



TAKING THE FEAR OUT OF FOOD

**SICKKIDS FOOD ALLERGY AND
ANAPHYLAXIS PROGRAM**

2019 IMPACT REPORT

SickKids



FoodAllergy

A LETTER FROM THE FAAP CO-DIRECTORS

WHEN SICKKIDS FOOD ALLERGY & ANAPHYLAXIS PROGRAM (FAAP) BEGAN IN 2013, our vision was: a future without fear of food. At the time though, we had no clinical trials and were only in the beginning stages of the research that would change the lives of so many children and their families.

Now, thanks to the generosity of donors like you, we have made major headway. We are offering oral immunotherapy (OIT) clinical trials for milk, peanuts and tree nuts, and by 2020, any major food for children with multiple food allergies. We are steadily working towards a future where children can safely eat food with their friends.

We are dedicated to bringing treatment options to children and youth. Whether it's a patient with multiple allergies, or a child whose anaphylaxis is too severe to try OIT, we are using different approaches to better understand the origins and treat food allergy and anaphylaxis.

These first six years have seen immense progress, and none of it would have been possible without our community of passionate patients and their families, donors, healthcare providers, clinicians and scientists. As we mark the end of Phase One, we are in a dramatically different place than when we started.

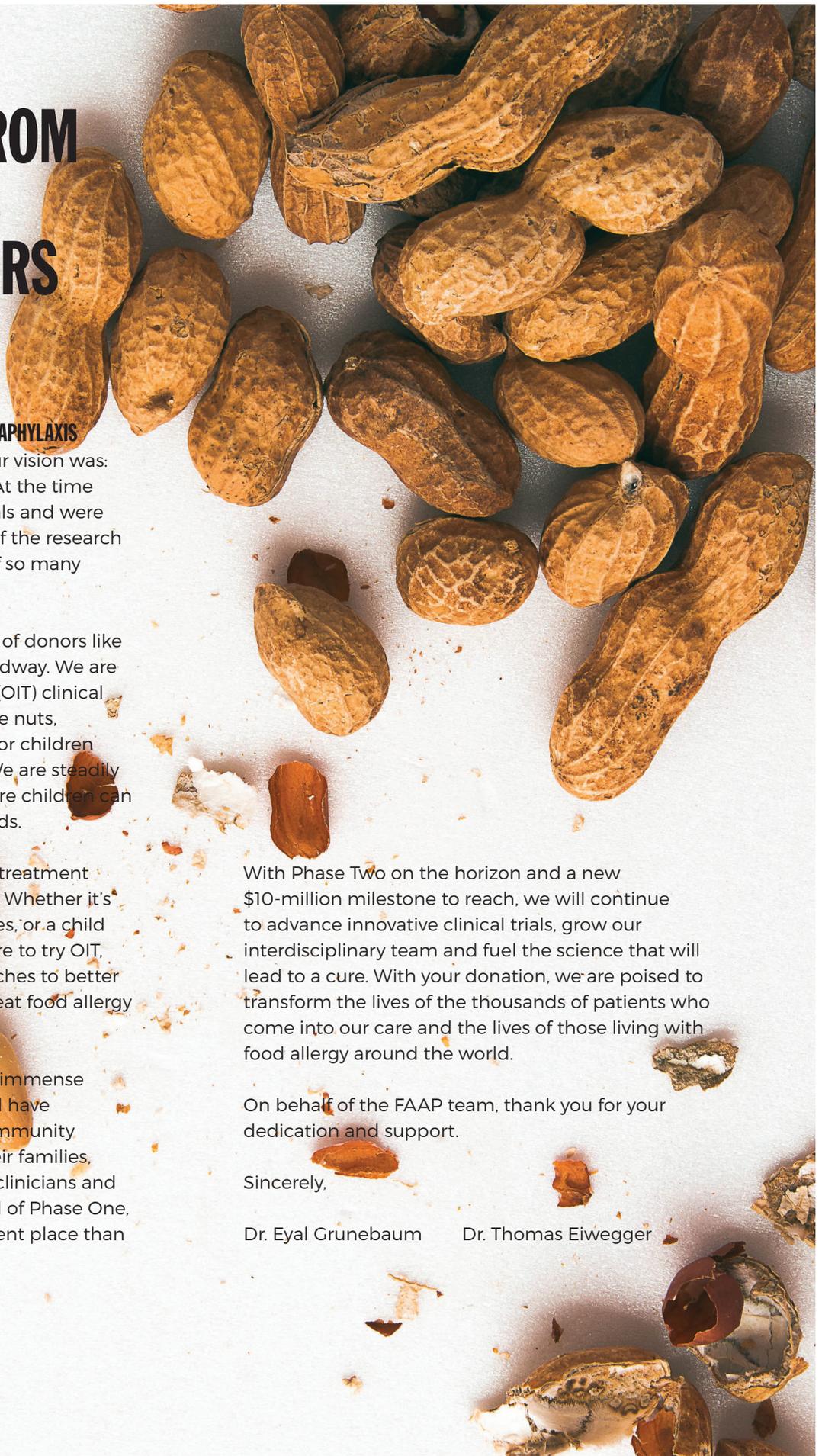
With Phase Two on the horizon and a new \$10-million milestone to reach, we will continue to advance innovative clinical trials, grow our interdisciplinary team and fuel the science that will lead to a cure. With your donation, we are poised to transform the lives of the thousands of patients who come into our care and the lives of those living with food allergy around the world.

