Food Allergy Program
at Texas Children's Hospital®

Winter 2020 Newsletter

Contents

Welcome from Program Director, Dr. Carla M. Davis

The Texas Children's Hospital Food Allergy Program has a mission to serve children with food allergies and their families. We provide personalized, high-quality patient care, increased access to cutting-edge research, innovative treatment advances and quality patient support groups. Although the coronavirus pandemic hindered us from seeing you, our food allergy families and supporters this year, our mission continued through telemedicine visits for patients, our annual Food Allergy Symposium, and the start of new research studies! We even developed new collaborations to care for allergic children with food insecurity and develop treatment for shrimp allergy.

The ability to diagnose and treat food allergic children has expanded in 2021 through the establishment of a new Food Allergy Diagnosis and Treatment Suite at the West Campus Hospital and the Main Campus Hospital and FDA approval of oral immunotherapy through the Food Manufacturing Center for development of treatment to tree nut allergies! This will enable all children to be seen in a timely manner to either treat tree nut allergy or clarify the foods causing their food allergic disease. Stay tuned for the opening of tree nut treatment trials in 2021!

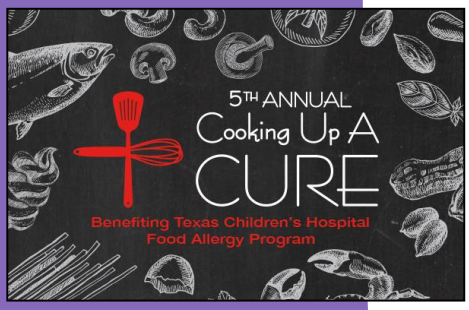
We are thankful for all the patients who we serve in our clinics, the children and families who engage in research in our program, our Food Allergy Family Network leaders and everyone who supports us or attends our events! We are an amazing community ! The TCH Food Allergy Program is excited about next year and looks forward to seeing everyone in person soon!

Happy Holidays and Happy New Year!

To make a donation to the Food Allergy Program, contact:
Priscilla L. Mondragón 832-824-2060 or plluna@texaschildrens.org

Texas Children's Hospital®

Cooking Up A Cure



Our 5th annual *Cooking Up A Cure* event at The Revaire drew in more than 300 guests and raised over $200,000 for the Food Allergy Program at Texas Children's Hospital.

We were honored to have been the 2020 co-chairs for this amazing event, and we are so grateful to the sponsors and talented culinary partners who helped make the evening such a success. **Check out the photo gallery from the evening.**

Guests enjoyed cocktails and delicious bites from some of the most renowned chefs in Houston. They were also assigned a food allergy in order to experience, for one night, how difficult it can be to find allergy-friendly dishes. It was a great way to raise awareness of a health issue that affects so many children, and everyone in the room was touched by **Elliot's personal story.**

Recent advances the program has made with funds raised through this annual event were highlighted. Dr. Carla Davis, Program Director, announced exciting new plans underway, including the opening of a Food Diagnostic Suite at the Texas Medical Center Campus and at Texas Children's Hospital West Campus to help ensure that every child with food allergies receives accurate diagnosis. Restaurants who have supported the program all 5 years were given awards.

The dedication of generous people in the community helps us work toward a future where food allergies will no longer be life threatening. Although the coronavirus pandemic prevented us from coming together in 2021, we hope to see everyone at our next event when the pandemic is over.

We give special thanks to the *2020 Cooking Up A Cure Co-Chairs:* Holly and Jose Bayardo, Amy and Jack Behan, Ellisa and Nick Gole, and Rebecca and David Luks for their tireless effort to hold this wonderful event!

P.S. — If you would like to support the Food Allergy Program at Texas Children's Hospital, please **make a donation here.**

Thank you to all our amazing culinary partners –

- A Fare Extraordinaire
- Awesome Bites Co.
- Benjy's
- Bloom & Bee
- Bouchée Patisserie
- Brennan's of Houston
- Doris Metropolitan Houston
- Emmaline
- La Table Houston
- Le Colonial Houston
- Royers Round Top Café
- State of Grace
- The Annie Café & Bar
- Uchi
- Weights + Measures

7th Annual Food Allergy Program Symposium Recap

By Carla M. Davis, MD

The Food Allergy Program Team held a spectacular virtual food allergy symposium in 2020! This is an example of one of the silver linings of this pandemic because we were able to extend our reach beyond the southern US. The symposium had 250 registrants, some as far away as Pennsylvania! Although, virtual, it was a dynamic program!

Our keynote speaker was Ms. Emily Brown, the CEO and Founder of the Food Allergy Equality Initiative. She spoke eloquently about her struggles as a mother without resources to feed her multiple food allergic child, and presented the transformative program she has proposed to relieve these struggles in under-resourced populations. We are excited to be partnering with the Food Equality Initiative this year! One of our Teen Advisory Board Leaders, Ms. Indrani Maitra, shared her amazing program to feed food allergic families here in the Greater Houston area!

Emily Brown

Indrani Maitra

Oliver Oldham

Mike Oldham

The other sessions were incredible, and special thanks go to our own Drs. Aikaterini Anagnostou, and Sara Anvari who spoke about the completed and ongoing research studies in our program. A parent panel led by Drs. Anirban Maitra and Aba Coleman were fantastic, providing practical tips to parents during the pandemic. We are grateful for the sessions led by Food Allergy Family Network leader Mr. Mike Oldham and his son, Oliver.

