with eczema in her teen years. Avoiding family time outdoors because we don't want her to flare up. The time it takes for nighttime routine; putting our other child to bed early so that we can complete that routine."*

*"The disease has worsened as our daughter has aged, as opposed to going away with more traditional eczema. The combination of asthma and allergy comorbidities, with growing severity of atopic dermatitis, has led to significant social, emotional, learning, overall wellness, and sleep disturbance challenges for our daughter and has affected the extended family."*

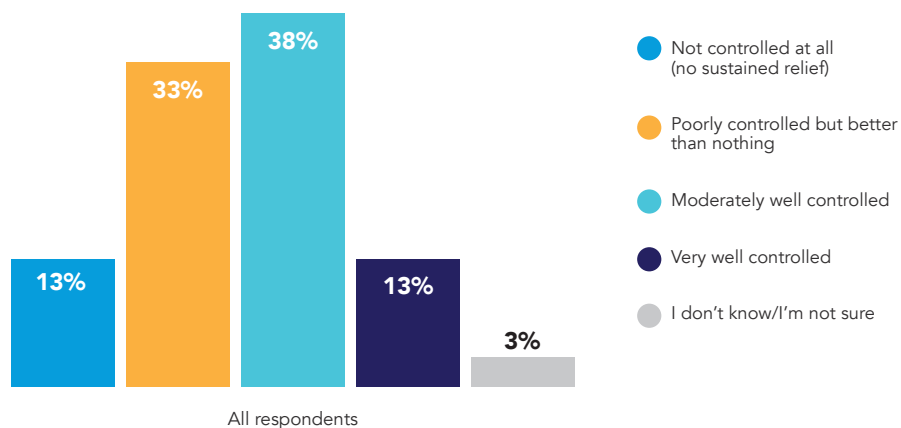
**"The sorrow that a parent feels for a chronically ill child is the most pervasive feeling that I can articulate. The frustration with the lack of knowledge of the disease causality and limited treatment options only compounds the situation."**

## TREATING AND MANAGING ECZEMA

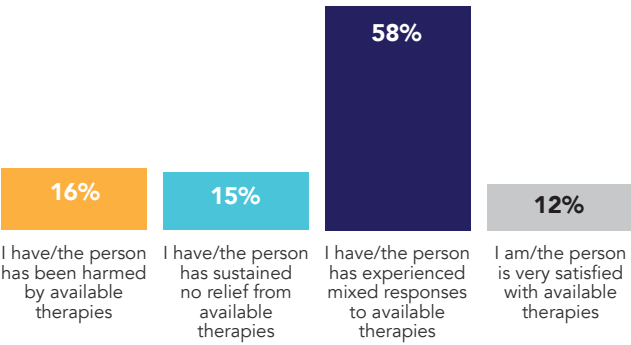
### UNMET NEEDS

Like meeting participants, survey respondents' answers to a series of questions about overall treatment satisfaction left little doubt about the gap in available therapies and unmet medical needs. Thirty-eight percent (38%) of respondents indicated that their eczema is moderately well-controlled using therapies available to them; however, a similar proportion (33%) expressed that the condition was "poorly controlled, but better than nothing." At the ends of the spectrum, 13% reported their eczema is "very well-controlled" and 13% responded that their symptoms were "not controlled at all/no sustained relief."

### UNCONTROLLED ECZEMA DRIVES NEED FOR NEW THERAPY OPTIONS



MAJORITY OF ECZEMA PATIENTS NOTE LIMITED EFFECTIVENESS OF AVAILABLE TREATMENTS

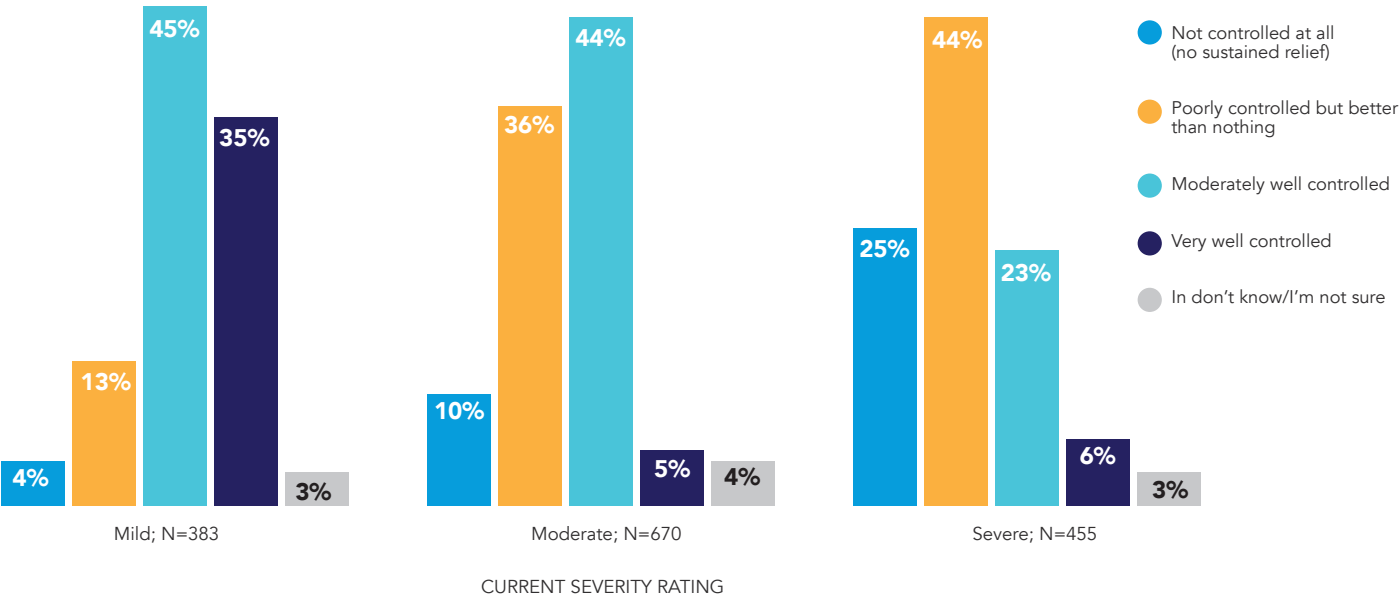


In terms of satisfaction with available therapies, overall, 58% of all respondents indicated that they have experienced mixed response to available therapies. There was a fairly even distribution among the other three responses: only 12% indicating being very satisfied with available therapies; 15% indicated no sustained relief, and 16% reported having been harmed by existing therapies.

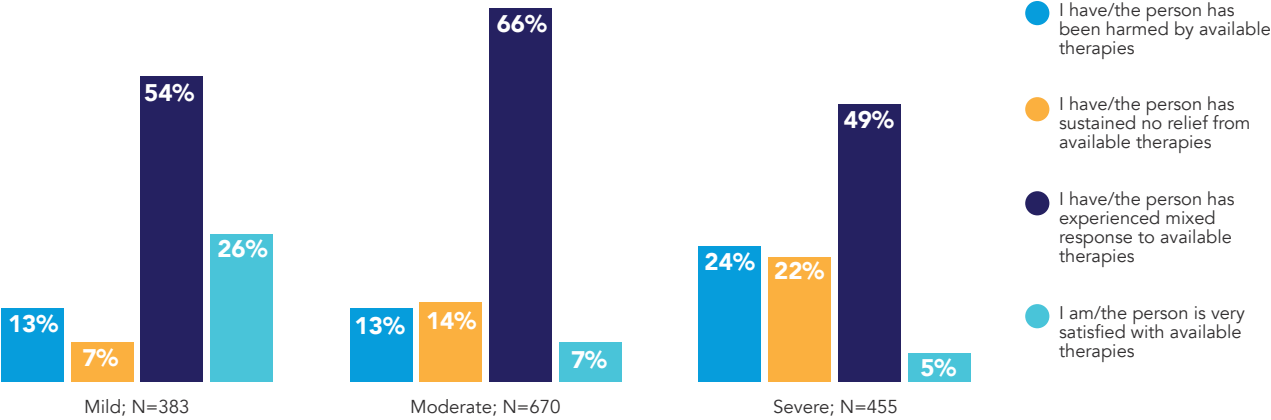
Responses to these questions differ when grouped by the current self-assessment of disease severity. A combined 80% of people rating the condition at present as mild indicated their eczema is “very well controlled” or “moderately well controlled,” compared to 49% of the moderately severe group and 29% of the severe

group. Similarly, those reporting current severity as mild were more likely to feel satisfied with available therapies – 26% compared to 7% of respondents rating themselves or their loved one as moderately severe or 5% rating as severe.

PERSPECTIVE ON DEGREE OF CONTROL CORRELATES WITH CURRENT SEVERITY

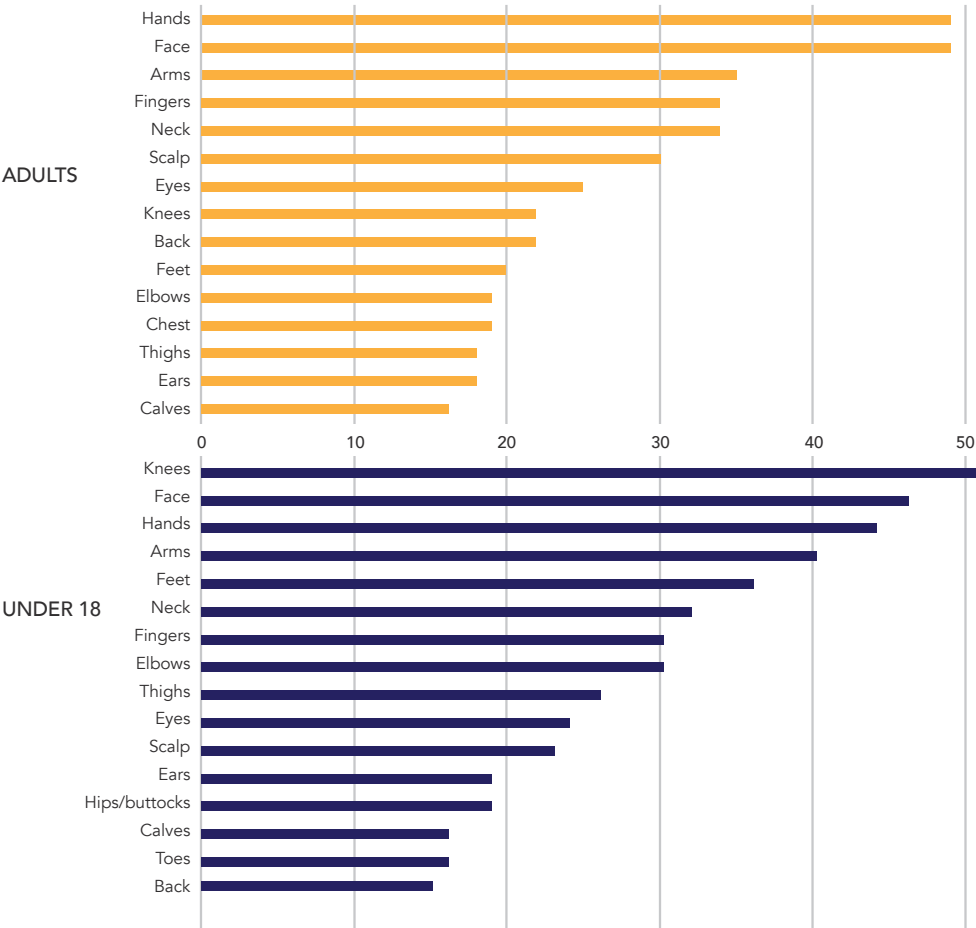


TREATMENT EXPERIENCE REPORTED BY CURRENT SELF-RATING OF SEVERITY



In response to a question about the most challenging areas of the body to treat, looking at all responses, the face and hands were each rated as most challenging by 48%. Other areas that were identified as challenging by at least one-fourth of all respondents are: arms (36%); fingers (33%); neck (33%); knees – front and/or back (30%); scalp (28%); and eyes (25%). There were some differences by patient’s age, with adults rating hands, face, arms, fingers, neck, and scalp as the most challenging areas to treat. By comparison, responses for children reflected the order as knees, face, hands, arms, feet, and neck.

