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## **Pilot Study: Program Evaluation of Peanut Oral Immunotherapy in a Private Clinic**

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## ABSTRACT

### PILOT STUDY: PROGRAM EVALUATION OF PEANUT ORAL IMMUNOTHERAPY IN A PRIVATE CLINIC

The privilege of providing a therapy perceived by patients and families as “life changing” has seasoned physicians describing food oral immunotherapy (OIT) as one of “the most impactful and rewarding thing that they have done in medicine” (Wasserman, Jones, & Windom, 2018). OIT is a medical treatment that allows the immune system to become desensitized to a food to which it may otherwise be allergic. This is not a cure for food allergies but a way to decrease the incidence of anaphylaxis due to accidental ingestion. Living with food allergies can be distressing due to the daily fear of exposures. The decreased quality of life for food allergic children and their families has prompted numerous OIT research projects over the past two decades. This evidence-based research is now being used in OIT treatment programs within hospitals and private practice allergy clinics. A pilot study program evaluation was completed for a newly implemented OIT program within a private allergy clinic. The focus of this study was two-fold: First, it shows how private practice OIT success and safety statistics compare to those reported from academic medical centers; Second, it examines parental anxiety and elements found helpful during their child’s OIT process. Finally, useful information will be offered for OIT implementation within private practices during the program evaluation recommendations section.

Kinga Olson

May 2019



PILOT STUDY: PROGRAM EVALUATION OF PEANUT ORAL  
IMMUNOTHERAPY IN A PRIVATE CLINIC

by

Kinga Olson

A project

submitted in partial

fulfillment of the requirements for the degree of

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APPROVED

For the California State University, Northern Consortium  
Doctor of Nursing Practice:

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## Table of Contents

CHAPTER 1: INTRODUCTION .....	1
THE PROBLEM.....	2
PURPOSE .....	2
BACKGROUND.....	3
Physical effects of Food Allergies .....	4
Psychosocial Consequences of Food Allergies.....	4
How OIT Works .....	6
Burdens To Enrolling In OIT.....	7
THEORETICAL FRAMEWORK .....	9
Implementation of Theoretical Framework .....	9
CHAPTER 2: LITERATURE REVIEW .....	11
European Guidelines Publish Evidence-based Recommendations.....	11
AR101- DBPCFC Clinical Trial.....	11
Incidence of Anaphylaxis with OIT.....	12
Gap Analysis.....	14
CHAPTER 3: METHODOLOGY .....	15
DESIGN .....	15
Potential Benefits .....	16
Potential Risks .....	16
SAMPLE.....	16
STUDY OVERSIGHT .....	18
MEASURES.....	18
PROCEDURE FOR DATA COLLECTION.....	20
DATA ANALYSIS .....	20
CHAPTER 4: RESULTS AND FINDINGS.....	22
DEMOGRAPHIC AND STUDY ANALYSIS .....	22
SUMMARY OF THE EVALUATION RESULTS .....	26
Evaluation Questions and Criteria Results: .....	28
CHAPTER 5: DISCUSSION.....	30
SURVEY BIAS.....	30
LIMITATIONS.....	30
PROGRAM EVALUATION RESULTS .....	31
Staff Education and Competencies .....	31
Parental Education is Key.....	32
Allergist Clinic Providing OIT .....	33
Cost effective practices .....	34
Offering Extra Social Support .....	35
CONCLUSIONS.....	36
REFERENCES .....	38
APPENDIX A: PARENTAL SURVEY AND RESULTS (MEANS OF RESPONSES).....	42



APPENDIX B: PARENT SURVEY RESULTS .....	viii
	43

LIST OF TABLES

	Page
Table 1 <i>Evaluation Questions &amp; Criteria</i> .....	19
Table 2 <i>Sample Analysis</i> .....	24
Table 3 <i>Parental Survey Questions</i> .....	25
Table 4 <i>Evaluation Questions &amp; Criteria</i> .....	27

## CHAPTER 1: INTRODUCTION

Food allergy awareness has become such a public health concern that Healthy People 2020 created goals to aid in the reduction of food allergy-related anaphylaxis (HealthyPeople.gov). Food allergies affect 8% of children in the United States (U.S.), and account for 53,700 episodes of anaphylaxis, 125,000 emergency department visits, and 150 deaths each year in the United States (Gupta et al., 2011). People with peanut or tree-nut allergies account for 80% of these anaphylactic reactions and only 20% of children will outgrow them (Broome, et al, 2015). Stress on the child and parents of children with peanut allergies may be overwhelming due to the daily threat of accidental ingestions. Peanut allergy research has developed promising new technologies over the past decade and according to Wasserman, et al., “with appropriate planning and precautions, peanut oral immunotherapy can be performed in an allergy office” (2019). Most recently, two biopharmaceutical companies (Aimmune Pharmaceuticals and Viaskin Peanut Technologies) have received Fast Track and Breakthrough Therapy designation from the US Food and Drug Administration (FDA), promising approved peanut desensitization therapy products commercially available as early as 2019, (Tilles, S. & Petroni, D., 2018). Once these therapies receive FDA approval, healthcare providers and institutions will be considering implementation; however, proper planning is warranted before starting any new program. This paper will highlight key elements of a peanut OIT program via program evaluation, and with input from parents of children that have experienced the OIT process.

## **The Problem**

Numerous peer-reviewed publications have discussed various peanut OIT study protocols, maintenance dosing, safety concerns, as well as the overwhelming evidence that peanut OIT improves quality of life for the recipients and their families (Panjo, et al., 2017; Bird, et al., 2018; Wasserman, et al, 2014 and 2019; Bégin, Chinthrahah, & Nadeau, 2014). Since OIT implementation in private practice is still considered to be in its pioneering stages, a program evaluation documenting specific outcomes of such a program offers insight for all allergists. It is imperative that clinicians considering this therapy for their own patients understand that food allergies and anxiety go hand in hand. Currently there are no published studies discussing how to decrease parental anxiety during OIT therapy, nor any discussions about what elements of a program are viewed as most valuable by parents themselves. Surveying parents about the specific anxiety-reducing facets of a program was determined to be a valuable outcome measure by the OIT providers of this private clinic and was measured as part of this program evaluation.

## **Purpose**

A private allergy clinic recently implemented a pilot program for peanut OIT and a year later has undergone program evaluation to identify process improvement needs before expanding to satellite locations. The CDC's Appendix F form was used as a template for the program evaluation, and for the purpose of this paper the following components will be reported:

- Effectiveness of therapy (measured by the number of patients reaching maintenance dose)
- Safety concerns related to adverse reactions during OIT (measured by total number of adverse reactions during escalation phase)
- Cost effectiveness

- Parent perception of anxiety reducing elements of OIT program (as reported by survey)
- Positive and negative impact of OIT program on the practice (impact on resources such as available staff, peanut free locations in clinic, parent satisfaction of program)

Assumptions underlying this program evaluation are those by careful evaluation of the above noted elements, successful activities and process improvement opportunities can be addressed. This is considered relevant due to the lack of published information related to OIT program implementation.

