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Food Allergy Oral Desensitization Information – SLIT and OIT

Food allergen "immunotherapy", or desensitization, is the process of exposing someone with a severe food allergy risk to a small amount of their food allergen(s) daily. The goal is to reduce the risk of accidental allergen exposures causing severe food allergy reactions. This is a delicate process with risk. There is a fine line between inducing tolerance to a food and inducing a severe, life-threatening allergic reaction, called "anaphylaxis". Currently there are two modes of food desensitization available:

- 1) sublingual (drops under the tongue) immunotherapy ("SLIT"), and
- 2) oral, or directly swallowed, immunotherapy ("OIT")

Most research about food desensitization involves peanuts. Protocols exist for other foods based on smaller research studies and allergists' shared experiences. SLIT and OIT are used in allergy centers worldwide and have been successful in preventing anaphylaxis outside the home.

Key points about SLIT and OIT:

- SLIT is the process of taking a very small amount of the food allergen in a liquid under the tongue and holding it there for two minutes before swallowing. OIT uses higher food doses than SLIT, and these are swallowed directly from a carefully measured food supply. The amounts of food allergen for SLIT and OIT are intended to be small enough that a severe allergic reaction is unlikely, but the immune system sees it enough to build tolerance to it, like a vaccine.
- Food immunotherapy is a marathon, not a sprint. The process requires determination, stamina, and patience. Expect to take doses seven days a week for at least one year, and long-term expect to take doses most days each week indefinitely to maintain protection.
- Build-up phase averages five to twelve months, depending on food(s) and process used:
 - **For SLIT**, liquid drops of the food preparation are dispensed under the tongue once daily. Amounts are increased **every one to four weeks**, depending on the protocol.
 - o OIT doses are swallowed once daily in amounts that increase every two weeks.
 - Each increasing dose (a.k.a. "up-dose") must be administered in scheduled
 appointments. For some SLIT patients, some up-doses may be given during televisits.
 - o The dose achieved at each appointment is taken at home **every day** until the next up-dose appointment.
 - o Patients must be observed after each dose escalation, or "up-dose", visit.
 - SLIT: depending on the protocol, the observation period in the office after each scheduled up-dose is **30 to 65 minutes**. Some up-doses may be coordinated through televisits.
 - For OIT, the first appointment may take 60 minutes to four hours on average, depending on the food(s) and the planned schedule. Up-dosing visits after the first visit require an observation period of 45 minutes.
- Maintenance phase:
 - o The goal dose is reached and is given at home on a consistent, daily basis.
 - When does it end? We don't know. We follow labs annually to follow progress, but you should expect to take doses indefinitely to maintain protection. If the maintenance dose is tolerated consistently, each year we may be able to decrease how many doses per week are required. The strategy may differ with each patient's situation.
 - o Doses given at home do not change unless there are allergic reactions or signs of illness.
 - Allergy skin or blood tests are performed within six months prior to starting therapy, and we repeat tests every year into therapy to see if risks may change.
 - o We may adjust dose strategies at regular visits based on test results and updated research.