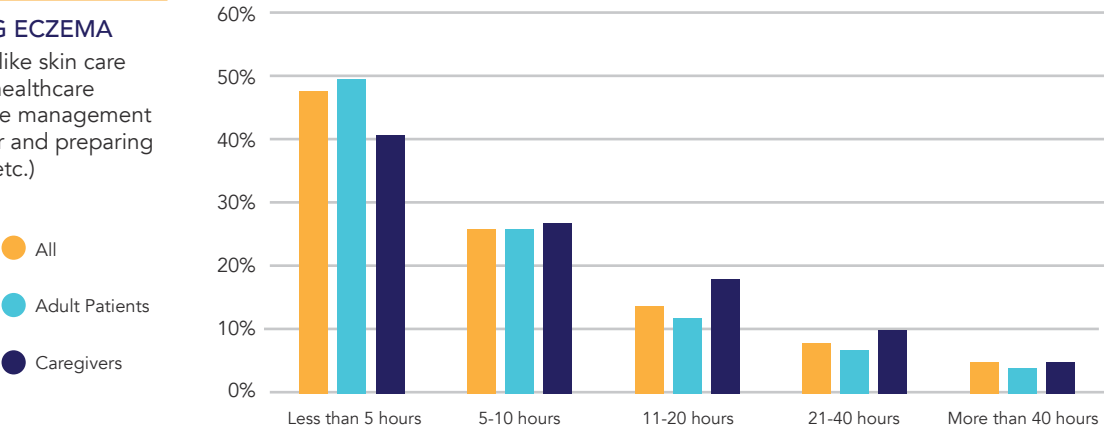
**MOST CHALLENGING AREAS TO TREAT BY AGE GROUP**



Eczema is a time-consuming condition to treat, with more than half of all respondents indicating that they spent more than 5 hours per week managing their eczema. Caregivers reported greater time commitment than adult patients, with 33% reporting spending 11 hours or more each week, compared to 23% of adult patients spending that amount of time.

**TIME SPENT MANAGING ECZEMA**

Includes direct treatments (like skin care routines or bleach wraps), healthcare appointments, or supportive management strategies (like shopping for and preparing special foods, meditation, etc.)





"It's full-time care. We are applying medications, bathing, trying to soothe him. It's all the time."

These comments from survey respondents reveal all the ways in which they dedicate time to managing eczema:

### COMMENTS FROM PATIENTS:

*"Impossible to assess really because managing my eczema is an ongoing thing built into my life. There's rarely a moment that I don't think about what I'm doing and how it will affect my eczema. Every meal I eat every day is affected by my eczema. Every bath, every visit to the hairdresser (No, I don't want your products in my hair – thank you!), etc."*

*"I probably spend 1-2 hours when I wake up, including showering and lotions. Then, there is probably another hour or two throughout the day spent applying more lotions and oils. Also, a total time of one hour twice a week for phototherapy. Then another hour at night before bed, and often one or more hours during my sleep time to get up and reapply, or just from the inability to sleep."*

*"When I had light therapy treatments, I went 3 times a week; it was extremely time consuming, and I used up all my work sick leave in the process."*

*"Time spent can be endless. The dryness part is awful and one of the worst symptoms and one of the hardest to treat. I can apply lotion and wet wraps 24/7 and I still feel unbearably dry."*

*"It varies, depending on the flare. During a non-major-flare week, with my daily bath and medication application, it's about 10 hours. During a major flare week, it can be up to four hours a day – more if it's affecting sleep."*

### COMMENTS FROM CAREGIVERS:

*"We had to bathe my son many times a day. We had mitts on him preventing the scratching damage. We had to constantly distract him from scratching, all night long. We rarely slept. He couldn't go to school for three years, and we had to home-school him. He was suicidal at age six. This wasn't just managing eczema; this was managing a chronically ill child who was suffering horribly."*

*"A lot of additional aspects are included such as washing bloody or allergen-tainted laundry, food preparation and planning, and meditating out of difficult moments."*

*"Overall time commitment for doctor visits, applying ointments, preparing baths and wraps, helping to put to bed at night, etc., is significant. The review and payment of associated medical bills, picking up new prescriptions, etc. is secondary work that takes up time as well. Our daughter requires constant supervision and care to monitor picking disorder, ensure treatment plan is followed, ensure reasonable amount of sleep, responsible food selections, etc."*

*"It's full-time care. We are applying medications, bathing, trying to soothe him. It's all the time."*

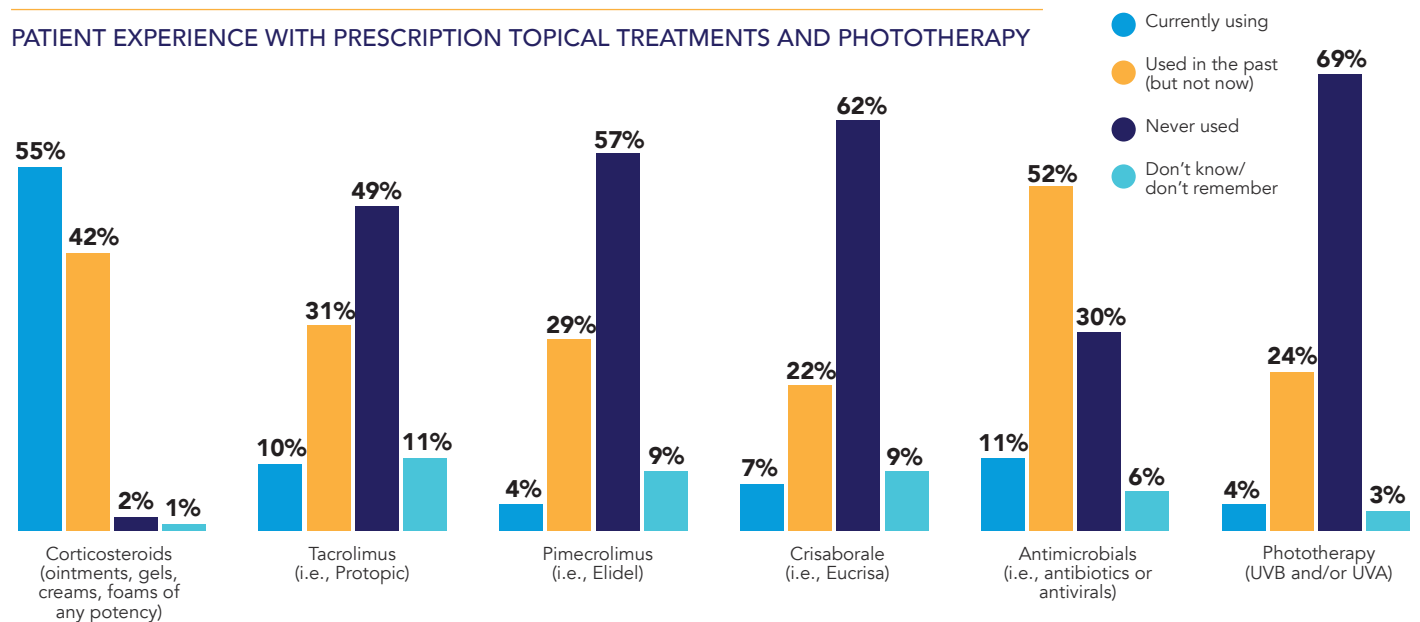
*"When my son had eczema, everything we did revolved around eczema. He did not like creams or anything on his skin. Every plan we made had to involve my son being comfortable. Food took hours to prepare and make; taking showers was compartmentalized, washing body parts separately; not to mention all the sleepless nights for everyone."*

## THERAPIES USED – CURRENT AND PAST

A large number of approaches to treatment are being used at present or have been used in the past, combining medications, medical devices, and supportive therapies. The most widely utilized treatment – both at present and in the past – is topical corticosteroids (55% at present and 42% in the past (but not at present)), for a combined 97% use at some point. Among those who have used topical steroids, 71% reported they had some relief for some period of time; 39% had limited or no relief; 35% had a severe or long-lasting flare after stopping use; and 27% reported that symptoms worsened while using topical steroids.

There was less experience with other topicals. Antimicrobials were used in the past by 52% but were in current use by only 11%. For specific topicals including Protopic (tacrolimus), Elidel (pimecrolimus), and Eucrisa (crisaborale), all have been used in the past by more than use them at present, but nearly half or more of all survey respondents have never used them. Phototherapy has been used by 24% in the past and just 4% at present; 69% have never tried it.