As always, special appreciation goes to Ms. Christina Cowperthwait for impeccable organization and Ms. Theresa Aldape for her consistent work with the TCH Food Allergy Family Network (FAFN), which keeps our families engaged and supported. We are grateful for Ms. Daisy Tran, who leads the TCH Food Allergy Program Teen Advisory Board, and all the volunteers, including Ms. America Lueso and Mr. Julian Gaton for technical support.

I received several complimentary emails from attendees! This continues to be a wonderful service to our community and I am hopeful next year will be in person!

The link to the symposium recording is here.

Poor and Minority Children with Food Allergies Are Overlooked and in Danger

The TCH Food Allergy Program is partnering with the Food Equality Initiative to help families in Texas! The incredible story of Emily Brown, Founder and CEO of this wonderful organization, highlights the need for this kind of support for food allergy families who need access to food.

Excerpts from an Article originally appearing in the Washington Post at https://www.washingtonpost.com/health/food-allergies-poor-children/2020/10/30/faadfe74-14ab-11eb-bc10-40b25382f1be_story.html

Emily Brown's Story

As Emily Brown stood in a food pantry looking at her options, she felt alone. Up to that point, she had never struggled financially. But there she was, desperate to find safe food for her young daughter with food allergies. What she found was a jar of salsa and some potatoes.

"That was all that was available," said Brown, who lives in Kansas City, Kansas. "It was just a desperate place."

When she became a parent, Brown left her job for lack of child care that would accommodate her daughter's allergies to peanuts, tree nuts, milk, eggs, wheat and soy. When she and her husband then turned to a federal food assistance program, they found few allowable allergy substitutions. The closest allergy support group she could find was an hour away. She was almost always the only Black parent, and the only poor parent, there.

Brown called national food allergy advocacy organizations to ask for guidance to help poor families find safe food and medical resources, but she said she was told that wasn't their focus. Support groups, fundraising activities and advocacy efforts, plus clinical and research outreach, were targeted at wealthier — and White — families. Advertising rarely reflected families that looked like hers. She felt unseen.

"Many times, a mother is frank and says, 'I have $20 to $40 to buy groceries for the week, and if I buy these foods that you are telling me to buy, I will not be able to feed my entire family,' " said Carla Davis, a pediatrician and director of the food allergy program at Houston's Texas Children's Hospital.

"If you are diagnosed with a food allergy and you don't have disposable income or disposable time, there is really no way that you will be able to alter your diet in a way that your child is going to stay away from their allergen."

Fed up with the lack of support, Brown founded the Food Equality Initiative advocacy organization in 2014. It offers an online marketplace to income-eligible families in Kansas and Missouri who, with a doctor's note about the allergy, can order free allergy-safe food to fit their needs.

Brown said her organization more than doubled its clientele in March through August, compared with the same period in 2019.

Allergy Friendly Choices

by Indrani Maitra
Teen Advisory Board Member

AFC: A program for families experiencing both food insecurity and food allergies or celiac disease

Allergy Friendly Choices (AFC) launched in 2020 in partnership with the Houston Food Bank and West Houston Assistance Ministries. AFC seeks to provide a reliable stream of allergy-friendly and gluten-free foods to families experiencing both food insecurity and celiac Disease or food allergies.

1.6 million Americans face both food insecurity and medical dietary restrictions (Allergic Living, 2018). Food insecurity is a particularly formidable challenge when it intersects with food allergies or celiac disease. Allergy-friendly and gluten-free foods are significantly more expensive than regular food. According to the Food Equality Initiative (FEI), gluten-free pasta costs 226% more than regular pasta.

When I volunteered at Houston Food Bank, my mother and I would always make separate boxes of Gluten-Free food when sorting. However, we never knew if the gluten-free food would reach the people who needed it.

Community contributions of allergy-friendly and gluten-free food often get mixed up with general Food donations, and there is no guarantee the food would reach the target population.

AFC works within the existing food pantry system and helps make it more effective for clients with food allergies or celiac disease. With Allergy Friendly Choices, allergy friendly donations can be matched to the families that need it.

I received seed money from a service-learning grant for the initial implementation of AFC. In order to make AFC a long-term, sustainable resource for this population, you can contribute- both monetary and in-kind.

In addition, we have raised almost 2000 dollars worth of allergy friendly donations as of December 2020.

You can donate money here - make sure to indicate that your donation is for AFC in the Additional Notes section

Contribute allergy-friendly or gluten-free foods to WHAM at 10501 Meadowglen Ln, Houston, TX 77042. Make sure to indicate on the box that the donations are for AFC

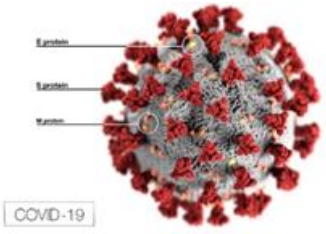
New Clinic & Survey on COVID-19 Impact on Food Allergy Families

by Melissa Hearrell, APRN, FNP-C

New Texas Children's Clinic at the West Campus (Katy, TX)

Effective November 2020, Melissa L Hearrell, APRN, FNP-C has opened a food challenge and food allergy prevention clinic. The clinic operates one day per week at the West Campus location in Katy, TX, and 1.5 days a week at the Main Campus location. Oral food challenges can be performed to any suspected food allergen. Recent guidelines show that early introduction of foods in high risk infants can help lower the risk of developing a food allergy. The food allergy prevention clinic is dedicated to performing supervised early food introduction for at risk infants. Please contact your TCH allergist for a referral.

