



# MY LIFE WITH FOOD ALLERGY

## Parent Survey Report

Asthma and Allergy Foundation of America • 2019



Asthma and Allergy  
Foundation of America

[aafa.org](http://aafa.org)



**KIDS WITH  
FOOD ALLERGIES**

A Division of the Asthma and Allergy  
Foundation of America

[kidswithfoodallergies.org](http://kidswithfoodallergies.org)

*This survey is an independent research project of the Asthma and Allergy Foundation of America with support from DBV Technologies.*

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**If you reference this report, please cite it accordingly:**  
Asthma and Allergy Foundation of America. (2019). *My Life With Food Allergy: Parent Survey Report*. Retrieved from [aafa.org/foodallergylife](http://aafa.org/foodallergylife)

# INTRODUCTION

The public health burden of food allergy (FA) among children in the United States continues to grow and is an area of active research. The current estimate is 7.6% of children in the country are living with food allergy—this is about one in every 13 children.<sup>1</sup>

The annual economic cost of food allergies in the United States is almost \$25 billion. This inflicts substantial financial strain on affected families.<sup>2</sup>

Researchers are increasingly aware of the significant burden of food allergies on the social, emotional and financial well-being of patients and families. Studies suggest that people impacted by FA have a lower quality of life compared to the general population.<sup>3</sup>

Reduced quality-of-life for the affected child (the patient) is well-documented. What is less evident in the current literature is the comprehensive toll FA takes on a child's family—and particularly, the parents.

There are two key reasons that food allergies present a higher burden to caregivers than other chronic conditions: food is an integral part of society and food allergy is a uniquely episodic disease.

Because food is a fundamental part of many daily activities and social events, families living with food allergy must be constantly vigilant to keep the child safe. The fear of anaphylaxis (a severe, life-threatening allergic reaction) can take a heavy toll on children and their caregivers.

Parents of children with FA can experience anxiety, depression, isolation and stress associated with risk of reaction and possible societal stigma. For many, the constant fear of accidental exposure to food allergens leads to a loss of normalcy and results in adjustments in decision-making and daily routines. Acute awareness at every meal and in every new environment can be stressful.

Food allergy introduces an added complexity in navigating school, childcare, social activities and extracurriculars. Many parents need to spend extra time, money and effort around meal preparation, grocery shopping and event planning/attendance.

A unique characteristic of food allergy may contribute to the increased psychosocial burden of FA among parents. Food allergy is a chronic disease that is largely episodic. Children with food allergy may generally be in good health most of the time—until an allergic reaction occurs. Symptoms of the disease are preventable, but the strain of fear and hypervigilance adds enormous burden to parents.

Living with this disease leads to obstacles that are often significant. The daily burden and challenges of living with food allergies—not only for the child but for their family—are overlooked and minimized.



## WHAT IS A FOOD ALLERGY?

A **food allergy** occurs when the body's immune system sees a certain food as harmful and reacts by causing symptoms. This is an allergic reaction.

**Immunoglobulin E (IgE) mediated food allergies:** IgE antibodies react to a certain food and rapidly trigger typical symptoms of an allergic reaction. The nine most common food allergies are:

- Peanut
- Tree Nuts
- Milk
- Egg
- Sesame seed
- Crustacean shellfish
- Fish
- Soy
- Wheat

**Non-IgE mediated food allergies:** Other parts of the body's immune system react to a certain food causing delayed digestive symptoms. Examples of non-IgE mediated food allergies are:

- Eosinophilic Esophagitis (EoE)
- Food Protein Induced Enterocolitis Syndrome (FPIES)
- Allergic Proctocolitis





## EXECUTIVE SUMMARY

### Objectives

In 2019, the Asthma and Allergy Foundation of America (AAFA) and its food allergy division, Kids With Food Allergies (KFA) conducted a three-part food allergy study titled “My Life With Food Allergy.” These surveys aimed to understand the burden of food allergy from: parents of children with food allergies, teen/young adult patients with food allergies and adults with food allergies.

Data collected in these surveys confirmed much of the existing literature around food allergy impact on children and adults. Additionally, data from the parent survey—the subject of this report—improved our understanding of the burden of food allergy on parents and caregivers. Most notably, results pointed to a higher negative impact on the emotional and mental well-being of parents when compared to the impact on their child.

This survey sought insights on the following topics:

- Experience with FA diagnosis
- Experience with symptoms and allergic reactions
- Experience with current treatment
- Emotional, social, financial impact of FA on the caregiver (parent)
- Parent-reported emotional and social impact on the patient (child)
- Challenges in navigating school, dining and social activities
- Confidence in daily FA management
- Awareness of and thoughts about future treatment

### Methods

- From April 11-20, 2019, AAFA/KFA invited people with food allergy and parents of children with food allergy to take an online survey
- Survey invitations were sent to the KFA online community



**DATA  
COLLECTED**  
April 11-20, 2019



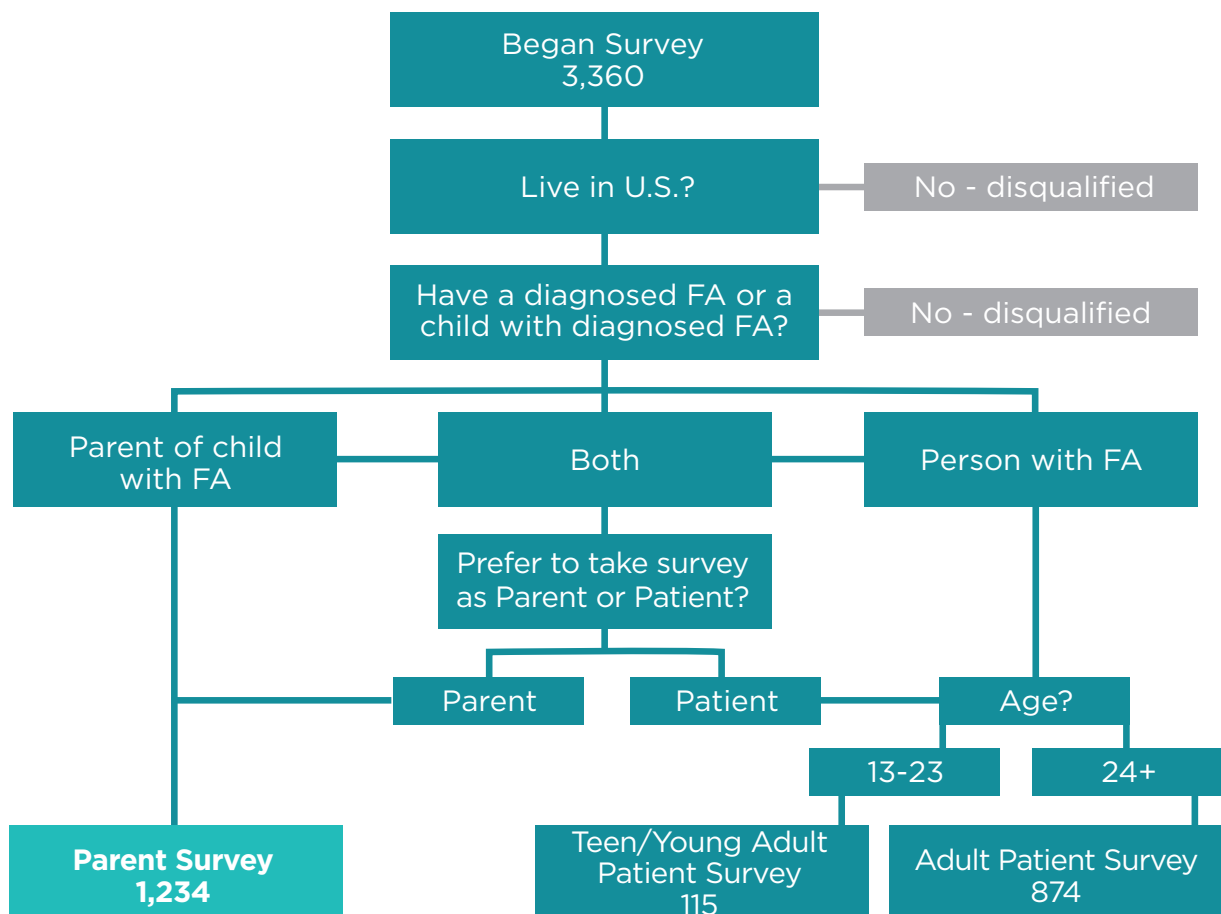
**AVERAGE  
COMPLETION TIME**  
18 minutes



**RESPONDENTS**  
U.S.-based parents  
of children with FA and  
patients with FA (age 13+)

## Survey Population

AAFA screened 3,360 people. Based on self-reported diagnoses, we identified 2,223 as U.S. parents of a child with FA or patients with food allergy age 13 and older.



## About This Report

**This document focuses on select data from the parent survey. In some sections of the report, data from the patient surveys have been included for comparison.**

Throughout this report, most of the graphs represent the aggregated results of all 1,234 respondents of the parent survey. Unless otherwise noted, the base for each graph is n=1,234. Percentages shown in the graphs have been rounded and may not always equal 100.

At times, we have included data from the patient surveys or analyzed various subgroups of respondents (detailed below) in an aim to deliver a comprehensive summary. Where noteworthy differences were revealed among subgroups, these insights have been called out in the report.

- Parents of children with peanut allergy
- Parents of children with eosinophilic esophagitis (EoE)
- Parents of teen/young adult patients age 13-23 with FA

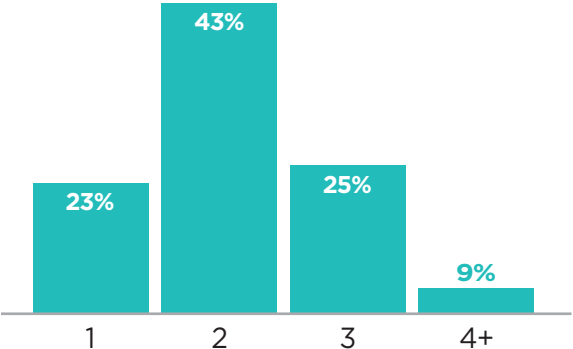
Additionally, we have included quotes and general commentary from survey takers throughout the report in an effort to better capture the patient and caregiver voice directly. Some quotes have been edited for length and clarity.

It is important to note that this survey is not representative of the U.S. population, and we acknowledge there may be selection bias in that the members of our community who responded to the survey may be significantly impacted by FA and therefore most motivated to participate.

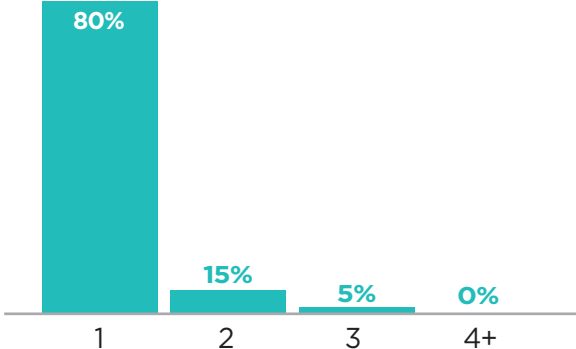
# PROFILE OF RESPONDENTS (PARENTS)

The majority of respondents (n=1,234) have between one and three children currently living in their household and 80% have one child with food allergies in their household.

**TOTAL CHILDREN CURRENTLY IN HOUSEHOLD**



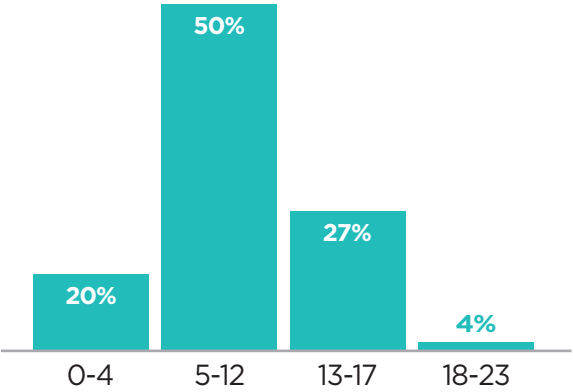
**CHILDREN WITH FA CURRENTLY IN HOUSEHOLD**



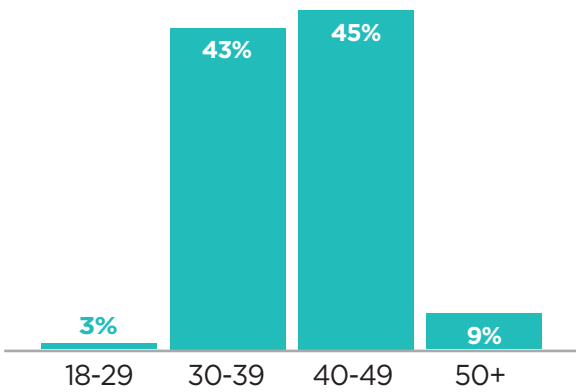
If parents indicated that they have more than one child with food allergy currently in their household, they were asked to complete the survey thinking about the child whose food allergy has the greatest impact on their family’s life.

The age of the child varied from infants to young adults, with half falling in the range of 5-12 years old. The majority of respondents were between the ages of 30 and 49 years old.

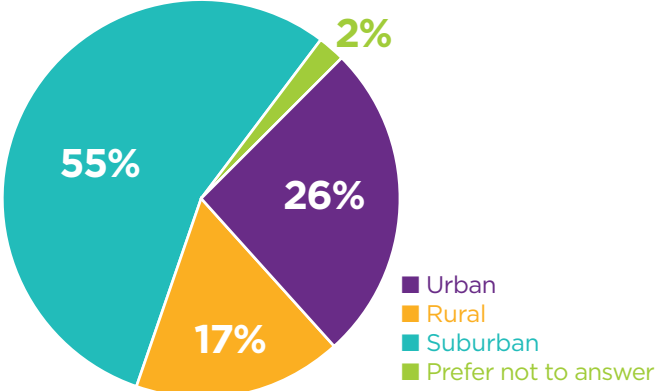
**CURRENT AGE OF CHILD (IN YEARS)**



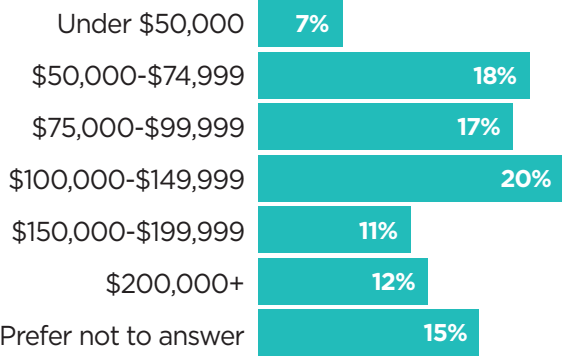
**CURRENT AGE OF PARENT (IN YEARS)**



**LOCATION**



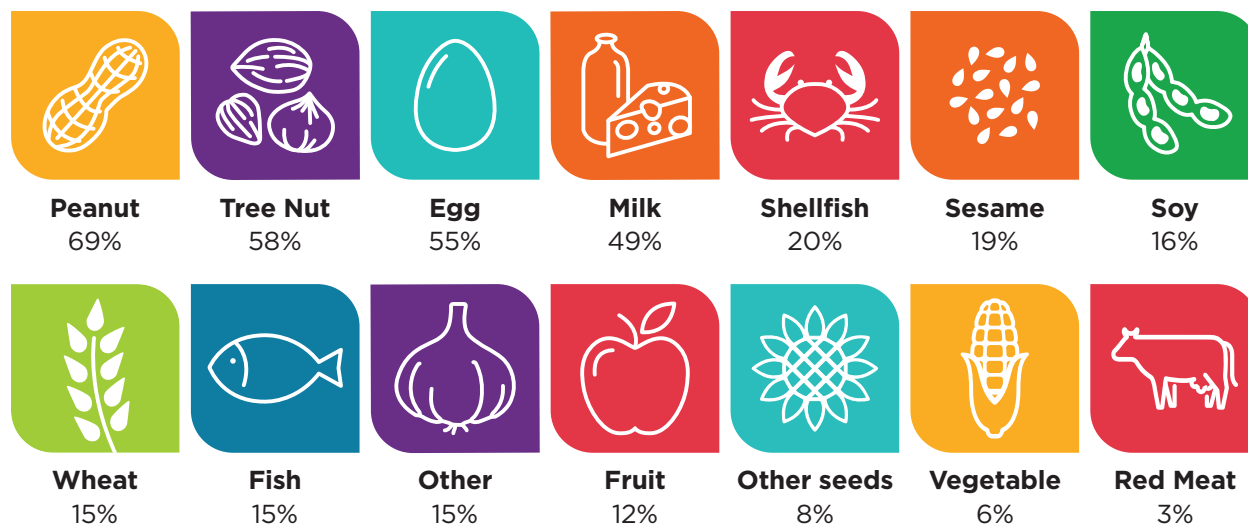
**HOUSEHOLD INCOME**



# DIAGNOSIS, SYMPTOMS AND TREATMENT EXPERIENCE

Parents were asked to report all food allergies their child has been diagnosed with by a health care provider. Peanut allergy was the most common reported food allergy, followed by tree nut, egg and milk.

