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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 peanut. 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 six to twelve months, depending on food(s) and process used:
  - For SLIT, liquid drops of the food preparation are pumped or placed under the tongue once daily in amounts that increase every week in the first two months and then every two weeks.
  - 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 SLIT patients, about half of up-doses may be given during televisits.
  - 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".
    - For SLIT, there is a thirty-minute observation period in the office after each scheduled up-dose, while some up-doses may be coordinated through televisits.
    - For OIT, the first appointment may take sixty 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 forty-five minutes.
- Maintenance phase:
  - $\circ~$  A 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.
  - 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.
  - We may adjust dose strategies at regular visits based on test results and updated research.

- Why we use SLIT:
  - 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:
  - $\circ$   $\,$  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.
  - If we aim for high-dose OIT, we discuss if eating the food freely may be an option.
  - There are cases when we 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. We do not know if the process helps a portion of patients outgrow a food allergy or if they were going to outgrow it anyway.
- Food desensitization has risks.
  - 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.
  - 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.
  - 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.
  - 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	Protection reached sooner – one to eight
protects 2/3 to 3/4 of patients from one peanut,	peanuts (or other foods in comparable
two years > two peanuts for most. We think	servings) proven tolerated as part of the
similar protection works for other foods	protocol
Less clear how much food exposure is	You can see how much food is eaten daily
protected	
Less research on foods other than peanut, but	Protocols available for more foods, some with
experience is building to show likely as	research support, others based on experience
successful	in OIT centers
Long-term has good chance of protecting from	Long-term has good chance of protecting from
accidental bites or contaminations	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	Most tolerate the protocol but may have more
taking five to six more months	side effects by going faster to higher doses
Lower risk of side effects	Greater risk of side effects
Rare need for epinephrine. Most research	Up to 25% have moderate to severe reactions,
shows that no SLIT patients need epinephrine	and about 5-10% may need epinephrine,
	usually treated at home without an ER visit
No signs of persistent gastrointestinal	Risk of gastrointestinal inflammation, rates
inflammation in peanut studies	5% to 15%, can adjust doses and slow down to
	bypass this in most cases
Tasteless until get to maintenance dose (may	Patients taste the food, sometimes get tired of
add Kool-aid, etc)	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,	Symptoms more common than SLIT but still
have less side effects	infrequent for most. Symptoms may add a
	stress factor for the patient or family.
Weekly up-dose visits for two to three months,	Up-dose visits in the office every two weeks.
then visits every two weeks for about three	Takes six to ten months depending on the
months. If doing well, about half of up-doses	food(s) and the goal dose
may be observed by televisit	