Impact of COVID-19 on Food Allergy Families



Survey Link

The novel coronavirus (COVID-19) pandemic has swept across the world affecting healthy people and people with all types of health related issues. Researchers at Baylor College of Medicine at Texas Children's Hospital and the Texas Children's Hospital Food Allergy Program are conducting a survey to assess the impact of the COVID-19 pandemic on the food allergy community as assessed by the parents of children with food allergies.

This survey aims to help us better understand how the novel coronavirus (COVID-19) pandemic is affecting the lives of people in the food allergy community. To help us better understand how people's physical, emotional and mental health are being affected, we would like to ask you questions about your possible exposure to the virus, your experiences with testing and treatment and some questions about how your life has changed as a result of COVID-19 and the preventive measures that have been put in place. We would also like to know what is needed by the food allergy community in the future.

If you fill out this anonymous questionnaire (survey), you are consenting or agreeing to take part in this research. We will take all steps legally possible to keep this information confidential.

If you have any questions about this survey or the study, please contact Dr. Carla M. Davis or Melissa L Hearrell, APRN, FNP-C at Melissa.hearrell@bcm.edu or 832-824-7986. If you have additional questions about your rights as a research subject, contact the Institutional Review Board for Human Subject Research for Baylor College of Medicine & Affiliated Hospitals at (713) 798-6970.

Food Oral Immuno-therapy (OIT) Program Update

by Aikaterini Anagnostou, MD, PhD

This year has been interesting (to say the least!) and challenging for all of us.

I am so proud of all our peanut oral immunotherapy patients for continuing their treatment and making sure they come in for their appointments, taking all safety precautions every time! Some families have actually told me it has been easier to do this over the past months, since the children were mostly at home and school time tables have been so flexible – there is always a silver lining!

Our Food Immunotherapy Program has grown a lot over the past year. We have now had a total of 78 peanut allergic children completing peanut oral immunotherapy and more are about to start this coming year. The feedback we have received has been very enthusiastic and encouraging and we are proud to continue serving our community and improving the quality of life of children with food allergies and their families.

We recently published results from our Peanut Oral Immunotherapy Program in the Annals of Allergy, Asthma and Immunology, the official publication of the American College of Allergy, Asthma and Immunology (Quality of Life Improves significantly following real-world oral immunotherapy for peanut-allergic children. *Ann Allergy Asthma Immunol*. 2020 Aug;125 (2): 196-201) and many colleagues around the country have approached me seeking advice on how to start a similar program in their clinics and Academic Institutions.

I am also excited to announce that the FDA has approved our proposed protocol for a Tree Nut Oral Immunotherapy trial! We are planning to launch this at Texas Children's as soon as we secure funding for the trial participants (all our families will receive an email once we are ready to start so they can express interest in participating).

The FDA has also approved the first food allergy drug for peanut OIT (Palforzia) in January of this year and we are working closely with the pharmacy staff on making this available at Texas Children's.

I am looking forward to an even brighter future, leading the way in novel food allergy treatments and enjoying a very productive year 2021!

If you are interested in participating in peanut OIT, please contact our allergy clinic on 832-822-3354 and ask for nurse Valerie Nichols.

Food Allergy Family Network (FAFN) Update by Kathy Pitts, PhD, APRN

The Food Allergy Family Network (FAFN) had its last meeting in August 2020 with Dr. Davis providing an update of current research protocols.

No FAFN meeting will be held until January 2021. Meantime we are thankful for the steadfast cadre of individuals who serve on the FAFN. Each of the members of the FAFN continues to make 10-12 contacts per month reaching out to families. There are currently fourteen men, women and youth covering all the greater Houston area.

The areas covered by region are:
Central; South; North; Southwest & West.