### **Background**

Peanut allergies affect 1 in 70 children in the United States (US), and are considered one of the most prevalent food allergies (Bird et al., 2018), and are responsible for over half of all food-related anaphylactic deaths in the US (Wood, 2017). Peanut allergies most commonly begin in childhood, and 80% do not outgrow it (FARE, 2018). As many as 50% of peanut allergic individuals have reported accidental ingestion over a 2-year period, portraying how minimal exposures can cause life-threatening reactions, as is the case with cross-contaminated foods (Bird, et al., 2018). Theories surrounding peanut allergy development are not clear since no studies have been able to pinpoint a precise cause. The hygiene hypothesis states too little exposure to bacteria and viruses weakens the immune system, versus the dietary hypothesis which states a broader exposure to various foods help strengthen the immune system (Rance & Goldberg, 2013). For decades pediatricians recommended infants avoid allergenic foods such as peanuts, and new research finds that this may have contributed to the recent rise of peanut allergies (Immune Tolerance Network, 2019). The new 2010 Guidelines for the Diagnosis and Management of Food Allergy in the United States was impacted by the LEAP (Learning Early about Peanut Allergy) studies and now recommends early introduction of peanuts to infants

(based on varying risk levels which would be determined by a physician) in order to stimulate a protective immune response (McCarthy, 2019).

Since there is no cure for peanut allergies, current evidence based practice guidelines direct health care providers to educate patients (and families) with peanut allergies to avoid this allergen, and to carry epinephrine injectables at all times since accidental peanut ingestion can be fatal for these individuals (FARE, 2018). Treating food allergies has become a highly debated topic in the world of immunology, with experts in the field discussing the merits and downfalls of food allergy immunotherapy (AAAAI, 2019). Potential therapies (not cures) for peanut allergies are being developed by pharmaceutical companies and expect FDA approval soon (Tilles, S. & Petroni, D., 2018). These new therapies are being considered by allergists for implementation into their own practices (Greenhawt & Vickery, 2015).

### **Physical effects of Food Allergies**

When a person ingests a food to which they are allergic, a variety of allergic reactions can occur, ranging from a simple skin rash to life-threatening anaphylaxis. These reactions occur because histamines are released by mast cells located in the skin, gut, lungs, mucosa, and around blood vessels. Symptoms vary and can be unpredictable, ranging from mild discomforts such as skin rash, urticaria, rhinitis, or mild abdominal pain to more moderate symptoms such as nausea, vomiting, angioedema, and wheezing. Anaphylaxis is the most severe symptom that can occur during an accidental ingestion of a food allergen, causing respiratory distress, throat swelling, or circulatory collapse with extreme hypotension.

### **Psychosocial Consequences of Food Allergies**

The daily threat of anaphylaxis causes much anxiety for food allergic (FA) children and caregivers (Broome et al., 2015), and for many it defines their lifestyle. Parents are under the

daily threat of their child potentially having a life-threatening reaction each time they eat. The anxiety that develops from this fear can also lead to overprotective behaviors by restricting a child's diet, playdates, social events, and travel; children may also develop learned behaviors such as helplessness when parents control every aspect of their child's life (Quach & John, 2018). A third of FA children report being bullied for their food allergies, (Peck & Larson, 2018), and according to Polk & Dinakar (2017), peanut allergic children experience greater anxiety when eating at social events than children with insulin-dependent diabetes. These and other similar experiences significantly affect quality of life in children and caregivers.

An alternative therapy for treating food allergies is oral immunotherapy (Panjo, et al., 2017). As this treatment becomes more available to healthcare institutions, managing FA anxiety may become a key element of any OIT program, as evidenced by a study focusing on the QOL of these patients and their families before, during, and after OIT, published by Epstien-Rigbi, et al., (2019). The authors report that quality of life (QOL) temporarily decreases during the process of OIT for some families, but improves significantly once maintenance dosing (or even partial desensitization) is achieved. This temporary decrease in QOL is most likely due to the fact that the first half of OIT encompasses challenges such as fear of reactions and general anxiety about the program. This temporary decrease of QOL during OIT therapy warrants further discussion, including how to minimize anxiety during therapy.

Investigating Lerwick's four treatment principles for minimizing anxiety during healthcare visits and therapies - choices, agenda, resilience, emotional support (CARE) - may provide useful information (2015). When *choices* are offered during OIT therapy, such as the vehicle the patient would like to use to mix the peanut powder in (applesauce or pudding), the patient feels a sense of empowerment by choice. When providers offer an *agenda* to the patient

and family, the healthcare experience becomes clear from the start reducing fear of the unknown, and can be easily provided during orientation meetings with families and patients, as well as throughout the course of the therapy. *Resilience* can be discovered by asking parents to describe how they have managed their child's peanut allergy, and what they would like to do differently. Fear is a common *emotion* for patients and parents of OIT therapy, especially with previous anaphylactic experiences from accidental exposures. Emotional support can be provided by discussing these emotions prior to and during therapy as reported by Lerwick (2016), as would offering availability of an OIT provider during therapy (i.e., by phone or electronic mail).

### **How OIT Works**

In the past decade research trials have been conducted in large academic institutions introducing oral desensitization to the most common food allergies with great success (FARE, 2018). It is important to note that oral immunotherapy is considered a desensitization program and not a cure, as long-term unresponsiveness continues to be researched and is unknown to date. The immunologic change during oral immunotherapy is described by Wood (2017) as a process that increases food-specific IgG4 while basophil and mast cell responsiveness decreases. The process of peanut OIT has three stages; first is the initial escalation, followed by a series of "up dosing" appointments which slowly increase the patient's reactivity threshold, until a target maintenance dose is achieved. The final phase is considered the maintenance phase where the patient must continue daily dosing in order to maintain tolerance. Since there is no ideal protocol, numerous studies publish a variety of approaches on how to conduct the three phases, including dosing recommendations and maintenance dosing (Panjo, et al., 2017; Bird, et al., 2018; Wasserman, et al, 2014 and 2019; Bégin, Chinthraah, & Nadeau, 2014). This pilot study



for which the program evaluation is being conducted chose a protocol that would be achievable in approximately six months.

### **Burdens To Enrolling In OIT**

Despite reported adverse reactions being common in OIT (mild skin or mouth itching, or abdominal discomfort), the ability to receive this therapy has become very desirable by many parents since the margin of safety for FA individuals is greatly improved, and safety is an essential concept for patients, parents, and clinicians (Shreffler et al., 2019). Since no pharmaceutical product is yet commercially available, private clinics that are pioneering OIT programs are hiring their own pharmacists and pharmacy technicians to carefully measure peanut protein powder into appropriate doses (using a commercially manufactured powder). Once FDA approval allows for a premeasured peanut powder to be prescribed, more independent allergy clinics will consider offering this therapy to patients in their communities (Greenhawt & Vickery, 2015).

While OIT therapy is considered a long-term commitment lasting years, since tolerance is still under investigation, at this time it appears that in most patients desensitization can be lost if dosing is discontinued (Wood, 2017). How long the “long term commitment” lasts continues to be analyzed with ongoing longitudinal studies (Wasserman et al., 2019). Fortunately there are a number of peanut products with calculatable protein measurements that Wasserman, et al., has published (2019), allowing for a variety of dosing options when one peanut product becomes less palatable than another (i.e. specific peanut containing candies, and powders that are commercially available).

