Designing a Food Allergy Database

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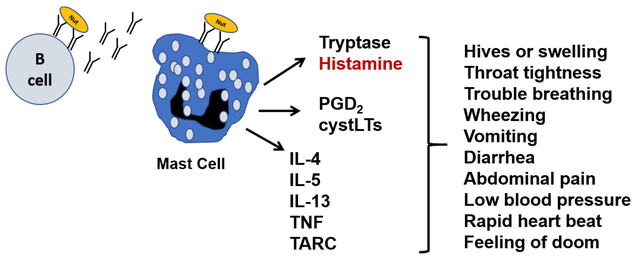
Introduction

- Food allergy impacts up to 8% of children.
- The most common food allergens are cow's milk, egg, soy, wheat, peanut, tree nuts, fish, and shellfish.
- Food allergy is caused by an IgE-mediated reaction to food allergens.



- Diagnosis of a food allergy is based on clinical history and evidence of sensitization.
- The current treatment for food allergy is avoidance and administration of epinephrine for allergic reactions.

- There are many emerging therapies for food allergy. Palforzia is the first FDA approved drug for the treatment of peanut allergy.
- No clinical trials on food allergy are being conducted at LSU Health Sciences Center/Children's Hospital New Orleans.
- The purpose of this study is to create a pre-consented database of patients with food allergy at Children's Hospital New Orleans for recruitment into future clinical research studies pertaining to food allergy.

Database Survey: Demographics

Gender	○ Female ○ Male
Ethnicity	○ Hispanic or Latino ○ Not Hispanic or Latino ○ Unknown/Not Reported
Race	○ American Indian/Alaska Native ○ Asian ○ Native Hawaiian or Other Pacific Islander ○ Black or African American ○ White ○ More Than One Race ○ Unknown/Not Reported
Street, City, State, Zip	_____
Phone Number	_____ (Include Area Code)
E-mail	_____
Consent Obtained	○ Yes ○ No
Provider Name	○ Andrew Abreo ○ Augusto Ochoa ○ Kenneth Paris ○ Luke Wall ○ Elizabeth Wisner

Demographic section of database enrollment survey.

Database Survey: Allergy History

Food Allergen(s)	☐ Cow's Milk ☐ Egg ☐ Wheat ☐ Soy ☐ Peanut ☐ Tree Nut(s) ☐ Fish ☐ Shellfish
Initial Symptoms (Cow's Milk)	☐ Urticaria (hives) ☐ Angioedema (swelling) ☐ Respiratory Symptoms (cough, wheezing, etc.) ☐ Gastrointestinal Symptoms (vomiting, diarrhea, etc.)
Most Recent SPT: date (Cow's Milk)	_____
Most Recent SPT: wheal size in mm (Cow's Milk)	_____
Most Recent Serum IgE: date (Cow's Milk)	_____
Most Recent Serum IgE: kU/L (Cow's Milk)	_____
OFC Date (Cow's Milk)	_____
OFC Result (Cow's Milk)	○ Pass (successfully completed) ○ Fail

Allergy history section of database enrollment survey.

Methods

- Subjects will be eligible for inclusion if they are diagnosed with at least one food allergy by a provider at the Children's Hospital New Orleans Allergy Clinic.
  - Food allergy diagnosis requires a convincing clinical history and evidence of sensitization to the suspected food.
- Consent and assent will be obtained to include protected health information (PHI) in the database and to contact patient about future clinical trials.
- All protected health information (PHI) will be stored in a Research Electronic Data Capture (REDCap) database.
  - REDCap's branched logic template allows for a streamlined survey. Once the diagnosed allergy has been selected, all subsequent questions pertain to the selected allergy.
- Institutional Review Board (IRB) application, consents, and assents have been completed and are awaiting submission to the IRB.

Timeline of Database Creation

- June 2020: Completed CITI training modules. Created and designed the Food Allergy Research Database in REDCap.
- July 2020: Completed the IRB application and created consents and assents for inclusion into the database.
- Fall 2020: Plan to submit IRB application and forms for approval by the LSUHSC and Children's Hospital New Orleans IRB. Once approved, will move REDCap database to 'production phase' for final approval.
- Late 2020-Early 2021: Begin enrollment of patients in the database with goal to enroll approximately 100 patients.

Conclusions

- The development of this recruitment tool is an important step to becoming a study site in a clinical trial.
- The database will add value by allowing clinicians to engage in food allergy research and patients to access new treatments.
- This study also illustrates how REDCap can be used in a clinical setting to facilitate clinical research.