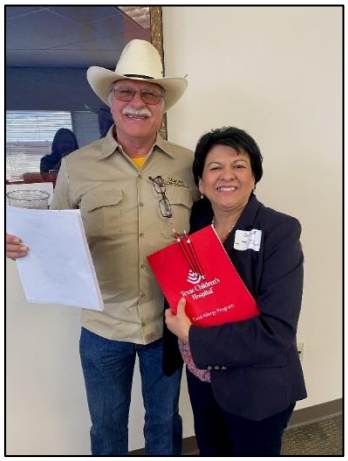
Food Allergy Family Network Leaders

Name	E-mail	Houston Area	Phone Number
Jennifer Mijangos	jenmijangos@att.net	East	(281) 793-8637
Mike Oldham	oldham@reynoldsfrizzell.com	Central	(713) 485-7207
Oliver Oldham	junior leader	Central	
Melanie Ringold	melanie.ringold@invesco.com	Central	(713) 214-5770
Rahma Sarwar	rahma.sarwar@gmail.com	South Central	(832) 570-1035
Thuy Tran	thuyatlaw@yahoo.com	West	(281) 772-9575
Danielle Williams	daniwill78@hotmail.com	Central/North	(202) 213-9896
Andrea Chaves Blackman	andreafchaves@hotmail.com	South	(832) 980-8029
David Greenberg	davidavital24@gmail.com	South	(773) 450-2292
Jyotsna Kottoor	Jyots76@gmail.com	South	(312) 731 3846
Sherril Mackie	Shaydon903@hotmail.com	Central	(346) 316-9668
Tammy Luster	tammy_prukop@yahoo.com	Southwest	(713) 254-7040
Sachin Menon	Sachin_menon@hotmail.com	West	(281) 687-5350
Texas Children's FAFN Support Staff			
Theresa Aldape, LMSW	tmaldape@texaschildrens.org	FAFN Liaison	(832) 824-1385
Daisy Tran Vita, RN	dxtran1@texaschildrens.org	Lead Research Coordinator	(832) 824-3398

Theresa Aldape, LMSW serves as the FAFN Liaison and Daisy Tran, RN serves as the Lead Research Coordinator.

The mission statement is to provide education, treatment, research opportunities and network family support to enhance the quality of life of children, adolescents and young adults with food allergies. The primary goal is to build a supportive network for families living with food allergies in Houston and surrounding areas by meeting on a regular basis to share information about treatment and research and to provide food allergy updates.

If you are interested In being a part of this network please contact Theresa Aldape at tmaldape@texaschildrens.org or Daisy Tran at dxtran1@texaschildrens.org



Mr. Joe Penland and Teresa Aldape.
The Penland Foundation has been instrumental in the community outreach arm of the Texas Children's Hospital Food Allergy Program. We are thankful for their support.

EGID/EoE Update

by Daisy Vita, RN

The mission of the Eosinophilic Gastrointestinal Disorders (EGID) Program at Texas Children's Hospital is to provide personalized, high-quality patient care and increased access to cutting-edge research, innovative treatment advances and quality patient support groups for children and adolescents with EGID.

The Eosinophilic Gastrointestinal Disorders (EGID) Clinic provides a multidisciplinary approach to the evaluation and treatment of these patients through the collaborative efforts of gastroenterologists, allergists, dietitians, nurses, social workers, and psychologists. Texas Children's Hospital is one of a few centers that provides food patch testing as part of the diagnostic evaluation of patients with eosinophilic esophagitis.

The EGID program currently recruits individuals for a number of research and clinical studies through the Consortium of Eosinophilic Gastrointestinal Disease Researchers (CEGIR) and industry sponsors. These include treatment studies with new therapeutic biologic medications, observational studies to determine the symptoms and outcomes of people with eosinophilic gastrointestinal disorders, and quality of life studies.

If you are interested in hearing more about the program and research studies, please email foodallergynurse@texaschildrens.org

Kimberley Alexander and her son, A. Jay

A. Jay's Fight, an organization dedicated to fighting EoE

A. Jay's Fight funds medical research, community education, and offers support to people with eosinophilic esophagitis (EoE), which requires severe food restrictions. Kimberley Alexander formed organization in honor of her son, A. Jay, who has this disease.

In 2017, A. Jay's Fight's inaugural Super Hero Walk/Run for EOE was the beneficiary of St. Thomas University's philanthropic sponsorship. This launched A. Jay's Fight's partnership with Texas Children's Hospital (TCH). In 2018, A. Jay's Fight successfully acquired 501c3 distinction under the internal revenue code. In 2019, A. Jay's Fight sponsors included Rare Patient Network, 88 Acres, Daiya Foods, The Dames Group, Spangler, and Williams Education Consulting. A. Jay's Fight is operated with a surplus, having an operating budget for the first time in 4 years. A. Jay's Fight was instrumental in pioneering TCH's acceptance into the Consortium of Eosinophilic Gastrointestinal Disease Researchers (CEGIR) and becoming a major research center for eosinophilic diseases.

Food Allergy QoL Update

Research continues on different levels and by many faculty/researchers in the TCH Food Allergy Program. What is important to mention is that it is the support of the many families who attended the Food Allergy Symposia in 2018 and 2019, and took the time to complete the Food Allergy Quality of Life Questionnaires provided at registration, can now see the results of their efforts. We thank you all as your participation and input has provided some very interesting and important findings.

by Kathy Pitts, PhD, APRN

Recently an abstract was accepted for the upcoming 2021 American Academy of Allergy, Asthma & Immunology (AAAAI) Virtual Annual Conference being held February 26, 2021-March 1, 2021. The title of the abstract is Quality of Life in Food Allergic Children and Adolescents at a Community Educational Symposium. The lead author is Diem-Tran Nguyen, MD along with Kathleen Pitts, PhD, APRN, Kristen Staggers. MS and Carla Davis, MD. The purpose of this research study was to determine whether quality of life (QoL) differed between food allergic (FA) adolescents and children who participated in an educational Food Allergy Symposium (FAS) from 2018-2019. Seventy-four surveys (82% children; 18% adolescents) were included. The conclusion found that adolescents had significantly lower QoL, with more concern about their disease and more reassurance by epinephrine carriage than children, which may reflect their increased autonomy. The higher incidence of dysphagia in teenagers may indicate eosinophilic esophagitis as an under-recognized cause of dysphagia among FA youth. This assessment of QoL and FA symptoms at a community event reveals a significant impact of FA in adolescent populations.

