2016

Parental therapy preferences for children with food allergy

Siracusa, Mary Lizetta

http://hdl.handle.net/2144/17024
Boston University
Thesis

PARENTAL THERAPY PREFERENCES FOR CHILDREN WITH FOOD ALLERGY

by

MARY L. SIRACUSA

B.S., University of Michigan, 2014

Submitted in partial fulfillment of the requirements for the degree of
Master of Science

2016
First Reader

Jean L. Spencer, Ph.D.
Instructor of Biochemistry
Boston University School of Medicine

Second Reader

Ruchi S. Gupta, M.D.
Associate Professor of Pediatrics
Ann & Robert H. Lurie Children’s Hospital of Chicago
Northwestern University Feinberg School of Medicine
ACKNOWLEDGMENTS

I would not have been able to complete this research without the support and guidance of my first and second readers, Dr. Jean Spencer and Dr. Ruchi Gupta. I would also like to thank Maggie Yarbrough, Dr. Bridget Smith, and Dr. Alana Otto for assisting me throughout this process. Finally, I would like to thank Northwestern University and the mothers of children with food allergy who participated in this study.
ABSTRACT

Background: Pediatric food allergy is increasing in prevalence, and a number of potential immunotherapies are being developed in an attempt to address this health issue. However, there have been no studies investigating parental concerns and priorities regarding selecting a potential immunotherapy for their child.

Objectives: To describe parental immunotherapy preferences and the factors influencing those preferences.

Methods: A survey was developed to understand parental food allergy therapy preferences. Cognitive interviews were performed with parents of food-allergic children (n = 6) to ensure the feasibility and comprehensibility of the survey. The online survey was then disseminated to parents of children with food allergies via social media venues from February 1, 2016 to March 7, 2016 (N = 246). Descriptive statistics were used to report and analyze the attitudes and perceptions of parents considering enrolling their child in a food allergy therapy.

Results: Among parents of food-allergic children, 50% (n = 123) reported that if food allergy therapies were made publicly available, they would enroll their children in a
therapy. Survey data demonstrated that 69.5% (n = 171) of participants ranked epicutaneous immunotherapy (EPIT) as their first choice, (22.8%, n = 56) ranked oral immunotherapy (OIT) as their first choice, and 7.7% (n = 19) ranked sublingual immunotherapy (SLIT) as their first choice. The majority of parents (62.60%, n = 154) cited the safety profile of a specific therapy as the principal factor influencing their choice of preferred immunotherapy.

**Conclusion:** This study suggests that many parents would choose to enroll their children in a food allergy therapy if given the opportunity. The majority of parents participating in this study preferred EPIT to OIT and SLIT. Though comfort and efficacy are important factors when choosing an immunotherapy, the principal concern of participants was the safety profile of the therapy.
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LIST OF ABBREVIATIONS

AAFA..............................................................Asthma and Allergy Foundation of America
AAN.................................................................................Allergy & Asthma Network
AE ..............................................................................Adverse Events
EOE..............................................................................Eosinophilic Esophagitis
EPIT ...........................................................................Epicutaneous Immunotherapy
IgE.............................................................................Immunoglobulin E
IRB..............................................................................Institutional Review Board
LEAP...........................................................................Learning Early About Peanut
MOCHA.................................................................Mothers of Children Having Allergies
OFC........................................................................Oral Food Challenge
OIT..........................................................................Oral Immunotherapy
SLIT........................................................................Sublingual Immunotherapy
INTRODUCTION

Food allergy is an adverse reaction of the immune system that occurs when exposed to a certain food (Boyce et al., 2010). In the United States, an estimated 8% of children have a food allergy, and evidence suggests the prevalence is gradually increasing (Gupta et al., 2011). Although many food-allergic reactions are mild, almost 40% of children with food allergy have experienced life-threatening reactions, most often with peanuts, tree nuts, and shellfish (Gupta et al., 2011; Lanser et al., 2015). Severe reactions can include respiratory, gastrointestinal, and cardiovascular system compromise, as well as skin and mucosal tissue symptoms. These reactions are referred to as “anaphylaxis” when two or more systems are affected (Welch et al., 2015). If left untreated, anaphylactic reactions can be fatal. Children with food allergy are also at increased risk for comorbid atopic conditions, such as asthma and atopic dermatitis. In addition to its impact on physical health, food allergy can have significant social and psychological effects on children and their caregivers; it is often associated with social limitations and impaired quality of life (Boyce et al., 2010; Gupta et al., 2011).

Eight foods account for nearly 90% of all food allergens in the United States. These eight foods are peanuts, tree nuts, milk, eggs, soy, wheat, fin fish, and shellfish (Kulis et al., 2011). Peanut allergies are most prevalent, affecting 24.8% of children with food allergies (Dyer et al., 2015). The prevalence of peanut allergy has steadily increased over time, and patients seldom outgrow allergies to peanuts (Anagnostou et al., 2014). Conversely, both egg and milk allergies are frequently outgrown.
The diagnosis of food allergy involves the measurement of specific serum immunoglobulin E (IgE) levels, elimination diets, skin prick tests, and oral food challenges, as well as a careful study of the patient’s medical history (Sicherer et al., 2006). The mainstay of food allergy management involves the avoidance of allergens in an attempt to prevent reactions. Avoidance, however, is often difficult to achieve because of factors such as cross-contact and hidden exposures (Sicherer et al., 2014). Food-allergic patients at risk for anaphylaxis are encouraged to carry epinephrine auto-injectors to treat the symptoms of an allergic reaction (Simons et al., 2011). Antihistamines may also be used to ameliorate symptoms, but they are not sufficient to treat an anaphylactic reaction and should not be used as a replacement for epinephrine.

The prevention of food allergy is a topic of active investigation. To date, few preventive strategies have proven beneficial. Current evidence suggests that maintaining a healthy, varied diet during pregnancy, without eliminating potential allergens, may reduce the risk of future food allergy in the fetus (Sicherer et al., 2014). The LEAP (Learning Early About Peanut) study, performed by DuToit (et al., 2015), demonstrated that infants exhibiting certain high risk factors for developing a peanut allergy (e.g., positive skin prick tests, severe eczema) benefit from early exposure to peanut. The study found that early and regular consumption of peanut products reduced development of peanut allergy among this population of children (DuToit et al., 2015). The investigators of this clinical trial proposed that early introduction of peanut products may elicit a protective immune response and that deliberate allergen avoidance may not be an effective strategy to impede the development of allergy.
Although epinephrine may be used to treat anaphylaxis in case of accidental exposure, there is no cure for food allergies. However, promising therapies are currently being studied. The goal of these studies is to desensitize patients by stimulating the immune system with steadily increasing doses of allergen. Eventually, patients may develop a tolerance for their allergen. Sustained unresponsiveness may be induced as a result of the therapy. This is determined by the patients’ ability to undergo an oral food challenge (OFC) without symptoms of an allergic reaction and to introduce the allergen into their diet after immunotherapy (Vickery et al., 2015).

Of the immunotherapies being tested, significant progress has been made with oral immunotherapy (OIT), sublingual immunotherapy (SLIT), and epicutaneous immunotherapy (EPIT) (Jones et al., 2014). These therapies are not currently available to the public but have demonstrated varying levels of effectiveness. Although multiple clinical trials have examined the safety and efficacy of these three potential treatments, to date, there has not been a study investigating the therapy preferences of participants in these clinical trials.

**Oral Immunotherapy (OIT)**

During OIT, patients ingest small doses of their food allergen, usually in the form of a powder, under medical supervision (Trendelenburg et al., 2014). The ingested dose is gradually increased over a period of time. OIT clinical trials have been performed for many food allergens, but the majority of studies have investigated peanut, cow’s milk, and egg protein. Although clinical trials have varied in method, OIT is generally
comprised of three phases: escalation, build-up, and maintenance (Figure 1) (Vickery et al., 2014).

During the initial escalation phase, subjects ingest small amounts of allergen protein in a clinical setting. In many studies, this dose is increased over specific time increments until a maximum dose is reached. The initial escalation phase commonly occurs over a seven-hour period, with 30-minute dosing intervals. The patient is observed in clinic for a minimum of two hours after ingestion and then discharged with an epinephrine auto-injector.

During the build-up phase, patients are given daily doses of their allergen. Doses are increased every two weeks until a maximum dose is reached. To an extent, the dosing and timing are at the discretion of the physician based on the patient’s reaction history, though a maximum dose of 5000 mg is common in many OIT trials (Vickery et al., 2014; Burks et al., 2012; Varshney et al., 2011). Depending on the study procedure, the build-up phase is performed either predominantly at home, with periodic clinic visits to increase the dosage, or during regular clinic visits. The build-up phase generally lasts six to nine months.

The maintenance phase of OIT occurs when patients are sufficiently desensitized to safely ingest a target dose of allergen. Patients continue to consume specific daily doses of their allergens, often at home, to maintain desensitization. The maintenance phase is often followed by OFC to assess sustained unresponsiveness (Varshney et al., 2011).
Figure 1: OIT Study Design. This time course outlines the phases of oral immunotherapy for one particular study, an investigation of the efficacy and safety of peanut OIT. The initial escalation phase was not included in this study. The arrows indicate a double-blind placebo-controlled oral food challenge. Original image from: Michaud et al., 2015.

