

Practical aspects of oral immunotherapy: The importance of optimal office design and workflow

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ABSTRACT

Oral immunotherapy (OIT) is an emerging treatment, but it is more than products and protocols. Office setup, including spacing, staffing, and logistics, is critical to assess to fully implement OIT into clinical practice. To provide insights into what needs to be considered in setting up an office to practically implement OIT into clinical practice. Most of the clinical research about OIT focuses on the products and protocols used for OIT. However, to safely and effectively integrate this into clinical practice, there are many practical aspects that need to be considered. Proper staffing, office space, scheduling, and on-call responsibilities all need to be considered because OIT will impact all of these aspects of practice. We provide suggestions and considerations as you think through these vital logistics in your office. These are practical considerations that must be determined to effectively handle OIT in an office setting. OIT products and protocols are one aspect of OIT. Actually delivering the treatment with staff, office space, and handling the patient needs after hours is really when OIT becomes more of a reality for the physician and the patient.

(J Food Allergy 4:45–48, 2022; doi: 10.2500/jfa.2022.4.220010)

Oral immunotherapy (OIT) is an emerging treatment option and rapidly growing in many clinical practices. Although much of the focus in clinical trials and the literature has been on various foods and methods, it is apparent that it takes much more than a product and a protocol to safely and effectively conduct OIT in practice.^{1–5} Other important aspects of OIT include appropriate office staffing, clinical spacing, and patient scheduling. This article addresses these needs. No human subjects were used in this study so no institutional review board approval was necessary.

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A. Williams is a speaker for Aimmune. The remaining authors have no conflicts of interest pertaining to this article

No external funding sources reported

This manuscript is part of the **Journal of Food Allergy** collection of published works referred to as the “Oral Immunotherapy Manual.” The contents of this work reflects the opinion(s) of the author(s) and is not intended to replace published guidelines or the clinician’s medical advice in the doctor-patient relationship

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STAFFING

The framework of OIT includes a multidisciplinary, integrative, and cohesive approach that involves different members of a clinical team. Each member should be delegated specific responsibilities. It is imperative that each member have a full understanding of his or her role in patient care. It is our recommendation that the director of an OIT clinic be an allergy/immunology board-certified physician. Further, they should have specialized training in food allergy diagnosis and management, including experience and proficiency in treating anaphylaxis and performing oral food challenges in addition to their competence in OIT. The duties of the clinical director include planning and overseeing all patient care and administrative responsibilities. It is encouraged that the director delegate clinical OIT responsibilities; however, remain intimately involved.

Well-trained advanced practice clinicians can, with proper training, work directly under the guidance and supervision of a board-certified allergist. Their duties may include evaluating patients, confirming the diagnosis of food allergy by standard methodologies, leading the educational discussion of OIT with patients with food allergy, administering doses of different foods during each stage of OIT, and serving as a point of contact to respond to patients’ questions during or after clinic hours. Nurses and medical assistants may also assist in the management of patients on OIT protocols. Their roles include, but not limited to, performing the initial patient assessment, performing testing to aid in the diagnosis of food allergy, ordering and preparing foods for office dose administration, monitoring of patients, and performing other clerical duties (e.g.,

scheduling patients on OIT for their continued care). It is imperative that a provider well trained in recognizing and treating anaphylaxis be present within the clinic for the duration of all OIT dose administration in the case that adverse events arise. All team members should be regularly updated on their skills and roles in the management of anaphylaxis under the direction of the provider in charge. Please refer to the 2020 updated practice parameter on anaphylaxis for a detailed description of the diagnosis and management of anaphylaxis.⁶

The authors make special note for staffing considerations for clinics that prescribe Palforzia, an Aimmune Therapeutics (Brisbane, CA) product that is approved by the U.S. Food and Drug Administration (FDA) for the mitigation of allergic reactions, including anaphylaxis, that may occur with accidental ingestion of peanut. To this date, Palforzia is the only FDA-approved product for the mitigation of food allergic reactions. The Palforzia Risk Evaluation and Mitigation Strategy is required by the FDA to ensure the potential benefits from Palforzia outweigh the risks.⁷ To that end, clinics that prescribe Palforzia must designate an authorized representative, whose duties include reviewing the education program for the health-care setting, submitting health-care and patient enrollment forms, overseeing implementation and compliance with Palforzia Risk Evaluation and Mitigation Strategy, and ensuring that a certified prescriber is on site whenever Palforzia is administered.