Based on these findings we hope to continue to request participants of the Annual Food Allergy Symposium to complete the FAQLQ and in this way we can identify interesting trends, unique findings and move forward in areas that we can report and research further.

If you are interested in participating in our research trials, please email foodallergynurse@texaschildrens.org

Food Allergy Studies

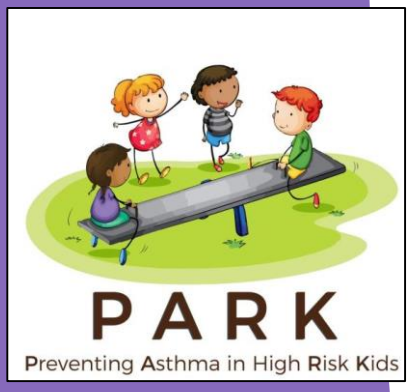
by
Sara Anvari, MD, MS
&
Daisy Vita, RN

Research Studies – Open to Enrollment

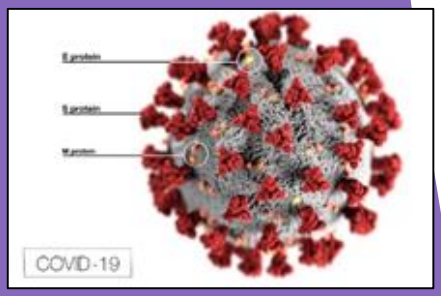
FARE patient registry

This is an online survey study sponsored by FARE, evaluating patients with food allergies and their caregivers. The goal is to create a registry where patients can conveniently and privately share their food allergy experiences through a simple online survey, in order to help advance food allergy research. It provides a unique opportunity for families to contribute directly to groundbreaking food allergy research and share their personal story with the food allergy community. The study is actively seeking participants of all ages with a food allergy diagnosis and completion of the online survey. A registry for food-allergic individuals and their caregivers to quickly, conveniently and privately share their food allergy experiences through simple online surveys in order to help advance food allergy research.
Study Sponsor: Food Allergy Research and Education (FARE)
Eligibility: Male or female of all ages with food allergy
What is requested: Online survey completion

Preventing Asthma in High Risk Kids (PARK)



This is an interventional clinical trial sponsored by the National Institute of Allergy and Infectious Diseases (NIAID/NIH). The PARK study is a randomized, double-blind, placebo-controlled trial designed to test whether two-year treatment of preschool children aged 2-3 years of age at high risk for asthma with omalizumab (anti-IgE monoclonal antibody) will prevent the progression to childhood asthma. The primary outcome of this study will measure an active asthma diagnosis and asthma severity and the secondary outcomes will measure the number of positive new allergies by skin prick testing and the decrease in number of wheezing episodes as a result of this therapy. The study is actively recruiting children between 24-47 months of age with 2-4 episodes of wheezing in the past 12 months and have at least one biological parent or sibling with a history of asthma or allergies.
Study Sponsor: The National Institute of Allergy and Infectious Diseases (NIAID)
Eligibility: The child should be between 24-47 months of age with 2-4 episodes of wheezing in the past 12 months. At least one biological parent or sibling with history of asthma or allergy.
What is requested: Monthly injection of Omalizumab or placebo, nasal swabs, saliva, blood, skin testing, environmental samples, urine, and stool sample.



COVID19 Survey for Parents of Children with Food Allergy

This is a survey study sponsored by Texas Children's Hospital/Baylor College of Medicine examining the effects of COVID-19 on households who have at least one child diagnosed with a food allergy. The study is actively seeking participants at least 18 years or older and the parent of at least one child diagnosed with a food allergy to complete the survey.
Study Sponsor: Texas Children's Hospital/Baylor College of Medicine
Eligibility: Male or female, 18 years or older and the parent of at least one child diagnosed with food allergy.
What is requested: Survey completion – Survey Link

If you are interested in participating in our research trials, please email foodallergynurse@texaschildrens.org

Open for Enrollment Research Studies (cont.)

Food Allergy Studies

by Sara Anvari, MD, MS & Daisy Vita, RN

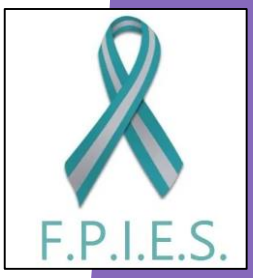
Outcome Measures for Eosinophilic Gastrointestinal Disease across Ages (CEGIR OMEGA)

This is a longitudinal observational study sponsored by the National Institute of Allergy and Infectious Diseases (NIAID/NIH). The OMEGA study is focused on finding the best measures to define how well a person with eosinophilic disorder is doing. Patients with eosinophilic esophagitis (EoE) and eosinophilic colitis (EC) normally undergo endoscopy and/or colonoscopy in order to have tissue specimens collected and examined microscopically. The treatments for these conditions are based on how the tissue looks. This study will follow EoE and EC patients over the course of time to see if standard questionnaires can provide an idea of how well the patients is doing. The study is actively seeking patients at least 3 years or older diagnosed with eosinophilic esophagitis (EoE), eosinophilic gastritis (EG) or eosinophilic colitis (EC). The caregiver will complete the questionnaire. An optional part of this study is to provide a sample tissue from your standard of care endoscopy and a blood sample.