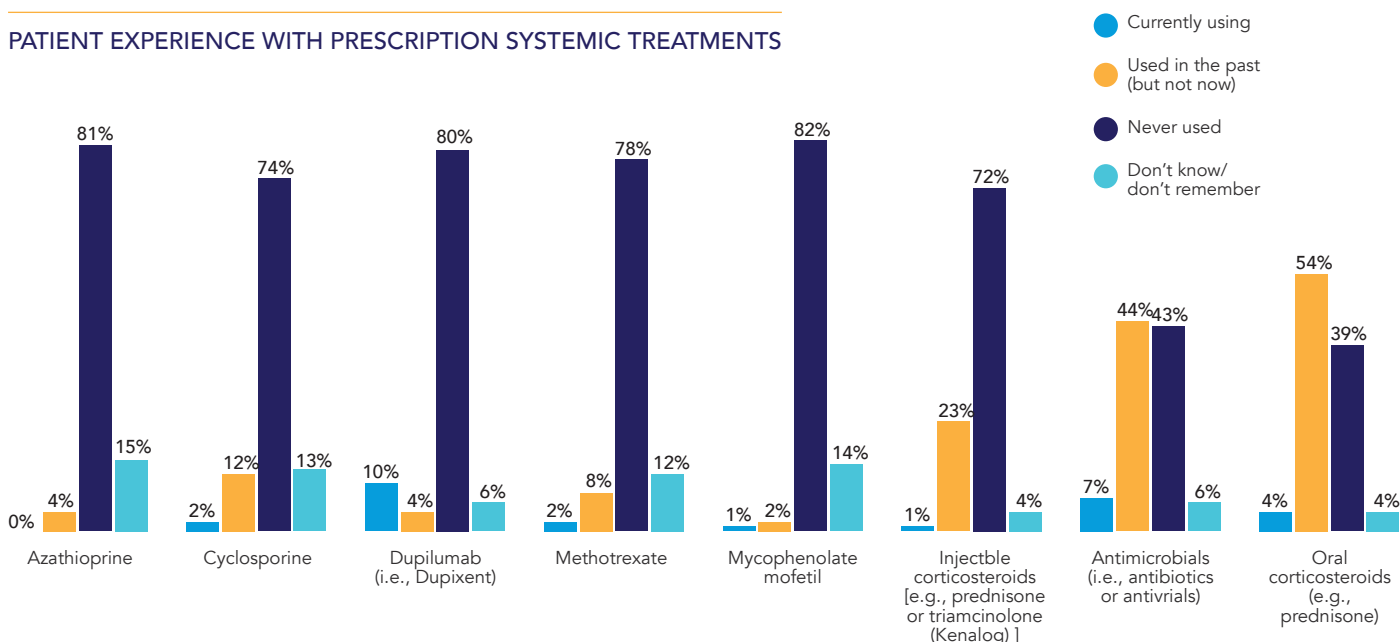
### PATIENT EXPERIENCE WITH PRESCRIPTION TOPICAL TREATMENTS AND PHOTOTHERAPY



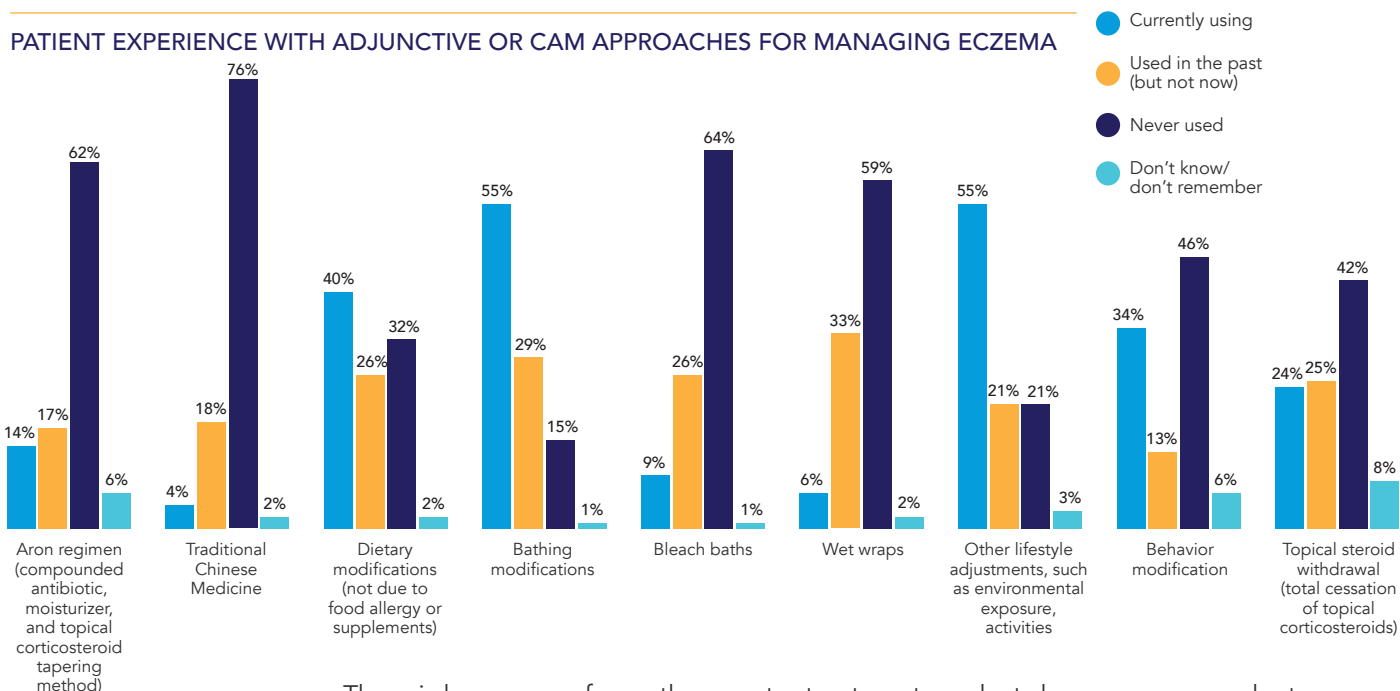
Among the systemic medications taken orally or by injection, again there was more experience with corticosteroids than other medications. Oral corticosteroids (such as prednisone) have been used by 54% in the past, with 4% reported current use; injectable corticosteroids were used by 23% in the past and 1% at present. Other oral immunosuppressive medications (i.e., azathioprine, cyclosporine, methotrexate, and mycophenolate mofetil) have been tried by few survey respondents. Dupilumab, the newest approved biologic therapy for eczema, was being used by 10% of survey respondents at present; 4% reported past use. Oral antibiotics and antivirals had been used by 44% of all respondents in the past, with 7% reporting current use.

The most highly reported self-care and adjunctive/complementary/alternative therapy in current use is bathing modifications (55% current; 29% past), followed closely by lifestyle adjustments (such as controlling exposures or activity; 55% current and 21% past), and dietary modifications, currently used by 40% and 26% in the past. Approaches with more past than current use include wet wraps (33% past; 6% current); the "Aron Regimen" (17% past; 14% current; see page 40 for more information); traditional Chinese medicine (18% past; 4% current); and bleach baths (26% past; 9% current). Topical steroid withdrawal, as a therapy, has been used in the past by 25% of respondents and is in current use by 24% (see page 38 for more information).

## PATIENT EXPERIENCE WITH PRESCRIPTION SYSTEMIC TREATMENTS



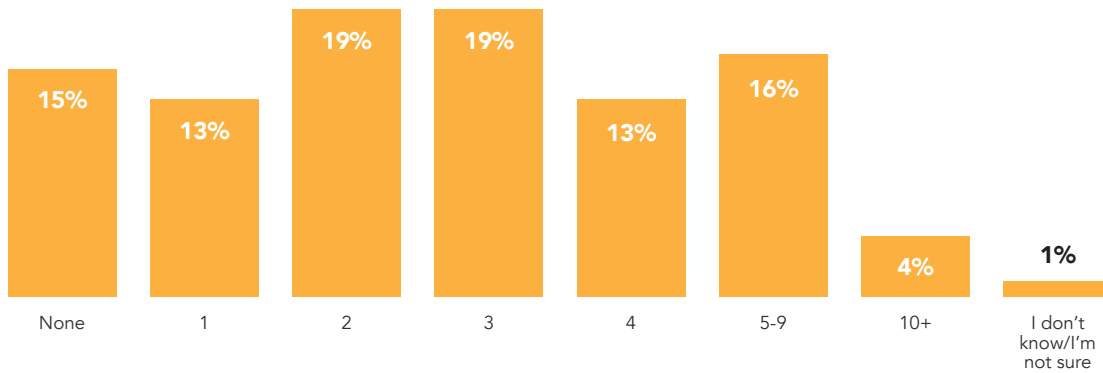
## PATIENT EXPERIENCE WITH ADJUNCTIVE OR CAM APPROACHES FOR MANAGING ECZEMA



There is heavy use of over-the-counter treatment products by survey respondents, with just 15% indicating no use and more than half (52%) indicating use of three or more products at present; 20% use five or more products. Some of the over-the-counter products and self-care strategies mentioned in the open text comments include the following: acupuncture and acupressure; avoidance of contact with many different substances or environments; bathing with many different additives (apple cider, baking soda, clay, coal tar, colloidal oatmeal, Dead Sea salts, Epson salts, and vinegar); biofeedback; Chinese or herbal medicine (including homeopathy, naturopathy, Ayurvedic treatments); chiropractic; cognitive behavioral therapy; coffee enemas; colloidal silver; diets that include or exclude a variety of foods, food groups, additives, and substances; healing mindset; ice packs; “no moisture therapy”; practices such as meditation, mindfulness, prayer, and yoga; probiotics; topical application of many different products (aloe vera, black seed oil, CBD oil, coconut oil, petroleum jelly, Vick’s VapoRub, zinc oxide); relocating to hotter, cooler, more humid or less humid climates; sunlight exposure or avoidance; tanning beds; and wearing cotton gloves (to diminish impact of scratching and/or hold in moisturizers/medications).

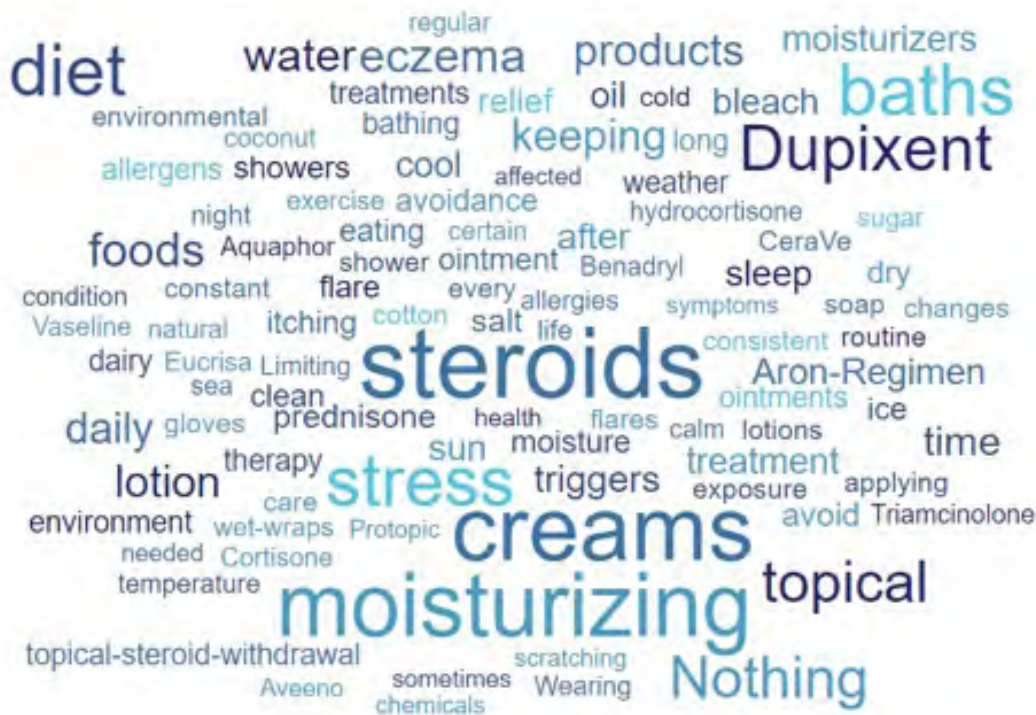


## 1 IN 3 ECZEMA PATIENTS CURRENTLY USING FOUR OR MORE OVER THE COUNTER (OTC) TREATMENTS



## WHAT HELPS THE MOST?

Survey respondents were invited to reply to the question, “What have you found that helps the condition the most?” A word cloud based on the open text responses appears below. The size of the word indicates its relative frequency among the responses.