## FOOD ALLERGIES DIAGNOSED BY HEALTH CARE PROVIDER

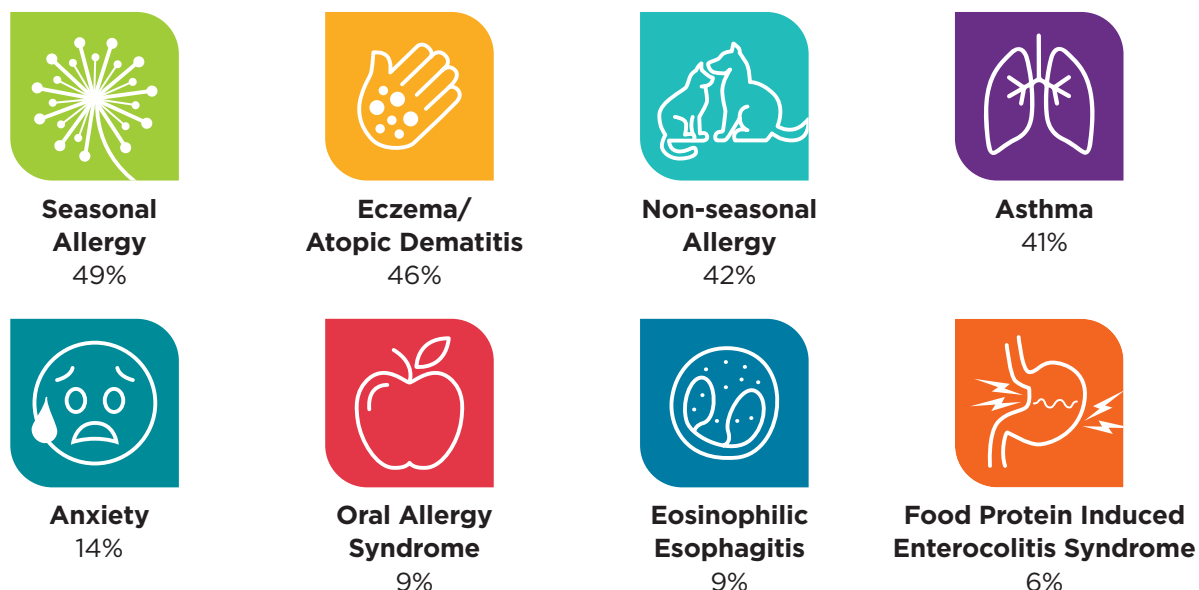


**14%**  
have one food allergy

**86%**  
have multiple food allergies

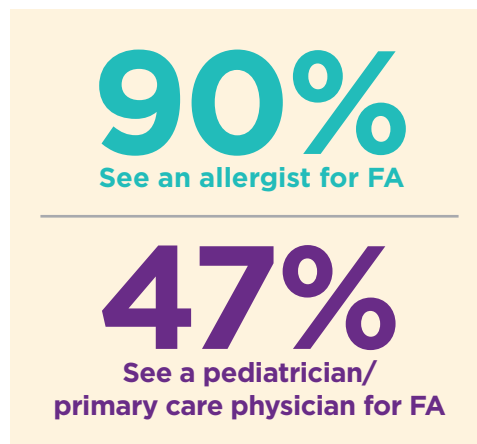
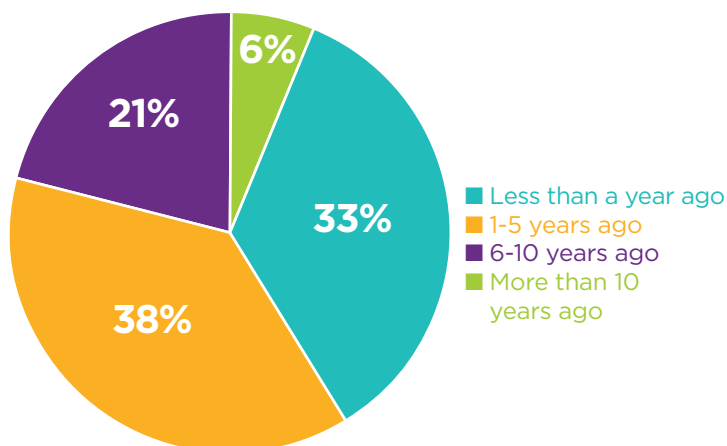
## COMORBID CONDITIONS DIAGNOSED BY A HEALTH CARE PROVIDER

Parents also reported other conditions their child has been diagnosed with by a health care provider.



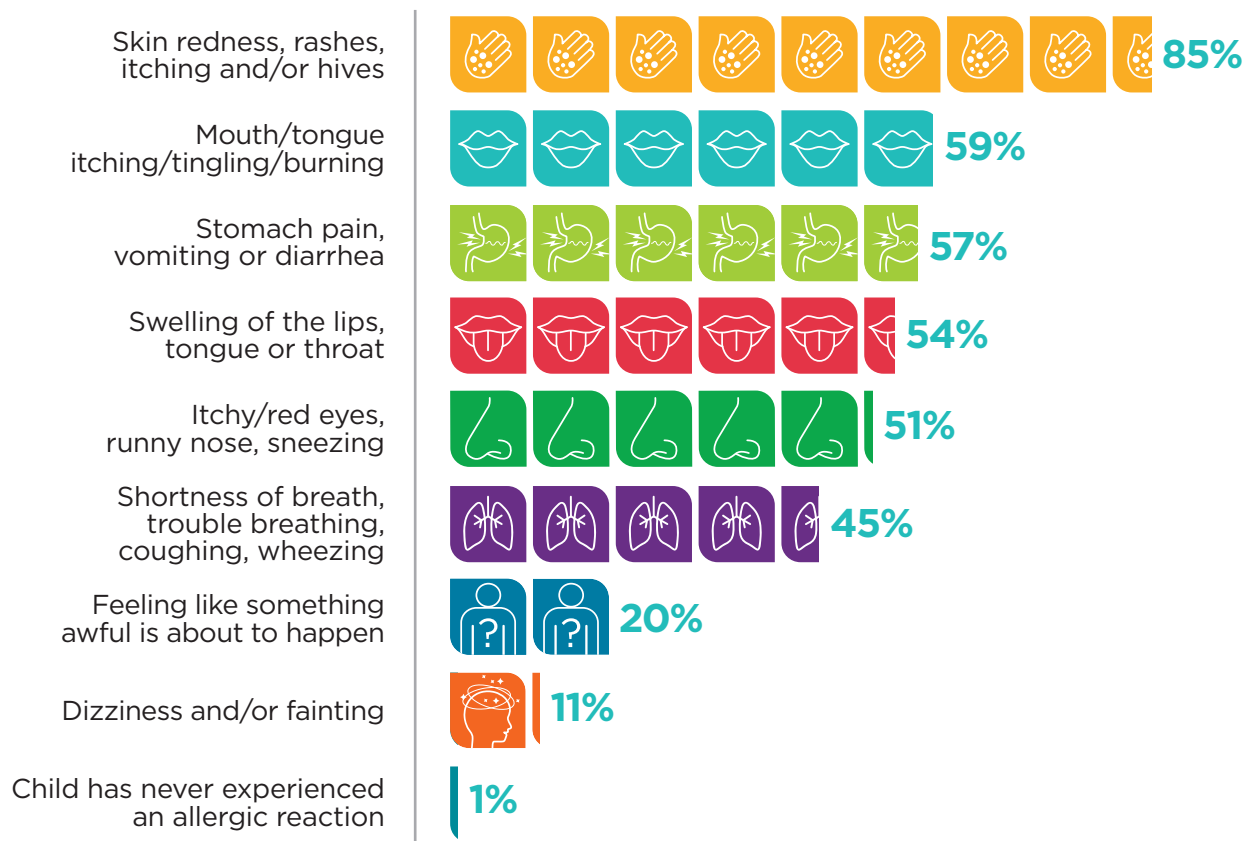
Length of experience with FA ranged from newly diagnosed to over ten years. Many families see more than one provider for food allergy. Nearly all of the parents (90%) said their child currently sees an allergist and 47% see a primary care physician (such as a pediatrician) for their food allergy. Parents were asked to indicate all health care providers their child sees for food allergies; other responses included nutritionists and gastroenterologists.

### TIME SINCE DIAGNOSIS



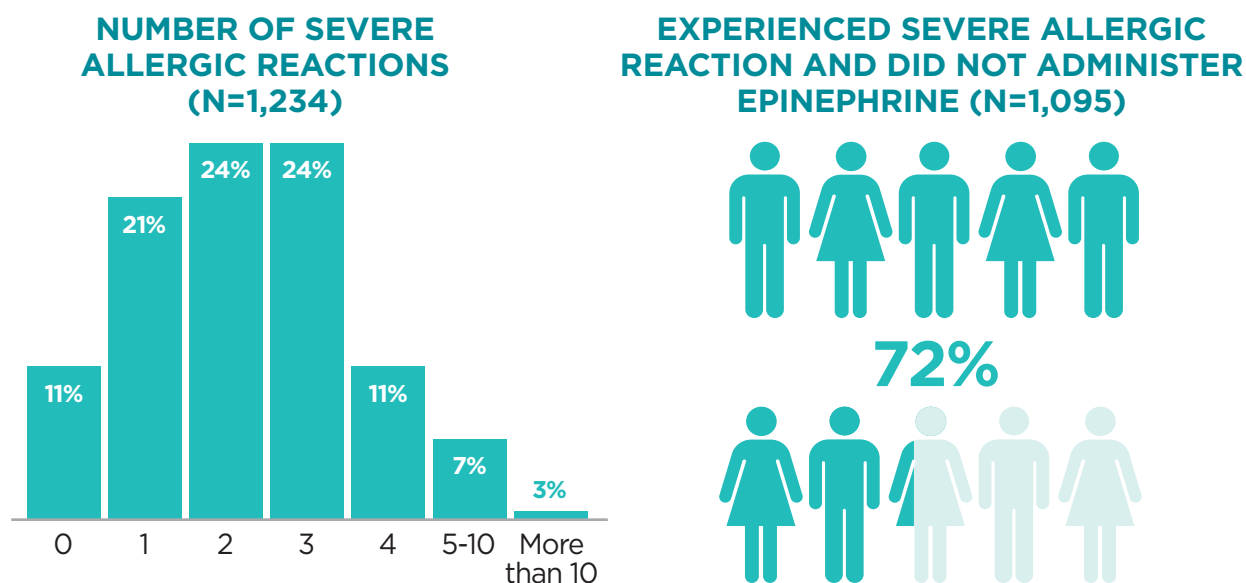
The most common symptoms experienced during an allergic reaction were related to the skin, stomach and mouth. Only 1% of respondents say their child has never experienced an allergic reaction to food.

### SYMPTOMS EXPERIENCED DURING AN ALLERGIC REACTION TO FOOD



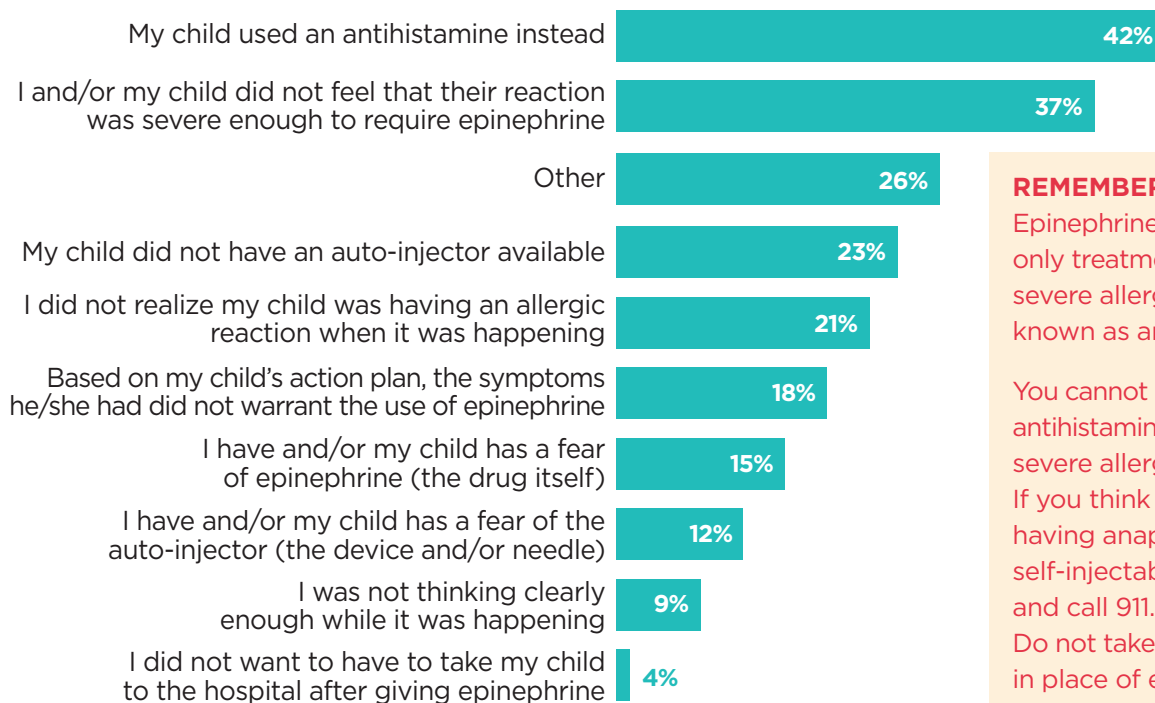


When asked if their child has ever experienced an allergic reaction that the parent would consider severe, 1,095 respondents (90%) reported that it happened at least once. Of those 1,095 parents whose child had experienced at least one “severe” allergic reaction, nearly three out of four (72%) said their child has experienced a severe allergic reaction and epinephrine was NOT administered.



When asked why epinephrine was not administered at the time of the severe allergic reaction, many respondents said that they administered antihistamine instead and/or did not feel the reaction was severe enough for epinephrine. The majority of people who chose “other” said that at the time of the reaction, the food allergy had not been diagnosed and they did not have a prescription for epinephrine.

**REASONS FOR NOT ADMINISTERING EPINEPHRINE DURING SEVERE ALLERGIC REACTION (N=792)**



**REMEMBER:**  
Epinephrine is the only treatment for a severe allergic reaction known as anaphylaxis.

You cannot rely on antihistamines to treat severe allergic reactions. If you think someone is having anaphylaxis, use self-injectable epinephrine and call 911. Do not delay. Do not take antihistamines in place of epinephrine.

*“The hardest part for me is just never letting my guard down. There are no breaks from food allergies.”*  
- Parent



## KEY FINDINGS

Due to the breadth of topics covered by the survey, responses provided a great deal of insights into patient and caregiver experiences, beliefs and knowledge. Throughout this report, the most notable data presented will focus on these three key findings:

1

### **Mental and emotional impact of food allergy on parents is greater than the impact on patients themselves.**

- Parent caregivers report a higher burden than do patients age 13 and over.
- FA has a major impact on many parents' mental, social and emotional well-being.
- Fear, anxiety and worry were common themes throughout the survey's responses from parents.

2

### **Food allergies have considerable impact on parents' social life.**

- Families experience a loss of normalcy leading to adjustments in decision-making and daily routines.
- Parents report skipping events including school functions due to food allergies.
- Birthday parties, traveling, dining out and entertainment activities present challenges for parents.

3

### **Food allergies cause significant financial strain and time burden for parents.**

- For some families, daily realities and needs for caring for children with FA present a major financial burden.
- Some families have had to make career decisions based on FA, leading to negative financial impact on the entire household.
- FA can also present a major time burden for some families.

# DETAILED FINDINGS

## 1 Key Finding 1: Mental and emotional impact of food allergy on parents is greater than the impact on patients themselves.

The survey asked a series of questions about the impact of the child's food allergy on the *parent's* mental and emotional health. Responses to questions about the parent's emotional and mental health are at times compared to two other groups: responses about their *child's* (perceived) emotional/mental health and responses from *adult patients* about their own mental/emotional health. Across the board, parents of children with FA seem to experience a more negative impact of FA than patients.