Parents report that undergoing OIT with their children causes much anxiety, especially when they are asking their peanut allergic child to eat the very food that can cause great harm

(Epstien-Rigbi, et al., 2019 ). Because it can be so anxiety-provoking, establishing trust between the parents, patients, and providers is crucial, as is for the provider to disclose potentially harmful effects of OIT even during the maintenance phase, such as eosinophilic esophagitis, and the continued threat of anaphylaxis if accidental ingestion of peanut is more than the individual's threshold tolerance. These discussions should take place when recommending OIT as an option, but discussed in more detail while obtaining consent for treatment.

### **Benefits to enrolling in OIT**

Shreffler et al., reports that according to FDA Allergenic Products Advisory Committee, achieving a level of protection that reduces the rate of or degree of allergic reactions is clinically meaningful, and goes on to report that by desensitizing a person to approximately one peanut (300 mg), anaphylaxis due to accidental ingestion may be reduced by 95%, thus providing a margin of safety for peanut allergic patients encountering trace levels of peanut (2018). This amount of safety allows the individuals to ingest products that report “trace amounts of peanut” on their labels. As noted earlier, achieving any level of tolerance to peanut that improves safety from anaphylaxis due to accidental ingestion increases QOL for the allergic individual as well as the family.

Undergoing OIT and achieving a maintenance level of 300 mg of peanut protein takes approximately six months, after which the individuals continue to dose daily at the maintenance level of 300 mg. Wesserman et al., has recently reported that Peanut Specific IgE levels commonly fall during the first year of maintenance dosing (2019), thus OIT patients may anticipate being able to tolerate ingesting higher than maintenance dose levels if challenged during an allergist's office visit (referred to as an oral challenge).

## **Theoretical Framework**

Nursing models of care encourage using evidence-based practice (EBP) to promote high quality care. Since both nursing models and EBP promote incorporating evidence into healthcare practice decisions, nurse practitioners (NP) are in an excellent position to lead EBP changes in healthcare (Dontje, 2007). The Iowa Model of Evidence Based Practice (EBP) was used to guide the implementation of OIT research into the clinical practice at a private allergy clinic. The model can be considered a type of holistic approach since it considers the entire healthcare system as well as its individual contributors and resources. The Iowa Model, developed by Marita G. Titler, is designed to guide clinical practice using a scientific method of evidence-based research in improved practice, with the ultimate goal of answering clinical questions, and predicting patients' outcomes (Titler et al., 2001). Elements of the IOWA Model are: (1) identify a problem, (2) determine a plan, (3) form a team, (4) gather evidence, (5) critique and synthesize the evidence, (6) determine the validity and appropriateness of the evidence, (7) pilot change, (8) determine if the change is appropriate for practice, (9) implement, and (10) disseminate results.

### **Implementation of Theoretical Framework**

The problem identified by this study's allergy clinic was the growing number of patients diagnosed with food allergies, (especially peanut allergies), without available treatment options. Providers conducted annual reviews with each family discussing their food allergy action plan, reiterating avoidance and how to use an epinephrine injectable for accidental ingestion and anaphylaxis as directed by the national guidelines (FDA, 2019). Resolving this problem by introducing OIT, which is anticipated to lead to improved QOL for their patients, is a priority for the private practice stakeholders, especially since research suggested that OIT can be successfully implemented in private allergy clinics (Wasserman et al., 2019, and Tilles &

Petroni, 2018). Step 2 of the IOWA model: Implementing a peanut OIT program, was determined by the physicians of the group. Step 3 led to the formation of the taskforce which was responsible for gathering the evidence (included in step 4), critiquing and synthesizing the evidence (step 5) in order to determine validity and appropriateness of the evidence (step 6). Guidelines were created with regard to protocols, safety, dosing, maintenance targets, utilizing published research (as described earlier), as well as establishing relationships with mentoring clinics that have reputable OIT programs. Step 7 of the model was defined as the pilot program implementation in May of 2018. Step 8 determines if change is appropriate for practice and utilized a template provided by the CDC, Appendix F (2019). This template was originally created to evaluate state and individual clinic asthma programs, but was found to be generic enough to be used for this peanut OIT program evaluation. The program evaluation took place during the month of February 2019. The program evaluation will determine the successes of the OIT program, as well as offer recommendations about quality improvements that may be considered. Step 9, or implementation of changes will occur after quality improvement recommendations are decided upon by the stakeholders of the clinic. Step 10 will take place in the future as the peanut OIT program continues to grow and as commercially available products become available. Utilizing the Iowa Model of EBP, and then transitioning to the CDC Program Evaluation helped guide the implementation of the new peanut OIT program and ultimately assisted with the program evaluation. Both were invaluable tools.

## CHAPTER 2: LITERATURE REVIEW

Prior to the clinic's implementation of the peanut OIT program, optimal therapy guidelines were addressed and agreed upon by the clinic physicians using the best available evidence and expert knowledge. Thus detailed clinical protocols were not reviewed during this program evaluation rather, emphasis was placed on measurable outcomes of the OIT program, and how the program can be improved. Since outcomes of the program evaluation entail food allergy treatment success, safety guidelines surrounding food OIT, the psychosocial aspects of living with food allergies and how to address the anxiety involved, the following publications were used as guides.

### **European Guidelines Publish Evidence-based Recommendations**

The European Academy of Allergy and Clinical Immunology Task Force on Allergen Immunotherapy for IgE-mediated Food Allergy published evidence-based recommendation for food allergen immunotherapy (Pajno et al., 2017). The Appraisal of Guidelines for Research & Evaluation (AGREE II) framework was used to design appropriate representation in terms of stakeholders, relevant literature, and non-bias recommendations. This guideline is the first of its kind assisting clinicians with the management of food allergen immunotherapy, pointing out general considerations before initiating therapy, general contraindications, effectiveness of the different immunotherapy approaches, safety, and addresses gaps for future research.

### **AR101- DBPCFC Clinical Trial**

Efficacy and safety of peanut OIT is reported in great detail in the randomized, double-blind, placebo-controlled clinical trial conducted by Bird, et al., (2018). The sample size was 55, including individuals aged 4 to 26 years, and an up-dosing phase lasting 20-34 weeks. The endpoint of this study was defined as the number of subjects successfully ingesting at least 300

mg of a pharmaceutically prepared peanut protein compound (AR101) without major dose-limiting symptoms. Adverse reactions occurred in 95% of the subjects, reporting at least one mild to moderate reaction during treatment, with the most common complaint being GI symptoms (mild oral pruritis, abdominal pain, or vomiting) reported by 66% of the group receiving peanut protein.

### **Incidence of Anaphylaxis with OIT**

Creating safety guidelines for a peanut desensitization program is a key component addressed in protocol development. Allergic reactions to peanut exposures can vary from mild symptoms to severe anaphylaxis. It is valuable for any clinic considering peanut OIT to review the literature regarding frequency of symptoms, especially severe symptoms warranting epinephrine auto injectors. Wasserman et al., (2014) completed a retrospective medical record review of 352 patients that underwent peanut OIT in 5 private clinic settings. This review included 79,726 escalation doses, with 57 dose-related reactions (0.7 per 1,000 doses) warranting epinephrine. All 57 reactions were effectively treated by the epinephrine and no hypotension warranting intravenous fluids or symptoms of shock was documented. The data analysis from this study suggests that the private clinic setting results are similar to trial results from larger institutional OIT studies (Wasserman et al., 2014), and overall systemic reactions warranting epinephrine is comparable with the 0.1% systemic reactions noted with the high dose subcutaneous immunotherapy used in what is commonly known as “allergy shots” (Wasserman et al., 2014). The final data points are encouraging, stating 79% of the 352 participants reached maintenance doses (taking into account attrition).