OIT Variations

Variations of OIT include modifications in procedure, such as timing between doses, phase length, or setting of the build-up phase (home vs. clinic). Additional studies have evaluated the effects of OIT for multiple food allergens and have combined OIT with probiotic and asthma medication administration.

A study performed by Begin (et al., 2014) concluded that multiple-allergen OIT is both relatively safe and a feasible option for patients with multiple food allergies. Another investigation focused on the effect of multiple-allergen OIT on health-related quality of life found that multiple-allergen OIT improves health-related quality of life and
may relieve some of the psychosocial and economic burden imposed by a food allergy (Otani et al., 2014). More studies are needed to determine the efficacy and safety profile of multiple-allergen OIT.

A recent study examined the effects of peanut OIT combined with a probiotic, with the hypothesis that the combination of allergen protein and bacterial adjuvant would increase sustained unresponsiveness to peanut protein (Tang et al., 2015). Although the coadministration of probiotics was effective in inducing sustained unresponsiveness, further studies are required to conclusively attribute desensitization to the probiotics.

Clinical studies investigating the effect of omalizumab, a monoclonal antibody to IgE commonly used to treat asthma, on OIT have also been performed. In a trial involving multiple food allergens, omalizumab was administered to patients eight weeks prior to and eight weeks following a “rush OIT” (Bégin et al., 2014). Rush OIT follows a procedure similar to conventional OIT trials but involves a rapid increase in allergen dosing. This study found that administration of omalizumab before and after multiple-allergen rush OIT facilitated rapid desensitization. A second omalizumab OIT study was performed with participants allergic to cow’s milk (Wood et al., 2015). The addition of omalizumab significantly decreased adverse reactions during OIT escalation but did not significantly improve desensitization or sustained unresponsiveness.

**OIT Results**

The majority of OIT studies have yielded positive results, though these studies have not used consistent outcome measures (Trendelenburg et al., 2014). Sustained
unresponsiveness to an allergen has been demonstrated in multiple studies, including clinical trials for peanut and egg allergies (Vickery et al., 2014; Burks et al., 2012). One study found that peanut OIT decreased subjects’ peanut-specific immune response and that 50% of subjects were able to successfully integrate peanuts into their regular diet (Vickery et al., 2014).

A review of multiple OIT studies found that after therapy, 61%-100% of participants achieved a 5- to over 1,000-fold increase in their maximum tolerated allergen doses (Trendelenburg et al., 2014). However, further studies are needed to determine the effect of OIT on long-term tolerance outcomes.

*OIT Side Effects*

OIT is associated with a number of acute and long-term adverse events (AEs), including anaphylaxis (Thyagarajan et al., 2010). Although many clinical trials have noted severe AEs associated with OIT, different grading systems have been used to define severity (Trendelenburg et al., 2014). Compared with SLIT and EPIT, OIT is associated with the most frequent acute AEs, such as abdominal pain and vomiting.

Long term, OIT has also been associated with new-onset eosinophilic esophagitis (EOE) in 2.7% of OIT participants (Lucendo et al., 2014). EOE is an inflammatory condition in which large numbers of eosinophils collect within the esophagus (American Academy of Allergy, Asthma, & Immunology, 2016). Children with EOE often experience dysphagia, food impaction, and gastroesophageal reflux disease-like symptoms, which include heartburn, chest pain, and regurgitation (Furuta et al., 2007).
Further symptoms include failure to thrive and diarrhea. Diagnosis of EOE requires endoscopy and biopsy of esophageal tissue. EOE is a chronic condition with no known treatment, though glucocorticoids and proton pump inhibitors have been found to alleviate some symptoms.

**Sublingual Immunotherapy (SLIT)**

SLIT is fairly similar to OIT in terms of procedure. During SLIT, the patient’s allergen protein is dissolved in a liquid. Patients administer the diluted allergen with a dropper under their tongue, wait for one to two minutes, and then swallow the solution (Calderon et al., 2012). In some variations, the patients spit out the allergen solution (Cox et al., 2006). Like OIT, this therapy begins with a relatively low allergen dose and is repeated over a period of time using increasing doses. SLIT trials have had greater discrepancies in dosing frequency than OIT trials. Administration of the allergen protein can vary from daily to every few days, and an optimal rate of dosing has not been established. There is also considerable variation in total procedure time, which largely depends on the allergen.

A potential benefit of SLIT is that the allergen proteins are directly absorbed by the oral mucosa (Novak et al., 2011); the proteins bypass gastric digestion, which may reduce gastrointestinal anaphylactic symptoms (Narisety et al., 2012). In addition, the amount of allergen protein used as the maintenance dose in SLIT clinical trials is generally much smaller than the amount used in OIT trials (usually 2500 mg), and this
reduced dose may account for the lower incidence of AEs (Chin et al., 2013; Jones et al., 2014).

**SLIT Results**

A review of SLIT clinical trials reported that in 14 of 39 trials (35%) there was significant improvement in both symptoms and amount of anti-allergic medications needed by participants after one year, compared with those in a placebo or randomized control group (Cox et al., 2006). In the long-term follow-up of a randomized multicenter trial of peanut SLIT, 98% of peanut protein doses were tolerated after 2 years of daily SLIT therapy, with significantly decreased immunologic activity (Burks et al., 2015). The dose of peanut protein given was a 10-fold increase from baseline threshold. There were no AEs reported with the exception of oropharyngeal symptoms, and epinephrine was not administered to any of the study participants. By the end of the third year, however, over 50% of participants had discontinued daily therapy and only 10.8% of participants remained fully desensitized to the peanut protein.

A study by Fleischer et al. (2013) found that the majority of subjects reached a modest level of desensitization after peanut SLIT. This study also demonstrated that patients who participated in SLIT for a longer duration of time were able to consume significantly higher doses of allergen. However, SLIT has been less effective than OIT in clinical trials measuring increase in threshold and number of desensitized patients (Trendelenburg et al., 2014).
**SLIT Side Effects**

One review found that AEs associated with SLIT were mostly local and mild (e.g., oropharyngeal symptoms) (Trendelenburg et al., 2014). Although there have been reports suggesting the development of EOE in predisposed individuals after participation in SLIT clinical trials for pollen, no studies have confirmed a causal relationship (Miehlke et al., 2013).

A study that investigated SLIT for the treatment of peanut allergy reported that 63.1% of participants had no AEs after seven weeks of immunotherapy (Fleischer et al, 2013). Another study comparing the safety and efficacy of SLIT and OIT demonstrated that although the rates of AEs were comparable between SLIT and OIT, OIT participants experienced more systemic reactions (Figure 2) (Keet et al., 2012). For this reason, SLIT may be considered as an alternative to OIT for severely allergic patients at high risk for anaphylaxis (Trendelenburg et al. 2014). However, further studies are necessary to effectively compare the safety profiles of OIT and SLIT.
Figure 2: Study Design Comparing the Safety and Efficacy of SLIT and OIT. This study, which investigated the treatment of cow’s milk allergy, included both SLIT and OIT arms. The study found that while SLIT produces less systemic reactions in participants, it is less effective for allergy desensitization. Original image from: Keet et al., 2012.

**Epicutaneous Immunotherapy (EPIT)**

EPIT is a relatively new therapy compared to OIT and SLIT and is still in developmental stages. Unlike OIT and SLIT, EPIT involves continuous exposure to an allergen, which is absorbed locally through the skin (DBV Technologies, 2016). Patients participating in EPIT clinical trials apply a 4x4-centimeter adhesive patch coated with allergen either between the shoulder blades or on the inside of the upper arm. The patch contains a layer of dry allergen at its center, with a “condensation chamber” between the skin and the center of the patch (Figure 3) (DBV Technologies, 2016). This chamber allows water to accumulate, solubilizing the dry allergen and allowing it to pass into the epidermis. Because EPIT directly targets lymph nodes by way of Langerhans cells in the epidermis, there is no systemic exposure to the allergen, thus lessening the risk of systemic reactions (Jones et al., 2014). This allows patches to be administered at home.
without clinical supervision. A common study protocol involves applying a patch once every week and leaving it in place for 48 hours (Mondoulet et al., 2011).

**Figure 3: EPIT Mechanism of Action.** This diagram illustrates the different components of the patch, including the dry allergen layer and the condensation chamber. The figure also includes Langerhans cells in the epidermis, which are targeted by EPIT. Original image from: DBV Technologies, 2016.

**EPIT Results**

A study using mice test subjects by Mondoulet (et al., 2012) found that allergen-specific EPIT improved gastrointestinal symptoms induced by sustained oral exposure to the peanut allergen. Although multiple animal studies have demonstrated efficacy with EPIT, few human studies have been performed (Jones et al., 2014). The few published studies utilizing human subjects have reported mixed results.

A recent clinical trial measured desensitization in peanut-allergic children before and after 18 months of EPIT. They found an increase in desensitization in 40% of patients exposed to EPIT (DuPont et al., 2014). A follow-up investigation reported that one child maintained desensitization a year after discontinuing EPIT (DBV Technologies,
Conversely, a clinical pilot trial to test the effects of EPIT on children allergic to cow’s milk showed no significant increase in tolerance after three months (Senti et al., 2014).