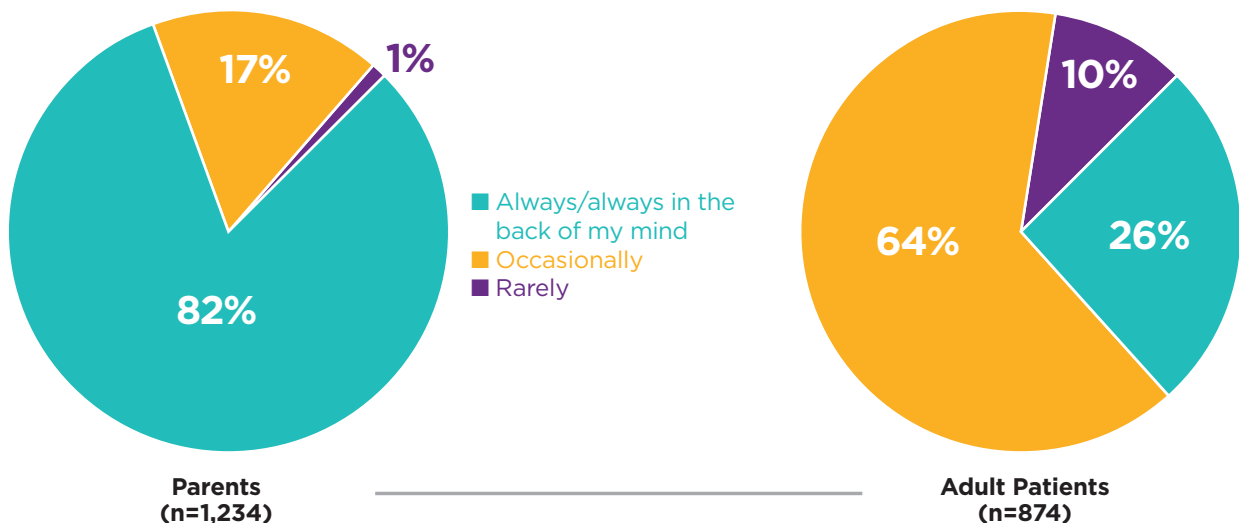
On a 5-point scale (with 1 being "no impact" and 5 being "major impact"), 61% of respondents rated the impact of their child's food allergy on their own mental health as a 4 or a 5. On the same scale, 60% rated the impact of their child's FA on their own emotional health as a 4 or a 5.

### IMPACT OF A CHILD'S FA ON VARIOUS ASPECTS OF PARENT'S LIFE (CHOSE "4" OR "5" ON FIVE-POINT SCALE)



When asked how often parents think about their child's food allergy, 82% say it's always in the back of their minds. In a parallel survey of adults with diagnosed food allergy, only 26% of adult patients said the same thing.

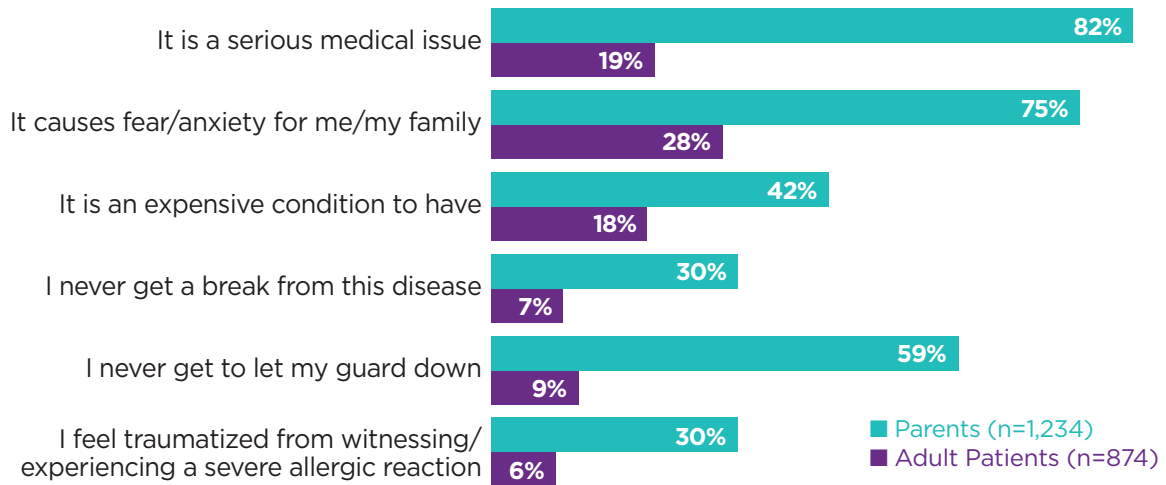
### FREQUENCY OF THOUGHTS ABOUT FA



*"It is emotionally exhausting, never out of my mind." - Parent*

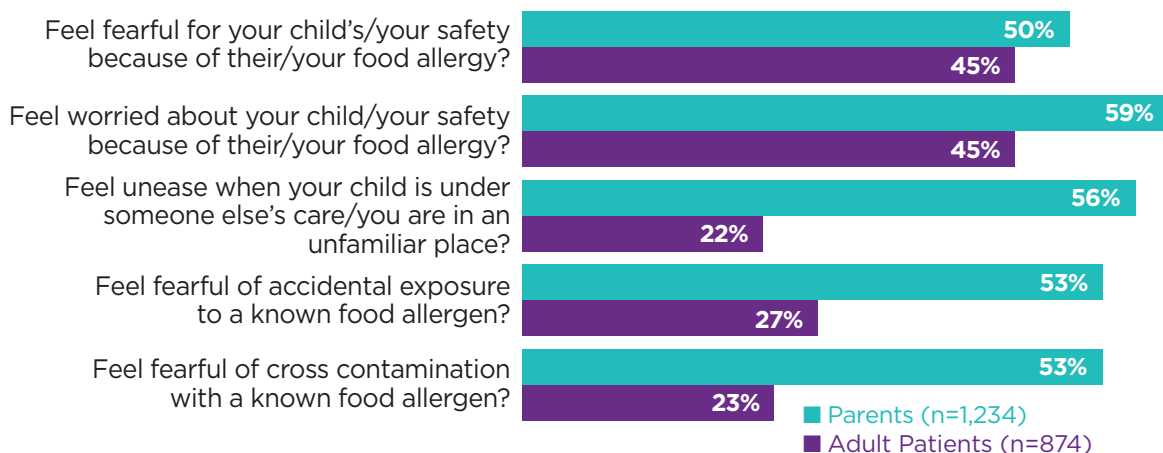
Parents of children with FA have more frequent and more negative thoughts about FA than adult patients with the same condition.

### THOUGHTS ABOUT FA

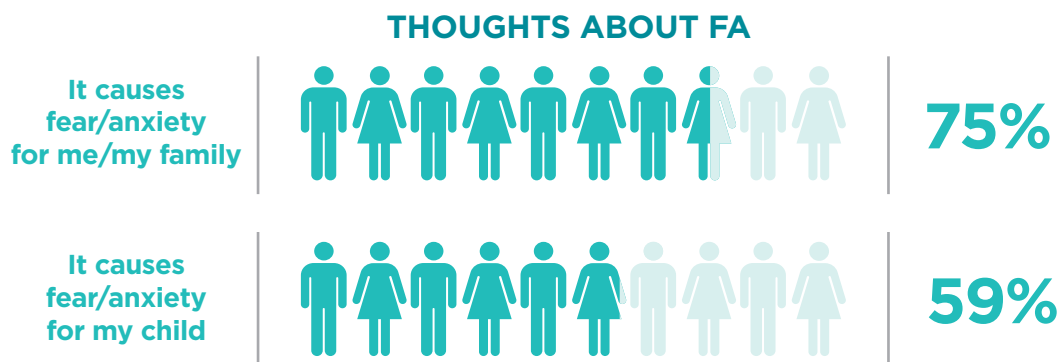


Parents report more frequent feelings of fear, worry and unease compared to adult patients.

### FREQUENCY OF FEAR, WORRY AND UNEASE DUE TO FA (RESPONSES TO “ALWAYS/OFTEN”)



Parents report higher fear/anxiety for themselves than perceived fear/anxiety for their child who has the disease.



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*“I think it’s harder on me as the parent. I dislike he can’t have a carefree childhood. That he can’t be spontaneous. I also carry the weight of trying to make sure I teach him everything he needs to know to manage his conditions as an adult and [educating] his father, and other family members and caregivers.” – Parent*

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Nearly one-third (31%) of parents say they are currently seeing (or have seen in the past five years) a mental health professional related to their child’s FA. Of the same group of respondents, 29% said their child was seeing (or has seen in the past five years) a mental health professional related to their FA.



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Parents reported FA affects other members of the family:

*“It affects the mental health of siblings as well.”*

*“I worry about my entire family’s mental health.”*

*“It does take a toll on the family. I have two other kids dealing with anxiety about their brother’s milk allergy. They have their own health issues that magnify the food allergy issue in their minds. It is hard on the family.”*

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## WHAT PARENTS SAY ABOUT THE IMPACT OF FOOD ALLERGY ON MENTAL OR EMOTIONAL HEALTH

*"It's relentless. It's probably the single most challenging and frustrating part of our lives as a family. And it's likely never going to go away."*

*"I suffer from PTSD from allergic reactions. It is just stressful to worry about when an exposure might happen."*

*"When you are constantly on alert trying to protect yourself from dangerous foods, the mental effects of food allergy are always present. We've found that we continuously walk around with a certain level of anxiety, and there is no way to escape it. While other parents can take a night away or 'night out', that only induces increased anxiety for us. We've found our own ways to have a tremendous amount of fun as a family, but food allergy is always at the center of all planning and activities."*

*"I feel I operate under higher levels of anxiety all the time. Particularly when he is out of my care. I feel that we can never really relax and do things non-FA families can do like go out to eat or participate in food related activities on a whim. Everything must be preplanned and accommodations ensured. It just feels like more stress than other parents have to face in regard to their child's safety and nutrition."*

*"I also have MS, but food allergies honestly scare me more."*

*"If we could afford it, we would all be in therapy."*

*"My anxiety has increased ten-fold since having a food allergic child. It's draining to always be on guard."*

*"Sometimes the fear is overwhelming. It is a monumental task of trying to navigate this life with so many restrictions. I have to teach my toddler that food that is healthy for most people is dangerous for him. I am finding it more difficult to hide my fear from him and to help him live his 'normal' life."*

### KIDS WITH FOOD ALLERGIES: A COMMUNITY OF SUPPORT AND PARTNERSHIP

Sometimes just knowing there is someone else out there who understands can provide a sense of relief. Our private community for parents of children with food allergies offers:

- Peer-to-peer support and help
- Ask the Allergist service
- Opportunities to participate in research to make a difference
- Timely news to keep you updated about food allergy treatments and research
- Tips and resources to help you manage food allergies with confidence
- Easy tools to take action and encourage federal and state policies to improve life with food allergies

Join the Kids With Food Allergies community at: [kidswithfoodallergies.org/join](https://kidswithfoodallergies.org/join)

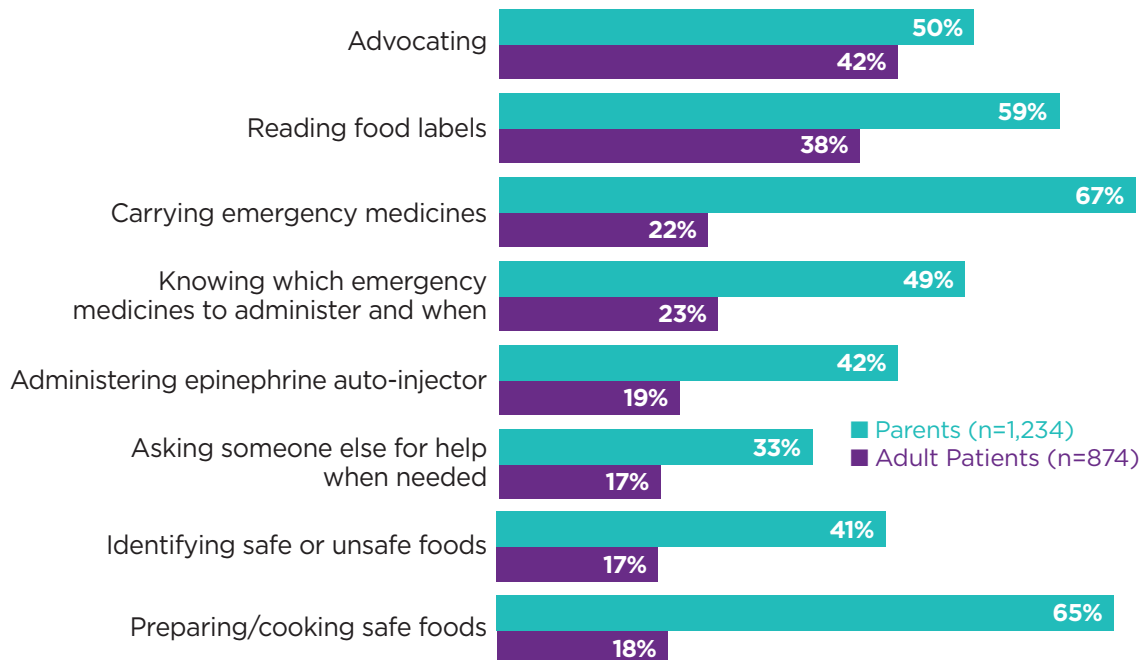


KFA member Patricia N. and her daughter work together to fight food allergies and raise awareness.



Despite reports of food allergies leading to nearly constant thoughts of fear, anxiety and worry, many parents say they are “very confident” in various parts of FA daily management. The area that parents indicate the least confidence is “asking someone else for help” with their child’s FA when needed. Across the board, parents report higher levels of confidence (than adult patients) with all activities that were asked.

### LEVEL OF SELF-CONFIDENCE (RESPONDED “VERY CONFIDENT”)



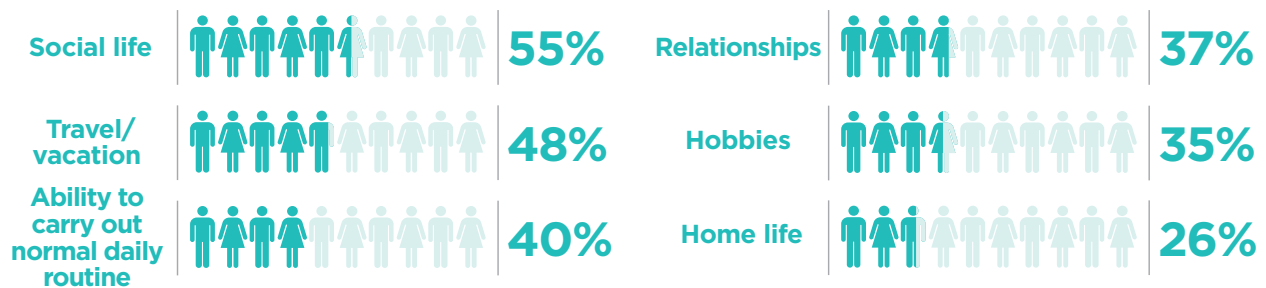
# 2

## Key Finding 2: Food allergies have considerable impact on parents' social life.

Because food is such an integral part of social activities, families affected by FA often experience social isolation. Most families report that food allergies impact their decision-making regarding social activities and most choose to miss out on social events.

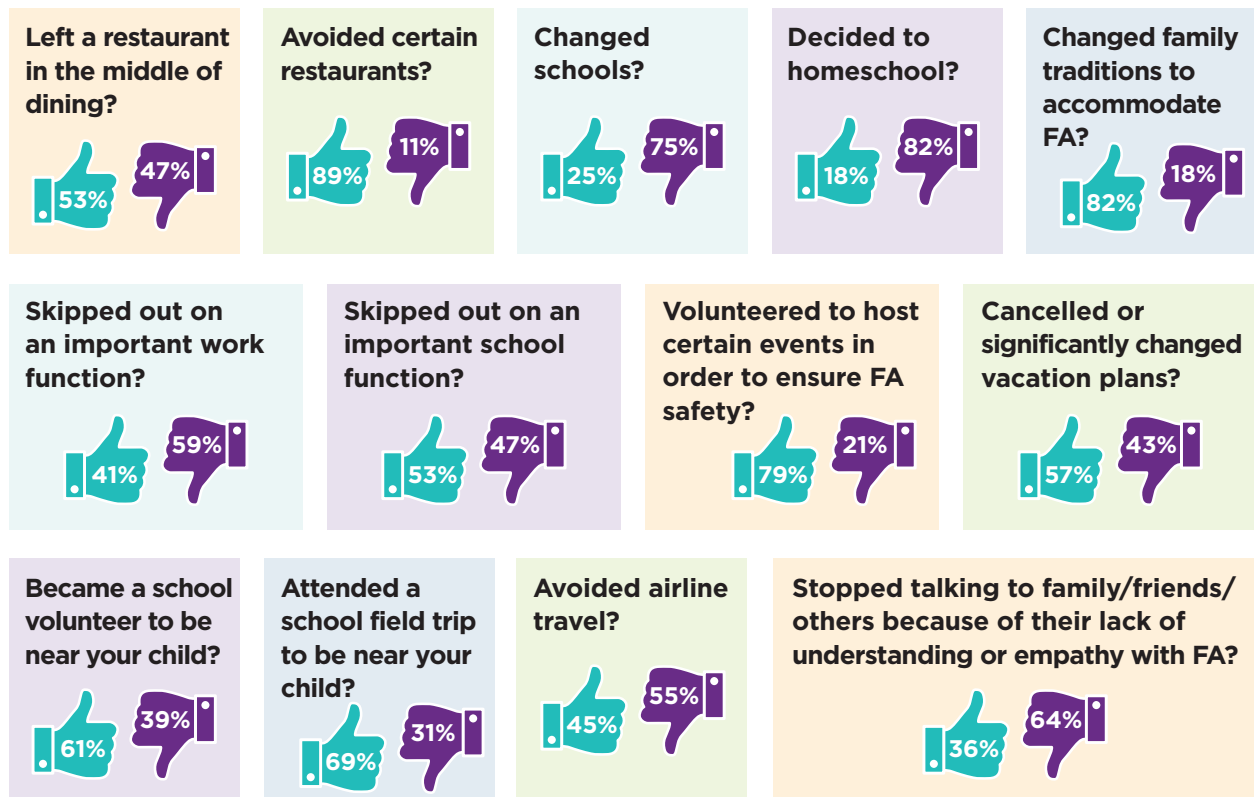
We asked parents about the impact of their child's FA on aspects of their own (the parent's) life. On a five-point scale (with 1 being "no impact" and 5 being "major impact"), 55% of respondents rated the impact of their child's FA on their own social life as a 4 or 5. On the same scale, 48% rated the impact of their child's FA on their travel/vacation plans as a 4 or 5. On the same scale, 48% rated the impact of their child's FA on their travel/vacation plans as a 4 or 5.