## **Reducing Parental Anxiety During OIT**

Since research regarding the impact of peanut OIT is still in progress, creating a program evaluation that includes important stress-reducing components may aid in future OIT program development. Herbert, Shamesh, and Bender's 2016 clinical management review article about food allergy anxiety described how families reported benefit from having their medical provider listen to their concerns while discussing food allergies. Behavioral interventions addressing parents needs of children with food allergies are few, but are touched upon in this report suggesting parent support groups and workshops improving food allergy competence and decreased burden. Other valuable findings of this review included parental anxiety and psychosocial concerns related to food allergies and parents admitting that they struggled to recognize symptoms of mild food allergy symptoms versus anaphylaxis (2016). Findings from Herbert et al.'s article (2016) are especially useful during educational protocol development for any private clinic OIT program, and was especially helpful during the parental survey creation for the program evaluation.

Another article from Epstein-Rigbi, et al., (2019) focuses on how QOL is affected throughout the OIT process. This prospective cohort study utilized the Food Allergy Quality of Life Questionnaire-Parent Form (FAQLQ-PF), a validated testing tool developed to examine the QOL of children as assessed by their parents. Again, this study's results report a consistent improvement in QOL for these families once the patient reaches maintenance. This article does points out however, that additional anxiety is experienced by these families during the OIT process itself, concluding that implementing methods to overcome these challenges are beneficial for the overall experience.

## **Gap Analysis**

All of the articles in this literature review served important and specific purposes within the peanut OIT pilot study evaluation. Since peanut OIT implementation within the private practice setting is relatively new, no published data is available to guide private allergy clinics regarding logistics, patient and family education, and reducing parental anxiety during therapy. These notable gaps in the literature will be addressed during the discussion of results highlighted by the program evaluation.



## CHAPTER 3: METHODOLOGY

### **Design**

The U.S. Center for Disease Control has a valuable website of resources and materials that can be utilized for program evaluations (CDC, 2018). Appendix F is the Individual Evaluation Plan Outline that was used for an asthma program evaluation guide, and has been used here to evaluate the OIT program. A separate survey was created by the researcher (and approved by the physicians of the group, prior to IRB submission) measuring the parent's perception of how specific elements of the OIT program helped reduce parental anxiety during their children's OIT experience.

Individuals involved in the program evaluation include stakeholders, identified as the board of directors for the private clinic, and individuals that were identified as "OIT champions" including practicing physicians, administrators, and healthcare providers (nurses and NPs) leading the implementation of the OIT program. Lerwick's CARE principles were considered during the peanut OIT program development so as to include elements in the program that would reduce parental anxiety during therapy. The importance of these elements were then tested by incorporating parental input of patients enrolled in the program. This was accomplished by having the parents complete a program survey containing ten questions rating anxiety-reducing elements of the program and other activities that helped ease anxiety.

The program evaluation focuses on three themes; (1) effectiveness of therapy (including safety evaluation via retrospective data collection), (2) parental anxiety-reducing elements of the OIT program (using a parent survey), and (3) the impact of adding an OIT program to a private allergy practice, (including cost effectiveness, and impact on resources). The pilot study started September 1, 2018 and was completed February 28, 2019, and parental surveys were

administered during the second half of their child's OIT program. The program evaluation took place during the month of February 2019. No special procedures were used.

### **Potential Benefits**

Potential benefits of this evaluation includes discovering program elements that may require quality improvements, thus allowing stakeholders the opportunity to make practice-changing decisions. Potential benefits of the parental survey findings will also help the stakeholders understand what improvements are necessary for parental satisfaction of the program. Findings from this pilot study evaluation will benefit future clinicians as well as patients considering OIT programs across the country.

### **Potential Risks**

Potential foreseeable risks are minimal since this project is focusing on the program evaluation of the pilot program, rather than the OIT peanut protein powder treatment. Potential OIT parental anxiety triggers were addressed within the program via pre-enrollment education meetings with the allergist and OIT nurse practitioner, as well as offering referral to a local food allergy anxiety specialist. Informational packets given during orientation allow parents to review the program with their families before committing to the approximately six-month program. Additional food allergy anxiety- reducing measures are included in the parental program survey (**Appendix A**).

### **Sample**

Participant size was small (n=15) since this was a pilot study consisting of parents of children undergoing peanut OIT, and was one of convenience taking place at a private allergy clinic. The 15 parents (12 mothers and 3 fathers) made up the evaluation sample and was

representative of the community since the allergy clinic has a diverse population of patients and providers (including Caucasian, Vietnamese, Chinese, Korean, Thai, Indian, and Filipino).

The average age of the children represented in the retrospective chart review was 10 (youngest at 4, and oldest at 16), with 9 males and 6 females. The clinic providers completed an OIT eligibility criteria form for recommendation to entering the program. The inclusion criteria for entry into OIT included children with 2 of the 3 positive test results: 1. positive serum peanut-specific IgE within the past 18 months, 2. positive skin prick test, 3. positive allergic reaction experience before entering the program. Five (30%) of the subjects had a lifetime history of at least one anaphylactic event requiring epinephrine. The average peanut-specific IgE was 48.6, (minimum 1.34, and max >100). Subjects were allowed to continue any asthma or eczema therapies during OIT provided that they were stabilized before starting therapy.

Criteria for inclusion for this program evaluation included all parents of children participating in OIT therapy at the private allergy clinic. Exclusion criteria included parents that chose not to provide informed consent or did not participate in the survey. All parents that were enrolled in the clinic's peanut OIT program volunteered to participate in the program survey during the second half of their child's desensitization program (after 20 weeks of starting OIT). No parents declined taking the survey and all gave consent for retrospective chart review for their children. Receiving honest parental survey answers were important to this evaluation, thus parents were informed that the surveys would be kept anonymous and was ensured by instructing parents to omit names from the survey, and by giving plain white envelopes for the parents to seal the completed survey in. The OIT nurse then placed the blank, sealed envelopes into a large legal file folder for storage until analysis.

### **Study Oversight**

The study protocol, survey, and consent forms first received approval letters from the Clinic Director, followed by approval by the Project Chair, committee members, and the California State University's Fresno Institutional Review Board. Two written informed consents were obtained from the parents of the subjects enrolled in the program evaluation. The first consent provided permission to use the parental survey results in this doctoral project, and the second provided a retrospective chart review for collecting adverse event and OIT success rates of each subject.

### **Measures**

The OIT pilot study evaluation follows the CDC's Appendix F utilizing the Individual Evaluation Plan Outline (CDC, 2018), and identifies process improvement elements the stakeholders will address before making decisions about expanding the current program. Since much of the evaluation outline involves protected information including names of stakeholders, and budgetary information, only applicable information will be reported deemed useful by readers of this study. In order to continue as a viable program, questions involving program success rates, safety outcomes, necessary resources, and long term goals were addressed (see Table 1) using what is known from the pilot study using fifteen patients over a 10 month retrospective time span.

All quantifiable outcomes were measured by means of descriptive statistics using data collected from chart audits in a retrospective fashion from the pilot study sample with no controls. Measures of frequency and central tendencies were used for calculating the total number of doses versus the number of reported mild, medium, and severe adverse reactions.