**EPIT Side Effects**

EPIT is generally well tolerated by participants and has a low incidence of severe AEs, including anaphylaxis (Senti et al., 2014). Localized eczematous skin reactions are commonly reported at the application site, with symptoms typically persisting for several days (Jones et al., 2014). However, more studies are required to thoroughly understand the effects associated with EPIT.

**Specific Aims and Objectives**

This pilot study aims to identify specific factors influencing the therapy preferences of parents with food-allergic children. The results may be used to inform the further development of the previously mentioned investigative therapies (OIT, SLIT, and EPIT), as well as potential novel therapies.

The objectives of this pilot study are to:

1. Develop an online survey that will effectively discern parental preferences for food allergy therapy and the reasoning behind them;
2. Administer this survey to parents of food-allergic children via social media platforms and food allergy organizations; and
(3) Identify themes among parent responses.

This pilot study hypothesizes that:

(1) Although parental preference with regard to specific immunotherapies is influenced by a variety of factors, the most common factor reported by parents is the safety profile of the therapy; and

(2) Parental preferences with regard to desired outcomes of immunotherapy clinical trials vary by specific allergen(s).
METHODS

This study was approved as exempt by the Institutional Review Board (IRB) of Northwestern University in Chicago, IL. The study involved a cross-sectional survey administered electronically to parents of food-allergic children. The survey was initially designed and evaluated by members of Dr. Ruchi Gupta’s research team at Northwestern University Feinberg School of Medicine Center for Community Health using a rapid-cycle improvement method.

Study Population and Eligibility

Eligible participants for both cognitive interviews and survey participation were over the age of 18 and parents of at least one food-allergic child under 18 years of age.

Cognitive Interviews

Cognitive interviews were performed with parents of food-allergic children (n = 6) before full administration of the survey to ensure its feasibility and comprehensibility. Cognitive interview participants were recruited through an electronic mailing that identified the purpose of the study, the aims of the study, and the participant inclusion criteria. Participants were provided with the contact information of a research assistant and the principal investigator in order to participate in the cognitive interviews. This electronic mailing was sent to a representative at Mothers of Children Having Allergies (MOCHA), a Chicago-based advocacy group, and disseminated via its electronic mailing
list. Consent was obtained verbally prior to the cognitive interview. A draft of the survey in Microsoft Word 2013 format (Microsoft Corporation, Redmond, WA) was sent to cognitive interview participants in advance of their interviews. A cognitive interview script and rubric were used to maintain consistency across all interviews (Appendix 1). Interviews were conducted for 30-45 minutes during which participants were asked about the feasibility of the survey, the clarity and difficulty of questions and answer choices, and the logic and flow of the survey. Participants were asked if additional questions pertaining to preferences for food allergy therapy should be included.

Responses were audio recorded and then transcribed by a research assistant. Transcribed responses were subsequently analyzed using qualitative coding methods to identify common themes. A separate member of the research team coded each interview, and the principal investigator reviewed the data collected to ensure validity. The identified themes were used to revise the survey in an effort to improve its feasibility, comprehensibility, and flow.

Survey Administration and Data Collection

Following cognitive interviews, the revised survey (Appendix 2) was administered electronically to eligible parents through social media (i.e., Dr. Ruchi Gupta’s accounts on Facebook, SquareSpace, and Twitter), food allergy organizations (e.g., MOCHA, Asthma and Allergy Network [AAN], and American Foundation for Asthma and Allergy [AAFA]), and food allergy blogs (e.g., Grateful Foodie). The food
allergy organizations informed parents of this study through electronic mailing blasts and newsletters.

A request to waive written consent for the survey was made and approved by Northwestern University’s IRB. The research team believed that not requiring participants to provide their names enhanced their willingness to be forthcoming in their responses to survey questions. In lieu of written consent, the research team provided detailed information about the study within the recruitment mailing and included the team’s contact information for use by participants with questions or comments. The survey was distributed between February 1, 2016 and March 7, 2016. Individual participants were involved in the study for approximately 20-25 minutes.

Participant responses were collected exclusively from the survey. Participants’ identities and responses were kept confidential using a secure server maintained by Northwestern University.

**Survey Content**

The collected data included information regarding each child’s reported allergic reaction history and the family’s previous experiences with immunotherapy clinical trials. The data also contained parents’ thoughts on participation in immunotherapy clinical trials. The survey asked participants to rank their immunotherapy preferences and to complete a series of questions explaining their ranking. Additional information included each child’s age, gender, receptiveness to potential therapies, and demographic information.
Outcome Measures

The primary outcome was immunotherapy preference. The participants were asked to rank their first, second, and third choices of immunotherapy. A follow up question asked about participants’ reasons for selecting their first and last choices. In addition, if a participant’s child was already enrolled in a clinical trial, they were asked for the reason(s) they chose to enroll their child in that particular immunotherapy.

A secondary outcome measure was parent willingness to enroll their child in a clinical trial. This information was gathered in order to determine predictors for parents’ desire to pursue food allergy therapies through associations with the child’s allergy history and characteristics.

Data Analysis

Statistical analysis was conducted using Stata 14.0 (StataCorp, College Station, TX). Data from incomplete surveys were excluded from the analysis. Descriptive statistics were used to report demographic information (including age, gender, race, and household income). Descriptive statistics were also used to analyze food allergy therapy preferences and participants’ reasons for selecting a therapy as their first choice.

Chi-square tests were performed to examine associations between willingness to participate in a clinical trial and patient characteristics, including reported allergens, allergy severity, age, gender, race, ethnicity, and self-reported quality of life. Fisher’s exact tests were used for comparisons with small sample sizes. The association between
willingness to participate in therapy trials and parent report of the allergy’s impact on fear and quality of life was also examined.
RESULTS

Survey Development

Survey Length and Difficulty

All cognitive interview participants believed that the survey length was “Just Right.” Five of the six cognitive interview participants described the overall difficulty of the survey as “Easy” or “Somewhat Easy.” One participant believed that the survey was “Not Hard or Easy” due to difficulty reviewing the survey draft in Microsoft Word format (Microsoft Corporation, Redmond, WA).

Five of the six cognitive interview participants believed that the layout of the survey was easy to follow. One participant reported that “Part One” of the survey was difficult to navigate.

Additional Answer Choices

Cognitive interview participants believed that additional answer choices were needed to explain why they selected their most and least preferred immunotherapy. These choices incorporated considerations such as FDA approval, health care provider recommendation, possible long-term repercussions, and accessibility (e.g., geographic and scheduling availability, supervision requirements, affordability).

Cognitive interview participants also believed that information regarding efficacy and safety of the three immunotherapies was a necessary addition to their descriptions.
When asked, “What other treatments would you like to see made available?” participants requested additional information about potential treatments indicated in the answer choices (e.g., subcutaneous immunotherapy, vaccinations).

*Differences in Allergen Reporting*

In the first draft of the survey, participants were asked, “To what extent do you/does your child want to treat your child’s food allergy?” The answer choices included, “I want my child to be protected only against accidental ingestion” and “I want my child to be able to eat the food allergen as if they were not allergic.” Many cognitive interview participants had difficulty answering this question and desired an additional answer choice allowing a possible intermediate outcome. One participant stated that because their child was allergic to many foods, the answer to the question was allergen-dependent. Another participant noted that the difference between raw egg and milk products and baked egg and milk products affected their response; the participant expected that the child would want to be able to eat baked goods as if they were not allergic but to be protected only against accidental ingestion for raw egg and milk products.

Because of these comments, the question was changed to “For your child’s (allergen) allergy, if you were to enroll your child in a clinical trial, what would be your/your child’s desired outcome?” This question was asked for each food that the child is allergic to. The response “To be able to eat limited amounts of this food with caution” was also included. If a participant indicated that his or her child cannot tolerate baked egg
or baked milk, this question was asked for both raw egg and baked egg or raw milk and baked milk to tease out the discrepancy.

**Survey Results**

Data were collected from 357 participants, with 246 surveys completed. Incomplete responses (n = 111) were not included in the final analysis. However, because participants were not required to respond to all survey questions, some demographic data was not reported for all 246 included participants.

**Demographic Characteristics**

Of the study population, 65.7% (n = 161) of participants’ children were male and 93.1% (n = 229) were White (Table 1). Most respondents (70.1%, n = 159) reported an annual household income of $100,000 or higher and most participants completing the survey reported having a college degree or higher (90.6%, n = 221).