### IMPACT OF FA ON ASPECTS OF PARENT'S LIFE (CHOOSE "4" OR "5" ON FIVE-POINT SCALE)



More than half of parents have missed important school functions, altered vacation plans and left a restaurant while dining because of their child's FA. Additionally, 89% have avoided certain restaurants, and 82% have changed family traditions to accommodate FA.

### IMPACT OF FA ON ACTIVITIES



On a five-point scale (with 1 being “not at all challenging” and 5 being “very challenging”), 74% of parents rated the challenge of eating out with FA as a 4 or 5. On the same scale, 69% rated the challenge of navigating birthday parties and 59% rated the challenge of navigating entertainment activities as a 4 or 5. “Entertainment activities” include outings such as visiting movie theaters, museums or amusement parks.

### HOW CHALLENGING TO NAVIGATE (CHOOSE “4” OR “5” ON FIVE-POINT SCALE)



Eating out  
**74%**



Birthday parties  
**69%**



Entertainment activities  
**59%**



#### **SAFE EATS® ALLERGY-FRIENDLY RECIPES: The Largest Collection of “Free Of” Recipes**

Birthdays can be challenging with food allergies, but that doesn’t mean allergies have to hinder your celebrations! Our Safe Eats® recipe collection offers inspiration ranging from single-ingredient dishes to complex desserts. You can search for recipes that are “free of” many different allergens, or browse by categories such as cakes, candies, snacks, sauces, soups, main dishes and many others.

KFA also has tips on how to party with non-food treats to help you plan an inclusive celebration for all dietary restrictions. No matter the occasion, KFA provides resources to help keep your child safe and healthy.

[kidswithfoodallergies.org/recipes](https://kidswithfoodallergies.org/recipes)



# 3

## Key Finding 3: Food allergies cause significant financial strain and time burden for parents.

The annual cost of childhood food allergies is \$24.8 billion in the United States overall, which breaks down to \$4.3 billion for direct medical costs, \$14.2 billion for lost work, \$5.5 billion for other out-of-pocket expenses such as special foods and \$770 million for family-related costs like time off work.<sup>2</sup>

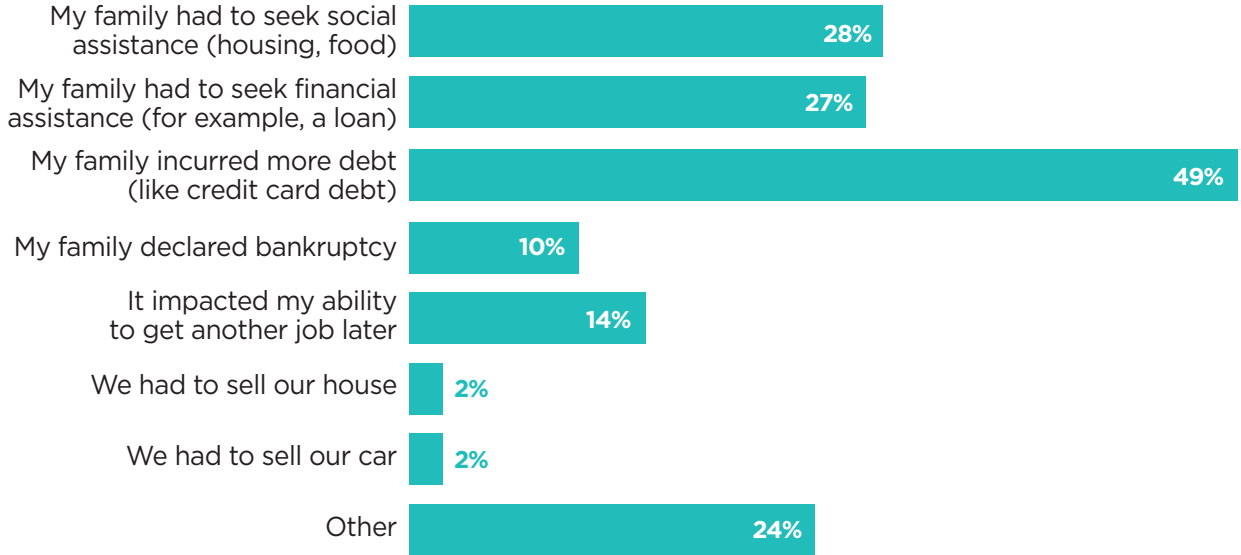
Our survey examined the financial strain on families, including debt accumulation and the need to seek assistance for food and housing. Reasons given for increased financial strain include cost of identifying and buying specialty foods, cost of medical care and treatment, and lost wages due to FA-related career choices.

When asked to indicate the impact of FA on finances on a five-point scale (1 being “no impact” and 5 being “major impact”) 44% of parents rated the impact as a 4 or 5.

Nearly half (44%) of parents say they or their spouse have had to make a career choice (such as quitting or changing jobs) in order to care for their child with food allergy. Of those 44% who have had to make a career choice due to FA (n=547), 84% report that this decision had a negative impact on their household finances. Of those who reported a negative impact on finances (n=457), 49% say they incurred more debt and 28% had to seek social assistance. Responses to “other” included loss of general savings, inability to save for retirement, inability to take vacations and impact on general lifestyle and comfort.



### IMPACT ON FINANCES (N=457)





## WHAT PARENTS SAY ABOUT THE IMPACT OF FOOD ALLERGIES ON FINANCES

*“I am on so many payment plans for my son’s doctor bills, and his food is expensive and his meds are expensive – it’s OVERWHELMING.”*

*“We are heavily in debt from years of testing, hospitalization, medications and allergen-free foods. We make too much money to qualify for medical assistance, so all of the financial burden has rested entirely on us.”*

*“Financially, this illness has ruined us. Three 401(k)s were depleted. Change of jobs was taken three times. Now I have a job that offers no benefits but forgives my multiple absences.”*

*“The impact has been on our extended family as well. Grandparent quit her job to stay home and care for her so she could be safe.”*

*“I had to quit my job to care for my daughter. We lost an entire income – a major financial burden!”*

*“We have a high deductible plan, so we pay out of pocket for all medical and prescription expenses until we hit the deductible, then 20% until we max out. That means thousands of dollars spent every year.”*

*“Working extra hours at my job is no longer possible because of the time I have to spend finding and/or preparing safe food. I also pay for a private day care close to my job so I can be close by in case of emergencies.”*

*“We have also struggled to find schools that will accommodate allergies, and as a result, we homeschool our kids. This makes the cost of food allergies my whole salary, in addition to medical bills and the cost of food.”*

### PATIENT ASSISTANCE PROGRAMS:

Many pharmaceutical companies, state programs and nonprofits have drug assistance programs that offer free or low-cost medicines if you don’t have insurance or can’t afford your medicine. Program benefits vary. Depending on your insurance and medicine, you may be eligible for help to reduce your medicine copay.

[kidswithfoodallergies.org/epinephrine-assistance](https://kidswithfoodallergies.org/epinephrine-assistance)

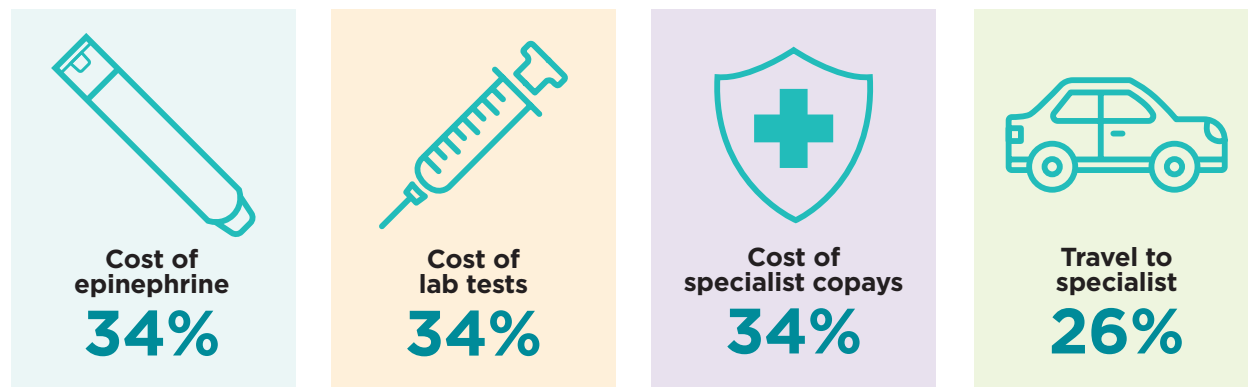
[aafa.org/patient-help](https://aafa.org/patient-help)

[aafa.org/asthma-assistance](https://aafa.org/asthma-assistance)



On a five-point scale (with 1 being “no burden” and 5 being “major burden”), 34% of respondents rated a 4 or 5 for the financial burden of the out-of-pocket cost of epinephrine, cost of lab tests or oral food challenges and the cost of copays for specialist doctor visits. On the same scale, 26% rated the time burden of the travel required to see a specialist care provider as a 4 or 5.

## FINANCIAL AND TIME BURDEN OF HEALTH CARE (CHOSE “4” OR “5” ON FIVE-POINT SCALE)



### COST OF EPINEPHRINE

The wholesale price of epinephrine auto-injectors has increased dramatically over the last decade. However, almost all brand and generic epinephrine auto-injectors offer patient assistance with copay coupons or patient assistance programs.

[kidswithfoodallergies.org/epinephrine-assistance](http://kidswithfoodallergies.org/epinephrine-assistance)

Recent shortages from some manufacturers have disrupted patients’ ability to get their prescriptions in a timely manner. Health care providers and pharmacists need to help patients and caregivers learn about the different options for epinephrine, how to use the different devices and what copay assistance may be available.

AAFA has met with the U.S. Department of Health and Human Services (HHS) and the U.S. Food and Drug Administration (FDA) on issues regarding epinephrine shortages, epinephrine pricing and barriers to affordable epinephrine. AAFA has also met with epinephrine auto-injector manufacturers and encourage the companies to continue to offer copay assistance so the out-of-pocket costs for families do not prevent them from using their medicines.

### CURRENT EPINEPHRINE DEVICES IN THE US



EpiPen® and EpiPen Jr.®



Authorized generic for EpiPen®



Generic equivalents of EpiPen® by Teva



Authorized generic for Adrenaclick®



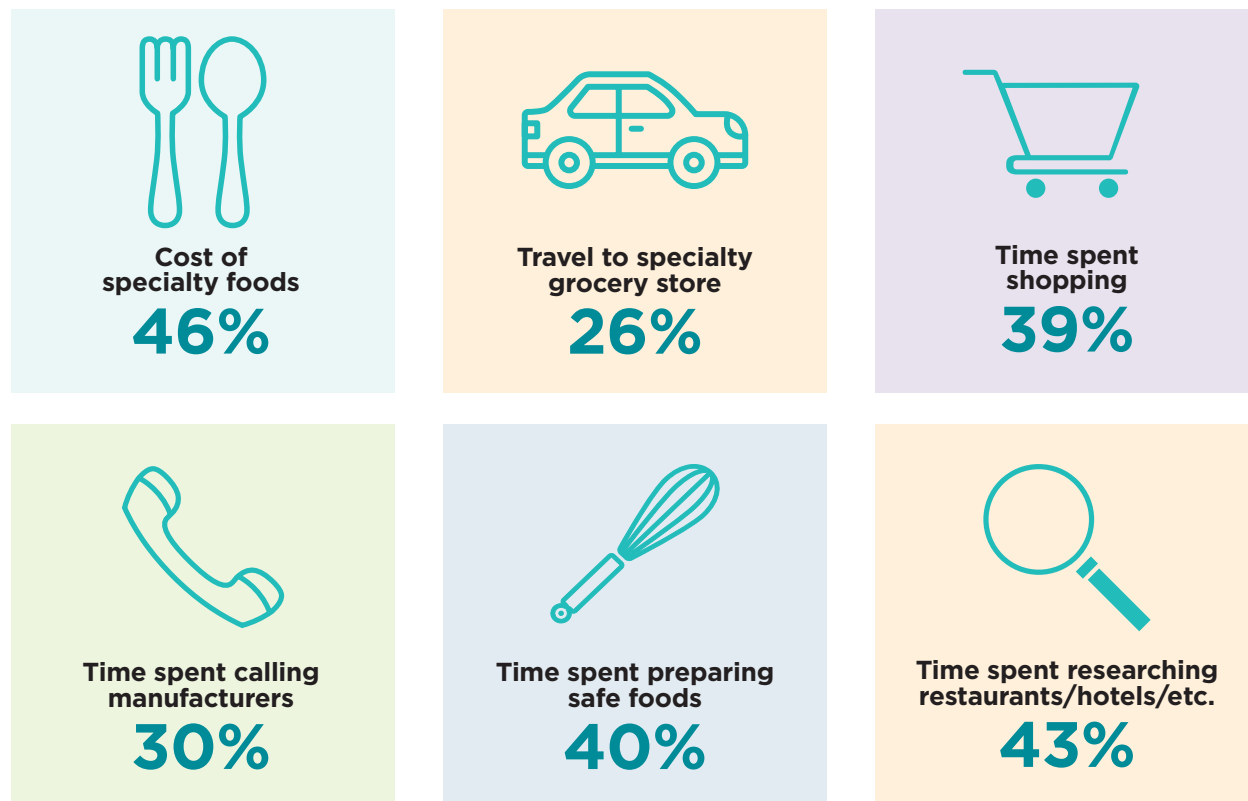
AUVI-Q®



SYMPJEPI™ pre-filled syringe

On a five-point scale (with 1 being “no burden” and 5 being “major burden”), 46% of respondents rated the financial burden of the cost of specialty foods as a 4 or 5. On the same scale, 40% rated the time burden of the time spent preparing safe foods as a 4 or 5.

## FINANCIAL AND TIME BURDEN OF SAFE FOODS (CHOOSE “4” OR “5” ON FIVE-POINT SCALE)



*“It’s mostly a financial burden because of the time required to prepare and serve safe meals. This takes away from time I could be working.” - Parent*

*“I can definitely say ‘safe’ foods are 4x the cost. Shopping at multiple stores, calling manufacturers... are all impacting our lives.” - Parent*

*“It’s hard to separate the cost of allergy-friendly food from other food, but it definitely makes it very difficult to spend less on groceries and our food bills are very high. It is also hard to estimate the financial value of time, but I do spend a great deal of time thinking about, shopping for, planning, researching foods and going to various stores to get all the things we need that are safe for the kids.” - Parent*

*“I hate how difficult and how much time it takes to call manufacturers because there is still no standard requirement for labeling for cross contamination [cross-contact with allergens]. My son has gone into anaphylaxis more than once due to cross contact only, despite being exceedingly vigilant and reading labels before he eats anything.” - Parent*

*“My son is so sensitive that the whole family avoids his allergens, so for his safety our grocery bill is huge.” - Parent*

*“It is a time burden primarily and requires incredible planning. Gone are the days of spontaneous restaurant dinners or last second food decisions. Potlucks and big holiday dinners are the worst!” - Parent*

# SPOTLIGHT: THE FUTURE OF FOOD ALLERGY TREATMENT

The current standard of care for food allergy is strict avoidance of triggers and timely administration of epinephrine in the event of a severe allergic reaction. However, recent advances in research have significantly improved our understanding of food allergy and are paving the way for the investigation of new treatment options.

One type of emerging treatment currently being evaluated by the FDA is immunotherapy—a process of gradually introducing an allergen until the body’s immune system becomes “desensitized” to or tolerant of the allergen. Immunotherapy is being studied for the treatment of IgE mediated food allergy.

The goal of immunotherapy is to protect against reactions to accidental exposure and reduce the risk of life-threatening allergic reactions. This extra layer of protection has the potential to greatly impact the quality of life for patients and caregivers by reducing some of the anxiety and fear related to constant vigilance against accidental exposure to food allergens.