A Prospective, Multicenter Study to Compare and Validate Endoscopic, Histologic, Molecular and Patient-Reported Outcomes in Pediatric and Adult Patients with Eosinophilic Esophagitis (EoE), Gastritis (EG) and Colitis (EC)

Study Sponsor: National Institute of Allergy and Infectious Diseases (NIAID)
Eligibility: Male or female 3 years of age or greater diagnosed with EoE, EG or EC.
What is requested: Completion of questionnaires. Optional: a sample of tissue from your standard of care endoscopy and blood sample collection.

Food Protein Induced Enterocolitis (FPIES) study



This study will be recruiting children with an active history of FPIES. Patients should be willing to consent to give a small sample of blood in order to evaluate immune cells and the genes regulating these immune cells in the development and resolution of FPIES.
Study Sponsor: Texas Children's Food Allergy Program
Eligibility: Concurrent TCH patients and physician's diagnosis of FPIES
What is requested: Blood sample

Shrimp Allergy Study

This is an observational study of shrimp allergic patients. The study will be recruiting patients between 3-65 years of age. The study will evaluate immune mechanisms associated with shrimp allergy.
Study Sponsor: Texas Children's Food Allergy Program
Eligibility: Concurrent TCH patients and physician's diagnosis of shrimp allergy
What is requested: Blood Sample

Food Allergy Program
at Texas Children's Hospital®

If you are interested in participating in our research trials, please email foodallergynurse@texaschildrens.org

Food Allergy Studies

by
Sara Anvari, MD, MS
&
Daisy Vita, RN

Upcoming Research Studies

Dupilumab Eosinophilic Gastritis Study (CEGIR DEGAS)

This is an interventional clinical trial sponsored by Regeneron Pharmaceuticals and is expected to start recruitment in January 2021. The study is a Phase 2, randomized, double-blind placebo-controlled studying the efficacy and safety of dupilumab (anti-IL4 receptor monoclonal antibody) in patients age 12 years and up with active eosinophilic gastritis (EG) demonstrated by biopsy with a peak gastric count of >30 eos/hpf in at least 5 hpfs in the gastric antrum and /or body of the stomach. Additionally, patients must have a report of severe EG symptoms (stomach pain, stomach cramping, nausea, bloating, burning sensation in the chest, starting to eat and feeling full too quickly, loss of appetite, vomiting, or diarrhea) at least 2 days per week in the 2 weeks prior to screening. Participants will receive a subcutaneous shot of dupilumab or placebo every 2 weeks for a total of 6 injections. After completing the blinded study (dupilumab or placebo), participants can continue into the open-label portion of the study, in which all subjects will receive 12 doses (every 2 weeks for 24 weeks) of dupilumab. Patients will be expected to complete an electronic diary, have tissue samples obtained from an endoscopy procedure, and have blood sample collection

Study Sponsor: National Institute of Allergy and Infectious Diseases (NIAID)
Expected start date: January 2021
Target enrollment:3 patients
Eligibility: Male or female age 12 years and up with active eosinophilic gastritis as demonstrated by biopsy with a peak gastric count of ≥30 eos/hpfin at least 5 hpfsin the gastric antrum and/or body. History by patient report of moderate to severe EG symptoms (stomach pain, stomach cramping, nausea, bloating, burning feeling in the chest, starting to eat and feeling full too quickly, loss of appetite, vomiting, or diarrhea at least 2 days per week in the 2 weeks prior to screening.
What is requested: Treatment with a shot of Dupilumabor Placebo, electronic diary completion, tissue sample from endoscopy procedure, and blood sample collection.

EOE Kids

This is an interventional clinical trial sponsored by Regeneron Pharmaceuticals and is expected to start recruitment in January 2021. The study is a Phase 3, randomized, 2-part double-blind placebo-controlled study to investigate the efficacy and safety of dupilumab (anti-IL4 receptor monoclonal antibody) in pediatric patients age 1 to 11 years of age with active eosinophilic esophagitis (EoE) based on histologic improvement meeting criteria. Part 1 will consist of a 16-week double-blind treatment period. Patients will be randomized to receive dupilumab or placebo subcutaneous shot every 2 weeks. Part 2 will consist of a 36-week extended treatment period. All patients will receive a subcutaneous shot of dupilumab every 2 weeks.
Study Sponsor: Regeneron Pharmaceuticals
Expected start date: January 2021
Target enrollment:3patients
Eligibility: Male or female between the age of 1-12 years diagnosed with active eosinophilic esophagitis. History of symptoms to be a result of EOE such as abdominal pain, chest pain, acid reflux, food regurgitation, dysphagia, vomiting, or refusal to eat in the month prior to screening.
What is requested: Treatment with a shot of Dupilumabor Placebo, electronic diary completion, tissue sample from endoscopy procedure, and blood sample collection.

If you are interested in participating in our research trials, please email foodallergynurse@texaschildrens.org

Upcoming Research Studies

Systems Biology of Early Atopy (SUNBEAM)

This is a prospective cohort research study sponsored by the National Institute of Allergy and Infectious Diseases (NIAID/NIH). The study will enroll ~2500 pregnant women (at any stage of pregnancy), the baby's birth father, and the baby. The baby will be observed from birth until 3 years of age. The study will start recruitment in Jan 2021. SUNBEAM is focused on studying the role of interrelationships of established and novel clinical, environmental, biological, and genetic prenatal and early-life factors affect the development of allergic diseases through age 3 years, with an emphasis on food allergy and atopic dermatitis. A systems biology approach will be used to identify mechanisms and biomarkers that may be responsible for the development of food allergy and eczema. Questionnaire information will be collected. The study will also collect, process, and test environmental and biological samples from mother, father and child for current and future use in the study of allergic disease development.