**Table 1: Demographic Variability of Children with Food Allergy.**

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<td>12-17</td>
<td>20.3 (50)</td>
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<td><strong>Gender</strong></td>
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<tr>
<td>Caucasian/White</td>
<td>93.1 (229)</td>
</tr>
<tr>
<td>Asian</td>
<td>7.7 (19)</td>
</tr>
<tr>
<td>African American/Black</td>
<td>3.3 (8)</td>
</tr>
<tr>
<td>American Indian/Native American</td>
<td>2.0 (5)</td>
</tr>
<tr>
<td>Native Hawaiian/Other Pacific Islander</td>
<td>0.8 (2)</td>
</tr>
<tr>
<td>Other</td>
<td>2.4 (6)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Allergy</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Peanut</td>
<td>77.2 (190)</td>
</tr>
<tr>
<td>Tree Nut</td>
<td>66.3 (163)</td>
</tr>
<tr>
<td>Egg</td>
<td>39.4 (97)</td>
</tr>
<tr>
<td>Milk</td>
<td>30.9 (76)</td>
</tr>
<tr>
<td>Shellfish</td>
<td>16.3 (40)</td>
</tr>
<tr>
<td>Soy</td>
<td>14.6 (36)</td>
</tr>
<tr>
<td>Wheat</td>
<td>14.2 (35)</td>
</tr>
<tr>
<td>Fin Fish</td>
<td>11.4 (28)</td>
</tr>
<tr>
<td>Other</td>
<td>45.1 (111)</td>
</tr>
<tr>
<td>Unknown</td>
<td>2.0 (5)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Comorbidities</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Seasonal Allergy</td>
<td>56.5 (139)</td>
</tr>
<tr>
<td>Eczema</td>
<td>55.7 (137)</td>
</tr>
<tr>
<td>Pet Allergy</td>
<td>47.6 (117)</td>
</tr>
<tr>
<td>Asthma</td>
<td>47.2 (116)</td>
</tr>
<tr>
<td>Indoor Allergy</td>
<td>29.3 (72)</td>
</tr>
<tr>
<td>Medication Allergy</td>
<td>12.2 (30)</td>
</tr>
<tr>
<td>Insect Allergy</td>
<td>5.7 (14)</td>
</tr>
<tr>
<td>None</td>
<td>8.5 (21)</td>
</tr>
<tr>
<td>Other</td>
<td>6.1 (15)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Approximate Household Income</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Less than $50,000</td>
<td>6.1 (14)</td>
</tr>
<tr>
<td>$50,000 to $74,999</td>
<td>10.6 (24)</td>
</tr>
<tr>
<td>$75,000 to $99,999</td>
<td>13.2 (30)</td>
</tr>
<tr>
<td>$100,000 or Higher</td>
<td>70.1 (159)</td>
</tr>
</tbody>
</table>
Table 1 Continued: Demographic Variability of Children with Food Allergy

<table>
<thead>
<tr>
<th>Parent Highest Level of School</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>High School Graduate or GED</td>
<td>2.9 (7)</td>
</tr>
<tr>
<td>Some College</td>
<td>6.5 (16)</td>
</tr>
<tr>
<td>College Degree or Higher</td>
<td>90.6 (221)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Food Allergy Therapies Offered in Area</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>31.3 (76)</td>
</tr>
<tr>
<td>OIT</td>
<td>75.0 (51)</td>
</tr>
<tr>
<td>SLIT</td>
<td>2.9 (2)</td>
</tr>
<tr>
<td>EPIT</td>
<td>10.3 (7)</td>
</tr>
<tr>
<td>Other</td>
<td>5.9 (4)</td>
</tr>
<tr>
<td>Not Sure</td>
<td>5.9 (4)</td>
</tr>
<tr>
<td>No/Not Sure</td>
<td>68.7 (167)</td>
</tr>
</tbody>
</table>

Allergy History

The three most common food allergens found within this population were peanut (77.2%, n = 190), tree nut (66.3%, n = 163), and egg (39.4%, n = 97). The most common comorbid condition was seasonal allergy (56.5%, n = 139).

Seventy-four percent of participants (n = 182) reported that their children had experienced at least one severe allergic reaction. Additionally, 67.0% (n = 165) of participants reported being fearful of their child having an allergic reaction, while only 27.6% (n = 68) of participants believed that their child was fearful of having an allergic reaction.

Therapy Preferences

This study found that, of the parents surveyed, 69.5% (n = 171) ranked EPIT as their top choice, 22.8% (n = 56) ranked OIT as their top choice, and 7.7% (n = 19) ranked SLIT as their top choice (Figure 4).
The most common reason participants selected their first choice was “I feel my child would be safe undergoing this treatment” (62.6%, n = 154). Other factors cited included comfort (45.1%, n = 111), a lack of association with significant side effects (35.4%, n = 87), and efficacy (35.0%, n = 86) (Table 2). Twenty-one participants (8.5%) responded “Other.” When these participants were asked to specify “Other” reason(s) for their first choice, they responded with a multitude of comments, which ranged from financial considerations to ease of participation.
Table 2: Reasons for First Choice Therapy.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Frequency, % (n)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Why Did You Choose Your First Choice Therapy?</td>
<td>N = 246</td>
</tr>
<tr>
<td>I feel my child would be safe undergoing this treatment</td>
<td>62.6 (154)</td>
</tr>
<tr>
<td>I feel comfortable giving my child this treatment</td>
<td>45.1 (111)</td>
</tr>
<tr>
<td>I feel this treatment is not associated with significant side effects</td>
<td>35.4 (87)</td>
</tr>
<tr>
<td>I feel this treatment would be most effective for my child</td>
<td>35.0 (86)</td>
</tr>
<tr>
<td>I have seen reports that this treatment yields good results</td>
<td>32.1 (79)</td>
</tr>
<tr>
<td>I feel this treatment will last long-term</td>
<td>19.1 (47)</td>
</tr>
<tr>
<td>Friends/Family have had a good experience with this treatment</td>
<td>10.1 (25)</td>
</tr>
<tr>
<td>My healthcare provider/physician recommended this treatment</td>
<td>8.5 (21)</td>
</tr>
<tr>
<td>Other</td>
<td>8.5 (21)</td>
</tr>
<tr>
<td>I feel I do not have enough information about this treatment</td>
<td>7.3 (18)</td>
</tr>
</tbody>
</table>

The most common reason participants gave for selecting their last choice therapy was “I do not feel my child would be safe undergoing this treatment” (28.1%, n = 69), with “I feel this treatment is associated with significant side effects” (24.8%, n = 61), “I do not feel comfortable giving my child this treatment” (23.6%, n = 58), and “I do not feel this treatment would be most effective for my child” (19.9%, n = 49) also frequently reported (Table 3). Of the parents who selected “Other” (12.6%, n = 31), the most common reason was that the participant felt their child was too young or their child’s allergy was too severe to enroll them in a particular clinical trial.
Table 3: Reasons for Last Choice Therapy.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Frequency, % (n)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Why Did You Choose Your Last Choice Therapy?</strong></td>
<td></td>
</tr>
<tr>
<td>I do not feel my child would be safe undergoing this treatment</td>
<td>28.1 (69)</td>
</tr>
<tr>
<td>I feel this treatment is associated with significant side effects</td>
<td>24.8 (61)</td>
</tr>
<tr>
<td>I do not feel comfortable giving my child this treatment</td>
<td>23.6 (58)</td>
</tr>
<tr>
<td>I do not feel this treatment would be most effective for my child</td>
<td>19.9 (49)</td>
</tr>
<tr>
<td>I feel I do not have enough information about this treatment</td>
<td>15.0 (37)</td>
</tr>
<tr>
<td>I have seen reports that this treatment does not yield good results</td>
<td>12.6 (31)</td>
</tr>
<tr>
<td>My child fears this treatment</td>
<td>12.6 (31)</td>
</tr>
<tr>
<td>Other</td>
<td>12.6 (31)</td>
</tr>
<tr>
<td>I feel this treatment will not last long-term</td>
<td>11.8 (29)</td>
</tr>
<tr>
<td>My healthcare provider/physician recommended against this treatment</td>
<td>6.1 (15)</td>
</tr>
<tr>
<td>This treatment does not have FDA approval</td>
<td>5.3 (13)</td>
</tr>
<tr>
<td>Friends/Family have had a bad experience with this treatment</td>
<td>4.1 (10)</td>
</tr>
</tbody>
</table>

Pursuing Food Allergy Therapy

Fifty percent of participants (n = 123) reported that if food allergy therapies were made publicly available, they would enroll their child in a therapy and 39.5% (n = 97) responded “Maybe” (Table 4).

Table 4: Parent Interest in a Clinical Trial.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Frequency, % (n)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Would You Consider Enrolling Your Child in a Trial?</strong></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>50.0 (123)</td>
</tr>
<tr>
<td>Maybe</td>
<td>39.5 (97)</td>
</tr>
<tr>
<td>No</td>
<td>7.7 (19)</td>
</tr>
<tr>
<td>Already Enrolled in a Trial</td>
<td>2.8 (7)</td>
</tr>
</tbody>
</table>
When participants were asked if their child would want to be enrolled in a clinical trial, 25.2% (n = 62) responded “Yes” and 41.5% (n = 102) responded “Maybe.”

Table 5: Child Interest in a Clinical Trial.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Frequency, % (n)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Would Your Child Want to Participate in a Clinical Trial?</td>
<td>N = 246</td>
</tr>
<tr>
<td>Yes</td>
<td>25.2 (62)</td>
</tr>
<tr>
<td>Maybe</td>
<td>41.5 (102)</td>
</tr>
<tr>
<td>No</td>
<td>10.1 (25)</td>
</tr>
<tr>
<td>Not Sure</td>
<td>23.2 (57)</td>
</tr>
</tbody>
</table>

The seven participants with children already enrolled in a clinical trial were asked why they enrolled their child in a trial (Table 6). Although the sample was small (n = 7), the most common reasons for enrolling in a clinical trial were geographic availability and reports that the therapy yielded good results (85.7%, n = 6).