Legend: 1,481 people responded to this question. Following are the number of times these words (or closely related words) were used: steroid(s)-360; moisturizing/moisturize/moisturizer-225; cream(s)-180; stress (accompanied by "no," "less," or "reduced")-137; topical-121; bath(s)-120; Dupixent (dupilumab)-102; nothing-89.

Here are representative comments that include some of the treatment approaches most frequently cited as being helpful:

*"Following a food intolerance regime. This was the first thing to get my eczema under control, when I was in my mid-30s, just over 30 years ago. Of course, I have flare-ups, including a couple of severe ones since then, and I still use steroids on and off. I still follow a specific bathing regime and I watch what I do, where I go, what I wear, etc. But I believe that changing my diet made a huge difference, because the change was dramatic at the time I tried it."*

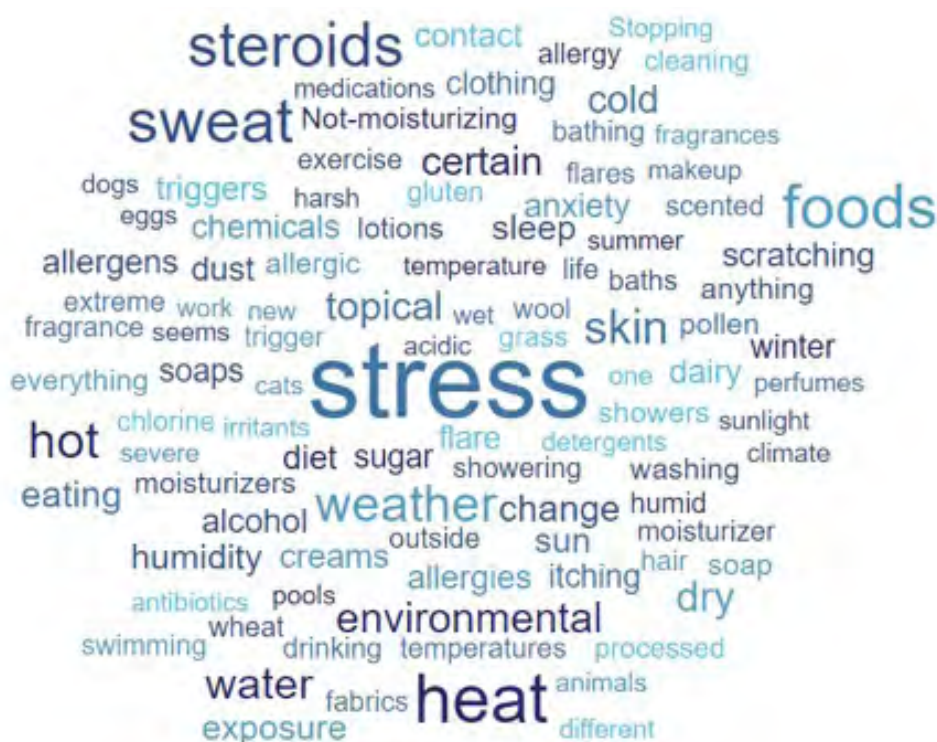
“The only thing that seems to help is prednisone, but I can’t take it all the time. About two weeks after stopping the prednisone, the eczema returns – sometimes with a vengeance!”

*"Cessation of steroids and going through withdrawal has had the most positive long-term impact on my life. It means that I now just have 'normal' adult eczema which is barely a blip on my radar. The symptoms of dependency were life-consuming for 30 years and going through withdrawal was awful for 5 years, but I have my life back now and can start over."*

*"Getting educated! Getting a good daily routine: cool to warm, short showers then moisturize immediately! Getting to know my triggers. Using a steroid ointment instead of cream. Being more aware of environmental factors: soaps, detergents."*

*"Nothing has really worked; it's all temporary."*

Similarly, respondents shared their observations in response to the question, "What have you found makes the condition worse?"



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Here are comments that represent some of the factors that survey respondents most often mentioned as contributing to worsening of their eczema:

*"Eating inflammatory foods; wearing most commercial makeup; being exposed to pets/mold/dust; stress overall; and cold dry air of wintertime."*

*"If I don't maintain my moisture regimen or if I don't take care of avoiding my triggers."*

*"Delay of treatment. If I am unable to get the right prescription because I need a doctor appointment, or I have to try another lesser treatment. Even if the pharmacy has changed distributors, the medication can be just different enough to be ineffective."*

*"Exposure to grass; heat; emotionally challenging situations; exposure to water."*

*"Alcohol-based products. Perfume in products. Sweat."*

*"Falling away from my management routine; stress; lack of sleep; worsening of allergies."*

*"Used topical steroids throughout childhood and now have horrible withdrawal symptoms (flareups) as an adult that are unmanageable."*

*"I can't figure out what triggers it. We will try a new product and it seems to improve his condition, but the same product might not be effective the next month. We've eliminated certain products and certain dietary supplements, but there doesn't seem to be much correlation."*

*"Nearly everything."*

## BARRIERS TO TREATMENT


There were a large number of reported barriers to therapy, led by "concerns about long-term use" (53%) and "treatment is ineffective" (52%). Other barriers that were indicated by at least one-fourth of all respondents include: "treatment is not beneficial" (36%); treatment has side effects they are not willing to accept (34%); "too many side effects" (33%); financial barriers (32%, including lack of insurance, lack of coverage, or high out-of-pocket costs); and "hard to use/accommodate in the school/workplace" (27%).

Barriers that posed a greater challenge for adults included the treatment being ineffective, not beneficial, having unacceptable or too many side effects, and financial barriers. Respondents on behalf of children with eczema were more likely to cite concerns about long-term use, inconvenience, discomfort, time-consuming nature, fear of the treatment, or complicated coordination of care.

There were many comments that illustrate the top-ranked concerns, including this sampling:

*"I have not tried long-term injections due to the fear of side effects and the long-term duration of the treatment. Also, I have tried to discontinue corticosteroids because of the long-term side-effects. I'm trying to follow a more natural way of dealing with this."*

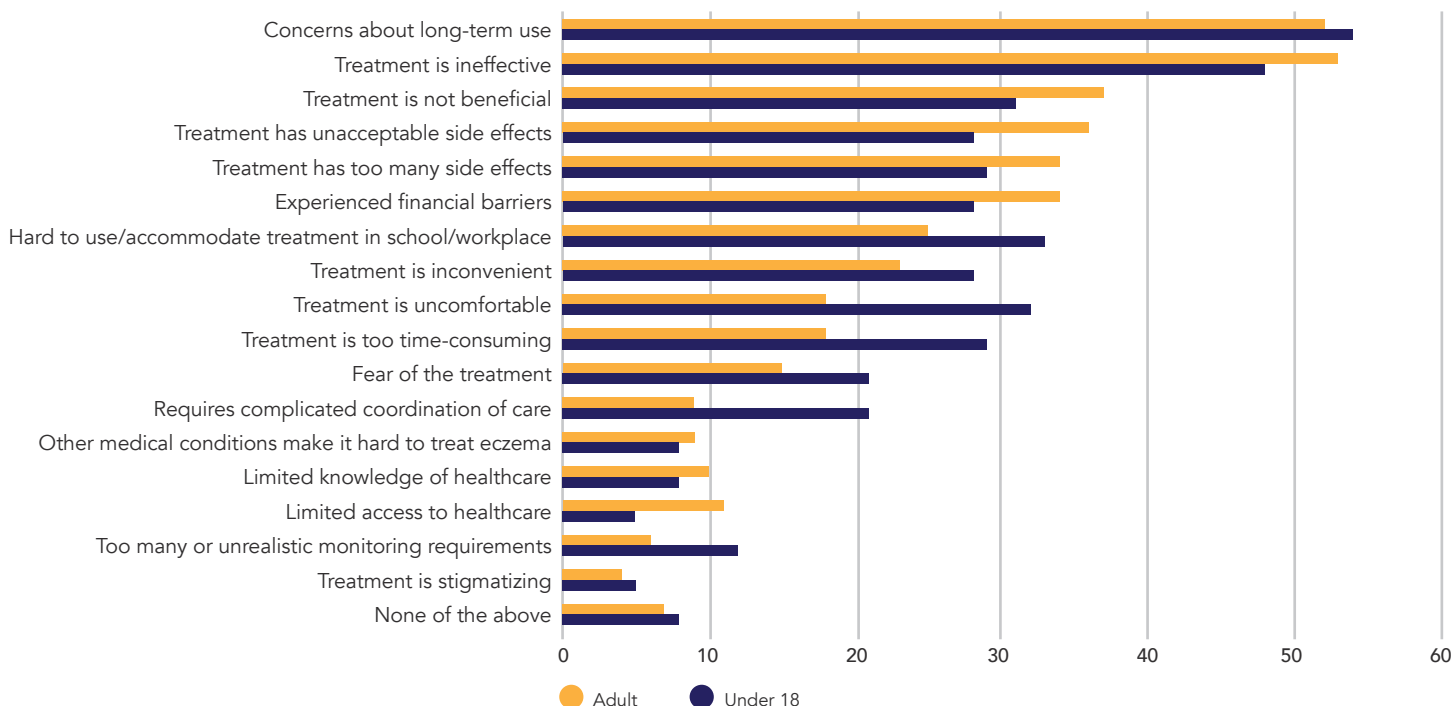
*"I have been told that I have no choice but to use stronger (more potent) steroid creams and was heavily suggested to use prednisone on many visits to a doctor, even after voicing my concerns about the effects they could have on my body."*



*"I can't figure out what triggers it. We will try a new product and it seems to improve his condition, but the same product might not be effective the next month."*



## BARRIERS TO MAINTAINING OR SEEKING TREATMENT VARIES BY AGE GROUP



**"Doing wet wraps 3-5 times a day is not possible for a working parent. Being covered in greasy lotions is inconvenient and unattractive."**

*"I was talked down to, and basically made to feel unintelligent and as if my concerns didn't matter by all doctors I have seen regarding my eczema. I was offered no treatment from doctors other than stronger topical steroids and oral steroids."*