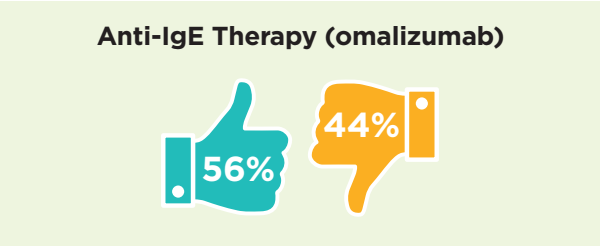
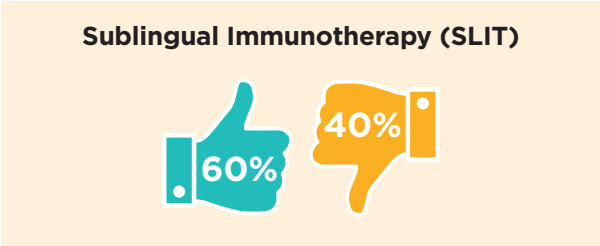
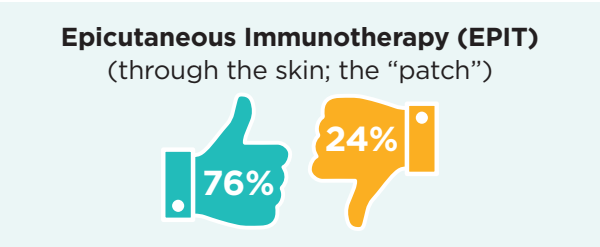
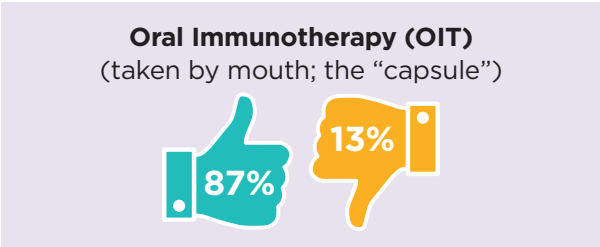
Three types of immunotherapy for the treatment of food allergy are being studied for specific allergens:

- Oral Immunotherapy (OIT) - allergen is swallowed by mouth
- Epicutaneous Immunotherapy (EPIT) - allergen contained on a patch is absorbed by the top layers of the skin
- Sublingual Immunotherapy (SLIT) - allergen is placed under the tongue

Some researchers are also studying the potential role of omalizumab—an existing subcutaneous (injected under the skin) treatment for asthma and chronic hives—in preventing severe allergic reactions to IgE mediated food allergies. Unlike immunotherapy, this treatment is non-allergen specific and targets the total amount of IgE in the body.

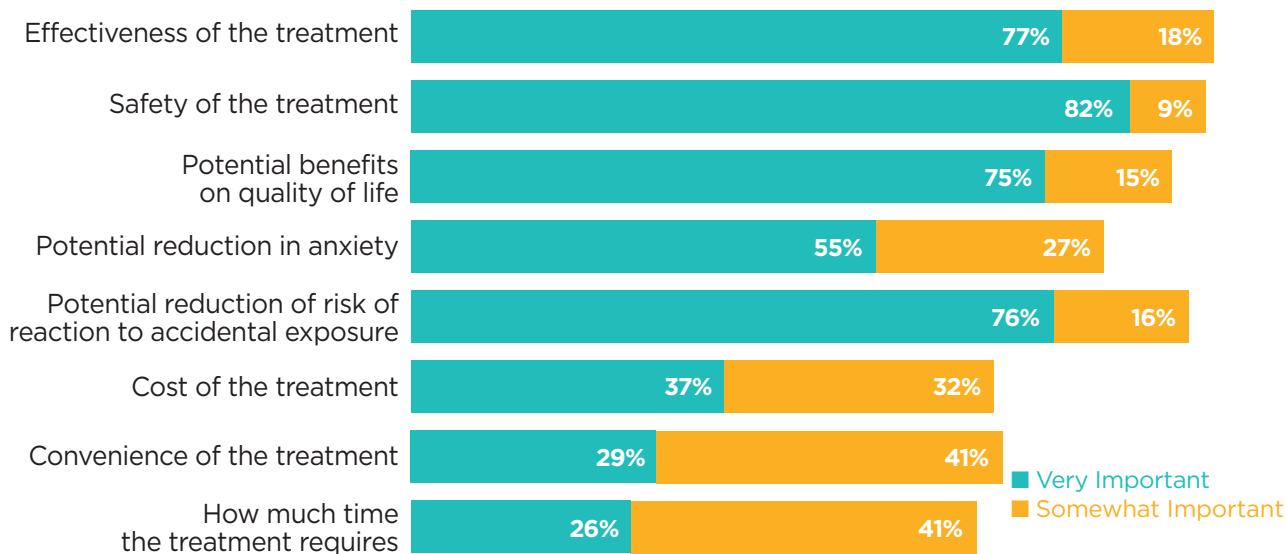
The knowledge of these emerging therapies for the treatment of food allergy varies among the patient and caregiver community. When asked about awareness of these treatments, 87% of parents say they are aware of OIT, 76% are aware of EPIT, 60% are aware of SLIT and 56% are aware of omalizumab.

## AWARENESS OF EMERGING TREATMENTS



When asked about the most important factors in determining their willingness to try new therapies for FA, 95% of parents say the effectiveness of the drug is somewhat or very important. Additionally, 92% say the potential reduction of risk is somewhat or very important and 91% say the safety of the treatment is somewhat or very important.

### IMPORTANCE OF FACTORS IN TREATMENT DECISIONS (CHOSE “VERY IMPORTANT” AND “SOMEWHAT IMPORTANT”)



### KIDS WITH FOOD ALLERGIES: A COMMUNITY OF SUPPORT AND PARTNERSHIP

Join our Kids With Food Allergies community at [kidswithfoodallergies.org/join](https://kidswithfoodallergies.org/join)

- Stay up to date on emerging treatments
- Learn about clinical trials and other research studies
- Get involved in food allergy research
- Opt-in to get notified about new research for your food allergies

Together, we can partner to advance research on food allergies. We are committed to patient-centered and patient-included research to ensure that advancements are made in areas that are most important to families impacted by food allergies and other allergic diseases.

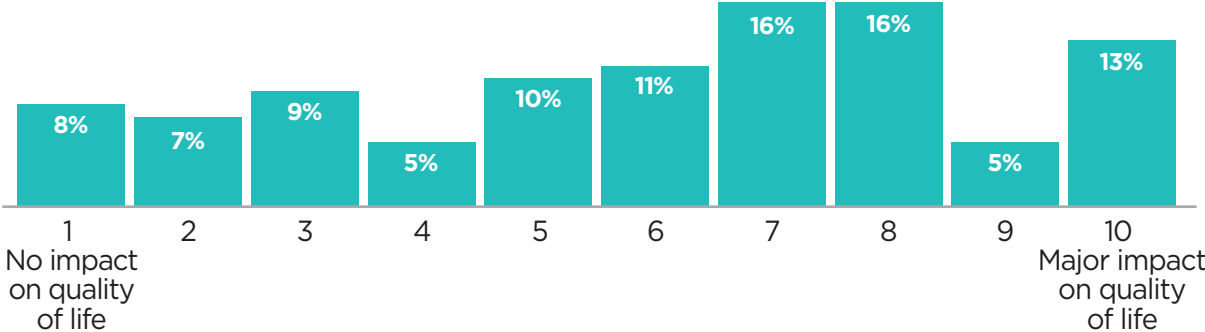


Although several approaches are being studied for the treatment of food allergy, two potential biotechnologies—both for peanut allergy—have advanced the furthest with respect to FDA approval. These two products—AR101 (OIT) and Viaskin® Peanut (EPIT)—aim to desensitize the patient’s immune system to peanut protein.

The survey included two peanut-specific questions that were seen only by the 853 (of the 1,234) parents who indicated that their child has a diagnosed peanut allergy. Both questions asked respondents to think only about their child’s current quality of life (QoL) when it comes to peanut allergy. The responses to these two questions are depicted in the graphs below.

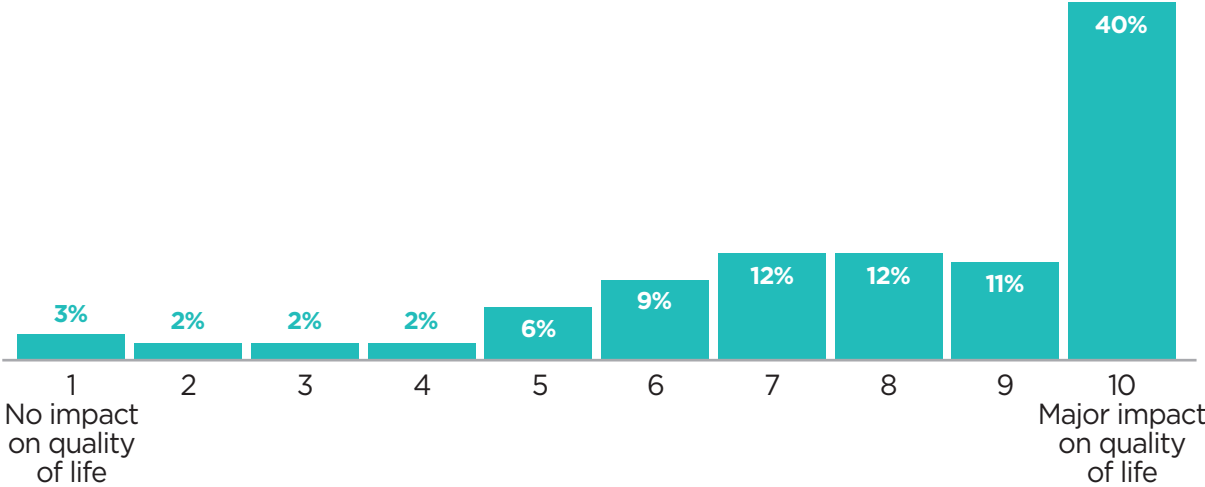
### DESENSITIZATION - PREDICTED IMPACT ON QOL (N=853)

*What parents believe the impact on quality of life of their child would be if the child were to **become less sensitive to peanuts**.*



### TOLERANCE - PREDICTED IMPACT ON QOL (N=853)

*What parents believe the impact on quality of life of their child would be if the child were to **become tolerant of peanuts**.*



There was a clear indication throughout our survey that peanut allergy has significant impact on quality of life for families. Written comments also confirmed that patients and their families want treatment options for food allergies.

# SPOTLIGHT: A LOOK AT EOSINOPHILIC ESOPHAGITIS (EOE)



EoE—a type of non-IgE mediated food allergy— can make eating difficult and painful. Diagnosis and management can be tricky due to delayed or intermittent symptoms. Removing foods that trigger EoE can help reduce symptoms, but not always. Diet modifications include eliminating multiple foods from the diet or subsisting on special medical formulas. EoE can have a costly impact on a family’s social, emotional and financial health.

To explore the burden of EoE, we compared survey data from parents who indicated their child is diagnosed with EoE (n=106) to data from parents whose children are diagnosed with food allergy, but not with EoE type food allergy (n=1,128).

For every aspect of life that we asked about, parents of children with EoE reported more negative impact from FA. On a five-point scale (with 1 being “no impact” and 5 being “major impact”), 68% of parents of children with EoE rated the impact of their child’s food allergy on their own emotional health as a 4 or 5 (compared to 49% of parents of children without EoE). On the same scale, 56% of parents of children with EoE rated the impact of their child’s FA on their own relationships as a 4 or 5 (compared to 36% of parents of children without EoE).

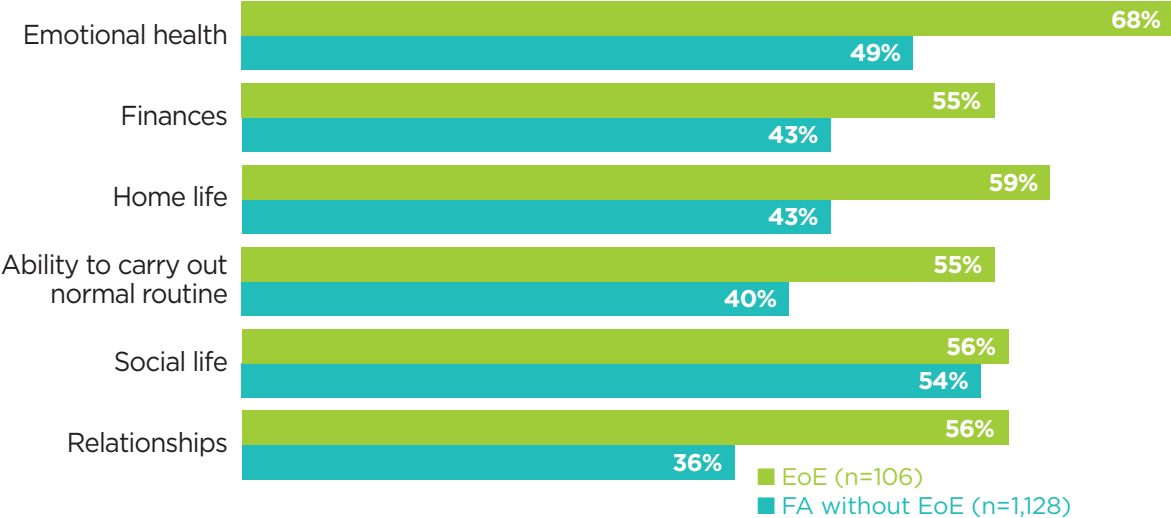
## WHAT IS EOE?

**Eosinophilic esophagitis (EoE)** is an allergic swallowing disorder. EoE occurs when eosinophils, a type of white blood cells, collect in the esophagus (throat). The condition is often triggered by food but may be triggered by pollen as well. EoE affects people of all ages, genders and ethnic backgrounds.

Symptoms can occur days or even weeks after eating a food allergen. However, symptoms may wax and wane, meaning they are not always present. This can be confusing. Common symptoms include:

- Reflux that does not respond to usual therapy
- Difficulty swallowing
- Food impactions (food gets stuck in the throat)
- Nausea and vomiting
- Failure to thrive (poor growth or weight loss)
- Abdominal or chest pain
- Poor appetite
- Malnutrition
- Difficulty sleeping

## IMPACT OF A CHILD’S FA ON VARIOUS ASPECTS OF PARENT’S LIFE (CHOOSE “4” OR “5” ON FIVE-POINT SCALE)



EoE impacted daily decision-making for all social activities we asked about: 71% of parents of children with EoE said they have changed vacation plans due to FA and 58% said they have avoided airline travel due to FA (compared to 56% and 43% of parents of children without EoE, respectively).

### IMPACT OF FA ON ACTIVITIES (RESPONDED “YES”)

Social Impact	EoE (n=106)	FA without EoE (n=1,128)
Skipped out on an important school function	67%	51%
Cancelled or significantly changed vacation plans	71%	56%
Avoided airline travel	58%	43%
Left a restaurant in the middle of dining?	60%	52%
Changed schools?	31%	24%
Decided to home school?	27%	17%
Stopped talking to family members/friends/ others because of their lack of empathy with/ understanding of food allergies?	52%	35%

Nutrition plays a critical role in a child’s development. But EoE can threaten a child’s growth, putting heavy burden and concern on families. Because symptoms can be intermittent or delayed, managing EoE and watching for nutritional deficiencies becomes a challenging task.

### “ALWAYS/OFTEN” FEEL CONCERNED ABOUT THEIR CHILD’S NUTRITION/GROWTH BECAUSE OF THEIR RESTRICTED DIET

**38%**  
of parents whose  
children have EoE

**25%**  
of parents whose  
children do not have EoE

Additionally, more than half (54%) of parents of children with EoE reported seeing a mental health professional in the past 5 years due to their child’s FA, compared to 29% of parents of children without EoE.

### HAVE SEEN A MENTAL HEALTH PROFESSIONAL (IN THE PAST 5 YEARS) RELATED TO THEIR CHILD’S FA

**54%**  
of parents  
whose children  
have EoE

**29%**  
of parents  
whose children  
do not have EoE

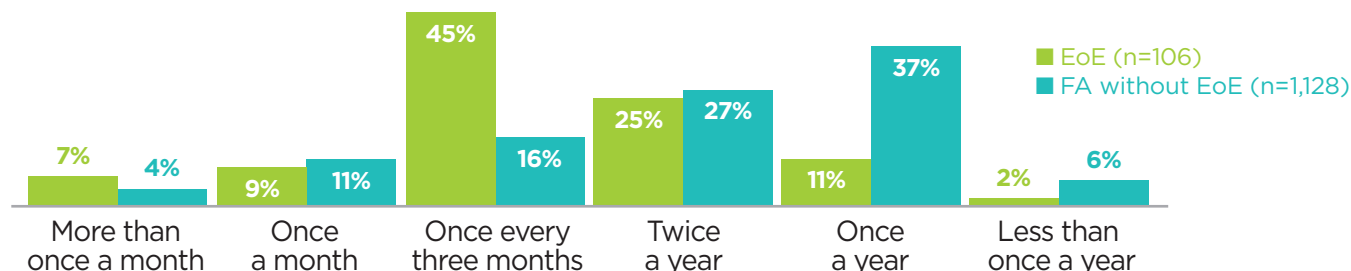
### SAID THEIR CHILD HAS SEEN A MENTAL HEALTH PROFESSIONAL (IN THE PAST 5 YEARS) RELATED TO THEIR FA

**47%**  
of parents  
whose children  
have EoE

**27%**  
of parents  
whose children  
do not have EoE

Due to the nature of EoE, many children with the condition may need more frequent doctor visits compared to children with IgE mediated FA. Parents of children with EoE reported more frequent visits to the doctor, higher burden of costs of doctor visits, and higher burden of travel related to doctor visits.