Study Sponsor: The National Institute of Allergy and Infectious Diseases (NIAID)
Expected start date: January 2021
Target enrollment: 200 patients
Eligibility: Pregnant women age 18 years or older planning to give birth at the Texas Children's Hospital Pavilion for Women who agree to enroll offspring into the study at birth.
What is requested: Clinical assessments will be conducted, questionnaire information collected, and biological and environmental samples collected on the mother, father, and child in the prenatal, perinatal, and postnatal periods of the child's life.

Grants Awarded in 2020

Carla M. Davis, MD
Project Title: New Horizons in the Prevention and Treatment of Food Allergy - SUNBEAM
Project Title: (PARK) Controlling and preventing Asthma progression and Severity in Kids (CASK)
Project Title: FARE Clinical Center of Distinction

Aikaterini Anagnostou, MD, PhD
Project Title: FARE Clinical Network ("FCN") Patient Registry Grant

Sara Anvari, MD
Project Title: Epitope Open-label Extension Study To Evaluate The Long-term Clinical Benefit And Safety Of Dbv712 In Peanut-allergic Children (Epopex)

In National News…

Carla M. Davis, MD was quoted in the Nature article, The peanut snack that triggered a fresh approach to allergy prevention. The article discusses early oral exposure to some allergenic foods is now seen as a key prevention strategy, but tackling inhalant allergies remains a challenge.

Food Allergy Studies - Grants - National News

by Sara Anvari, MD, MS & Daisy Vita, RN

If you are interested in participating in our research trials, please email foodallergynurse@texaschildrens.org

Publications by the Food Allergy Program

Anagnostou A, Hourihane JO, Greenhawt M. The Role of Shared Decision Making in Pediatric Food Allergy Management. J Allergy Clin Immunol Pract. 2020 Jan;8(1):46-51. doi: 10.1016/j.jaip.2019.09.004.

Davis CM, Gupta RS, Aktas ON, Diaz V, Kamath SD, Lopata AL. Clinical Management of Seafood Allergy. *J Allergy Clin Immunol Pract*. 2020 Jan;8(1):37-44. doi: 10.1016/j.jaip.2019.10.019.

Miller J, Blackman AC, Wang HT, Anvari S, **Joseph M, Davis CM, Staggers KA, Anagnostou A.** Quality of life in food allergic children: Results from 174 quality-of-life patient questionnaires. Ann Allergy Asthma Immunol. 2020 Jan 11. pii: S1081-1206(19)31528-5. doi: 10.1016/j.anai.2019.12.021
Koplin JJ, **Davis CM**. Food Allergy: More Than Peanut. *J Allergy Clin Immunol Pract*. 2020 Jan;8(1):68-69. doi: 10.1016/j.jaip.2019.11.001.

Davis CM, Gupta RS, Aktas ON, **Diaz V,** Kamath SD, Lopata AL. Clinical Management of Seafood Allergy. J Allergy Clin Immunol Pract. 2020 Jan;8(1):37-44. doi: 10.1016/j.jaip.2019.10.019.

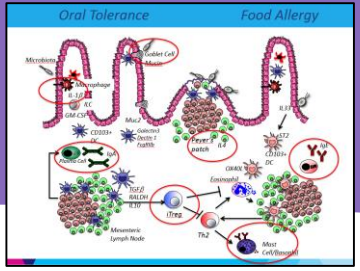
Wang HT, Warren CM, Gupta RS, **Davis CM**. Prevalence and Characteristics of Shellfish Allergy in the Pediatric Population of the United States. *J Allergy Clin Immunol Pract*. 2020 Jan 7. pii: S2213-2198(19)31061-X. doi: 10.1016/j.jaip.2019.12.027.

Lee J, Frey C, Miller J, Minard C, Noor M, **Anagnostou A, Olive A, Davis CM, Anvari S**. Skin testing with different food formulations in pediatric patients with eosinophilic esophagitis.*Pediatr Allergy Immunol*. 2020 Apr;31(3):329-332. doi: 10.1111/pai.13181. Epub 2019 Dec 12.

Eiwegger T, **Anagnostou K**, Arasi S, Bégin P, Ben-Shoshan M, Beyer K, Blumchen K, Brough H, Caubet JC, Chan ES, Chen M, Chinthrajah S, **Davis CM**, Des Roches A, Du Toit G, Elizur A, Galli SJ, Håland G, Hoffmann-Sommergruber K, Kim H, Leung DYM, Long A, Muraro A, Nurmatov UB, Pajno GB, Sampath V, Saxena J, Sindher S, Upton J, Worm M, Nadeau KC. Conflicting verdicts on peanut oral immunotherapy from the Institute for Clinical and Economic Review and US Food and Drug Administration Advisory Committee: Where do we go from here? *J Allergy Clin Immunol*. 2020 Apr;145(4):1153-1156. doi: 10.1016/j.jaci.2019.10.021.