*"My partner's use of topical steroids under his doctors' supervision and as indicated has resulted in severe skin atrophy, red skin syndrome, and severe side effects."*

*"Some things work for a while, then don't. Systemic treatments were always damaging in the long run. I want to try dupilumab if I have another flare but am worried they'll put me through the damaging treatments I've used before so that I'll qualify for the new treatment."*

*"The biggest barrier we are currently encountering is age. The only treatment that hasn't been trialed is immunosuppression and her current pediatric dermatologist is reluctant to put her on an immunosuppression agent. We are pushing for it as she needs some quality of life, and chronic itching, open skin, pain, and infections are a daily battle."*

*"He hates the sticky feeling of moisturizers. Also, some of the topical solutions sting him."*

*"Doing wet wraps 3-5 times a day is not possible for a working parent. Being covered in greasy lotions is inconvenient and unattractive."*

*"Light therapy, in particular, can be hard to coordinate with my child's school schedule and requires a long drive time. My child has sensory issues which make it difficult to apply emollients and skin barriers on certain areas of the body."*

*"I have private insurance but so far neither my dermatologist nor my allergist has been able to get Dupixent approved for me. I only have ever used Eucrisa with a sample the allergist had. It worked well, but the insurance company won't approve it."*

*"I just made a pediatric dermatology appointment, and it will take us five months to get in! I will also have to drive 2.5 hours. Local care is hard to find in rural areas."*

*"Between charlatans, supplement marketers, chiropractors, Chinese medicine people, and – to some degree – evidence-based medicine people, our community is bombarded with a lot of 'good idea fairies.' Often times the hypothesis is hyped months or years before the evidence and data come in and are available."*

*"There has been much frustration and anxiety provoked by the many barriers listed. Because of the disorganized nature of the approaches to treatment options, the lack of a consistent protocol in treatment options, and the inconsistencies of treatment between healthcare providers, each of the barriers does not begin to reflect the real psycho-emotional and physical damage. My granddaughter has become a group family project!"*

*"My biggest concern is that there are treatment options I was not even aware of. I have never been prescribed or offered anything other than steroid creams."*

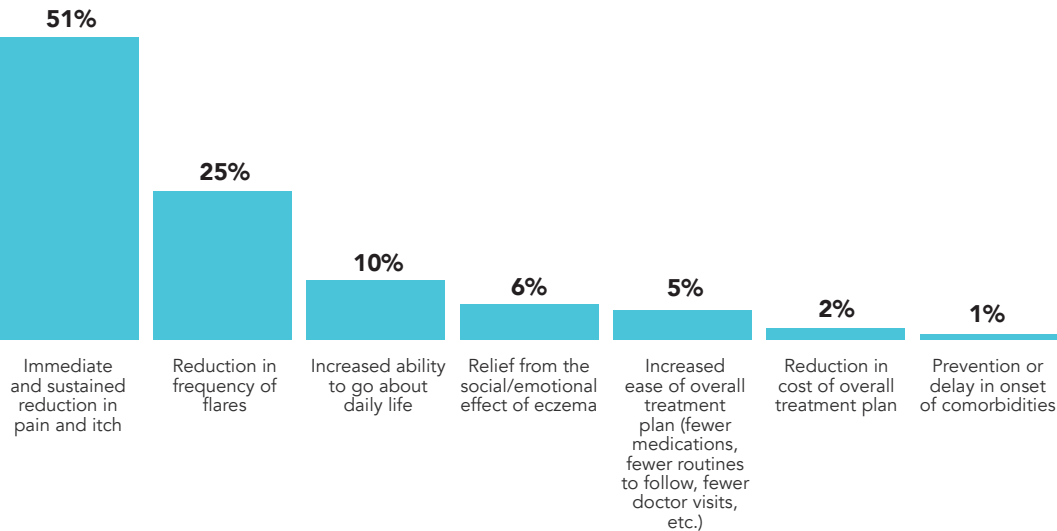
**"My biggest concern is that there are treatment options I was not even aware of. I have never been prescribed or offered anything other than steroid creams."**

Nearly half of respondents (44%) reported having discontinued prescribed medications for eczema. When this group was asked the reason(s) for stopping prescribed medications, nearly two-thirds indicated negative side effects (63%); concern over long term use (63%); and ineffectiveness of treatment (62%). One-third (30%) reported having decided to pursue non-prescription approaches.

LOOKING AHEAD

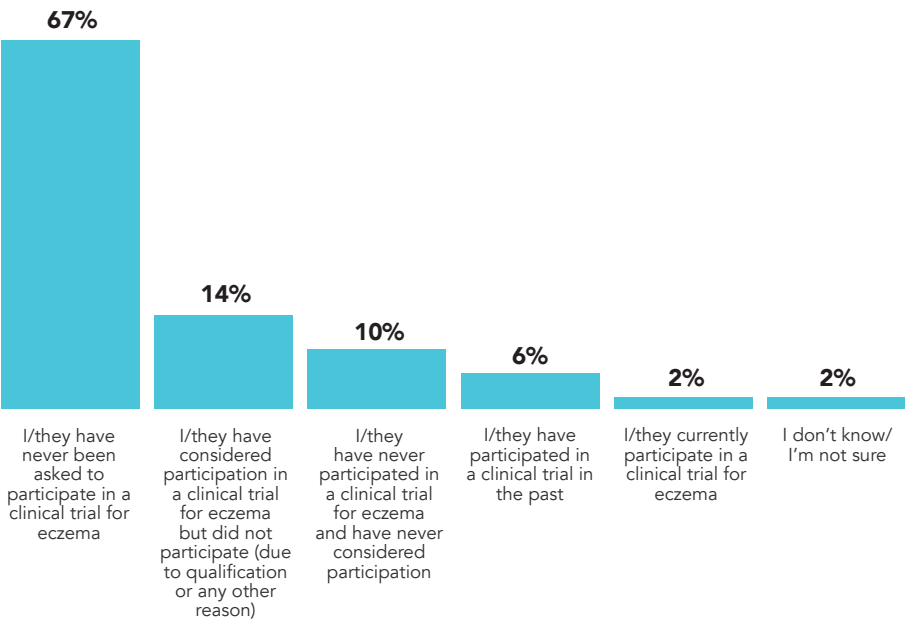
The most important result that a treatment could provide was "immediate and sustained reduction in itch and pain" for 51% of respondents. Another 25% sought to experience a reduction in frequency of flares and 10% sought "increased ability to go about their daily life."

MOST IMPORTANT RESULT THAT A TREATMENT COULD PROVIDE PATIENTS WITH ECZEMA



There was limited experience with clinical trial participation among survey respondents. Two-thirds (67%) have never been asked to participate in a clinical trial for eczema; 14% have considered participating, but did not, whether due to failure to qualify or for some other reason. Just 6% have participated in a clinical trial for eczema in the past.

ECZEMA PATIENTS HAVE LIMITED EXPERIENCE WITH CLINICAL TRIALS



"I am wary of side effects of treatments, and this is the reason I have not considered clinical trials."

The responses for adults and children were similar, with the greatest difference being 7% of adults have participated in clinical trial in the past, compared to just 3% of children.

Some comments respondents offered about clinical trials are provided below:

"Fear of the unknown keeps me from participating."

"I'd love to participate in one, but they're always in some town that's too far away and I don't drive."

"Given the limited effective treatment options we are willing to participate in trials. We recently enrolled in a few research studies and have

researched new drugs in development that we may consider if the companies establish trials for adolescents."

"I am at a point where we would be open to have our 6-year-old participate in a trial. We feel we have been to every specialist and done everything to help her in our power. The itch and lack of sleep as well as flares are severely impacting our child and our family unit."

"I am wary of side effects of treatments; this is the reason I have not considered clinical trials."

"I couldn't stay off the steroids or creams long enough to start the trials!"

"I have mixed feelings. At this point, his father and I think it would ultimately be up to our son whether we participated or continued to participate in a clinical trial. He is only 7, but we are realizing that he has strong opinions about his own care. We have been teetering on that edge of seriously needing to consider a systemic treatment therapy—and he has made it very clear that he doesn't like bloodwork and shots. I am not saying that we would let him make the final decision about his medical treatment at this age, but we do realize that he needs to be a more active participant in his own healthcare the older he gets."

"Love them; I have enrolled in two trials. I would never be able to afford this medication on my own, and it is the only thing that has significantly helped my eczema over the many years I have sought treatment."

"It was a wonderful experience. Gave me an opportunity to give back. It took something negative in my life and turned it into something very positive."

FURTHER ANALYSES WILL CONTINUE

This report barely skims the surface of this rich trove of lived experience with eczema. Each of the five organizations has access to the dataset and will continue exploring it and learning from it. The initiative organizers wish, again, to thank the 1,508 individuals who generously contributed their experience to the **More Than Skin Deep** survey.



# APPENDIX

## ACKNOWLEDGEMENTS: THE PROJECT TEAM

Working on behalf of their organizations and collectively as a cohesive team, these women have contributed their skills, talents, and boundless energy to planning and delivering the **More Than Skin Deep** initiative. The titles and affiliations are current as of the release of this report.



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**ELISA ZIZZA**

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## FURTHER ACKNOWLEDGEMENTS

With gratitude for the following individuals who have enhanced the **More Than Skin Deep** initiative:

**Meghana Chalasani** of the FDA's Office of Strategic Initiatives, Center for Drug Evaluation and Research for providing counsel and encouragement throughout the entire planning process.

**John Dudley & Eric Quigley** of Dudley Digital Works for creative and technical services to broadcast the meeting to a live remote audience and preserve it for later on-demand viewing.

**Kim McCleary** of the Kith Collective for strategic, communications, survey development, and outreach support in preparation for the meeting. Kim moderated the meeting webcast and is the principal author of this "Voice of the Patient" report.

**Julie Rathjens** of Hello Brand for design of the More Than Skin Deep logo and design and production of other creative materials, including this report.

**James Valentine** of Hyman, Phelps & McNamara, PC for strategic counsel about PFDD, preparing panelists to convey their experiences, and moderating the meeting.

**Panelists and Meeting Participants** who contributed photographs to this report.

# ALLERGY & ASTHMA NETWORK (AAN)

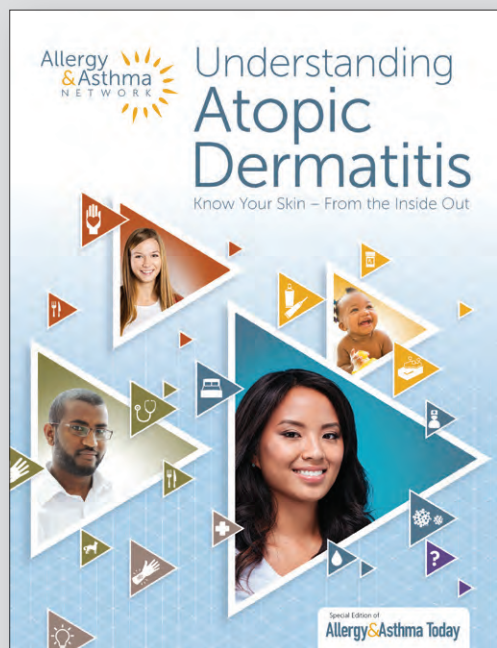


## OUR MISSION

To end needless death and suffering due to asthma, allergies, and related conditions through outreach, education, advocacy, and research.