On behalf of the FAAP team, thank you for your dedication and support.

Sincerely,

Dr. Eyal Grunebaum

Dr. Thomas Eiwegger



CLINICAL TRIALS

THE SICKKIDS FOOD ALLERGY & ANAPHYLAXIS PROGRAM

currently has eight clinical trials in progress.

LOW-DOSE ORAL IMMUNOTHERAPY (OIT) FOR MULTIPLE NUT ALLERGIES IN CHILDREN

Last year, we reported on how Drs. Julia Upton, Thomas Eiwegger and their team, were running low-dose oral immunotherapy clinical trials to help patients with nut allergies. Through exposure to very low doses of the allergen (think a maximum of 1/32 teaspoon of nut butter), the SickKids team wanted to help kids develop a tolerance to reduce the severity of a reaction in the case of accidental exposure (through things like cross-contamination at a restaurant or at school). Clinically, 30 percent of SickKids FAAP patients have multiple nut allergies so both studies include a variety of nuts. There are now **two** clinical trials under this low-dose umbrella underway.

MILK OIT

Milk is one of the most common allergies in children. And milk is everywhere in a kid's world, from pizza parties to birthdays. Not being able to eat cheese and icing can be socially isolating and, ultimately, hard to sustain. That's where Drs. Upton, Eyal Grunebaum and their Canadian collaborators come in. The team has now completed two arms of the milk OIT trial at SickKids, and it has been highly successful. The purpose of this study was for the participants to actually be able to consume milk, not just tolerate it in case of contamination. The trial is ongoing, with patients continuing to be monitored in the maintenance phase.

EPICUTANEOUS IMMUNOTHERAPY IN YOUNG CHILDREN WITH PEANUT ALLERGIES

In this clinical trial, allergic children don't eat a single peanut—they get the peanut allergen delivered directly to the skin through a patch, known as epicutaneous immunotherapy. This type of exposure has a much lower risk of reaction than oral immunotherapy. This peanut patch trial is taking place at more than 20 sites worldwide. Sponsored by DBV Technologies, these clinical trials will look at the short term (one year) and the long term (up to three years) to determine if children can be desensitized to their allergen.



DUPILUMAB USE IN KIDS WITH PEANUT ALLERGY

This clinical trial will assess whether dupilumab, a drug used for eczema, can help give meaningful protection against accidental exposure for peanut allergic kids. The study goal is to improve a child's ability to tolerate peanut proteins.

BLOCKING IGE AND REDUCING REACTIONS WITH OMALIZUMAB

The FAAP team is moving forward with their OIT study using omalizumab, an asthma medication, to see if it can make OIT with multiple foods safer and faster. The team received CIHR funding for the clinical aspect of the study and it was excitingly ranked #1 in its grant category. It is currently in Health Canada approval stages. The next steps will focus on the scientific side of the project, involving a full immunological workup using a blood form to better understand IgE antibodies. In this trial, the FAAP is exploring the immunological mechanisms that facilitate tolerance to foods.