Table 6: Reasons for Enrolling Child in a Clinical Trial.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Frequency, % (n)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Why Did You Choose to Enroll Your Child in a Clinical Trial?</td>
<td>n = 7</td>
</tr>
<tr>
<td>I had seen reports that this treatment yields good results</td>
<td>85.7 (6)</td>
</tr>
<tr>
<td>This treatment was made geographically available</td>
<td>85.7 (6)</td>
</tr>
<tr>
<td>I trusted the healthcare provider offering this treatment</td>
<td>71.4 (5)</td>
</tr>
<tr>
<td>I felt my child would be safe undergoing this treatment</td>
<td>71.4 (5)</td>
</tr>
<tr>
<td>I felt this treatment would be most effective for my child</td>
<td>71.4 (5)</td>
</tr>
<tr>
<td>I saw no other solutions for my child to live a safe and happy life</td>
<td>71.4 (5)</td>
</tr>
</tbody>
</table>
Table 6 Continued: Reasons for Enrolling Child in a Clinical Trial

<table>
<thead>
<tr>
<th>Reason</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>I felt comfortable giving my child this treatment</td>
<td>57.1 (4)</td>
</tr>
<tr>
<td>I felt this treatment would last long-term</td>
<td>28.6 (2)</td>
</tr>
<tr>
<td>I felt this treatment was not associated with significant side effects</td>
<td>28.6 (2)</td>
</tr>
<tr>
<td>Participating in this trial presented no scheduling issues</td>
<td>14.3 (1)</td>
</tr>
<tr>
<td>Other</td>
<td>14.3 (1)</td>
</tr>
<tr>
<td>Friends/Family had a good experience with this treatment</td>
<td>0 (0)</td>
</tr>
<tr>
<td>This treatment was made financially available</td>
<td>0 (0)</td>
</tr>
</tbody>
</table>

There were no statistically significant associations (p < 0.05) between willingness to participate in a clinical trial and patient characteristics, including reported allergens, severity of allergy, quality of life, and demographic information.

Using a less conservative significance level of 0.10, having a child with wheat allergy was associated with being less willing to participate in a clinical trial (62.9% vs. 37.1% of children with wheat allergy, p = 0.067), as were having a child with localized enlargement/swelling as a symptom (53.4% vs. 46.6% of children with swelling, p = 0.056) and having a child with a comorbid pet allergy (54.5% vs. 45.6% of children with pet allergy, p = 0.084). Conversely, having a child with an almond allergy was associated with being more willing to participate in a clinical trial (71.4% vs. 28.6% of children with almond allergy, p = 0.055).

Survey Design Feedback

The survey recruitment mailing sent to parents contained the name and contact information of a member of the research team in case of questions or concerns. In
addition, participants were able to submit comments and questions at the end of the survey.

A number of participants used the space to discuss their child’s allergy history and experiences with food allergy therapies. For instance, one participant found the survey difficult to complete due to their child having deficits in pragmatic language and detailed how that had affected the management of their child’s allergy. Participants also expanded on their opinions of specific food allergy therapies and their desires to increase therapy accessibility.

Few participants had comments about specific survey questions. For example, one participant could not remember all of the reactions her child had experienced. Another participant could not define her child’s desired treatment outcome because, after eliminating peanuts from the child’s diet for 12 years, the child has no desire to eat peanuts at all.

The biggest concern about the survey design came from representatives of a biopharmaceutical company, who believed that the descriptions of the three therapies showed bias. After reading through the survey, representatives of the company took issue with EPIT being described as “safely” releasing the allergen. The representatives also believed that the characterization of OIT seemed “unfriendly” compared to the descriptions of SLIT and EPIT due to the inclusion of safety and efficacy information.

Although the comments received from survey participants were both positive and negative, a theme common to most feedback was a passion for food allergy research and an appreciation for investigators actively exploring food allergy therapy preferences.
DISCUSSION

This survey is the first to describe the therapy preferences of parents with food-allergic children. The survey results were also valuable in gaining an understanding the myriad of factors that may affect therapy preferences, as well as potential associations between willingness to undergo therapy and participant characteristics.

This data is particularly important because, despite the increased prevalence of food allergies in children, there has not been research comparing these three immunotherapies in terms of patient and parent preference. Although the findings from studies examining OIT, SLIT, and EPIT have progressed in terms of clarifying safety profile and efficacy, an understanding of the needs of the patients and their families is crucial to the evolution of these novel therapies. This pilot study, and the survey developed for the purposes of this study, may be used to redesign current or develop new immunotherapies based on parental priorities and concerns.

Food Allergy Therapy Preference

This pilot study demonstrated a tendency for parents to prefer EPIT to OIT and SLIT. The foremost reason for this preference was the safety profiles of the therapies; although EPIT has not been as effective as OIT in completed trials, the reduced risk of anaphylaxis was crucial to its appeal.

In the space available to provide comments, many participants reported that they felt uncomfortable with their child ingesting the food allergen, especially if the child was
not old enough to voice their discomfort or if the child’s allergy was particularly severe. In these cases, participants indicated that they believed that EPIT would be safer and more comfortable for their child.

**Impact on Quality of Life**

Many of the comments explaining why participants selected their first choice therapy centered on parental stress level and the comfort of their child. Most parents reported that their child’s food allergy greatly affected their daily lives and that they are fearful of their child having an allergic reaction. Nearly 70% of parents with children who had experienced a severe reaction in their lifetime were interested in pursuing a food allergy therapy. Further study is needed to determine if fear of a severe allergic reaction is a significant predictor of parent willingness to pursue therapy.

This data underscores the significant impact of food allergies on the quality of life of children and their families. The findings suggest that fear and anxiety are major motivating factors in parents’ attempts to alleviate their children’s allergic responses through therapy.

**Limitations**

There were multiple limitations to this study. First, respondent burden was not taken into account when developing this survey. Many participants (n = 111) began the survey but did not complete it. Feedback indicated that the primary reason for participant drop-off was the length of the survey and the difficulty of the survey questions. Future
investigations may benefit from developing a shorter survey that only includes questions that are directly relevant to the research question.

In addition, there is the possibility of selection bias within the survey population. Although the survey was distributed through a variety of social media platforms, the data demonstrate that 70.04% of participants had an approximate household income of $100,000 or higher. To combat this issue in future studies and ensure the validity of this survey, the protocol may be replicated with a larger sample size. It may be beneficial to obtain survey data through school and health care systems (e.g. Chicago Public Schools) rather than via recipients of food allergy network newsletters and electronic mail blasts. This may expand the survey data to include a lower socioeconomic sample.

Another potential limitation was the language used to describe the three immunotherapies. According to survey feedback, participants believed that the inclusion of safety profiles in the descriptions might create bias against OIT due to the higher associated risk of anaphylaxis. In order to mitigate this bias, future studies may exclude an explanation of the immunotherapies’ efficacy and safety profiles.

Because both symptoms and allergic reaction history were self-reported in the survey, there may have been misclassification or misreporting. Feedback given by participants also suggested that survey participants might have had difficulty remembering the details of their children’s reaction history. Although these data points were based on the participants’ memories, they were not crucial to the hypothesis of this study, and, therefore, do not affect the outcome.
**Future Studies**

Future studies performed on this topic may include a more comprehensive comparison of the three immunotherapies. Although studies have examined the efficacy and side effects of each immunotherapy separately, there has not been a clinical trial directly comparing the three therapies. This may give parents a better idea of which therapy to pursue for their child, based on their child’s health history and lifestyle.

Because fear and anxiety are a major concern of food-allergic children and their parents, it may also be beneficial to include quality of life comparisons within these trials. Although this study demonstrated that safety was a primary concern, parent responses also indicated that comfort was also a significant factor in a family’s decision to pursue food allergy immunotherapy.