### FREQUENCY OF FA-RELATED CLINICAL VISITS



On a five-point scale (with 1 being “not a burden at all” and 5 being “major burden”), 46% of parents of children with EoE rated the burden of travel required to see specific health care provider as a 4 or 5 (compared to 23% of parents of children without EoE). On the same scale, 48% of parents of children with EoE rated the burden of the cost of copays for specialist doctor visits as a 4 or 5 (compared to 32% of parents of children without EoE).

### FINANCIAL AND TIME BURDEN OF HEALTH CARE (CHOSE “4” OR “5” ON FIVE-POINT SCALE)



*“The overwhelming problems with dealing with multiple food and environmental allergies, EoE, and asthma has led us to home school — not by choice. This has had major negative impacts on our quality of life and family relationships.” – Parent*

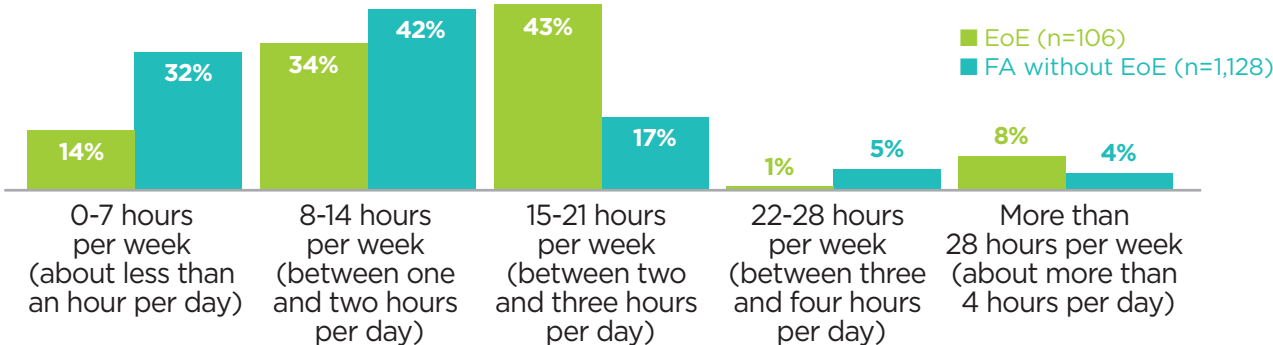
*“This new diagnosis [EoE], the inability to move forward with treatment at this time, and the need to go on an elimination diet to work out triggers has impacted our emotional and financial state.” – Parent*

*“The cost of formula related to her EoE [is a financial burden]. An 18-day supply of amino acid-based formulas is \$260. I worry about how long she’ll need the supplement, and whether or not it will continue to keep weight on her.” – Parent*

Parents of children with EoE reported a higher time burden of FA. Across the board, these parents said they spend more time shopping, researching products and preparing food than parents of children without EoE.

Over half (52%) of parents whose child has EoE say they spend 15 or more hours per week managing their child’s food allergy, compared to only 26% of parents whose child does not have EoE. This includes time spent preparing foods, reading labels, visiting/traveling to doctors and volunteering at school.

**TIME SPENT PER WEEK FOR FA**



On a five-point scale (with 1 being “not a burden at all” and 5 being “major burden”), 54% of respondents of children with EoE rated the burden of time spent shopping for safe foods as a 4 or a 5 (compared to 38% of parents of children without EoE). On the same scale, 58% of parents of children with EoE rated the burden of time spent preparing/cooking safe foods as a 4 or a 5 (compared to 39% of parents of children without EoE).

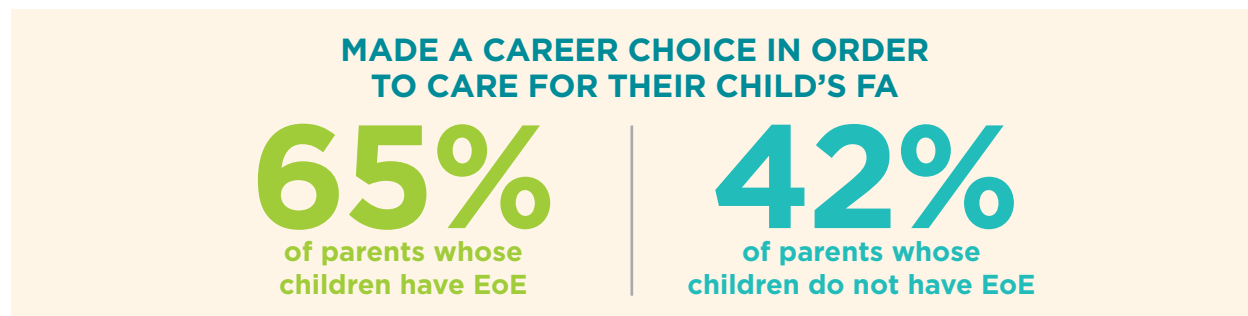
**TIME BURDEN OF HEALTH CARE (CHOSE “4” OR “5” ON FIVE-POINT SCALE)**



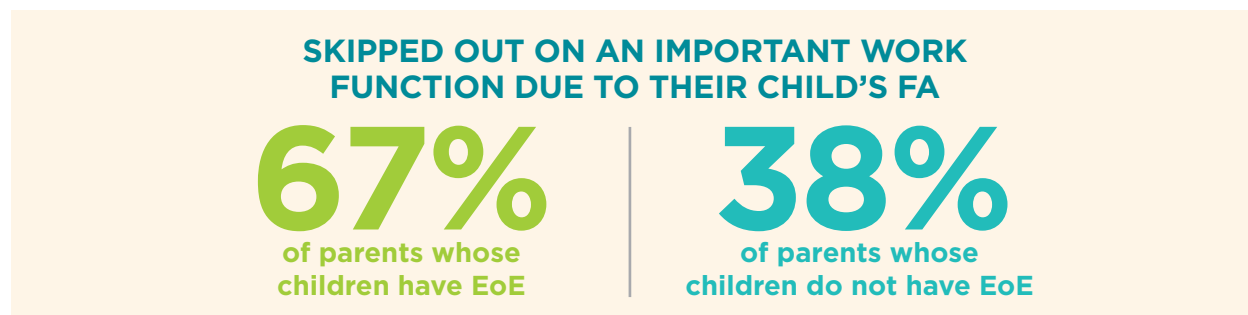


For every question related to the parent’s work, respondents whose children have EoE reported more significant burden of FA. When asked on a five-point scale the impact of their child’s FA on the parent’s work life (1 being “no impact” and 5 being “major impact”), 47% of parents of children with EoE (compared to 34% of parents of children without EoE) responded as a 4 or 5.

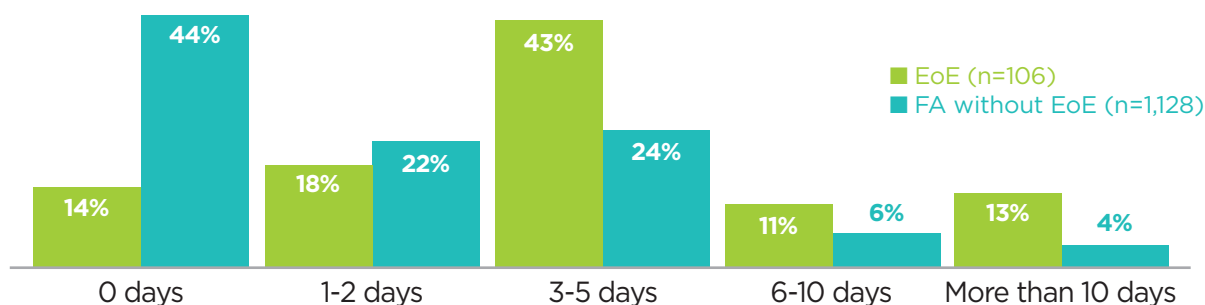
When asked whether they or their spouse had made a career choice in order to care for their child’s FA, 65% of parents of children with EoE confirmed “yes” (compared to 42% of parents of children without EoE).



Additionally, when asked if they have ever skipped out on an important work function due to their child’s FA, 67% of parents of children with EoE confirmed “yes” (compared to only 38% of parents of children without EoE).



**MISSED WORK DAYS DUE TO FA (IN PAST 12-MONTH PERIOD)**



Eosinophilic esophagitis is a complicated type of food allergy to manage. Parents managing their child’s EoE overwhelmingly report a higher negative impact on their quality of life than parents managing other food allergies.

Families living with eosinophilic esophagitis need emotional and social support, financial assistance/work accommodations and treatment options that are less burdensome and isolating.

# SPOTLIGHT: TRANSITIONING TO ADULTHOOD

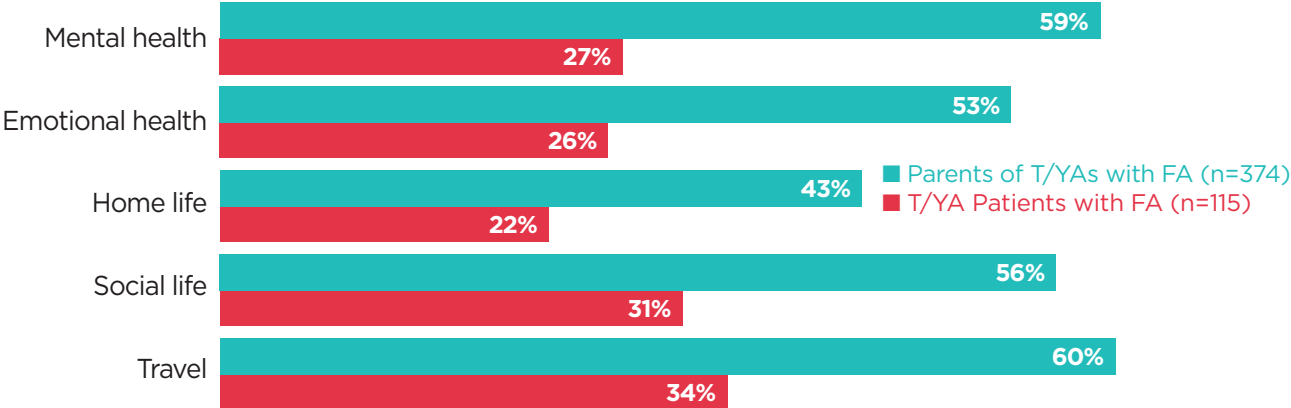
The transition to self-management and care during adolescence and young adulthood is a period of increased risk for people with FA. It is also a time of significant anxiety for their parents. Teens and young adults are at higher risk of food-induced anaphylaxis with fatal outcomes.<sup>4</sup> Research shows teens and young adults with FA engage in more risk-taking behavior (e.g. eating unsafe foods, not carrying or delaying emergency treatment of epinephrine).

To better understand the burden of FA on teens/young adults (T/YA) and their families, we analyzed responses from parents who indicated their child with FA is currently between the ages of 13 and 23 (n=374). This data was then compared to responses from our parallel T/YA patient survey (n=115).

**Throughout this report, “T/YA” refers to people whose age falls in the range of 13-23.**

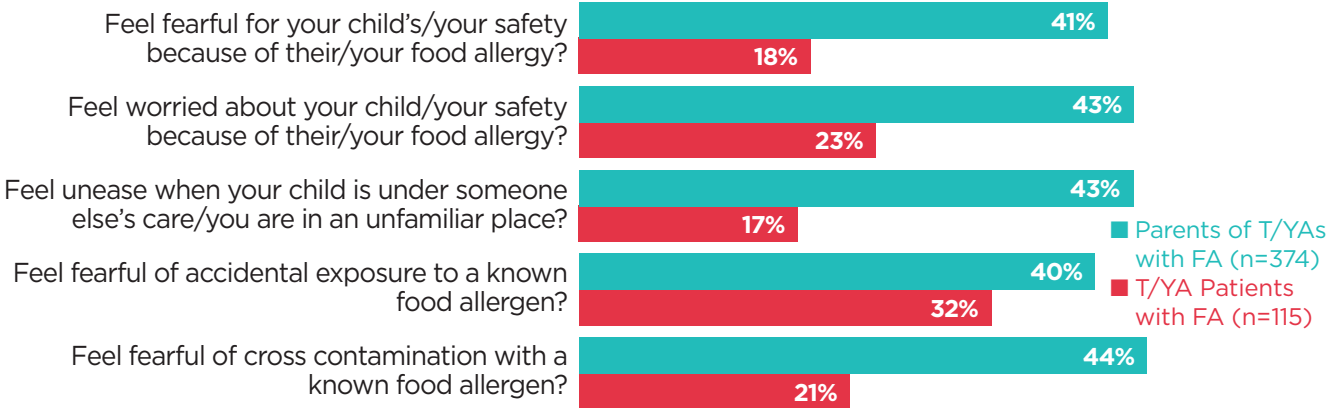
For every aspect of life that we asked about, parents of T/YA with FA reported more negative impact of FA than the T/YA patients themselves. On a five-point scale (with 1 being “no impact” and 5 being “major impact”), 59% of parents of T/YA patients rated the impact of their child’s food allergy on their own mental health as a 4 or 5 (compared to 27% of T/YA patients). On the same scale, 56% of parents of T/YA patients rated the impact of their child’s FA on their own social life as a 4 or 5 (compared to 31% of T/YA patients).

## IMPACT OF FA ON VARIOUS ASPECTS OF LIFE (CHOSE “4” OR “5” ON 5-POINT SCALE)



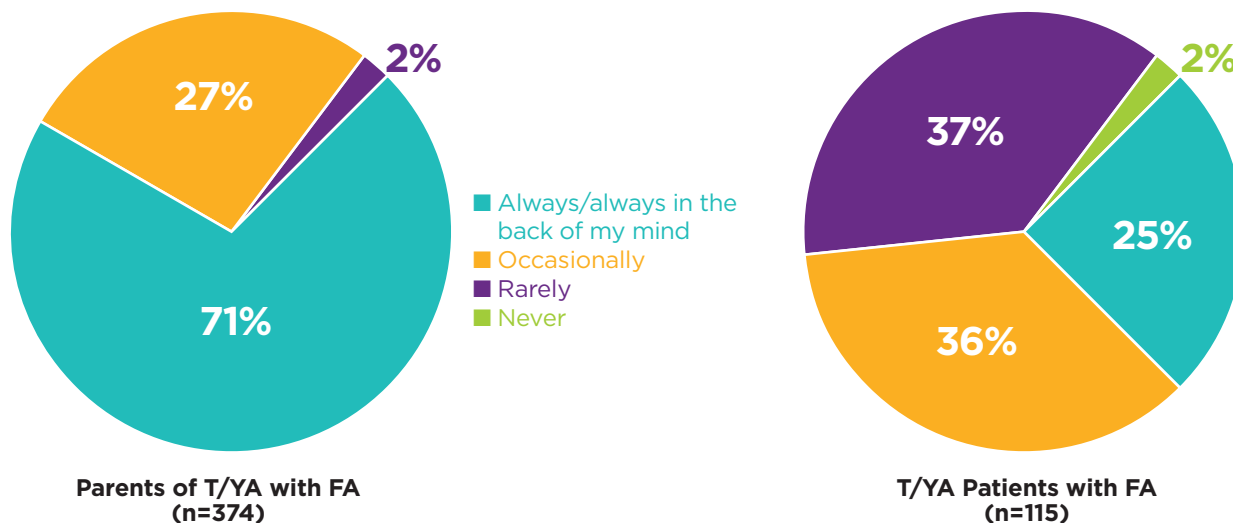
Parents of T/YA patients report more frequent feelings of fear, worry and unease compared to T/YA patients.

## FREQUENCY OF FEAR, WORRY AND UNEASE DUE TO FA (RESPONDED “ALWAYS/OFTEN”)



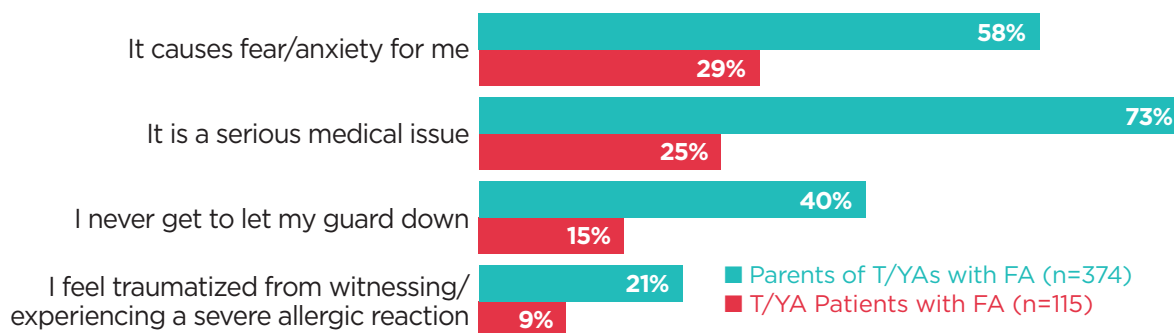
When asked how often parents of T/YA think about their child's food allergy, 71% say it's always in the back of their minds. In the parallel survey of T/YA with food allergies, only 25% said the same thing. Only 2% of parents of T/YA said they rarely think about their child's FA, while 37% of T/YA patients say they rarely think about their own FA.