These safety measures were then compared to the data reported by published studies from respected research institutes where considerably more rigor and larger sample sizes were used.

**Table 1**  
*Evaluation Questions & Criteria*

<b>Evaluation Question</b>	<b>Criteria or Indicator</b>	<b>Standards (What Constitutes “Success”?)</b>
1. How effectiveness is OIT therapy compared to published studies?	<i>Number of subjects completing OIT program vs dropping out.</i>	<i>&gt;79% success (number of patient reaching maintenance (Wasserman, et al., 2014)</i>
2. How common are adverse reactions during escalation phase of OIT?	<i>% of reported symptoms:  Mild</i>	<i>Mild/moderate: occurring in ≤ 95% of escalations (per results reported by Bird et al., 2018)</i>
	<i>Moderate</i>	
	<i>Severe:</i>	<i>≤ 0.7 per 1000 doses (per results from Wasserman et al., 2014)</i>
3. Is the allergy clinic addressing anxiety reducing practices for families with food allergies?	<i>Parent survey: rating anxiety reducing elements of OIT program</i>	<i>Parent survey ratings average “strongly agree/ agree”.</i>
4. Do parents feel the OIT information and education they are receiving help reduce their anxiety about the program?	<i>Parent survey Questions 1, 2, 3, 4,</i>	<i>Parent survey ratings average “strongly agree/agree”.</i>
5. Cost Effectiveness	<i>NP vs DR visits for OIT</i>	<i>N/A – Program evaluators will determine</i>
6. What pros/cons are parents reporting about OIT?	<i>Parent survey open-ended question responses</i>	<i>Review of answers will direct stakeholder decisions about OIT program.</i>

(Taken from CDC’s Appendix F: Program Evaluation Form)

Measures involve patient caregivers’ anxiety with OIT therapy, included a ten-question survey listing anxiety-reducing elements the providers considered useful for any OIT program.

The parents were asked to give a Likert Scale rating of how helpful each element of their OIT experience was in decreasing their anxiety (5=most helpful, 1=least helpful). The survey was given to each child's parent during the second half of their OIT therapy (during weeks 16-26) and took place during the months of September 2018 through February 2019. Before completing the survey, the parents signed a consent form that explained confidentiality and anonymity of the completed questionnaires.

### **Procedure for Data Collection**

Precautions taken to minimize risks included confidentiality and anonymity of parental evaluations; the survey was administered by the OIT nurse, no names of patient, parent, or associated provider were on the survey and the completed survey were placed in blank individual envelopes that the parent could seal upon completion. To insure 100% return of surveys, parents were given the survey during their child's up-dosing appointment, where they had 60 minutes to complete the survey. The anonymous surveys were stored in a locked file that only the OIT nurse researcher had access to at the private allergy clinic. Once the program evaluation was complete, all questionnaires were destroyed by professional shredding service. No compensation was provided for the parents participating in this project.

OIT success rates and adverse reaction rates were gathered by the researcher using retrospective chart review. The total number of doses per subject were counted as well as the total number of mild, moderate, and severe reactions.

### **Data Analysis**

Parental survey answers were given a Likert scale number: "Strongly agree" became a 5, "Agree" a 4, "Neither Agree or not" a 3, "Disagree" a 2, and "Strongly disagree" a 1. These scores were loaded into an Excel Spreadsheet and mean scores were computed by the researcher.

Safety analysis was also conducted via Excel by calculating the total number of doses administered by all 15 of the children, and adding up all the dose related adverse reactions, further specifying mild, medium, and severe allergic reactions. Patients are required to keep a dosing diary, and to bring them to each up-dosing appointment for further review by the provider before increasing to the next dose. The data from these diaries were collected and uploaded for data analysis.

## CHAPTER 4: RESULTS AND FINDINGS

The pilot study evaluation focuses on three major themes:

1. Success and safety of OIT program in a private clinic setting was compared to established research center data, using previously published results by Wasserman, et al. (2014 & 2019), and Bird, et al. (2018).
2. Parental food allergy anxiety was examined by parental survey.
3. Evaluation of logistical requirements within OIT program generated recommendations for process improvements or modifications to the current program, (which will be further discussed in the final chapter of this paper).

### **Demographic and Study Analysis**

#### **Theme 1:**

Of the 17 parents in the evaluation study sample, discontinued within the first three appointments due to their children reporting adverse symptoms. One patient took a six month leave due to abdominal pain and vomiting and followed up with a GI specialist (no endoscopy was done, but a proton-pump inhibitor was prescribed). The second individual complained of “difficulty swallowing” that did not improve with antihistamines, steroids, nor ENT and GI follow up. Since his symptoms continued six months after withdrawal from OIT, the providers suspected OIT was not the cause of his symptoms. The remaining analysis included the 15 parents with children that achieved maintenance therapy or reached at least 20 or more weeks of therapy. Of the 15 patients all but 2 reached 300 mg by the time the data was collected, resulting in an 87% success rate of reaching maintenance, (the remaining two are anticipating to reach maintenance within 5 escalations).

The peanut OIT data of 15 patients between the ages of 4 and 16 (mean 10) was collected via retrospective chart review at a time when all had either reached maintenance or were within 5



up-dose appointments to maintenance (See Table-2). A total of 2826 doses were administered between May 2018 until February 2019, with 12 (80%) of the subjects complained of adverse symptoms during OIT escalations, and 3 (20%) had no symptoms at all. The peanut-specific IgE for the three subjects without symptoms ranged from 3.85 to >100, suggesting that IgE levels have no bearing on the number of adverse symptoms expected.

“Mild” symptoms were defined by this project as transient symptoms that resolved within 30 minutes without the use of antihistamines, such as stomach ache, mouth tingling, mild skin pruritis/urticaria. “Moderate” symptoms included any symptom that warranted antihistamines for resolution of symptoms such as abdominal pain lasting greater than 30 min or multiple areas of urticaria. “Severe” symptoms were classified as any symptom warranting the use of epinephrine injectable for resolution. Four of the patients (27%) started reporting moderate symptoms regularly and were prescribed either a daily antihistamine and/or H2 blocker, thus improving symptoms for the remainder of the therapy. Mild symptoms were reported by 8 patients, a total of 80 times (3%), and moderate symptoms were reported by 4 of the patients 102 times (4%). It is also noted that 4 of the 15 patients reported >10 adverse events versus the remaining 11 patients reported <10 or no symptoms throughout their escalation period (phase 2 of OIT).

Two anaphylactic events (0.07%) were reported by two patients (once by each) both occurred toward the end of the escalation period of therapy. One injection of epinephrine was reported to have immediately stopped the reactions of epidermal erythema, chest tightness, and difficulty with swallowing, no IV fluids were warranted during the emergency room follow up. In both cases, parents reported that the patients did not follow the 2-hour rest protocol. Fortunately, both patients reached maintenance and have reported no further adverse symptoms with OIT.