**Conclusion**

The findings of this pilot study suggest that parents prefer EPIT to OIT and SLIT. Although efficacy and comfort are important factors when choosing an immunotherapy, the principal concern of participants was the safety profile of the therapy. This study also found that a large proportion of parents would choose to enroll their child in a food allergy therapy if given the opportunity, with half of the participants definitely interested in finding a therapy and another 40% possibly interested. However, there was no significant variation in decision to pursue a clinical therapy based on food allergen, severity, or other patient characteristics. The data from this investigation demonstrate that food allergy has a substantial negative impact on the quality of life of children and their
families. This effect is so great that most parents participating in this study would be interested in enrolling their child in a potential food allergy therapy, in spite of the fact that the therapies are still in developmental stages.
APPENDIX 1

Cognitive Interview Template

STEP 1: Record start time of interview

Interviewer Initials:  
Date of Interview:  
Interview Start Time:

STEP 2: Administer survey; record start/stop time

Survey Start Time:  
Survey End Time:

STEP 3: Ask preliminary questions

a. (Length) Do you feel the survey is:
   □ Too Long
   □ Just Right
   □ Too Short

b. (Difficulty) How easy or hard do you think it was to read the survey?
   □ Hard*
   □ Somewhat Hard*
   □ Not Hard or Easy
   □ Somewhat Easy
   □ Easy

*If response is Hard or Somewhat Hard, ask:

What do you think made the survey hard?
Participant Comments:

How would you make the survey easier to read?
Participant Comments:

c. (Comfort) Did any questions make you feel uncomfortable? Why?
   □ Yes*
   □ No

*If Yes, ask:

Which questions made you uncomfortable? Why?
Participant Comments:
STEP 4: Assess individual questions

1. Would you be interested in enrolling your child in a clinical trial for potential food allergy treatment?
   - Yes
   - Maybe
   - My child is already enrolled in a clinical trial for food allergy treatment
   - No

a. How easy or hard do you think this question is to understand?
   - Hard*
   - Somewhat Hard*
   - Not Hard or Easy
   - Somewhat Easy
   - Easy

*If response is anything other than Easy, ask:

What do you think this question is asking?
Participant Comments:

b. Do you have any ideas about how to make this question easier to understand?
   - Yes*
   - No

*If Yes, indicate proposed changes:

Participant Comments:

c. Do you have any additional comments about this question?
   - Yes*
   - No

*If Yes, record comments:

Participant Comments:

Follow Up: Why did you choose to enroll your child in this clinical trial? Please mark all that apply
*Only for subjects that have enrolled their child in a clinical trial (Question 1)
   - This treatment was made available
   - I felt my child would be safe undergoing this treatment
□ I felt this treatment would be most effective for my child
□ I felt comfortable giving my child this treatment
□ Friends/family had a good experience with this treatment
□ I had seen reports that this treatment yields good results
□ I felt this treatment will last long-term
□ I felt this treatment is not associated with many side effects
□ I feel I do not have enough information about this treatment
□ Other
□ Additional comments

a. How easy or hard do you think this question is to understand?
   ○ Hard*
   ○ Somewhat Hard*
   ○ Not Hard or Easy
   ○ Somewhat Easy
   ○ Easy

*If response is anything other than Easy, ask:

What do you think this question is asking?
Participant Comments:

b. Do you have any ideas about how to make this question easier to understand?
   ○ Yes*
   ○ No

*If Yes, indicate proposed changes:

Participant Comments:

c. Do you have any additional comments about this question?
   ○ Yes*
   ○ No

*If Yes, record comments:

Participant Comments:

2. To what extent do you want to treat your child’s food allergy?
   ○ I want my child to be protected only against accidental ingestion
o I want my child to be able to eat the food allergen as if they were not allergic

a. How easy or hard do you think this question is to understand?
   o Hard*
   o Somewhat Hard*
   o Not Hard or Easy
   o Somewhat Easy
   o Easy

*If response is anything other than Easy, ask:

What do you think this question is asking?
Participant Comments:

b. Do you have any ideas about how to make this question easier to understand?
   o Yes*
   o No

*If Yes, indicate proposed changes:

Participant Comments:

c. Do you have any additional comments about this question?
   o Yes*
   o No

*If Yes, record comments:

Participant Comments:

3. To what extent does your child want to be treated for their food allergy?
   o My child wants to be protected only against accidental ingestion
   o My child wants to be able to eat the food allergen as if they were not allergic

a. How easy or hard do you think this question is to understand?
   o Hard*
   o Somewhat Hard*
   o Not Hard or Easy
   o Somewhat Easy
   o Easy
4. Do you think your child would want to undergo treatment?
   o Yes, my child is ready to undergo treatment
   o Maybe, my child fears treatment but would consider it
   o No, my child is not ready to undergo treatment

   a. How easy or hard do you think this question is to understand?
      o Hard*
      o Somewhat Hard*
      o Not Hard or Easy
      o Somewhat Easy
      o Easy

   *If response is anything other than Easy, ask:
   What do you think this question is asking?
   Participant Comments:

   b. Do you have any ideas about how to make this question easier to understand?
      o Yes*
      o No

   *If Yes, indicate proposed changes:

   Participant Comments:
Participant Comments:

c. Do you have any additional comments about this question?
   - Yes*
   - No

*If Yes, record comments:

Participant Comments:

5. There are currently a number of experimental therapies for food allergy being tested:

   **Oral Immunotherapy (OIT):** During OIT, patients ingest small but steadily increasing doses of their food allergen. The ultimate goal is to teach the person’s immune system to tolerate their allergen.

   **Sublingual Immunotherapy (SLIT):** During SLIT, patients ingest the food allergen under their tongue after the allergen is dissolved in a solution. Patients ingest small but steadily increasing doses of their food allergen.

   **Epicutaneous Immunotherapy (EPIT):** During EPIT, patients apply a 4x4 cm patch between their shoulder blades that safely and gradually exposes them to small amounts of their allergen through the skin.

After reviewing the information provided, if you were to pursue treatment for your child’s food allergy/allergies, which therapy would you most prefer? Please rank the treatments in order of preference (1: most preferred, 3: least preferred)

1. 
2. 
3. 

a. How easy or hard do you think this question is to understand?
   - Hard*
   - Somewhat Hard*
   - Not Hard or Easy
   - Somewhat Easy
   - Easy

*If response is anything other than Easy, ask:

What do you think this question is asking?
Participant Comments:
b. Do you have any ideas about how to make this question easier to understand?
   □ Yes*
   □ No

*If Yes, indicate proposed changes:

Participant Comments:

c. Do you have any additional comments about this question?
   □ Yes*
   □ No

*If Yes, record comments:

Participant Comments:

6. Why did you choose [insert their first choice here] as your first choice? Please mark all that apply:
   □ I feel my child would be safe undergoing this treatment
   □ I feel this treatment would be most effective for my child
   □ I feel comfortable giving my child this treatment
   □ Friends/family have had a good experience with this treatment
   □ I have seen reports that this treatment yields good results
   □ I feel this treatment will last long-term
   □ I feel this treatment is not associated with many side effects
   □ I feel I do not have enough information about this treatment
   □ Other
   □ Additional comments

a. How easy or hard do you think this question is to understand?
   □ Hard*
   □ Somewhat Hard*
   □ Not Hard or Easy
   □ Somewhat Easy
   □ Easy

*If response is anything other than Easy, ask:

What do you think this question is asking?
Participant Comments:
b. Do you have any ideas about how to make this question easier to understand?
   o Yes*
   o No

*If Yes, indicate proposed changes:

Participant Comments:

c. Do you have any additional comments about this question?
   o Yes*
   o No

*If Yes, record comments:

Participant Comments:

7. Why did you choose [insert their last choice here] as your last choice? Please mark all that apply:
   □ I do not feel my child would be safe undergoing this treatment
   □ I do not feel this treatment would be most effective for my child
   □ I do not feel comfortable giving my child this treatment
   □ Friends/family have had a bad experience with this treatment
   □ I have seen reports that this treatment does not yield good results
   □ I feel this treatment will not last long-term
   □ I feel this treatment is associated with many side effects
   □ I feel I do not have enough information about this treatment
   □ Other
   □ Additional comments

a. How easy or hard do you think this question is to understand?
   o Hard*
   o Somewhat Hard*
   o Not Hard or Easy
   o Somewhat Easy
   o Easy

*If response is anything other than Easy, ask:

What do you think this question is asking?
Participant Comments:

b. Do you have any ideas about how to make this question easier to understand?
o Yes*
o No

*If Yes, indicate proposed changes:

Participant Comments:

c. Do you have any additional comments about this question?
o Yes*
o No

*If Yes, record comments:

Participant Comments:

8. What would you like to see in order to consider these treatments? Please mark all that apply:
  □ More studies demonstrating the success of these treatments
  □ For my child to be comfortable undergoing these treatments
  □ For the treatments to work long-term
  □ To understand the side effects of these treatments
  □ For treatments to be made affordable
  □ Other
  □ Additional comments

a. How easy or hard do you think this question is to understand?
o Hard*
o Somewhat Hard*
o Not Hard or Easy
  o Somewhat Easy
  o Easy

*If response is anything other than Easy, ask:

What do you think this question is asking?
Participant Comments:

b. Do you have any ideas about how to make this question easier to understand?
o Yes*
o No
*If Yes, indicate proposed changes:

Participant Comments:

c. Do you have any additional comments about this question?
   □ Yes*
   □ No

*If Yes, record comments:

Participant Comments:

9. What other treatments would you like to see made available?
   □ Vaccinations
   □ Subcutaneous Allergen Immunotherapy (SCIT)
   □ Pills taken daily
   □ Other
   □ Additional comments

a. How easy or hard do you think this question is to understand?
   □ Hard*
   □ Somewhat Hard*
   □ Not Hard or Easy
   □ Somewhat Easy
   □ Easy

*If response is anything other than Easy, ask:

What do you think this question is asking?
Participant Comments:

b. Do you have any ideas about how to make this question easier to understand?
   □ Yes*
   □ No

*If Yes, indicate proposed changes:

Participant Comments:

c. Do you have any additional comments about this question?
   □ Yes*
   □ No
STEP 5: Ask closing questions

a. Are there any questions that you think are missing from this survey?
   □ Yes*
   □ No

*If Yes, ask:

What questions would you ask?
Participant Comments:

b. Do you think the layout of the survey was easy to follow?
   □ Yes
   □ No*

*If No, ask:

What did you find hard or confusing about the layout?
Participant Comments:

c. Do you have any additional comments about this survey?
   □ Yes*
   □ No

*If Yes, record comments:

Participant Comments:

d. If we have additional questions to ask in the future, would it be okay for study staff to contact you by email?
   □ Yes
      ▪ Preferred email: 
   □ No
APPENDIX 2

Parental Therapy Preferences for Children With Food Allergy Survey

Please answer the following questions to the best of your ability. All responses are anonymous and will not be shown to anyone outside of research personnel.