- Why we use SLIT:
 - o SLIT uses smaller doses of food protein, is simpler to administer, and has less risks than OIT. However, it takes more time to protect from greater amounts of food allergen exposure. The advantages may reduce risks and anxiety for patients and families. Research for peanut SLIT shows that in six to twelve months, most patients can accidentally eat up to one peanut without an allergic reaction; and in two years, most patients tolerate two peanuts or more. We expect that most patients who successfully complete the SLIT build-up for any food will be safe from small accidental allergen exposures, such as cross-contact or contamination of prepared foods.
 - SLIT can provide a safer, slower introduction to OIT. You may discuss with the provider if a transition to OIT is an individual goal after SLIT maintenance is tolerated.
- Why we use OIT:
 - o Reaching higher doses of food protein proves tolerance of greater food amounts.
 - More food options are available at goal doses that are easier to purchase from stores.
 - o If we aim for high-dose OIT, we discuss if eating the food freely may be an option.
 - o For some patients, we can start OIT without SLIT, which we decide case-by-case.
- **Do not expect SLIT or OIT to be a "cure" for food allergy**. Patients who stop desensitization may return to anaphylaxis risks. For those whose allergy tests improve, we do not know if the process helps some patients outgrow food allergy or if they were going to outgrow it anyway.
- Food desensitization has risks.
 - o **Most patients will have mild side effects**, such as mouth or throat itching. Other common side effects include nausea, stomach pain, vomiting, itchiness, or rash (such as hives or eczema). SLIT is less likely to cause side effects than OIT.
 - o **Severe anaphylaxis is uncommon but can occur**. Patients tolerating desensitization have a reduced risk of anaphylaxis with accidental food allergen exposure. However, immunotherapy increases the risk of anaphylaxis in the home by intentionally taking food allergen doses every day. If allergy symptoms or signs of anaphylaxis occur, medications may be needed for treatment, as for all food allergy reactions.
 - o There is a chance that patients may develop **gastrointestinal inflammation**, such as "eosinophilic esophagitis", which can be very uncomfortable and debilitating. Such inflammation is unusual with SLIT. OIT research indicates it may occur in about 5% of patients. The most common symptoms of nausea, abdominal pain, vomiting, and difficulty swallowing usually resolve by stopping desensitization or reducing doses. We are not certain if therapy creates this inflammation as a new disorder or if the risk was always there and was uncovered by eating the food allergen.
 - Patients with eosinophilic esophagitis or other gastrointestinal inflammation, uncontrolled asthma, or uncontrolled eczema are not allowed to start SLIT or OIT due to risks of worsening symptoms and anaphylaxis.
- SLIT and most OIT protocols are not FDA-approved as treatments for food allergy. If you choose to proceed with SLIT or OIT, you acknowledge that 1) there may be risks that have not been fully established, and 2) research may reveal improvements in safety and effectiveness that were not established with earlier research studies.
- The decision to start SLIT or OIT is a personalized decision. Each patient and family will need to decide if the benefits are worth the risks. For some, food immunotherapy will be worth the investment to improve safety and to reduce anxiety or fear outside the home. For others, avoiding the food allergen(s) without desensitization may be less risky or less stressful.
- SLIT and OIT have strict conditions for safety.
 - o Please read through details in the instructions and consent forms that explain dose timing and adjustments with certain circumstances, such as with exertion or illnesses.
 - We reserve the right to cancel therapy if these conditions are not being met.
- Do not start this process unless everyone involved agrees to cooperate and to follow the guidelines. We need a supportive team mindset to enjoy the benefits of this marathon!

SLIT	OIT
Takes longer to build protection – one year protects 2/3 to 3/4 of patients from one peanut, two years > two peanuts for most. We think	Protection reached sooner – one to eight peanuts (or other foods in comparable servings) proven tolerated as part of the protocol
similar protection works for other foods Less clear how much food exposure is protected	You can see how much food is eaten daily
Less research on foods other than peanut, but experience is building to show likely as successful with other foods	Protocols available for more foods, some with research support, others based on experience in OIT centers
Long-term has good chance of protecting from accidental bites or contaminations	Long-term has good chance of protecting from larger accidental bites or contaminations AND may have chance to eat freely if push dose higher
Can lead to more tolerable OIT at cost of taking four to six more months	Most tolerate the protocol but may have more side effects by going faster to higher doses
Lower risk of side effects	Greater risk of side effects
Rare need for epinephrine. Most research shows that no SLIT patients need epinephrine	Up to 25% have moderate to severe reactions, and about 5-10% may need epinephrine, usually treated at home without an ER visit
No signs of persistent gastrointestinal inflammation in peanut studies	Risk of gastrointestinal inflammation, rates 5% to 15%, can adjust doses and slow down to bypass this in most cases
Less taste aversion using very small amounts of food or adding sweet flavor to mixes (ex. may add Kool-aid, etc)	Patients taste the food and texture, sometimes get tired of it, especially at higher doses. If there is an aversion, it can be reduced by creative flavoring or masking
May reduce anxiety to taste less, go slower, have less side effects	Symptoms more common than SLIT but still infrequent for most. Symptoms and taste may add a stress factor for the patient or family.
Two protocols:	Each food has a different protocol.
1) Weekly up-dose visits for two to three months,	Typically, up-dose visits in the office every two
then visits every two weeks for about three	weeks.
months. If doing well, about half of up-doses may	Can adjust up-dose visits every three to four
be observed by televisit	weeks if travel, illness, side effects, etc.
2) For some patients, five visits every 2 to 4	Takes six to ten months to reach top dose, depending on the food(s) and the goal dose for
weeks, all in person. (discuss with your provider)	depending on the food(s) and the goal dose for each food.
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