**Table 2**  
*Sample Analysis*

Total number (%)	
Sample Size of study	15*
Total number (%)	
Sample Size of study	15*
No of patients achieving Maintenance	13 (87%)
Maintenance target dose	300 mg
Mean Age:	10 (4-16)
Female:	6
Male:	9
Mean PS-IgE:	48.6 (1.35->100)
Pts without Rxns:	3 (20%)
Pts with Rxns:	12 (80%)
Total Doses:	2826
Total # Reactions	184 (7.1%)
Mild	80 (3%)
Moderate	102 (4%)
Severe	2 (0.07%) or (0.7/1000)
Average weeks on OIT	30 (26 - 34)**
*2 subjects temporarily stopped OIT due to adverse symptoms	
- One has recently restarted OIT (premedicated with daily H2 blocker)	
- Second subject continues to describe “dysphagia” 6 months after OIT stopped.	
** One outlier took 43 weeks to reach maintenance	

**Theme 2:**

Parents were asked to complete the peanut OIT program evaluation survey as part of this report in order to assess what elements of the OIT experience were found to be most valuable in decreasing their food allergy-related anxiety (See Table 3 for survey questions). All 15 parents of the program sample agreed to complete the survey (chart of responses in Appendix B), achieving 100% return. This was accomplished by requesting survey completion during the patient’s escalation visit observance time of 60 minutes post up-dosing. The ten questions

measured activities that helped ease a parents anxiety about the food allergy program. The answers were assigned a Likert scale value in order to calculate mean scores for each question (Strongly Agree = 5, Agree = 4, Neither Agree or Disagree = 3, Disagree = 2, and Strongly Disagree = 1).

**Table 3**  
*Parental Survey Questions*

- |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <ol style="list-style-type: none"> <li>1. Discussing peanut OIT with my child's allergy provider helped ease my anxiety about the program</li> <li>2. The OIT orientation meeting helped ease my anxiety about the program.</li> <li>3. The orientation folder was helpful and easy to use</li> <li>4. Education provided on the first day of OIT helped ease my anxiety about dosing at home.</li> <li>5. Knowing I could speak to a provider 24/7 helped ease my anxiety about the program.</li> <li>6. Knowing I could speak to a psychologist about my child's food allergies was helpful.</li> <li>7. Completing my own OIT research helped ease my anxiety about the program</li> <li>8. Having quiet activities available during escalation appointments was helpful.</li> <li>9. Being involved in an on-line food allergy website/blog has helped ease my anxiety about food allergy desensitization.</li> <li>10. Speaking to friends about their experiences with peanut desensitization helped ease my anxiety about OIT.</li> </ol> |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

The results of the survey were compiled in Appendix A with the following scores: The parental survey conveyed that education provided by their allergist is considered very helpful (score mean=4.7) in easing parental anxiety. Attending an hour long orientation meeting discussing how OIT works and the commitment that is involved also scored high in reducing parental anxiety (mean =4.8). The parent's take-home orientation folder explaining OIT, timelines, how to treat adverse symptoms, and contact information also received high scores in easing anxiety (mean=4.7). The first phase of OIT includes the initial escalation day that takes approximately 5 hours and involves a series of very small doses increasing in peanut amount spaced 30 minutes apart referred to as oral challenges (OC). After the OC is completed, the OIT

providers have the opportunity to educate the patients and parents in more detail about how to treat a variety of symptoms at home (allergic versus viral illness, etc). Patients and parents are also encouraged to practice using the epinephrine injectables as part of the education provided. Completing this education scored high among the parents in easing anxiety, resulting in a 4.7 rating. Having an allergist provider available to speak to the parents 24 hours a day, 7 days a week also rated high with a mean score of 4.7 in easing parental anxiety. Since food allergy anxiety can be serious, allergist that have a relationship with psychologists specializing in food allergy anxiety could be seen as beneficial, and was a priority for the pilot study providers. None of the parents or subjects in this program evaluation warranted or requested referral to counseling, but having the option available proved value in decreasing parental anxiety with a rating of 4.3. Having quiet diversional activities available during the lengthy appointments were also rated 4.1 in easing anxiety, however most families brought their own activities and electronic devices for entertainment. Parents today are more apt to initiate their own research about food allergies and OIT, and those that did or spoke to friends about OIT rated these exercises 4.3 and 4.1 respectively in easing anxiety. Interestingly enough, online searches and blogging on food allergy websites only scored an average of 3.5 in easing parental food allergy anxiety. A chart of these responses is found in Appendix B.

### **Summary of the Evaluation Results**

Indicators of success were decided upon in collaboration with the clinic stakeholders and the program evaluation author, and is summarized in Table 4:

**Table 4: Evaluation Questions & Criteria**

Evaluation Question	Criteria or Indicator	Standards (What Constitutes “Success”?)	Program Evaluation Results
1. How effectiveness is OIT therapy compared to published studies?	<i>Number of subjects completing OIT program vs dropping out.</i>	<i>&gt;79% success (number of patient reaching maintenance (Wasserman, et al., 2019)</i>	<i>87% of patients achieved maintenance.</i>
2. How common are adverse reactions (AR) during escalation phase of OIT?	<i>% of reported symptoms:</i>  <i>Mild</i>	<i>Mild/moderate: occurring in ≤95% of escalations (per results reported by Bird et al., 2018)</i>	<i>Total number of patients reporting AR: 80%</i>  <i>3% (8 patients)</i>
	<i>Moderate</i>		<i>4% (4 patients)</i>
	<i>Severe:</i>	<i>≤ 0.7 per 1000 doses (per results from Wasserman et al., 2014)</i>	<i>0.7 in 1000 doses (2 patients)</i>
3. Is the allergy clinic addressing anxiety reducing practices for families with food allergies?	<i>Parent survey: rating anxiety reducing elements of OIT program</i>	<i>Parent survey ratings average “strongly agree/ agree”.</i>	<i>4.6/5.0</i> <i>Mean score</i>
4. Do parents feel the OIT information and education they are receiving help reduce their anxiety about the program?	<i>Parent survey Questions 1, 2, 3, 4,</i>	<i>Parent survey ratings average “strongly agree/agree”.</i>	<i>Yes (mean score of 4.7/5.0)</i>
5. Cost Effectiveness	<i>NP vs DR visits for OIT</i>	<i>N/A – Program evaluators will decide</i>	
6. What pros/cons are parents reporting about OIT?	<i>Parent survey open-ended question responses</i>	<i>Review of answers will direct stakeholder decisions about OIT program.</i>	<i>Parents report: “this is a life changer for our family!”</i>  <i>(See notes for complete set of responses)</i>

(Taken from CDC’s Appendix F: Program Evaluation Form)

**Evaluation Questions and Criteria Results:**

**Evaluation Question 1:** Pilot Study OIT program success rate of achieving maintenance dosing is equal to published results as measured by the number of subjects completing OIT program versus dropping out. The 2014 study by Wasserman et al., was the first to publish adverse events during peanut OIT using 5 private practice clinics (see details in literature review), and reported 80% of participants reaching maintenance. In comparison, this pilot study was able to report 87% of patients reaching maintenance (13 out of 15) by the time data was collected, (with the two remaining patients within 5 escalation doses of reaching maintenance).

**Evaluation Question 2:** The number of patients experiencing adverse reactions (AR) during escalation dosing is similar to the 95% reported by Bird et al., (2018) as measured by twelve of the 15 patients reported AR during the escalation period thus 80% of the patients reported “mild” to “moderate” symptoms. The number of adverse reactions requiring epinephrine occurred in 2 separate dose related episodes (out of a total of 2826 doses), resulting in 0.7 per 1000 doses. The 2014 study by Wasserman et al., published adverse events requiring epinephrine occurred 57 times during 79,726 escalation doses, also resulting in 0.7 per 1000.