1. How many of your children have a current food allergy?
   - 1
   - 2
   - 3 or more

2. For how many of your children with food allergy would you like to complete this survey?
   - 1
   - 2
   - 3

   (Repeat the whole survey based on the answer to this question. Max: 3 times)

Part 1: Current Food Allergies

3. How old was your child when he or she was diagnosed with a food allergy?
   [Drop down numbers >1 to 17 years]
   - (If >1 chosen) Months:

4. To which food(s) is/are your child currently allergic? Please mark all that apply.
   - Peanut
   - Tree nut
   - Type of tree nut:
     - ALL tree nuts
     - Almond
     - Cashew
     - Hazelnut
     - Pecan
     - Pistachio
     - Walnut
     - Other
       - Please specify: (Text box)
   - Milk
     - Can your child tolerate baked milk products?
       - Yes
       - No
• I am not sure
□ Egg
  ○ Can your child tolerate baked egg products?
    • Yes
    • No
    • I am not sure
□ Shellfish (e.g., shrimp, crab, or lobster))
 □ Fin Fish (e.g., cod, salmon, or tuna)
 □ Wheat
 □ Soy
 □ Other
 □ Please specify: (Text box)
 □ Unknown

5. How many food allergic reactions has your child had in his or her LIFETIME?  
   [Drop down numbers 0-30, greater than 30, I cannot recall]
   • How many reactions in your child’s LIFETIME would you consider severe or potentially life threatening?  
     [Drop down numbers 0-30, greater than 30, I cannot recall]

6. How many food allergic reactions has your child had in the PAST YEAR?  
   [Drop down numbers 0-30, greater than 30, I cannot recall]
   • How many reactions in the PAST YEAR would you consider severe or potentially life threatening?  
     [Drop down numbers 0-30, greater than 30, I cannot recall]

7. What food(s) have caused your child to have a severe or life-threatening reaction?  
   Please mark all that apply:
□ Peanut
□ Tree Nut
□ Milk
□ Egg
□ Shellfish (e.g., shrimp, crab, or lobster)
□ Fin Fish (e.g., cod, salmon, or tuna)
□ Wheat
□ Soy
□ Other
□ Unknown
□ My child has never had a severe reaction

8. What symptoms has your child had during a food allergic reaction? (All reactions – mild to severe)
□ Hives or rash
□ Itching/tingling
Swelling
Trouble breathing
Throat tightening
Coughing
Wheezing
Nausea
Vomiting
Diarrhea
Low blood pressure
Fainting/passing out
Fear/anxiety
Feeling of impending doom/feeling that something bad is going to happen
Other
My child has never had a reaction

Part 2: Food Allergy Therapy Preference

9. How much does your child’s food allergy affect HIS or HER daily life?
   - Not at all
   - A little bit
   - Moderately
   - Very much
   - Extremely
   - Not applicable

10. How much does your child’s food allergy affect YOUR daily life?
    - Not at all
    - A little bit
    - Moderately
    - Very much
    - Extremely
    - Not applicable

11. How fearful is YOUR CHILD of having an allergic reaction?
    - Not at all
    - A little bit
    - Moderately
    - Very much
    - Extremely
    - Not applicable

12. How fearful are YOU of your child having an allergic reaction?
    - Not at all
    - A little bit
o Moderately
o Very much
o Extremely
o Not applicable

13. Desired clinical trial outcome: *(Allergen only appears if selected in Question 4, both questions are asked for all allergens selected in Question 4)*
   - For your child’s ALLERGEN allergy, if you were to enroll your child in a clinical trial, what would be YOUR desired outcome?
     - To be protected only against accidental ingestion
     - To be able to eat limited amounts of this food with caution
     - To be able to eat the food allergen as if they were not allergic
   - For your child’s ALLERGEN allergy, if you were to enroll your child in a clinical trial, what would be YOUR CHILD’S desired outcome?
     - To be protected only against accidental ingestion
     - To be able to eat limited amounts of this food with caution
     - To be able to eat the food allergen as if they were not allergic

14. If clinical trials for potential food allergy treatments were publicly available, would you consider enrolling your child in a trial? Clinical trials involve exposing the subject to increasing doses of their food allergen. The first phase of current clinical studies is clinician-supervised, and is generally followed by a daily at-home maintenance phase.
   - Yes
   - Maybe
   - No
     - (Text box)
   - My child is already enrolled in a clinical trial for food allergy treatment
     - What kind of clinical trial is your child enrolled in?
       - Oral Immunotherapy
       - Sublingual Immunotherapy
       - Epicutaneous Immunotherapy
       - Other
         - Please specify: (Text box)
     - Why did you choose to enroll your child in [insert clinical trial here]?
       - Please mark all that apply:
         - This treatment was made financially available
         - This treatment was made geographically available
         - Participating in this trial presented no scheduling issues
         - I trusted the healthcare provider offering this treatment
         - I felt my child would be safe undergoing this treatment
         - I felt this treatment would be most effective for my child
         - I felt comfortable giving my child this treatment
• Friends/family had a good experience with this treatment
• I had seen reports that this treatment yields good results
• I felt this treatment would last long-term
• I felt this treatment was not associated with significant side effects
• I saw no other solutions for my child to live a safe and happy life
• Other:
  o Please specify: (Text box)
• Additional Comments: (Text box)
• My child initiated a clinical trial for food allergy treatment, but was not able to complete it
  o What kind of clinical trial was your child enrolled in?
    • Oral Immunotherapy
    • Sublingual Immunotherapy
    • Epicutaneous Immunotherapy
    • Other
    • Please specify: (Text box)
  o Why did you choose to enroll your child in [insert clinical trial here]?
    Please mark all that apply:
    • This treatment was made financially available
    • This treatment was made geographically available
    • Participating in this trial presented no scheduling issues
    • I trusted the healthcare provider offering this treatment
    • I felt my child would be safe undergoing this treatment
    • I felt this treatment would be most effective for my child
    • I felt comfortable giving my child this treatment
    • Friends/family had a good experience with this treatment
    • I had seen reports that this treatment yields good results
    • I felt this treatment would last long-term
    • I felt this treatment was not associated with significant side effects
    • I saw no other solutions for my child to live a safe and happy life
    • Other:
      • Please specify: (Text box)
• Additional Comments: (Text box)
  o Why was your child unable to complete the clinical trial? Please mark all that apply:
    • Severe reaction/side effects
    • Financial constraints
    • Time constrains/scheduling conflicts
    • Geographical constraints
    • Eosinophilic Esophagitis (EOE) development
    • Anxiety/fear
    • Other
      • Please specify: (Text box)
15. Do you think your child would want to participate in a clinical trial for food allergy therapy?
   • Yes, my child is willing to undergo therapy
   • Maybe, my child would consider undergoing therapy
     • Why is your child hesitant to initiate treatment?
       ▪ Time constraints/scheduling conflicts
       ▪ Geographic constraints
       ▪ Fear/anxiety
       ▪ Other
         □ Please specify: (Text box)
         ▪ Additional Comments: (Text box)
   • No, my child is not willing to undergo therapy
     • (Text box)
   • I am not sure

16. For how long would you be willing to enroll your child in a clinical trial for food allergy therapy?
   • 4-6 months
   • 6-12 months
   • 1 year
   • 2 years
   • 3 years
   • More than 3 years

17. There are currently a number of experimental therapies for food allergy being tested:
   o **Oral Immunotherapy (OIT):** During OIT, patients ingest steadily increasing doses of their food allergen (e.g. peanut powder) over a short period of time under the supervision of their clinician. Once patients reach a target dose amount, they begin a maintenance phase. This involves ingesting a daily dose of their allergen. Recent studies have shown that many patients become desensitized to their allergen after OIT but have more reactions during the “build up” phase compared to other treatments.
   
   o **Sublingual Immunotherapy (SLIT):** During SLIT, the patient’s allergen is dissolved in a liquid. This liquid is then held under the patient’s tongue and swallowed. Patients begin by ingesting a small dose, which is gradually increased. Although the results of these studies have not been as successful compared to OIT, patients tend to have fewer reactions.
   
   o **Epicutaneous Immunotherapy (EPIT):** EPIT is a new therapy, during which the patient applies a 4x4 cm patch, typically on the back for children and on the inside of the upper arm for adolescents. This patch safely and gradually releases small amounts of their allergen through the skin. Although this technology is still in development, studies have shown that it presents less risk of reaction than oral ingestion.
After reviewing the information provided, if you were to pursue treatment for your child’s food allergy/allergies, which therapy would you most prefer? Please rank the treatments in order of preference (1: most preferred, 3: least preferred)