Allergy & Asthma Network is the leading nonprofit patient outreach, education, advocacy and research organization for people with asthma, allergies, and related conditions. Our patient-centered network unites individuals, families, healthcare professionals, industry leaders, and government decision-makers to improve health and quality of life for millions of people affected by the conditions.

An innovator in encouraging family participation in treatment plans, Allergy & Asthma Network specializes in making accurate medical information relevant and understandable to all while promoting standards of care that are proven to work. We believe that integrating prevention with treatment helps reduce emergency healthcare visits, keep children in school and adults at work, and allow participation in sports and other activities of daily life.



## PROGRAM HIGHLIGHTS

### UNDERSTANDING ATOPIC DERMATITIS GUIDE

Atopic dermatitis is a lifelong condition that involves skin symptoms, often when you least expect them. Get to know your skin – from the inside out – with our comprehensive guide. It addresses diagnosis, symptoms, treatment, and prevention and details the latest innovative medications that can help keep severe atopic dermatitis in check.

### ALTOGETHER ECZEMA AWARENESS CAMPAIGN

A microsite ([altogethereczema.org](http://altogethereczema.org)) launched by GlobalSkin to allow the global eczema and atopic dermatitis community to directly share experiences of life with eczema or AD; interact with content and features to explore key issues; and use tools to campaign for changes that will improve the lives of those living with eczema and AD.

## CONTACT US

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Twitter: @AllergyAsthmaHQ  
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# ASTHMA AND ALLERGY FOUNDATION OF AMERICA (AAFA)

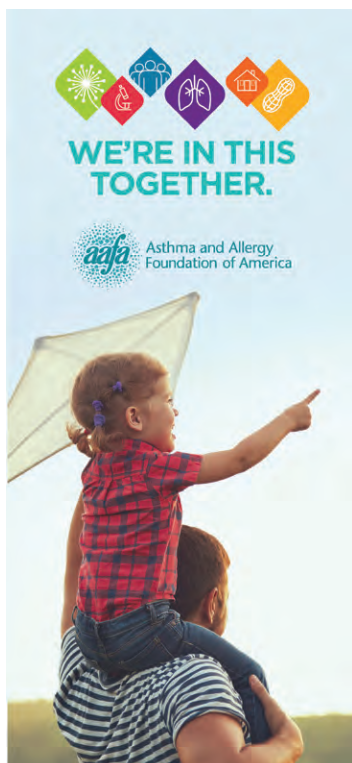


Asthma and Allergy  
Foundation of America

## OUR MISSION

To save lives and reduce the burden of disease for people with asthma and atopic diseases through support, advocacy, education, and research.

Founded in 1953, the Asthma and Allergy Foundation of America (AAFA) is the oldest and largest asthma and allergy-focused patient advocacy organization in the world. Through our education and support programs, AAFA empowers people living with chronic conditions like eczema, asthma, and allergies to take charge of their health. Because these conditions are often connected in a progression known as the “atopic march,” AAFA provides resources and support to people and families managing these overlapping conditions. Through our advocacy initiatives, AAFA continues to fight for patient rights and advocates to bring the patient voice to policy discussions. Our patient-centered research works to elevate patient insights and improve health outcomes for people with atopic conditions.



## AAFA'S ONLINE COMMUNITY FOR PATIENTS AND FAMILIES

Living with chronic diseases like eczema, asthma, and allergies can be overwhelming because they can affect many aspects of everyday life. Sometimes, it just helps to know you're not alone. AAFA's online community provides a safe and supportive place to connect with others who have experienced similar challenges in living with these conditions.

Our online community offers evidence-based information and expert advice, but also provides peer-to-peer support for the less visible impact of chronic conditions—such as the emotional toll and burden. It offers a platform to connect with others who understand that sometimes symptoms can make you feel defeated, helpless, anxious, or isolated.

By joining the community, you can access science-based, age-by-age, stage-by-stage support for atopic conditions. Our trained staff and volunteers monitor the online community to share resources and respond directly to questions. The community is comprised of patients and caregivers at various stages throughout the patient journey who can support and give advice regardless of wherever you happen to be in your personal journey.

We're here to help you overcome obstacles at any stage in your journey. AAFA's online community is a place for encouragement, inspiration, understanding, and support. Join us at [aafa.org/join](https://aafa.org/join).

## CONTACT US

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Instagram: @AAFANational



# GLOBAL PARENTS FOR ECZEMA RESEARCH (GPER)



GLOBAL PARENTS FOR  
ECZEMA RESEARCH

## OUR MISSION

To dramatically improve quality of life for children living with eczema by advancing research that fills critical knowledge gaps from the patient and family perspective.

Global Parents for Eczema Research (GPER) is an international coalition of parents of children with eczema comprised of and led by parents. GPER formed in 2015 to address the critical need for research that answers questions of importance to children and families, and was selected by the Patient-Centered Outcomes Research Institute (PCORI) for a three-year award to pursue that purpose.

GPER is uniquely focused on bringing the patient and family perspective to the research and innovation process and policy discussions – and on sharing critical research that pertains to the treatment and management of eczema with families.

GPER engages in four strategic areas: influencing research, conducting research, engaging in public policy, and sharing evidence-based information with families.



The full “Burden of Eczema on Children and Families” video can viewed at: [www.parentsforeczemaresearch.org](http://www.parentsforeczemaresearch.org)

## PROGRAM HIGHLIGHTS

### RESEARCH AND POLICY

GPER brings the patient and family perspective to the research and innovation process. We advocate for parent and caregiver priorities for research, outcomes that matter to families, and funding that accelerates patient-centered research. GPER conducts its own research on topics of interest to its members; GPER parent leaders have co-authored numerous peer-reviewed papers on eczema.

### PROMOTING EVIDENCE-BASED TREATMENT

GPER shares critical research that pertains to the treatment and management of eczema with families through innovative programs such as our “Eczema Breakthroughs” podcast and quarterly research symposia featuring leaders in eczema research. GPER shares breakthrough discoveries from global scientific conferences with its members and disseminates new research of interest to families as soon as its published via its closed Facebook group.

### SUPPORTING CAREGIVERS

As a grassroots caregiver organization, we understand the hardships that parents of children with eczema face. In response to parents’ isolation, burnout and high levels of stress we offer peer mentoring, psycho-social support, and other assistance to help families better face the challenges with managing a chronic, relapsing, difficult to treat condition.

## CONTACT US

Global Parents for Eczema Research  
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[info@parentsforeczemaresearch.com](mailto:info@parentsforeczemaresearch.com)

Facebook: @groups/globalparents  
Twitter: @eczemaresearch

# INTERNATIONAL TOPICAL STEROID AWARENESS NETWORK (ITSAN)



## OUR MISSION

To raise awareness of Topical Steroid Withdrawal Syndrome (TSW) and to support all affected individuals.

ITSAN is the only non-profit serving the global TSW community as a resource for the individual, the caregiver, and the healthcare provider. From its origin as a small support group, ITSAN has evolved into a vast network of thousands of TSW sufferers around the world who comfort, share, and encourage one another. Today ITSAN conducts outreach and member engagement through webinars, newsletters, social media, and moderated online support groups. We also participate in numerous national and international coalitions and advocacy initiatives to advance our mission.

**TSW Syndrome** is a debilitating condition that can arise from the use of topical corticosteroids to treat a skin problem, such as eczema. It is characterized by red, itchy, burning skin that can appear after ceasing topical steroid treatments, or even between treatments. The original problem escalates as it spreads to new areas of the body. This “progression” is often mistaken for worsening eczema. Treatment becomes less effective, even with increased potency and strict adherence. This is why TSW Syndrome is also known as Topical Steroid Addition or Red Skin Syndrome.”

TSW is an iatrogenic condition, which means it is a condition caused inadvertently by a medical treatment. Not everyone who uses topical corticosteroids will develop TSW syndrome.

**Symptoms:** Inflamed skin, constant itching, stinging, burning, edema, lymphadenopathy, altered thermoregulation, hair loss, insomnia, profound limitations on mobility, and relentless skin flaking and shedding. Symptoms are severe and protracted, often lasting months to years.

**More than skin deep:** The sufferer may also endure depression, anxiety, job loss, financial burdens, delays in education or other life plans, and changes in family dynamics or romantic relationships.

## OUR GOAL

Prevention, early detection, accurate diagnosis, and proper treatment

## CONTACT US

[www.itsan.org](http://www.itsan.org)  
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Facebook: @InternationalTopicalSteroidAwarenessNetworkitsan/  
Facebook Support group: @groups/ITSANSupport/  
Twitter: @ITSANnonprofit

## LOOKING AHEAD:

ITSAN is a small non-profit with very big plans!

- TSW Awareness Campaign: Plans include regional informational sessions for the medical community, highlighting prevention diagnostic criteria for TSW vs. eczema, non-steroidal treatment options, and patient data collected by ITSAN.
- Patient registry: In support of research efforts and making the first estimate of TSW prevalence.
- Physician registry: Connecting our patients with doctors who understand how to diagnose and treat TSW is a top priority.

# NATIONAL ECZEMA ASSOCIATION (NEA)



**NATIONAL**  
**Eczema**  
**ASSOCIATION**



Research



Support



Education



Advocacy



Awareness

We're here because you're here. We are the voice, the resource, and the hub for the more than 30 million Americans and their families who are living with all forms of eczema.

The National Eczema Association (NEA) is a non-profit, 501(c)(3) organization with a mission to improve the health and quality of life for individuals with eczema through research, support, and education.

This means that day in and day out, NEA provides people with eczema the information they need to best manage their condition, while fast-tracking research towards better treatments and a cure.

NEA has an aggressive strategic plan with the goal of improving the health and well-being of people with eczema. NEA's strategic plan promises the following key impacts:

- Eczema will be better understood as the serious disease it is – driven by expanded research and the contributions of empowered community members.
- Patients will increasingly be active partners in their own care.
- People with eczema will be more connected to the community and the support they need and deserve.
- NEA's commitment to people living with eczema will improve lives.

IT'S A BIG CHALLENGE,  
BUT WE'VE GOT MILLIONS ON OUR SIDE.