RUPATADINE AND PEANUT OIT AS MODERATORS OF PEANUT ALLERGY IN CHILDREN (ROPAC)

A prospective study is in progress evaluating the ability of an anti-PAF medication to prevent/reduce allergic reactions during oral immunotherapy for peanuts in the challenging teenage population. The one-year study in 12-17 years olds will be conducted at Dr. Gordon Sussman's clinic using Rupatadine, recently approved for use in Canada for another indication. Results of the study will inform whether anti-PAF medications taken over prolonged periods can provide protection during accidental exposure.

PLATELET ACTIVATING FACTOR (PAF) DURING ANAPHYLAXIS IN SICKKIDS EMERGENCY DEPARTMENT

To better understand the role of PAF in severe allergic reactions, the team enrolled children who came to the SickKids Emergency Department experiencing anaphylaxis, and then followed up again six months later. The team—Drs. Upton, Grunebaum, Eiwegger, Yaron Finkelstein and Peter Vadas, enrolled 40 children in the four-year study. The goal is to help SickKids develop a PAF-inhibitor to manage the symptoms of a reaction, an important part of the team's OIT trials.

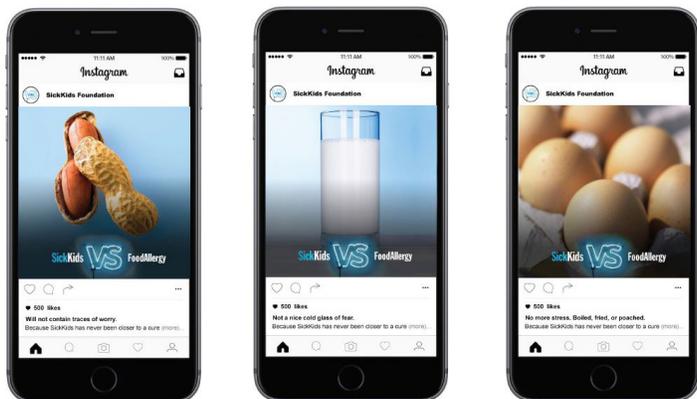
DRIVING ALLERGY AWARENESS

SickKids is raising awareness of food allergy and FAAP in a variety of ways.

SICKKIDS ALLERGY BRAND CAMPAIGN

This past August, SickKids Foundation launched a food allergy brand awareness campaign to support the Program. This four-week campaign focused on digital, social and print advertising in market. Overall, the campaign was successful in raising awareness about the program and food allergy:

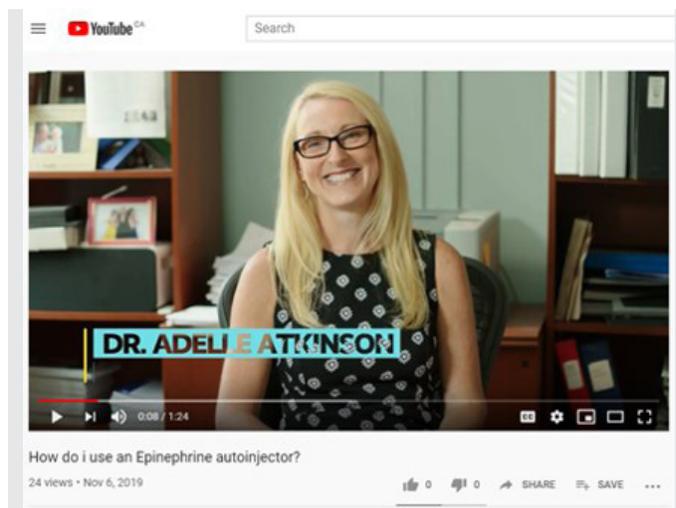
- Reached more than 894,241 people on Facebook and Instagram
- Generated more than 3,519,336 impressions and 6,659 clicks to the website
- An additional 1,532,989 impressions via digital ads on The Toronto Star
- Print ad in The Toronto Star garnered 1,965,000 impressions and reached 1,028,000 people



SICKKIDS YOUNGSTER PARTNERSHIP

SickKids Foundation partnered with Youngster, Insight Productions' parenting-focused lifestyle brand in an exclusive collaboration to provide trusted health content for parents.

In 2020, we will develop a series of allergy-focused videos to promote fresh content as part of our continued commitment to support the program and drive donations.



RESEARCH & INNOVATION

Our Program is driving breakthroughs in food allergy.