Matthew C. Altman, Avraham Beigelman, Christina Ciaccio, James E. Gern, Peter W. Heymann, Daniel J. Jackson, Joshua L. Kennedy, Kristen Kloepfer, Robert F. Lemanske, Laurie M. McWilliams, Lyndsey Muehling, **Christina L. Nance**, and R. Stokes Peebles. Evolving Concepts in How Viruses Impact Asthma. *Journal of Allergy and Clinical Immunology*. 2020; 145:1332-1344.

Nance CL, **Deniskin R**, Diaz VC, Paul M, **Anvari S** and **Anagnostou A**. The Role of the Microbiome in Food Allergy: A Review. Children 2020, 7(6), 50; https:// doi.org/10.3390/children7060050 - 26 May 2020.



Publications by the Food Allergy Program

Knight JM, Wu J, Mauk K, Weatherhead J, **Anvari S**, Kheradmand F, Corry DB. Airway Mycosis and the Regulation of Type 2 Immunity. J Fungi. 2020;6(2):E74

Hearrell, M., & Anagnostou, A. Journal of Food Allergy. "*Diagnosis and management of anaphylaxis*". Volume 2 (1) , 2020

Joseph M, Chew WT, Seeborg F, Satter LF, **Anvari S**, **Chinn IK**, **Davis CM**, **Gupta MR**, **Nicholas S**, **Noroski LM**, **James M**, **Deniskin R**, **Diaz VC**, Lowe J, Lee GL, Craddock MF, Chan AJ, **Rider NL**. Intralesional Corticosteroids as Adjunctive Therapy for Refractory Cutaneous Lesions in Chronic Granulomatous Disease. *J Allergy Clin Immunol Pract*. 2020:S2213-2198(20) 30507-9

Kourosh A, Nsobundu CK, Khosla R, Guffey D, Minard CG, Levinson AJ, **Davis CM**. The Effects of School Staff Food Allergy Education in a Large Urban School District. Health Behavior Policy Re-view. 2020;7(3):238-247.

Sara Anvari, MD, MSc, Invited Lecture Speaker in the IAR Fellows Lecture Series: Food Protein Induced Enterocolitis Syndrome (FPIES) on Friday, June 12, 2020

Fleischer DM, Shreffler WG, Campbell DE, Green TD, **Anvari S**, Assa'ad A, Bégin P, Beyer K, Bird JA, Brown-Whitehorn T, Byrne A, Chan ES, Cheema A, Chinthrajah S, Chong H, **Davis CM**, et. al. Long-Term, Open-Label Extension Study of the Efficacy and Safety of Epicutaneous Immunotherapy for Peanut Allergy in Children: PEOPLE 3-Year Results. *J Allergy Clin Immunol*. 2020 Jul 10:S0091-6749(20)30957-X.

R Deniskin, D Fleischer, M Greenhawt, A T Fox, **A Anagnostou**. Differences in the Evaluation of Skin Prick Testing Results for Food Allergy Diagnosis Between US and UK Physicians. *J Allergy Clin Immunol*. 2020 June 9;

Anagnostou A. CON: Skin testing with fresh foods. *Ann Allergy Asthma Immunol*. 2020 May;124(5):443-444

Blackman AC, Staggers KA, Kronisch L, **Davis CM**, **Anagnostou A**. Quality of Life Improves significantly following real-world oral immunotherapy for peanut-allergic children. *Ann Allergy Asthma Immunol*. 2020.

A Blackman, K A Staggers, L Kronisch, **CM Davis**, **A Anagnostou**. Insights from a real-world peanut oral immunotherapy quality improvement program in a tertiary academic center in the United States. EAACI virtual meeting, London, UK. Allergy 2020. 75 (Suppl)

James M, **Anvari S, Anagnostou A.** Development of peanut allergy despite early introduction: A real-world case series in the United States. *Pediatr Allergy Immunol*. 2020 Jul;31(5):589-592. doi: 10.1111/pai.13226. Epub 2020 Mar 20.

Anagnostou A. Food immunotherapy: Choosing wisely. *Clin Exp Allergy*. 2020 Sep 24. doi: 10.1111/cea.13742. Online ahead of print.

Fleischer DM, Shreffler WG, Campbell DE, Green TD, **Anvari S**, Assa'ad A, Bégin P, Beyer K, Bird JA, Brown-Whitehorn T, Byrne A, Chan ES, Cheema A, Chinthrajah S, Chong HJ, Davis CM, Ford LS, Gagnon R, Greenhawt M, Hourihane JO, Jones SM, Kim EH, Lange L, Lanser BJ, Leonard S, Mahler V, Maronna A, Nowak-Wegrzyn A, Oriel RC, O'Sullivan M, Petroni D, Pongracic JA, Prescott SL, Schneider LC, Smith P, Staab D, Sussman G, Wood R, Yang WH, Lambert R, Peillon A, Bois T, Sampson HA. Long-term, open-label extension study of the efficacy and safety of epicutaneous immunotherapy for peanut allergy in children: PEOPLE 3-year results. *J Allergy Clin Immunol*. 2020 Oct;146(4):863-874. doi: 10.1016/j.jaci.2020.06.028.

Anvari S, Davis CM. Food protein-induced enterocolitis syndrome. J Food Allergy. 2020;1:48-54.