**NATIONAL**  
**Eczema**  
**ASSOCIATION**

## CONTACT US

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#nationaleczema  
#unhideeczema  
@nationaleczema



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Thank you to these generous sponsors for their unrestricted educational grants in support of the **More Than Skin Deep** initiative:

## PLATINUM

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## BRONZE

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 NOVARTIS

# MORE THAN SKIN DEEP | ECZEMA PFDD MEETING AGENDA

SEPTEMBER 23, 2019

8:00 – 9:00 am	<b>Registration and Continental Breakfast</b>
9:00 – 9:15 am	<b>Welcome and Opening Remarks</b> Julie Block – President & CEO, National Eczema Association (NEA) Korey Capozza – Founder, Global Parents for Eczema Research (GPER)
9:15 – 9:35 am	<b>Patient-Focused Drug Development at the U.S. Food and Drug Administration (FDA)</b> Jill Lindstrom, MD – Deputy Director, Division of Dermatology and Dental Products, FDA
9:35 – 9:55 am	<b>Clinical and Epidemiological Overview of Atopic Dermatitis</b> Jonathan Silverberg, MD, PhD, MPH – Associate Professor, Feinberg School of Medicine, Northwestern University
9:55 – 10:05 am	<b>Introduction of Moderator &amp; Overview of Meeting Format and Live Polling Process</b> Kelly Barta – President & CEO, International Topical Steroid Awareness Network (ITSAN) James Valentine, JD, MHS – Meeting Moderator
10:05 am – 12:00 pm	<b>Session 1: Symptoms and Daily Impacts That Matter Most to Patients</b> <b>Key Questions:</b> <ul style="list-style-type: none"><li>• Of all the symptoms that you experience because of your condition, which 1-3 symptoms have the most significant impact on your life?</li><li>• Are there specific activities that are important to you but that you cannot do at all or as fully as you would like because of your condition?</li><li>• How has your condition and its symptoms changed over time?</li><li>• What worries you most about your condition?</li></ul> <b>Panel:</b> Kelly Barta; Raelle Brown; Brianna Cox; Joseph Cutaran; Keri Kelley; Sarah Pry <b>Live Polling</b> (On-site & Webcast Participants) <b>Moderated Discussion Among All Meeting Participants</b> (On-site & Webcast Participants)
12:00 – 12:05 pm	<b>Morning Wrap-Up and Invitation to Lunch</b> Tonya Winders – President & CEO, Allergy & Asthma Network (AAN)
12:05 – 12:55 pm	<b>Networking Lunch</b>
1:00 – 3:15 pm	<b>Session 2: Current and Future Approaches to Treatments</b> <b>Key Questions:</b> <ul style="list-style-type: none"><li>• What are you currently doing to help treat your condition or its symptoms?</li><li>• How well does your current treatment regimen treat the most significant symptoms of your disease?</li><li>• What are the most significant downsides to your current treatments, and how do they affect your daily life?</li><li>• Assuming there is no complete cure for your condition, what specific things would you look for in an ideal treatment for your condition?</li></ul> <b>Parent/Caregiver Panel:</b> Lynell Doyle; Ashley Ellis; Angela Fox; Heather Sullivan; Kathryn Tullos <b>Adult Panel:</b> Tyler Berryman; Lisa Choy; Pamela Friedman; Steve Gawron; Lindsay Swire Jones <b>Live Polling</b> (On-site & Webcast Participants) <b>Moderated Discussion Among All Meeting Participants</b> (On-site & Webcast Participants)
3:15 - 3:30 pm	<b>Summary and Closing Remarks</b> Kenneth Mendez – President & CEO, Asthma and Allergy Foundation of America (AAFA)

# “MORE THAN SKIN DEEP” SURVEY TO INFORM PATIENT-FOCUSED DRUG DEVELOPMENT FOR ECZEMA

Thank you for taking time to respond to this survey. We value your experience and your participation in this project. To thank you for your participation, you may choose to enter for a chance to win one of ten \$50 Amazon gift cards upon completion of the survey.

## About this Survey:

The U.S. Food and Drug Administration (FDA) has placed a high priority on hearing directly from individuals with lived experience about what it's like to live with medical conditions. On September 23, 2019, five organizations serving the atopic dermatitis (i.e. eczema) community (listed below) will host the “More Than Skin Deep” meeting so that the FDA can hear directly from people living with eczema and their family members about their experiences.

This survey provides a way for people living with eczema (either as a patient, family member/caregiver, or both) to share their experiences with the FDA, researchers, and the hosting organizations. It is designed to collect information about symptoms, impacts on daily life, and how individuals are managing their condition with medical and supportive treatment approaches. These are the topics that FDA is most interested in, to help them understand patient and family/caregiver perspectives as medical products (medications, medical devices, etc.) are being evaluated for safety and effectiveness.

- Here is some additional information to keep in mind as you go through this survey:
- If you are a person with eczema or a family member, partner, or caregiver (someone in close regular contact with the person living with eczema), we welcome you to participate in this survey and the September 23, 2019 meeting - in person or by webcast. (You can learn more about it at [MoreThanSkinDeep-Eczema.org](http://MoreThanSkinDeep-Eczema.org)).
- All responses are anonymous and completely confidential. We are not requesting or collecting any identifying information that can be traced back to individual respondents.
- Answer questions to the best of your ability. Only the first question requires an answer to proceed; the rest are optional and voluntary.
- You can work on the survey a bit at a time and your answers will be saved as you move from page to page.
- There are 3 sections of the survey. Depending on how much information you choose to share in the open comment fields, the survey may take 15-20 minutes to complete. Please pace yourself.
- Demographic information is requested only to help us understand a range of varying perspectives that might be shaped by different backgrounds and experiences.

We will share interim results of the survey at the September 23 meeting and will include an analysis of final results in the meeting report that will be made publicly available as a lasting resource for FDA, medical product developers, other researchers, and the eczema community.

We greatly value your perspective and the time and energy you'll invest. Please feel free to share the survey link with others whose lives are affected by eczema, including your own family members and caregivers.

If you are willing to participate, please continue to the next screen. If at any time, you do not wish to participate, please close the survey screen.

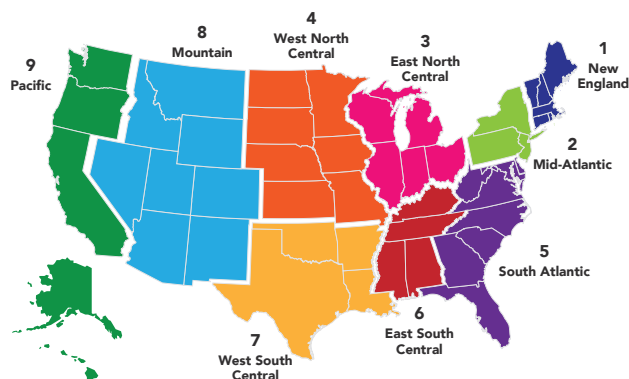
If you have any questions, please contact [info@eczemaPFDD.org](mailto:info@eczemaPFDD.org).

The following questions are about you or the person with eczema on whose behalf you're responding to this survey.

1. Which of the following best describes your (primary) relationship to atopic dermatitis (i.e. eczema)? (Please note: We will use the term “eczema” throughout the rest of the survey for ease of reference).
  - a. I have eczema
  - b. I am a parent, family member, and/or primary caregiver for one or more **children/teens under age 18** who has eczema.
  - c. I am a parent, spouse, partner, family member, and/or primary caregiver for one or more **persons age 18 or older** who has eczema.
  - d. Other (please specify):

If caregiver: Please think about the person who has eczema as you respond to the questions in this survey. We will use “the person with eczema” to describe that person throughout this survey. For ease of reference, we will use the term “caregiver” throughout the rest of the survey to describe you.

2. Including yourself, how many family members in the household have eczema?
  - a. 1
  - b. 2
  - c. 3
  - d. 4 or more
3. [You describe yourself/The person with eczema describes themselves] as:
  - a. Female
  - b. Male
  - c. Non-binary/other
  - d. Prefer not to answer



4. Looking at the U.S. map above, in which region of the country [do you/does the person with eczema] live most of the year?
- 1 – New England
  - 2 – Mid-Atlantic
  - 3 – East North Central
  - 4 – West North Central
  - 5 – South Atlantic
  - 6 – East South Central
  - 7 – West South Central
  - 8 – Mountain
  - 9 – Pacific
  - Outside the U.S. (please specify the country):

The following questions will ask about the journey with eczema.

5. What is [your/the person with eczema's] current age, in years?
- 5 or younger
  - 6-10
  - 11-17
  - 18-24
  - 25-34
  - 35-50
  - 51-64
  - 65 or older
6. At what age did eczema symptoms first begin?
- Under 6 months (newborn)
  - 6-23 months (infant)
  - 2-5 years
  - 6-10
  - 11-17
  - 18-24
  - 25-34
  - 35-50
  - 51-64
  - 65 or older
  - I don't know/I don't remember
7. [Have you/Has the person with eczema] been diagnosed with eczema by a healthcare provider?
- Yes
  - No [SKIP TO Q9]
  - I don't know/I don't remember [SKIP TO Q9]
8. How much time passed between when [your/the person with eczema's] symptoms started and when [you/they] were diagnosed by a healthcare provider?
- Less than 3 months
  - 3-12 months
  - 1-2 years
  - More than 2 years
  - I'm don't know/I don't remember

- 8a. Please provide any additional comments about the process of getting a diagnosis. If you do not have any additional comments, please leave this box blank and choose "continue."
9. Currently, what is the severity of [your/the person's] eczema?
- Mild
  - Moderate
  - Severe
10. When [your/the person's] eczema was at its worst, what was the severity?
- Mild
  - Moderate
  - Severe
11. In general, how has [your/the person's] eczema changed from initial onset to present day? Please select one answer in each column. The first column asks about changes in eczema severity, the middle column asks about changes in affected areas, and the third column asks about changes in frequency of eczema flares.

Change in severity?	Change in affected areas?	Change in frequency of flares?
<input type="checkbox"/> Severity lessened	<input type="checkbox"/> More or different areas affected	<input type="checkbox"/> Frequency of flares lessened
<input type="checkbox"/> Severity worsened	<input type="checkbox"/> Fewer areas affected	<input type="checkbox"/> Frequency of flares worsened
<input type="checkbox"/> No change to severity	<input type="checkbox"/> No change in number or location of affected areas	<input type="checkbox"/> Frequency of flares unchanged

12. What are the three most problematic eczema symptoms [you/the person with eczema] has experienced? Please choose those that **most** impact [you/them]. You may choose up to three responses.
- Dry, sensitive skin
  - Red, inflamed skin
  - Itching
  - Dark colored patches of skin
  - Rough, leathery or scaly patches of skin
  - Oozing or crusting
  - Areas of swelling
  - Blistering skin
  - Peeling or flaking skin
  - Depression
  - Skin tightness
  - Skin pain
  - Anxiety
  - Sleep disturbance
  - Other (please specify):
- 12a. Please provide any additional comments about eczema symptoms. If you do not have any additional comments, please leave this box blank and choose "continue."
13. On a scale of 1 to 5 (with 1 being "no impact" and 5 being "significant impact"), how much have [your/the person's] eczema symptoms negatively impacted your own life over the past month?
- 1 = no impact
  - 2 = low impact
  - 3 = moderate impact
  - 4 = high impact
  - 5 = significant impact
- 13a. If caregiver: On a scale of 1 to 5 (with 1 being "no impact" and 5 being "significant impact"), how much have the person's eczema symptoms negatively impacted their life over the past month?
- 1 = no impact
  - 2 = low impact



- c. 3 = moderate impact
- d. 4 = high impact
- e. 5 = significant impact

14. [Have you/Has the person with eczema] ever been diagnosed with one or more of these other conditions by a healthcare provider? Choose all that apply.