GUT SLICE MODEL

Healthy gut tissue has been a window into allergy for the SickKids team. This tissue, left over from operations at SickKids and the University Health Network, has become part of a bank for the allergy team to test drugs for a variety of different levels of allergic reactions. The gut slice is “allergenized” by incubating it with the serum of a peanut-allergic patient. This unique idea, piloted by Dr. Eiwegger, helps researchers understand the physiology of an allergic response. “It’s a very important model to screen for drugs in a human system,” says Dr. Eiwegger. The model is established and the team is waiting for final data before submitting it for publication.

FOOD ALLERGY IN CHILDREN WITH IMMUNODEFICIENCY

Dr. Grunebaum and his team have come a long way in understanding how immune system defects predispose children to food allergies. They have identified more and more patients with problems in immune system control, and while treating these patients for various other concerns, the team was able to also understand how it affected their food allergy. The team now understands that a certain type of cell, called a regulatory T-cell, plays an important role. In this study, Dr. Grunebaum identified a medication that helps restore balance to the immune system to help reduce or control a food allergy reaction.

FOOD ALLERGY & ORGAN TRANSPLANTATION

Forty percent of paediatric patients who undergo liver transplants develop new allergies. And until now, doctors didn’t understand exactly why. But thanks to a major paper submitted for publication, they have a much better understanding. The study of approximately 25 transplant patients was led by Drs. Yaron Avitzur, Grunebaum, and members of SickKids transplant team. They gathered three samples from each transplant patient over one year, to analyze their cytokines and immune phenotyping to better understand how immune system abnormalities lead to food allergies.

CELLULAR AND ANIMAL MODELS

It can be challenging to get blood from patients and the approvals to test medications in the clinic, especially when it comes to children. Dr. Grunebaum’s lab has been working together with Dr. Peter Vadas, SickKids researcher Matilde Leon-Ponte and a team at Southwest Florida University, to create animal models to better understand and test food allergy medications. These genetically-engineered mice (who are severely allergic to peanuts) are the key to understanding the role of PAF in anaphylaxis.

PATTERNS OF ALLERGEN RECOGNITION

The Markers of Nut Allergy Study is a major step in helping to provide the first set of Canadian data on allergen recognition to help doctors better diagnose peanut and tree nut allergies in children and adolescents. Led by Dr. Eiwegger, this study has almost finished recruiting approximately 200 children (from Toronto and Vienna) with nut allergies or asymptomatic sensitization. The data is set to be published early next year.

INVESTIGATING SEVERE ASTHMATICS WITH FOOD ALLERGIES

This observational trial is investigating preschool asthmatics with Emergency Department admissions to see how many of them also have food allergies. These patients are ineligible for trials because their asthma is not managed, so this study will help better understand the connection. The team published a paper on this in collaboration with SickKids Dr. Padmaja Subbarao (Respiratory Medicine) and Dr. Suzanne Schuh (Emergency Department).

LIPIDS IN TREE NUTS AS KEY FACTORS DRIVING FOOD ALLERGY

Dr. Eiwegger is conducting a research project focusing on lipids in peanut and tree nuts as immune modulators facilitating allergic sensitization. The hypothesis is that lipids have components that induce inflammation in the skin that facilitate desensitization with allergens. For example, if a child has eczema, and comes into contact with a nut protein, the lipids can sensitize the immune system through the skin. If researchers can better understand the process of sensitization, they can better prevent it. Dr. Eiwegger has identified a novel pathway which could be crucial for the development and treatment of food allergy using an innovative gene-editing system.

THE ALLEVIATE RESEARCH PROJECT

The ALLEVIATE program is a multi-national project to develop new treatments for milk and peanut immunotherapy. It is a government funded project that consists of chemists, biochemists, and immunologists working on animal models, clinician scientists treating children with food allergies, and industry partners who focus on the scalability of potential products. Dr. Eiwegger’s lab is leading the work to perform the immunological characterization of candidate products in the human immune system before they can be considered for use in clinical trials.

THANK YOU.

Every day, SickKids is working towards improving the lives of children, and our success depends on the generosity of donors like you. Your commitment to SickKids Food Allergy & Anaphylaxis Program ensures that we can continue to offer the best possible health outcomes for children around the world so they can live longer and healthier lives. Thank you for your remarkable generosity.



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