**Evaluation Question 3:** Parental survey scores rated high for the food allergy anxiety reducing elements that were implemented prior to the start of the pilot study, generating scores averaging 4.6/5.0.

**Evaluation Question 4:** Parents reported the OIT information and education they are receiving helped reduce their anxiety about the program with a mean score of 4.7/5.0

**Evaluation Question 5:** Cost effectiveness was not reported here, due to limiting reportable financial data, but reportable elements will be discussed in Chapter 5.

**Evaluation Question 6:** Additional comments given by the parents in an open-ended question at the end of the survey read: “Please offer any further suggestions on how to decrease anxiety during the desensitization program”

Response #1: “Put the allergy clinic phone number on the front of the Orientation Folder for quick reference”

Response #2: “Being able to schedule appointments on dependably regular basis and having appointments start and finish on time are immensely helpful”

Response #3: “Nothing can truly prepare nor alleviate the anxiety that comes with watching your child eat the very thing that can cause them extreme harm for the first time. However, the reassurance from the staff went a long way in quelling that fear enough to proceed with the program. The FNP an RN staff are all truly special people – whom we are grateful for each and every day! After that initial appointment, the anxiety has continued to diminish and now have no fear as we continue escalation appointments. I feel confident in this program! Thank you!”

Response #4: “If the other moms going through at same time were open to a group email/text, that may have been added bonus – even just one other mom, not that they weren’t – just a suggestion. A bonus would be a one-page laminate or some type of chart that we could hang up in the kitchen:

- 1      Calm
- 2      dose with food
- 3      swish
- 4      Calm”

## CHAPTER 5: DISCUSSION

Despite several limitations to this paper, analysis of the quantitative data resembled the data published from larger more rigorous studies, as noted in Chapter 4. The program evaluation template provided formal talking points about the logistics of implementing a new peanut OIT program, and were addressed with the OIT staff and stakeholders. Key points will be discussed in this final chapter.

### **Survey Bias**

The evaluation sample of parents that was used for this study was one of convenience, and represented a skewed gender population with 12 mothers and 3 fathers. A nonresponse bias occurred with three of the surveys that had no response to questions that the parents reported as “non-applicable” (N/A) but were addressed specifically to non-OIT program elements (such as conducting outside research about OIT), and these N/A responses were not calculated into the survey mean results. A voluntary response bias may result since parents may have strong opinions about their children having the opportunity to be desensitized to peanuts. The researcher attempted to reduce response bias by keeping the surveys anonymous as described in chapter 4.

### **Limitations**

The sample size of this pilot study is limited, with 15 parents and 15 children. An attempt to compare data from the 15 patients (children) with larger, more rigorous studies gave promising results for the overall program evaluation outcomes. Since this program evaluation used a sample of convenience, no blind or control groups were applied. Parental roles (mothers versus fathers) may have led to survey response bias, and in the future, surveying both parents would be recommended. Adverse reaction reporting in the daily dose diaries may have also been



biased since most of the reported symptoms were subjective, such as abdominal pain, or itchy mouth. These reactions may have also been under or over reported as well, depending on parent's perception of severity. Another limitation may be that the sample came from a geographically non-diverse group of parents living in the Silicon Valley.

### **Program Evaluation Results**

The following discussion will cover key points the evaluation noted including program modifications that may be warranted. This discussion may be viewed as useful information for allergy providers contemplating implementation of a peanut OIT program.

### **Staff Education and Competencies**

During pre-implementation of the peanut OIT program, the champion nurses, nurse practitioners, and doctors created protocols for how the initial escalation day will proceed, including safety requirements and equipment. Templates were created for nursing and providers for easy documentation. The same was created for the up-dosing appointments. Once the protocols were agreed upon by the stakeholders, competency checklists were created and all OIT providers were signed off on standard procedures required for OIT appointments and handling anaphylaxis. OIT nurses are also responsible for fielding calls from parents with children undergoing OIT during office hours thus protocol-driven vignettes are used by nurses to refer to for the advice line. The NPs are responsible for auditing these calls and following up with any concerning questions.

Administrative duties such as insurance billing, scheduling OIT appointments, and collecting payments were assigned to one person in order to ensure smooth processes. After re-evaluation of this facet, it appeared that the duties would be better served by two administrators, in order to have better coverage when one is out. It was decided that training more administrators

did not make sense since following a few weeks of trialing this option resulted in too many miscommunications and dropped call backs for scheduling, causing frustration for the families involved.

### **Parental Education is Key**

Parents appreciate the time spent teaching them about their child's food allergies. The key point of providing an orientation hour with the parents before starting a peanut OIT program is to teach them about how OIT works, how their child may react, and how the provider will help them manage the next 6 months. It is crucial that parents understand the daily commitment involved, and the protocols that are required for their child's safety. Having all this information provided in an informational guide book allows the parent to go home and process the information before making the commitment. The pilot study found that approximately 25% of the families that attended orientation decided that they were either not ready or postpone starting OIT until they had more time (such as summer months). As a result however, 100% of families that enrolled into the program were fully committed, followed the protocols carefully, and were either on their way or graduated successfully from the program. While providers discuss OIT as an optional therapy with their patients, it is important to include the risks and benefits of OIT for clear understanding of the therapy, thus providers need to stay current with food allergy research since breakthrough studies continue to be published.

Program safety discussions with the families have been found to be the cornerstone to the success of this program, and were valued by parents with high survey ratings. The best opportunity for this occurs once the final oral challenge is complete on day-1 of initial escalation. During this time the patient remains in the office for additional observational time, providing time for more detailed education to occur for parents. This information covers how to treat mild,

moderate, severe symptoms (including epinephrine injectable demonstration and practice), what to do if the child is sick with viral illness, travels to higher elevations, or misses a dose. All this information is documented and kept in the patient's personal OIT diary for further reference, thus empowering the parents with their own detailed information. Having this individualized education period at the end of the first day works well since the anxiety levels tend to decrease once the escalation dosing is complete, and parents are more focused on the education that is being provided.

### **Allergist Clinic Providing OIT**

Privately managed (non-academic, and "for profit") institutions are beginning to offer OIT services (i.e., [LatitudeFoodAllergyCare.com](http://LatitudeFoodAllergyCare.com)), and are providing allergy desensitization for a variety of foods. However, parents that prefer working with their own trusted allergist cannot be underestimated. Parents are looking for a quality of life improvement with OIT, yet they fear harm will come to their child. Therapy being provided by an allergist they have developed a relationship with while being treated for various environmental allergies, asthma, immunology disorders, and/or food allergy management, gives the entrusted allergist an advantage when adding peanut OIT to their services. Since increasing the patient's peanut tolerance occurs in a safe clinic environment, parents can rest assured that emergency treatment can be provided immediately if needed. When a parent has a question about their child's OIT therapy, (especially one that warrants immediate attention), providing 24/7 on-call provider coverage is also invaluable. The pilot study clinic where this evaluation was done has eleven providers (MDs and NPs) that take call without sharing the service with outside providers. This way all calls are personalized within the group, and immediate call back can be provided. Interestingly enough, OIT parents rarely called for assistance during the pilot study, speculating they were provided

with a guide in their orientation book that empowers parents and patients to take care of minor/moderate/severe allergic reactions themselves. Secure electronic mail was also found to be a convenient means of communication when parents had less timely information they need to discuss (such as scheduling conflicts, upcoming travel plans, etc.).