- a. Asthma
- b. Allergic rhinitis (also called hay fever, nasal/ environmental allergies)
- c. Food allergy
- d. Frequent/persistent skin infections
- e. Anxiety
- f. Depression
- g. ADHD
- h. Cardiovascular disease (including hypertension)
- i. Obesity
- j. Autoimmune disease
- k. Lymphoma
- l. I don't know/I'm not sure

14a. Please provide any additional comments about related conditions. If you do not have any additional comments, please leave this box blank and choose "continue."

15. Mood changes, including anxiety and depression, can commonly occur with eczema. Symptoms include: Feeling sad, empty and/ or anxious; feeling hopeless; loss of interest in hobbies or other activities; decreased energy; feeling tired more often; difficulty concentrating; restlessness, unable to sit still; problems sleeping; weight change; thoughts of death or suicide.

How would you rate the current presence of these symptoms in [yourself/the person with eczema]?

	Not present	Mild	Moderate	Severe
Currently	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
At worst point of eczema	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

16. For each of the items below, please indicate on a scale of 1 to 5 (1 being "no impact" and 5 being "significant impact"), how much eczema has impacted the following areas of your life. If you are responding as a caregiver, please think about the effects on YOUR OWN life.

	1 - No impact	2 - Low impact	3 - Moderate impact	4 - High impact	5 - Significant impact
Sleep	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Ability to concentrate, think and/or process/recall/retain information	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Diet	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Physical activity	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Self-confidence, identity	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Intimate relationships	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Work-related and/or educational activities/responsibilities	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Family-related activities/responsibilities	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Ability to take part in leisure activities	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Ability to handle stress or recover from stressful events	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Social relationships	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Life decisions	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Family dynamics	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

16a. **If patient:** Please comment more on any other ways in which eczema impacts your life.

**If caregiver:** Please comment more on any other ways in which caregiving for someone with eczema impacts your life.

This is the final section! The following questions will ask about experience with treating and managing eczema.

17. Please indicate [your/the person with eczema's] experience with each of the following prescription topical treatments and ultraviolet (UV) therapies (i.e. phototherapy) for managing eczema. Topical treatments are medicines applied on the surface of the skin or mucosa. Phototherapy is a UV light therapy targeted to exposed skin.

	Currently using	Used in the past (but not now)	Never used	Don't know/don't remember
Corticosteroids (ointments, gels, creams, foams of any potency)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Tacrolimus (i.e. Protopic)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Pimecrolimus (i.e. Elidel)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Crisaborole (i.e. Eucrisa)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Antimicrobials (i.e. antibiotics or antivirals)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Phototherapy (UVB and/or UVA)				
Other prescription topical (please specify):	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

17a. If topical corticosteroids are one of the eczema treatments used (currently or in the past), have you ever experienced (check all that apply):

- a. Relief from eczema symptoms for a period of time.
- b. Relief of eczema symptoms for long periods of time
- c. Limited or no eczema symptom relief
- d. Worsening of eczema symptoms
- e. A severe or long-lasting flare after stopping use
- f. Limited or no flare after stopping use

18. Please indicate [your/the person with eczema's] experience with each of the following prescription systemic treatments for managing eczema. Systemic treatments are medicines taken by mouth or by injection.

	Currently using	Used in the past (but not now)	Never used	Don't know/don't remember
Azathioprine	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Cyclosporine	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Dupilumab (i.e. Dupixent)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Methotrexate	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Mycophenolate mofetil	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Injectable corticosteroids (e.g. prednisone or triamcinolone (Kenalog))	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Antimicrobials (i.e. antibiotics or antivirals)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Oral corticosteroids (e.g. prednisone)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other prescription systemic (please specify):	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

19. To the best of your knowledge, please indicate how many over the counter (OTC) treatments [you are/the person with eczema is] **currently** using to manage eczema? OTC treatments include hydrocortisone, moisturizers and hair products.

- g. None
- h. 1
- i. 2
- j. 3
- k. 4
- l. 5-9
- m. 10+
- n. I don't know/I'm not sure

20. Please indicate [your/the person with eczema's] experience with each of the following adjunctive or complementary/alternative approaches for managing eczema?

	Currently using	Used in the past (but not now)	Never used	Don't know/don't remember
Aron regimen (compounded antibiotic, moisturizer, and topical corticosteroid tapering method)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Traditional Chinese Medicine	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Dietary modifications (not due to food allergy) or supplementations	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Bathing modifications	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Bleach baths	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Wet wraps	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other lifestyle adjustments, such as environmental exposure, activities	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Behavior modification	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Topical Steroid Withdrawal (total cessation of topical corticosteroids)				

20a. Please tell us any other treatment approaches [you have/the person with eczema has] tried. If you do not have anything to add about other treatment approached, please leave this box blank and choose "continue."

21. What barriers [have you/has the person with eczema] encountered when attempting to stick with (or seek) treatments to help manage eczema? Please think about barriers [you/they] have had to any types of treatment for eczema. Choose all that apply.

- a. The treatment is inconvenient
- b. The treatment is too time-consuming
- c. The treatment is uncomfortable
- d. The treatment is stigmatizing (regarded as disgraceful)
- e. The treatment has too many side effects
- f. The treatment has side effects that I am not willing to accept
- g. I/they have concerns about the long-term use of the treatment
- h. I/they have experienced financial barriers to receiving the treatment (such as out-of-pocket costs, lack of insurance or specific coverage, etc.)
- i. I/they have limited access to healthcare
- j. I/they have limited knowledge of healthcare
- k. I/they have other medical conditions that make it hard to treat eczema
- l. It is hard to use (accommodate) the treatment in the school/workplace
- m. The treatment has too many or unrealistic monitoring requirements

- n. The treatment requires complicated coordination of care
- o. I/they have a fear of the treatment
- p. The treatment is ineffective
- q. The treatment is not beneficial
- r. None of the above – [I do not/the person does not] do not encounter any barriers with any treatments for eczema
- s. I don't know what barriers have been encountered for treatment of eczema

21a. Please provide any additional comments about any of the issues listed above or other barriers encountered. If you do not have any additional comments, please leave this box blank and choose "continue."

22. In general, how well-controlled are the symptoms of eczema with the therapies available to [you/the person with eczema]?

- a. Very well controlled
- b. Moderately well controlled
- c. Poorly controlled but better than nothing
- d. Not controlled at all (no sustained relief)
- e. I don't know/I'm not sure

23. Have [you/the person with eczema] elected to stop taking any prescribed medications for eczema?

- a. Yes
- b. No [SKIP TO Q25]
- c. I don't know/I'm not sure [SKIP TO Q25]

24. For what reason have [you/the person with eczema] elected to stop taking any prescribed medications for eczema? Please choose all that apply.

- o. Negative side effects
- p. Inability to maintain regimen requirements
- q. Desire to try non-prescription approaches
- r. Cost of medication
- s. Concern over long-term use
- t. Ineffectiveness of treatment
- u. Fear of treatment
- v. The treatment was effective and [I/the person] did not need it anymore
- w. Other (please specify):
- x. I don't know/I don't remember

25. To the best of your knowledge, what treatment has had the most positive impact on [your/the person's] eczema? Why?

26. Overall, how well do you feel that available treatments help [you/the person with eczema] manage eczema?

- a. [I have/the person has] been harmed by available therapies
- b. [I have/the person has] sustained no relief from available therapies
- c. [I have/the person has] experienced mixed responses to available therapies
- d. [I am/the person is] very satisfied with available therapies

27. Which areas of [your/the person's] body are more challenging to treat? Choose all that apply.

- a. Scalp
- b. Face
- c. Ears
- d. Eyes
- e. Neck
- f. Shoulder(s)
- g. Arms

- h. Elbows
- i. Hands
- j. Fingers
- k. Back
- l. Chest
- m. Stomach
- n. Hips/buttocks
- o. Genitals
- p. Thighs
- q. Knees (front or back)
- r. Calves
- s. Feet
- t. Toes
- u. Other (please specify):

This completes the survey; thank you so much for your time. Your willingness to share this information and be part of the “More Than Skin Deep” meeting is vital to the success of this initiative. We hope you’ll take part in the September 23, 2019 meeting, either by webcast or in person. You’ll be directed to the website where you can learn more when you exit the survey.

Thank you again!

28. How much time over the period of a week would you estimate you spend managing [your/the person’s] eczema? This can include direct treatments (like bleach wraps or skin care routines), healthcare appointments, or supportive management strategies (like shopping for and preparing special foods, meditation, etc.).
- a. Less than 5 hours
  - b. 5-10 hours
  - c. 11-20 hours
  - d. 21-40 hours
  - e. More than 40 hours
- 28a. Please provide any additional comments about the amount of time spent managing eczema. If you do not have any additional comments, please leave this box blank and choose “continue.”
29. What have you found helps the condition the most?
30. What have you found makes the condition worse?
31. Assuming there is no complete cure for eczema, what would be the MOST IMPORTANT result that a treatment could provide [you/the person with eczema]?
- a. Reduction in frequency of flares
  - b. Prevention or delay in onset of co-morbidities (related conditions)
  - c. Relief from the social/emotional effects of eczema
  - d. Increased ability to go about daily life
  - e. Increased ease of overall treatment plan (fewer medications, fewer routines to follow, fewer doctor visits, etc.)
  - f. Reduction in cost of overall treatment plan
  - g. Immediate and sustained reduction in pain and itch
32. Please describe [your/the person with eczema’s] experience with clinical trials.
- a. [I/they] have **never been asked to participate** in a clinical trial for eczema
  - b. [I/they] have **participated in the past** a clinical trial for eczema in the past
  - c. [I am/they are] **currently participating** in a clinical trial for eczema
  - d. [I/they] **have never participated** in a clinical trial for eczema and **have never considered participation**
  - e. [I/they] **have considered participation** in a clinical trial for eczema but did not participate (due to qualification or any other reason)
  - f. I don’t know/I’m not sure

32a. Optional comments about clinical trials:



**More Than Skin Deep** is a collaboration of the following organizations:



Find this report and other resources at: [morethanskindeep-eczema.org](https://morethanskindeep-eczema.org)