### FREQUENCY OF THOUGHTS ABOUT FA

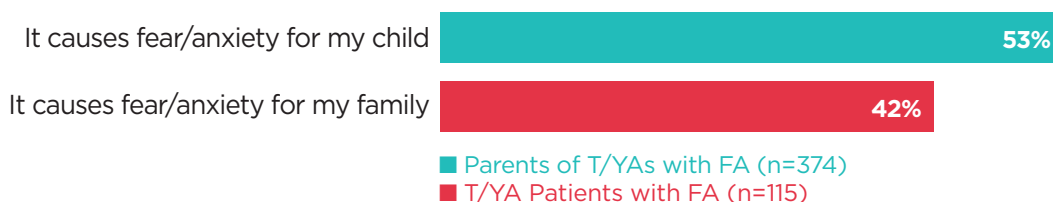


When asked if they believe various statements about FA are true, 73% of parents of T/YA with food allergies say they think FA is a serious medical issue (compared to 25% of T/YA patients), 40% feel they can never let their guard down (compared to 15% of T/YA patients), and 21% feel traumatized from a past experience (compared to 9% of T/YA patients).

### THOUGHTS ABOUT FOOD ALLERGIES

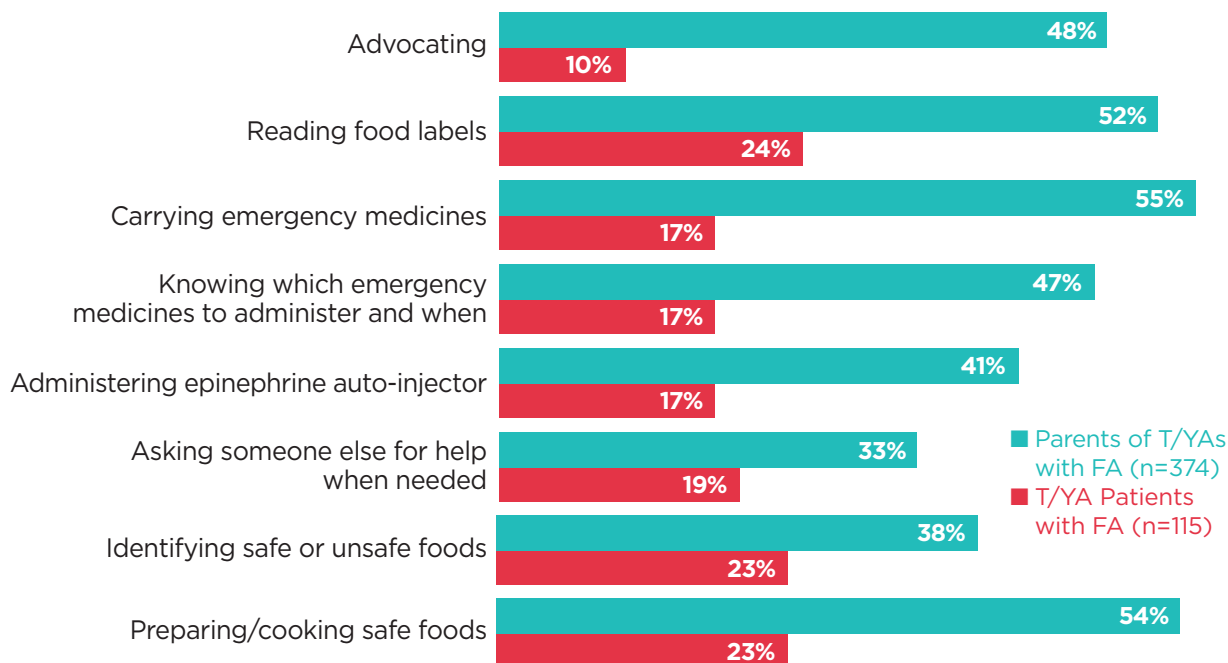


Parents of T/YA with FA acknowledge that they believe their fear/anxiety is higher than the perceived fear/anxiety of their child. The data from this subgroup of parents is supported by data from the T/YA patient survey: T/YA with food allergies believe their FA causes greater fear/anxiety for their family than themselves.



Despite reports of major impact of FA on the parent’s anxiety and mental health, parents say they are “very confident” in many parts of FA daily management. The area that parents indicate the least confidence is “asking someone else for help” with their child’s FA when needed. Across the board, parents report higher levels of confidence than T/YA with food allergies for all activities that were asked.

### LEVEL OF SELF-CONFIDENCE (RESPONDED “VERY CONFIDENT”)



*“My son dreams of being in the military but his allergies will prevent him from serving. This is a heartbreak.” - Parent*

*“Most people just never understand or get it. It is hard to hang out with my friends who love the foods I can’t be around.” - Patient, age 15*

*“When I was younger, I was really anxious about my food allergies (and still am, but not nearly as much). I often felt like an outcast/weird person because of my food allergies. I was almost embarrassed to advocate for myself at times. Now, I am a lot less anxious and much more self-advocating. I am starting college in the fall and I’m going to work with the university dietician to help me set up my meal plan.” - Patient, age 17*

*“The bullying incident my daughter was subjected to at 6 years old caused panic attacks and resulted in years of therapy. At 13, her sadness over her allergies mostly centers around wanting to be like everyone else, that she’s missing out on something and always being made to feel different. Young teens just want to fit in.” - Parent*

*“As my daughter approaches 18, her option to go to college is extremely hindered by her allergies.” - Parent*

*“Transitioning from kid doctors to adult doctors is really hard. The allergies didn’t magically go away because I had a birthday but some doctors seem to think that. It sucks.” - Patient, age 19*

*“My son is 16 and will be starting to date in a couple of years and I fear he won’t find a girl who will understand his allergies.” - Parent*



## CONCLUSION AND DISCUSSION

In addition to gathering quantitative insights about the overall burden of food allergy, this survey also prompted parents to provide general commentary about challenges or experiences related to their child's FA. Specifically, four open-ended questions were intended to capture the caregiver narrative in their own voice and to explore the needs of the parent community:

- Do you feel you have enough resources to manage your child's FA? ("Resources" can be educational, emotional, clinical, financial or any other type of support.)
- Do you have any comments about the impact of FA on mental or emotional health?
- Do you have any comments about the impact of FA on finances?
- Are there any experiences you would like to share with AAFA and others that were not captured by this survey?

Analysis of written comments to these open-ended questions (as well as analysis of multiple-choice responses presented throughout this report) helped us identify unmet needs among parents of children with FA. The following pages provide an overview of these identified needs as well as key areas of opportunities for AAFA and other stakeholders in the FA community.

This discussion will focus specifically on the unmet social, emotional, educational, financial and policy-related needs. While we acknowledge a critical need for approved treatments and better diagnostic tools, the unmet clinical and therapeutic needs for FA are well-documented in current literature.

### Unmet Needs in Emotional and Social Support

This survey clearly identified emotional and social stressors—such as mental health issues and difficulty navigating social activities—as major areas of concern for parents of children with FA.

#### Mental health support

Specifically, the need for better mental health support for parents of children with FA emerged as a prominent theme. This is an area of growing interest for FA advocates who are developing resources to support families. Resources include the Food Allergy Behavioral Health Association's "Food Allergy Counselor Directory."

*"I have wanted to see someone for my own mental health a few times—particularly after my son's diagnosis and his severe reactions. I was hoping to find someone with experience treating anxiety in caregivers. I wasn't able to find anyone." – Parent*



Although we are beginning to see movement in this space, there remains a compelling opportunity to address this unmet need.

**AAFA supports the integration of mental health services into primary and specialty care.**

With an integrated clinical and mental health care team, health care professionals can work together to support and treat the “whole patient.”

**Peer support**

Survey comments also reiterated the importance of peer-to-peer support—both for parents and for children—among families living with FA.

*“It’s important to have support and while [the] family tries being supportive, it would be nice to have support from other parents and kids experiencing the same thing—we understand each other.” – Parent*

AAFA provides a safe and secure online support community through our Kids With Food Allergies (KFA) division that largely focuses on providing a platform for peer-to-peer social and emotional support for parents. The KFA community provides evidence-based information and a safe environment for parents to learn and share about managing food allergies.

**AAFA encourages health care professionals to refer parents to our KFA community for support in managing day-to-day issues related to FA.**

## Unmet Needs in Education

Daily management of FA relies on strict avoidance of triggers and timely administration of emergency medicines in the event of a reaction. Because allergic reactions can be serious and life-threatening, patients and families must be educated in preventing reactions and prepared to treat reactions if they occur. It is critical that caregivers can identify anaphylaxis (a severe allergic reaction) and administer epinephrine (the only treatment for anaphylaxis).

**Anaphylaxis and epinephrine**

When asked why they did not use epinephrine during what they considered to be a “severe allergic reaction,” 42% of parents reported use of antihistamines instead. This data raises concern that some parents may not be prepared to properly identify and treat anaphylaxis according to clinical guidelines. Comments submitted by parents affirmed this concern.

*“I don’t think the explanation on when to use an auto-injector is clear enough. I still need more training on how to identify when to use one.” – Parent*

**AAFA advocates for increased food allergy patient and family education at the point of care as well as outside the clinical setting.**

We continue to develop and promote educational materials about identifying anaphylaxis and properly using life-saving epinephrine.

We also encourage the use of Anaphylaxis Action Plans for all children at-risk for anaphylaxis. With an action plan in place, it is critical for parents, school staff and others who care for the child to be aware of the plan and prepared to act if needed.



## Unmet Needs in Food Allergy Awareness

In written comments, parents expressed frustration with the lack of understanding and empathy from people who are not impacted by FA. Many parents felt that the need for better public awareness should be addressed through education. Subsequently, parents requested resources to help foster greater public understanding of the challenges faced by families living with FA.

*“Food allergies are a hidden disability and the mental anguish can be overwhelming. I wish more people were as empathetic to this life-threatening condition as they are with more overt disabilities.” – Parent*

Numerous strategies for heightening public awareness of FA have been implemented by AAFA and others. Public awareness campaigns are designed to educate about the daily challenges in managing food allergies in a society where food plays an integral part of so many activities. Large-scale public service announcements can be cost-prohibitive for patient advocacy groups.

***AAFA calls on the Centers for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH) to spotlight food allergy awareness in their public health initiatives.***

Public awareness is also generated through efforts by families living with FA. In written comments, parents requested resources to help guide conversations with others in order to increase knowledge and understanding of FA among those who are not personally impacted by the disease. Parents asked specifically for support in talking to other parents in the context of play dates, parties and similar social activities.

The need for additional resources such as conversation guides for parents of children with FA to help improve communications with others continues to be an area of opportunity.

The portrayal of food allergies in the media remains an area of concern for AAFA. Stereotyping children with FA as “weak” or using the disease as the punchline for jokes prevents the public from learning about the seriousness of FA and how to properly accommodate and care for someone with food allergies.

***AAFA urges professionals in the film and television industries to accurately portray food allergies and anaphylaxis in their storytelling.***

## Unmet Needs in Schools

Many parents shared concerns regarding the lack of proper FA policies and protocols in their child's school. In some cases, parents felt unsupported by school staff and helpless in protecting their child while at school. Parents expressed needing help with navigating school forms and reiterated a demand for proper FA education among school staff and better FA policies in schools.

*"We have struggled every year since our oldest started public school. School administrators and teachers need to be better educated about the risks of cross contact as well as the emotional impact of food allergies in young children." – Parent*

We provide resources for parents and school staff—including our Teal Classroom Kit and School Planning Tips—to help support children with FA while at school. These resources align with the CDC's "Voluntary Guidelines for Managing Food Allergies in Schools."

***AAFA encourages schools to establish a comprehensive food allergy policy that follows the CDC's Voluntary Guidelines for Managing Food Allergies in Schools.***

In accordance with the CDC's voluntary guidelines, AAFA urges that schools take measures to:

- Properly train school staff on administering epinephrine
- Stock undesignated epinephrine for use in case of emergency
- Encourage and cultivate inclusiveness in the classroom with non-food rewards and avoidance of food in lesson plans
- Ensure each child with FA has a filed Anaphylaxis Action Plan, Individualized Health Care Plan (IHCP) and/or 504 Plan
- Implement a zero-tolerance policy for FA bullying

## Unmet Needs in Labeling Laws and Policies

Currently, the standard of care for FA requires strict avoidance of allergens. This means that parents of children with FA must be able to accurately identify potential allergens in all foods and products.

The Food Allergen Labeling and Consumer Protection Act (FALCPA), a federal law that was passed in 2004 and took effect in 2006, sought to ensure clearer labeling of foods so that people impacted by FA could identify allergens quickly and easily. FALCPA applies to foods regulated by the FDA and requires that all added ingredients are listed on food labels and that the top eight allergens are identified in plain language.

Despite the regulations set by FALCPA, there are a number of labeling issues that continue to burden the FA community.

### Sesame allergy

The major eight allergens as defined by FALCPA are peanuts, tree nuts, milk, eggs, fish, crustacean shellfish, wheat and soy. Sesame seed allergy prevalence has been increasing in the United States, with recent studies suggesting it is more prevalent than wheat or soy allergies. Sesame ingredients are not required to be declared in plain language and so they can hide in foods as "benne", "tahini", "gingelly" or even "natural flavorings". This makes sesame an allergen that is difficult to identify and avoid.

***AAFA advocates for adding sesame to the list of major allergens that must be declared in plain language on food ingredient labels. We urge the FDA to use its regulatory authority to add sesame to the list of major allergens.***

As sesame continues to gain attention as a top allergen among our community, sesame labeling remains a priority advocacy issue for AAFA and other stakeholders:

- 2004 - The Food Allergen Labeling and Consumer Protection Act (FALCPA) passes requiring the top 8 major food allergens to be labeled in plain language.
- 2006 - FALCPA goes into effect for all FDA-regulated food produced on or after Jan. 1, 2006.
- 2008 - Sesame starts to gain attention as a top allergen in the U.S. and in the KFA Community.
- 2014 - Center for Science in the Public Interest (CSPI) submits a Citizen Petition to the FDA asking them to require sesame products be regulated as a major allergen.
- 2015 - Food Labeling Modernization Act (FLMA) is introduced to the 114th Congress. It includes a provision to add sesame to the list of major food allergens.
- 2017 - AAFA/KFA and CSPI co-write a letter to FDA in support of the 2014 Citizen Petition asking for sesame labeling. We ask our community to do the same.
- 2018 - The FLMA is reintroduced to the 115th Congress.
- 2018, June - AAFA/KFA ask our community to send us their experiences with allergic reactions to sesame.
- 2018, August - AAFA seeks regulatory solution directly by meeting with the FDA. AAFA shares printed copies of dozens of stories from our community. The FDA says it needs more data.
- 2018, September - AAFA, CSPI and other allergy advocacy groups (APFED, FAACT, FARE and others) form a coalition to advance sesame labeling.
- 2018, October - AAFA develops a survey for people to send requested data to the FDA. The CSPI launches a different but similar survey. Together, over 500 adverse reports are submitted to the FDA.
- 2018, November - AAFA meets with representatives of Congressional Asthma and Allergy Caucus to garner support for the inclusion of sesame on food labeling.
- 2018, November - Congressional Asthma and Allergy Caucus sends a letter prepared by AAFA to FDA Commissioner Gottlieb urging the addition of sesame to the list of major food allergens.
- 2019 - FASTER Act is introduced in 116th Congress.
- 2019 - New research estimates that 0.2% of children and adults in the U.S. have sesame allergy (similar prevalence to pistachio and soy).<sup>5</sup>

*"In addition to our growing concerns about sesame allergies, this request for information is designed, in part, to help inform our response to a citizen's petition to the FDA from medical professionals and consumer advocacy groups who asked us to require that sesame-based ingredients be listed specifically by name on the ingredient lists of all food labels. We take the concerns of people with sesame allergies seriously."*

*- FDA Commissioner Scott Gottlieb, 2018*

AAFA is meeting with the FDA again in August 2019 to discuss progress on sesame labeling and to ask for the Acting Commissioner of the FDA, Norman Sharpless, MD, to support the work started by former Commissioner Gottlieb.

**AAFA also supports legislative action to add sesame as a major allergen. We urge Congress to pass the FASTER Act of 2019 or other legislation that amends FALCPA to include sesame.**

If it becomes law, the FASTER Act (for Food Allergy Safety, Treatment, Education and Research) would achieve the following goals:

- Collection of food allergy data: The FASTER Act would direct HHS to increase the collection of information on the prevalence of food allergies, including through existing CDC national health surveys.
- Sesame labeling: The bill would extend FALCPA allergen labeling requirement to sesame (see discussion above).
- Patient experience: The FDA would be required to incorporate patient experience information in regulatory decision-making regarding food allergies.
- Economic costs: The NIH would be required to commission a report on the economic costs of food allergies for families and nationally.