### **Cost effective practices**

This pilot study evaluation considered nurse practitioner led OIT programs that are overseen by physicians as a cost effective practice, provided these NPs are comfortable with conducting oral challenges and handling anaphylaxis. NPs are well practiced in educating patients and families, recognizing and treating the signs and symptoms of allergic reactions, prescribing treatments and medications (such as epinephrine injectors), and ordering initial diagnostic tests for potential patients. This evaluation also found that having one provider overseeing the OIT program (i.e., lead nurse practitioner) allowed for better management of the program and flow of communications with doctors, nurses, and administrators, thus not interfering with the daily appointment schedules and prescribed therapies of physicians.

Creating a guideline that specifies the eligibility criteria for potential OIT patients was considered cost effective by this pilot study since it ruled out candidates with contraindications to OIT. In order to create a comprehensive eligibility criteria guideline, Box 8 (general contraindications to FA desensitization) in the report published by Panjo, et al., (2017) was utilized. The one-page criteria form that was developed allowed prescribing physicians to check off the appropriate criteria that must be met in order for the patient to be eligible for peanut OIT.

This eligibility form was then given to the OIT lead NP to evaluate followed by initiating an OIT orientation meeting for the patient and family. This orientation meeting included the OIT administrator which conducted the Q&A of the financial aspects of the program, including

individualized discussions about insurance coverage for each family. By taking the time to orient the patient and family to the program, the OIT champions felt less time was spent with multiple phone calls for clarifications about the program, and dropout rates would most likely be minimized by explaining the program in detail before starting OIT.

Based on this pilot study evaluation, other staffing recommendations depend on the size of the practice but should include at least one to two nurses and NPs that specialize in OIT. Continuity of care greatly reduces parental anxiety during therapy because the parents learn to trust these caregivers as they do their allergist. In order to reduce miscommunication and scheduling conflicts, it is also recommended that one (or two) administrators champion the scheduling of OIT patients and handles the insurance claims. This administrator helps keep schedules running smoothly and handles all the non-medical aspects of running the program.

It is important to set aside a “nut free” space that can be used only for OIT allowing multiple children to be observed by one nurse during up dosing appointments. This pilot study found that 4 children per nurse were the limit in terms of safety and space available in the clinic. Since the children are required to be observed for approximately 45-60 minutes (Wasserman, et al., 2019), separating the OIT patients allows for uninterrupted provider visits in the rest of the clinic. When clinic space is limited, OIT programs can be scheduled during the afternoons of less busy days, or even a few evenings a week to optimize office space. This pilot study found most parents preferred afternoon up-dosing appointments as well as Saturday appointments due to work and school commitments.

### **Offering Extra Social Support**

Having a working relationship with a licensed psychologist specializing in food allergy anxiety can also be beneficial when referring any parents requiring more specialized counseling.

A few parents that had children up-dosing at the same time were able to connect and create their own “parent support group” where they were able to discuss various topics while their children were being observed after up-dosing. Creating an environment which facilitates this type of community within the clinic would benefit many parents and children. The pilot study found it useful to have quiet diversional activities available to keep children motivated to stay calm while enjoying time with their parents and other children attending therapy. These activities included age appropriate books, coloring pages and crayons, playing cards for games, origami crafts, and board games.

### **Conclusions**

Peanut OIT is recognized as an optional therapy that decreases the incidence of anaphylaxis due to accidental peanut ingestion (Shreffler, et al., 2018). Peanut OIT has also shown to improve QOL for peanut allergic individuals and their families (Epstein-Rigbi et al., 2019). With careful review of this program evaluation via a pilot study, it appears that OIT therapy that takes place in non-institutional settings can be as successful as conventional research environments. However, further research using larger sample sizes is warranted and currently being collected by the Food Allergy Support Team (FAST), (Wasserman, Jones, & Windom, 2018). The survey results of this program evaluation points to key strategies for minimizing food allergy related anxiety for parents. These strategies include developing and implementing educational programs within OIT to help prepare patients and their families with knowledge about the process and what to expect during therapy, and how to treat allergy related symptoms, including anaphylaxis. An effective means of communications between providers and patients is also encouraged since provider availability is seen as an anxiety-reducing element of therapy by this evaluation.

Allergy care providers eagerly anticipate evidence-based practice guidelines to be published once FDA approves the new peanut immunotherapy pharmaceutical products. This is the first pilot study program evaluation that takes into consideration parental anxiety reducing elements as well as logistical aspects of implementing a peanut OIT program. Providers interested in providing a similar program may find helpful suggestions in this doctoral project.

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## Appendix A: Parental Survey and Results (means of responses)

<b><u>Peanut OIT Program Evaluation</u></b>	Strongly Agree (5)	Agree (4)	Neither Agree or Disagree (3)	Disagree (2)	Strongly Disagree (1)
1. Discussing peanut OIT with my child's allergy provider helped ease my anxiety about the program	4.7		Range 5-4		
2. The OIT orientation meeting helped ease my anxiety about the program.	4.8		Range 5-4		
3. The orientation folder was helpful and easy to use	4.7		Range 5-4		
4. Education provided on the first day of OIT helped ease my anxiety about dosing at home.	4.7		Range 5-4		
5. Knowing I could speak to a provider 24/7 helped ease my anxiety about the program.	4.7		Range 5-3		
6. Knowing I could speak to a psychologist about my child's food allergies was helpful.		4.3	Range 5-3		
7. Completing my own OIT research helped ease my anxiety about the program		4.3	Range 5-3		
8. Having quiet activities available during escalation appointments was helpful.		4.1	Range 5-3		
9. Being involved in an on-line food allergy website/blog has helped ease my anxiety about food allergy desensitization		3.5	Range 5-3		
10. Speaking to friends about their experiences with peanut desensitization helped ease my anxiety about OIT.		4.1	Range 5-3		

## Appendix B: Parent Survey Results

Question Response:  
1=strongly agree, 2=agree, 3=neither agree or disagree, 4=disagree, 5=strongly disagree

Survey	Quest 1	Quest 2	Quest 3	Quest 4	Quest 5	Quest 6	Quest 7	Quest 8	Quest 9	Quest 10
1	5	5	5	5	5	5	5	5		
2	4	5	4	4	5	4	4	3	3	5
3	4	4	5	5	4	4	4	4		5
4	4	4	4	4	5	5	5	4		4
5	5	5	5	5	5	5	5	5	3	5
6	5	5	5	5	5	5	4	4	3	3
7	5	4	4	4	3	3	4	4	4	4
8	5	5	5	5	5		5	3	3	4
9	5	5	4	5	5	4	4	3	3	4
10	4	5	4	5	4	3	3	3	3	4
11	5	5	5	4	4	4	5	5	5	4
12	5	5	5	5	5	5	5	5	3	5
13	5	5	5	5	5	5	4	4	3	3
14	5	5	5	5	5	5	5	5	5	5
15	5	5	5	5	5	3	3	5		3
Mean	4.7333	4.8	4.6667	4.7333	4.6667	4.2857	4.3333	4.1333	3.454	4.14286