1. (Drop down: treatment options)
2. (Drop down: treatment options)
3. (Drop down: treatment options)

18. Why did you choose [insert their first choice here] as your first choice? Please mark all that apply:
- I feel my child would be safe undergoing this treatment
- I feel this treatment would be most effective for my child
- I feel comfortable giving my child this treatment
- Friends/family have had a good experience with this treatment
- I have seen reports that this treatment yields good results
  - Where did you find this information? Please mark all that apply:
    - Advocacy groups
    - Food allergy blogs
    - Physician
    - Manufacturer website
    - Research manuscript
    - Social media
    - Other
    • Please specify: (Text box)
    - Additional Comments: (Text box)
- I feel this treatment will last long-term
- I feel this treatment is not associated with significant side effects
- My healthcare provider/physician recommended this treatment
- I feel I do not have enough information about this treatment
- Other:
  - Please specify: (Text box)
  - Additional Comments: (Text box)

19. Why did you choose [insert their third choice here] as your last choice? Please mark all that apply:
- I do not feel my child would be safe undergoing this treatment
- I do not believe this treatment would be effective for my child
- I do not feel comfortable giving my child this treatment
- Friends/family have had a bad experience with this treatment
- I have seen reports that this treatment does not yield good results
  - Where did you find this information? Please mark all that apply:
    - Advocacy groups
    - Food allergy blogs
    - Physician
• Manufacturer website
• Research manuscript
• Social media
• Other
  • Please specify: (Text box)
• Additional Comments: (Text box)

□ I feel this treatment will not last long-term
□ I feel this treatment is associated with significant side effects
□ My healthcare provider/physician recommended against this treatment
□ There may be possible long-term issues associated with this treatment (i.e. EOE, cancer)
□ This treatment does not have FDA approval
□ My child fears this treatment
□ I feel I do not have enough information about this treatment
□ Other:
  ○ Please specify: (Text box)
□ Additional Comments: (Text box)

20. What would you like to see in order to consider these treatments for your child? Please mark all that apply:
□ More studies demonstrating the success of these treatments
□ For my child to be comfortable undergoing these treatments
□ For these treatments to work long-term
□ To understand the potential side effects of these treatments
□ For these treatments to be made accessible
  • What would you like treatment providers to consider? Please mark all that apply:
    □ Parental availability/supervision requirements
    □ Geographic availability
    □ Financial availability
    □ Scheduling flexibility
    □ Hygiene requirements
□ FDA approval for these treatments
□ Allergist recommendation
□ Pediatrician recommendation
□ Other clinician recommendation
  ▪ Please specify: (Text box)
□ Other:
  ▪ Please specify: (Text box)
□ Anything else that you would like to see?: (Text box)

21. What other treatments would you like to see made available? Please mark all that apply:
Vaccinations are periodic but limited injections that teach the patient’s immune system to recognize their allergen.

Subcutaneous Immunotherapy (SCIT): SCIT involves the injection of the patient’s allergen under the skin. It consists of weekly injections under the supervision of a clinician during the build up phase, followed by monthly maintenance injections over a period of years.

Pills/oral medications

Traditional Chinese herbal therapy

Probiotics

Other:
  - Please specify: (Text box)

Additional Comments: (Text box)

Part 3: Demographic Information

22. What is the child’s age
   [Drop down numbers >1 to 17 years]

23. What is the child’s gender?
   - Male
   - Female
   - Other/would not like to report

24. Is the child Hispanic or Latino?
   - Yes
   - No
   - Unknown
   - Not specified

25. What is the child’s race/ethnicity? (Please select all that apply)
   - Black/African American
   - White
   - Asian
   - American Indian/Alaska Native
   - Native Hawaiian or other Pacific Islander
   - Other
     - Please specify: (Text box)

26. Does your child have any of the following medical conditions? Please mark all that apply:
   - Asthma
   - Eczema
   - Seasonal Allergy
□ Indoor Allergy
□ Pet Allergy
□ Insect Allergy
□ Medication Allergy
□ None
□ Other
  ○ Please specify: (Text box)

27. What is your relationship to the child?
   • Mother
   • Father
   • Grandparent
   • Other
  ○ Please specify: (Text box)

28. What is the highest grade of school you have completed?
   • Some Secondary School (9th grade and above)
   • High School Graduate or GED
   • Some College
   • College degree (e.g., BA, BS, BFA)
   • Master’s degree (e.g., MA, MS, MFA, MBA, MPH)
   • Doctoral degree (e.g., PhD, MD, JD, PharmD)

29. What was your approximate household income last year (including government assistance)?
   • Less than $50,000
   • $50,000 to $74,999
   • $75,000 to $99,999
   • $100,000 or higher

30. What are the first 3 digits of your current zip code?
    [Fill in numbers]

31. Do you know if there are any food allergy clinical therapies being offered in your area?
   • Yes
  ○ What therapy is being offered? Please mark all that apply.
    ▪ Oral immunotherapy
    ▪ Sublingual immunotherapy
    ▪ Epicutaneous immunotherapy
    ▪ Other
      ● Please specify: (Text box)
      ● I am not sure
   • No
• I am not sure

Do you have any additional comments?
• (Paragraph box)
REFERENCES


CURRICULUM VITAE

MARY L. SIRACUSA

Address: 1920 N. Burling Street, Chicago, IL 60614 • Phone: (312) 543-9708

Email: mscusa@bu.edu • Year of Birth: 1992

Education

Boston University School of Medicine, Boston, MA
Master of Science in Medical Sciences
September 2014 – May 2016 (anticipated)

University of Michigan, Ann Arbor, MI
Bachelor of Science in Neuroscience
September 2010 - May 2014

Work Experience

Northwestern University Feinberg School of Medicine, October 2015 - Present
Research Assistant at Center for Community Health
• Conduct national food allergy therapy study
• Recruit patients for Natural History Cohort study
• Assist with the coordination of current and future clinical studies

University of Illinois, October 2015 – Present
Research Associate at Institute for Minority Health Research
• Assist with data entry for UIC Cohort of Patients Family and Friends
• Organize and sort data collected for Cohort study

DeNova Research, Chicago, IL, July 2014 – August 2014
Research Assistant
• Involved in the recruitment and retention of patients for clinical trials
• Co-authored research paper based on quality of life study
• Collected, organized, and analyzed data for research studies
• Received HIPAA and NIH training

University of Michigan, Ann Arbor, MI, October 2011 – January 2014
Research Assistant at Department of Psychiatry
• Designed and performed experiments based on the effects of contextual processing on fear expression
• Evaluated the effects of available post-traumatic stress disorder medications
• Improved proficiency in laboratory-based computer programs, including ANY-maze Video Tracking and SPSS Statistics
• Worked in collaboration with the VA Ann Arbor Healthcare System
Rush University Medical Center, Chicago, IL  May 2012 – August 2012

**Intern at Heart Center for Women**

- Published research concerning reclassification of intermediate to high-risk cardiovascular disease patients
- Participated in the evaluation and analysis of patient medical histories
- Observed patient appointments and bypass surgeries
- Attended resident lectures and information sessions on a variety of medical topics

Volunteer Experience

**American Heart Association**

*Go Red for Women Committee Member* September 2015 – Present

- Organize and direct fundraising events throughout the year
- Provide information on heart health to the community through media and volunteer opportunities

**Boston Medical Center, Boston, MA**

*Volunteer at Endoscopy Clinic* February 2015 – May 2015

- Observed various endoscopic procedures
- Facilitated the handling and maintenance of medical equipment
- Assisted visiting patients and family members

**AIDS Foundation of Chicago, Chicago, IL**

*Volunteer* June 2014

- Interdepartmental liaison between prevention, care, and advocacy programs
- Communicated with victims of HIV/AIDS seeking housing assistance and case management
- Gained understanding of non-profit infrastructure

Clinical Shadowing Experience

**Chicago Center for Facial Plastic Surgery, Chicago, IL**

*Dr. Steven H. Dayan, MD, Plastic Surgery* Summer 2014

- Observed filler and Botox injections
- Worked with patients involved in various medical studies
- Supervised organization of procedures

**Rush University Medical Center, Chicago, IL**

*Dr. Annabelle Volgman, MD, Cardiology* Summer 2012

- Exposed to cardiac catheterization lab (both diagnostic catheterization and Percutaneous Coronary Intervention)
- Observed patient appointments, hospital rounds, and diagnosis discussions
- Attended weekly informational meetings with residents, physicians, physician assistants, and nurses

*Dr. Randolph McConnie, MD, Pediatric Gastroenterology* Summer 2011

- Observed patient appointments and diagnosis discussions
- Gained familiarity with doctor-patient interactions within pediatric office
- Well acquainted with a hospital setting
**Gold Coast Gynecology**, Chicago, IL  
*Dr. Randall Toig, MD, Gynecology*  
- Observed surgeries for the removal of ovarian cysts  
- Became comfortable with operating room protocol

**University of Chicago Medical Center**, Chicago, IL  
*Dr. David H. Song, MD, Plastic and Reconstructive Surgery*  
- Observed pre- and post-operation consultation sessions for patients diagnosed with breast cancer  
- Observed patient care in emergency department  
- Gained experience working with patients in a clinical environment

**Publications and Presentations**