### Precautionary allergen labeling

Survey comments also confirmed that the lack of standardized regulation around precautionary allergen labeling leads to increased anxiety and fear among parents and makes it more challenging to navigate daily life with FA. Precautionary allergen labels are voluntary and manufacturers use non-standard phrases to warn consumers about possible cross contact with potential allergens due to shared equipment or shared facilities.

May contain...

Produced on shared  
equipment which  
also processes...

Made in a facility  
that also processes...

*“The FDA really needs to make it mandatory for all products that are made in shared lines and in same facilities to be labeled. This would give back hours and hours of time to parents calling and emailing companies.” – Parent*

*“Companies should be required to label all of their food ingredients. We just want to know if the product is safe. This applies to pet foods, people foods, personal care products and craft foods. We know food allergies are a problem. So, we should have transparent labeling of all food ingredients.” – Parent*

### **AAFA encourages the FDA to adapt an evidence-based, standardized and regulated approach to precautionary allergen labeling.**

Fear of cross-contact and accidental allergen exposure due to weak labeling laws necessitates significant time spent communicating with manufacturers to better understand the risk imposed by each product.

### Restaurants and dining out

Another limitation of FALCPA is that it does not apply to foods consumed in restaurants. One of the most challenging activities to navigate with FA continues to be dining out; this is due largely to the lack of standard regulations and policies for labeling and staff training in restaurants and other establishments that serve food.

*“After 9 years of managing [my son’s] allergies, I’m pretty confident on how to handle them. The only [need] I can think of is restaurants having better info available and training of staff. They don’t understand that cross contamination is a really big deal for some of us.” – Parent*

*“The food labeling is so confusing – I’m a physician and my husband is an attorney and it’s incredibly confusing. We need stricter regulations for this. Restaurants also need to have stricter guidance for allergies. Just like they are rated for cleanliness, they should be rated for how they accommodate food allergies.” – Parent*

*“Restaurants cater to specialty trend diets, there should be higher standards and awareness in restaurants to avoid cross contamination and label ingredients.” – Parent*



Six states – Maryland, Massachusetts, Illinois, Michigan, Rhode Island and Virginia – have passed laws increasing food allergy awareness and safety in restaurants, as have New York City and St. Paul, Minnesota. These laws all contain one or more of the following requirements:

- Placement of posters with information on food allergy in food service establishments, in appropriate languages for the region.
- Requiring training for food safety managers to include food allergy training.
- Inclusion of food allergy content and training in state regulations of restaurants.
- Requiring the state department of health to develop food allergy resources and training for restaurants.
- Designation of restaurants as “food allergy friendly,” with a publicly searchable database.

***AAFA supports passage of restaurant food allergy laws in all states, incorporating all the provisions above.***

Restaurants are a common location for adverse reactions to foods. Making restaurants safer could reduce preventable reactions, including death, and allow people with food allergies to engage more fully in social activities with their family and friends with less fear and stress.

**Allergens in non-food products not regulated by the FDA or covered by FALCPA**

When children are young, they are more likely to put their hands in their mouths and/or put non-food items in their mouths. However, products such as personal care products and craft items are not required to plainly list their ingredients.

*“The main burden is time. We email and follow up about all foods, personal care products and arts & crafts.” – Parent*

*“[Allergens such as] wheat, corn, rice, oats, and cocoa are in many health and beauty products, and corn is in almost everything, including many fragrances and household cleaners, toothpastes, shampoos, soaps, etc. Allergies to these foods involve much more than simply avoiding the food.” – Parent*

*“The time and expense of having to provide homemade wheat-free play dough the entire time my kid was in preschool. Having to explain to teachers how food products are not a great thing to use for art supplies. Trying to convince schools to find alternatives to food as learning tools (candy, etc.) or food as treats.” – Parent*

AAFA provides lists and travel cards for “hidden names of allergens” to help parents of young children identify potential allergens in products. We also offer a list of craft supplies that may contain allergens and possible substitutions to replace those products.

When children are older, alcoholic beverages become a concern. FALCPA’s allergen labeling requirements only extend to those products that FDA regulates and therefore do not apply to alcoholic beverages, which are regulated by the U.S. Department of the Treasury (USDT) which oversees the Alcohol and Tobacco Tax and Trade Bureau (TTB).

Wines, distilled spirits and beers can contain undisclosed allergens, either used as processing agents or as ingredients.<sup>6</sup>

Allergen labeling on alcohol is voluntary, creating gaps and confusion for consumers. When someone is under the influence of alcohol, it also impacts their response time and decision making. For these reasons, alcohol poses additional risks to young adults with food allergies.

***AAFA champions policy efforts to make allergen labeling for all products (including USDT-regulated alcoholic beverages and USDA-regulated meat, poultry and egg products) consistent with those in place for FDA-regulated products.***

AAFA continues to fight for better allergen labeling laws in the U.S. We recently submitted public comments to the TTB on the proposed rule “Modernization of the Labeling and Advertising Regulations for Wine, Distilled Spirits, and Malt Beverages.” Our comments called for the TTB to move quickly to modernize the allergen labeling regulations for wine, distilled spirits and malt beverages, aligning the regulations with the labeling requirements for food as regulated by the FDA under FALCPA.

## Unmet Needs in Financial Support

FA imposes a significant economic burden on society as a whole, but “unlike other common childhood diseases in which most costs are borne by the healthcare system, childhood food allergy disproportionately burdens family finances.”<sup>2</sup>

Expenses related to caring for a child with FA include direct costs (such as out-of-pocket costs of medical copays and specialty foods) and indirect costs (such as lost wages and lost opportunities). The findings from our survey confirm that such expenses can pose a significant burden on a family’s finances. In addition to multiple-choice questions about direct and indirect costs, parents were invited to submit optional comments about the impact of FA on their family’s finances.

Unsurprisingly, there remains a substantial opportunity for lawmakers/policymakers, health care payors and food and drug manufacturers to help relieve some of the financial burden of FA.

### Direct Medical Costs

The medical costs for managing FA include cost of medication (epinephrine), cost of clinical visits (primary and specialty care) and cost of lab tests and oral food challenges. The out-of-pocket costs for these expenses are dependent on each patient’s health care coverage.

In written comments, parents shared their experiences with these medical costs, often adding commentary about their specific coverage.

*“I don’t think the cost of [my son’s] last skin test was covered by our insurance too well. Out of pocket was about \$500. Unfortunately, we are still paying that off before he goes back to the allergy specialist.” – Parent*

*“The cost of epinephrine is outrageous. I need three; one for the bus, one for the nurse, and one for at home. You pray to never use them and when they expire in 18 months or less, it’s devastating to throw out \$1000+ of expired medication.” – Parent*

*“How will my child transition to paying for all of this as a young adult?” – Parent*

*“We are heavily in debt from years of testing, hospitalization, medications and allergen-free foods. We make too much money to qualify for medical assistance, so all of the financial burden has rested entirely on us.” – Parent*

AAFA applauds pharmaceutical companies, state programs and nonprofits that offer patient assistance programs providing free or low-cost medicines. Despite these existing programs, many parents of children with FA report barriers in paying for epinephrine, highlighting the continued need for financial support programs for FA.

**AAFA supports transparency in drug pricing and encourages continued and expanded programs designed to alleviate out-of-pocket costs for epinephrine.**

Like epinephrine, the out-of-pocket costs of clinical visits, lab tests and oral food challenges vary from person to person and are largely subject to individual health care coverage and formulary. For some families, these expenses become cost-prohibitive and result in avoidable burdens and worsened health outcomes.

When a child is diagnosed with potentially life-threatening food allergies, this diagnosis affects many aspects of the child's and family's quality of life. The many precautions that must be taken in order to avoid the allergen can be quite challenging and stressful. If the child is allergic to multiple foods, the diet must be carefully monitored to avoid malnutrition and the potential development of an oral aversion (i.e., the reluctance or fear of eating a food).

Getting an accurate diagnosis is therefore critical. Oral food challenges are the gold standard for food allergy diagnosis. These tests are done under clinical supervision and are the only way to confirm if a patient has outgrown their food allergy.

*"We do not have adequate insurance to cover allergy costs. We do not get allergy shots currently because of it, and we don't orally challenge foods that we could." – Parent*

*"The food challenges/ER visits and ambulance rides have cost us thousands out of pocket. The last food challenge was \$600 out of pocket and that was our fifth food challenge. We have many follow-ups with the allergist and are fortunate that it is only an hour away (to see one of the top pediatric allergists) but it still is an out of pocket and travel expense. I never anticipated the financial burden of this disorder." – Parent*

Food avoidance should not be done unless it is necessary because of the significant negative impact on quality of life and financial well-being for families with FA.

**AAFA calls for increased health care coverage of necessary clinical tests (such as oral food challenges) for the diagnosis of food allergy.**

**Specialty Food Costs**

The cost of providing safe meals for children with FA can be unexpectedly high for many families. Allergy-friendly foods are often priced higher than comparable versions of the food and are challenging to find at convenient grocery stores. Additionally, some parents choose to keep their child's food allergens out of the house and feed their entire family (including those without FA) foods that are safe for their child(ren) with FA.

Because of these reasons, the cost of providing safe foods for children with FA can add up quickly. Written comments provided insights to the burden of FA on families' grocery costs.



*“Buying allergen-friendly foods for my son more than doubled my weekly grocery bill and it is very difficult to eat out as a family.” – Parent*

*“More financial resources are necessary. Our grocery budget is blown because of the cost of purchasing allergy free foods.” – Parent*

*“Financial help lacks, no help with the cost of special foods available unless one were to qualify for food stamps or assistance such as that. Makes it difficult when you make too much but then the amount spent on food and epinephrine and other needs takes a big toll on your finances.” – Parent*

IRS Publication 502 states the cost of special food can be deducted as itemized expenses only if the food alleviates or treats an illness and the need is substantiated by a physician. To qualify for deductions people must itemize and the amount of allowable medical expenses must exceed 10% of adjusted gross income before the deductions can be claimed. The amount that can be included is limited to the portion of the special food cost that exceeds the cost of a normal diet. There are other considerations for what can be deducted and so it is recommended to consult with a tax preparer or accountant when calculating deductions.

*“When my son was a baby and allergic to every formula, we had a much lower income. We couldn’t afford to get his formula without assistance from the formula company.” – Parent*

*“The cost of formula related to her EoE [is a major expense]. She receives this supplement as it is allergen free (she is allergic to milk and the soy triggers her EoE) and her growth was poor.” – Parent*

**AAFA recommends better and clearer tax deductions for medical expenses such as allergy-safe foods and formulas.**



**Lost Career and Work Opportunities**

With nearly half of parents reporting that they have made a career change decision based on food allergies, it is a staggering prospect to quantify the impact on a family’s long-term financial stability. Survey findings suggest that women have shouldered a large burden in lost economic and personal development opportunities with many mothers reporting they have left their jobs to care for their child(ren) with FA.

Parents also miss workdays to care for their child with FA. In the last year, 56% reported missing work; this jumped to 85% of parents with children with EoE reporting missing work. Unpaid leave puts an additional financial strain on families who are already bearing a large financial burden.

*“The adjustments I’ve had to make in my life, like quitting my job and working from home with a major pay decrease, in order to accommodate the needs and safety of my daughter has been the largest financial struggle. It was impossible to deal with her needs and safety while holding down a workplace job.” – Parent*

*“I work part time so I only missed 3-4 days [in the past 12 months]. However, during the six months of his many hospitalizations, I may have needed to take short term disability to accommodate all the days I would have missed. He had MANY food challenges, doctor appointments and hospitalizations.” – Parent*



## Unmet Needs in Research

Throughout the survey, parents reported and acknowledged a generally low awareness of clinical trials and latest research in FA. Respondents also expressed a common desire to be better-informed about these research updates and opportunities.

These comments present a clear opportunity for patient groups like AAFA to work closely with the medical community and research partners toward increased involvement of patients and family members (P/FM) in FA research. We strongly recognize the benefits of P/FM involvement in all stages of research. Studies that include P/FM representation in research prioritization, design, recruitment and evaluation are better equipped to address the outcomes most important to the FA community.

***AAFA upholds patient-centered and patient-included research and advocates for the development of patient-reported outcome measures that matter most to the people living with food allergies.***

AAFA developed a Patient and Family Advisory Council (PFAC) to guide the development of our own research projects as well as to connect external researchers with P/FM advisors. We engage patients and caregivers throughout our research process as full research partners.

We are in the process of building out a scalable infrastructure to connect patients and researchers in a more systematic fashion. Our aim is to encourage researchers to establish relationships with patient partners.

At the same time, we are launching a new clinical trials database to inform patients and parents of current studies that they may qualify for.

Low clinical trial enrollment is often a cause for delayed research. By matching researchers to patients based on location, age and food allergy, we can provide pivotal advancements in food allergy treatment, prevention and cures.





## Summary of Unmet Needs and Opportunities

The table below summarizes the unmet needs and opportunities presented in this report.

Unmet needs (for parents of children with FA)	Opportunities (for AAFA and other stakeholders)
Lack of mental health support	<ul style="list-style-type: none"> <li>Promote awareness of mental health professionals with FA knowledge</li> <li>Integrate mental health services for family into primary and/or specialty care</li> <li>Advocate for access to and coverage of mental health services</li> </ul>
Lack of peer-to-peer emotional and social support	<ul style="list-style-type: none"> <li>Refer parents to reputable online support groups like AAFA/KFA</li> <li>Develop social support and resources for parents managing EoE</li> </ul>
Lack of knowledge of proper use of epinephrine	<ul style="list-style-type: none"> <li>Educate parents to better identify anaphylaxis and properly administer epinephrine</li> </ul>
Lack of public awareness and understanding	<ul style="list-style-type: none"> <li>Develop resources to help parents of children with FA better educate and communicate with others</li> <li>Launch local and national campaigns to increase awareness of FA challenges among the public</li> <li>Increase accurate representation of FA in media</li> </ul>
Lack of school policies to support children with FA	<ul style="list-style-type: none"> <li>Encourage application of CDC voluntary guidelines for FA management in schools</li> <li>Foster inclusiveness of students with FA</li> <li>Provide ongoing FA training for school staff</li> </ul>
Lack of comprehensive labeling laws	<ul style="list-style-type: none"> <li>Advocate for inclusion of sesame as a major allergen</li> <li>Advocate for better precautionary advisory labeling</li> <li>Advocate for food allergy safety policies in restaurants and allergen labeling on menus</li> <li>Increase awareness of food allergens in non-food products such as craft supplies and hygiene items</li> <li>Advocate for labeling of allergens in alcohol</li> </ul>
Lack of financial support	<ul style="list-style-type: none"> <li>Advocate for drug pricing transparency and patient assistance</li> <li>Advocate for increased health care coverage of treatments and diagnostic tests for food allergy</li> <li>Facilitate easier use of tax deductions</li> </ul>
Lack of awareness of and involvement in clinical trials and research	<ul style="list-style-type: none"> <li>Promote patient engagement on Patient and Family Advisory Councils</li> <li>Strengthen infrastructure to connect patients and researchers</li> <li>Provide regular updates and outreach to families regarding trials and research</li> <li>Develop patient reported outcome measures important to people living with food allergies</li> </ul>

Identifying these unmet needs and opportunities is only the beginning. Collaboration between patient organizations, patients and caregivers, health care professionals, policymakers, payors, government and regulatory agencies, food and drug manufacturers, school systems and the general public is critical in reducing the burden of FA on families and society.

## Looking Ahead

This is an unprecedented time for FA. The prevalence and awareness of FA continue to increase, as do the breakthroughs in research and emergence of first-of-their-kind treatments. In this rapidly changing landscape, AAFA remains committed to supporting families with FA through our research, advocacy, education and support programs. Seeking insights from patients and caregivers is critical to AAFA's mission and ensures that the patient voice is at the center of our work.

The data presented in this report constitute only a selection of data collected from patients and caregivers in AAFA's three-part "My Life With Food Allergy" study. Further insights from the two patient surveys will be presented and analyzed in a separate report.

"My Life With Food Allergy" parent survey is only a snapshot of our continued commitment to serving the FA community. We welcome partnerships with all stakeholders and look forward to continuing to fight on behalf of patients and families living with FA.



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## Disclosures and Conflicts of Interest

Michael Pistiner: consultant for kaléo, DBV Technologies and Allergenix; recipient of grants from kaléo, National Peanut Board and DBV Technologies; Co-founder AllergyHome and Allergy Certified Training; and member of the Medical Advisory Board for AAFA New England.

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## Special Thanks

### Nicole Gaghan

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### Kimberly Rafferty

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## DBV Technologies

The "My Life With Food Allergy" parent survey is an independent research project of the Asthma and Allergy Foundation of America with support from DBV Technologies. **The editorial content in this report represents the views of AAFA only.**

## ABOUT AAFA

Founded in 1953, AAFA is the oldest and largest non-profit patient organization dedicated to saving lives and reducing the burden of disease for people with asthma, allergies and related conditions through research, education, advocacy and support. AAFA provides practical health information and community-based services. Through its Kids With Food Allergies (KFA) division, AAFA offers the most extensive online support community for families raising children with food allergies. For more information, visit [aafa.org](http://aafa.org) and [kidswithfoodallergies.org](http://kidswithfoodallergies.org).