There is no specific designation for the authorized representative. This role may be filled by any staff member. It is our recommendation that clinics new to OIT protocols make restrictions that allow for only a few patients on active therapy at one time. This will allow the clinic to become accustomed to the protocols and workflow, and to make adjustments as necessary. This approach will also limit the need for additional staffing; however, as the number of patients on active OIT protocols increases, additional staffing may be needed.

SPACING

Certainly, clinics should anticipate an increased number of consultations for food allergy once OIT is initiated in a practice. This will lead to increased demands on office space. When planning, it is important to realize that more oral food challenges will be done before patients start OIT and this needs to be accounted for in determining space and office flow. Initially, OIT may be performed within the existing space of the clinic. Additional spacing is typically unnecessary until a threshold of patients on active OIT is reached. A clinic can limit the number of patients on active OIT to prevent additional spacing requirements.

Table 1 Supplies for the oral immunotherapy clinic*

- Precision weigh gram scale accurate to 0.01 g
 - Kitchen supplies
 - Measuring spoons
 - Measuring cups
 - Utensils (disposable forks, spoons, and knives)
 - Plates and bowls for mixing vehicle with food dose
 - Refrigerator
 - Cleaning supplies
 - Glass bottles for storage of liquid doses
 - Containers for bulk food and flour
 - Food vehicles for dose administration (pudding, applesauce, yogurt)
 - Mortar and pestle
 - Sink
 - Oral dispensing syringes
 - Office supplies
 - Calculator
 - Markers for labeling
 - Computer and printer
 - Cabinets and drawers for storage of supplies
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**Reproduced from Ref. 3.*

Some OIT clinics use a wait list with patients being added to the active OIT schedule after other patients have completed therapy.

Although the configuration of spacing is individualized and unique to a particular clinic's workflow, there are a few absolutes. Diagnostic testing can be labor and time intensive and may occupy examination rooms, especially because the number of oral food challenges conducted will increase once OIT is started in a practice. Examination rooms are primarily used for consultations, diagnostic testing, food challenges, and OIT dose administration. However, as OIT becomes more prevalent as a therapeutic measure, many offices will have a dedicated dosing space and patient monitoring area where clinical staff can have direct visualization of patients. Careful consideration should be given to these time requirements when designing the optimal space and workflow.

Postdose observation can occur in an examination room, lobby area, or other designated spaces. Given the time requirements of initial dose escalation and updose appointments, there should be consideration of amenities for patients and their families. Internet access, television programming, and activities for children (e.g., crayons, board games) are encouraged. In addition, OIT clinics should prepare for the spacing requirements of food storage. All foods with potential for spoilage must be properly stored and correctly labeled in a refrigerator to avoid cross-contamination

Table 2 Recommended equipment and medication for OIT clinics

Category	Equipment
Airway and oxygen	Blood pressure cuff monitor
	Stethoscope
	Pulse oximeter
	Facemask (adult and pediatric)
	Nasal cannula
	Oxygen tank
	Oxygen tubing
	Oxygen nasal cannula
	Artificial manual breathing unit*
	Oropharyngeal airway (adult and pediatric)*
IV supplies	Oral endotracheal tube*
	Intubation laryngoscope*
	IV fluids (normal saline solution)
	Catheter needles (gauge 16, 18, 20, 22)
	Connection tubing
	Syringes with needles (1 mL, 10 mL)
	Tourniquet
	1-inch tape
	Latex-free gloves
	Alcohol swabs
Medications	IV pole
	Epinephrine 1:1000 for intramuscular injection
	First- and second-generation antihistamine
	Methylprednisolone 125-mg vial
	Albuterol metered-dose inhaler or nebulizer
	Glucagon 1-mg/mL vial

*OIT = Oral immunotherapy; IV = intravenous.
Denotes additional equipment to consider, depending on the OIT clinic's proximity to emergency services.

and administration error. Practitioners should have storage space for dried foods, disposable utensils, and containers (Table 1). In addition, there should also be a separate and easily accessible storage space for emergency medications and equipment for the management of anaphylaxis (Table 2).

SCHEDULING

Scheduling of patients is dependent on staff and space needs as well as office workflow. The first thing to consider is the scheduling of the new food allergy consultations but also how and when to

handle increased oral food challenges. You will need to determine when those best fit into your workflow. Furthermore, an OIT clinic may have dedicated OIT schedules separate from the office schedule, and other clinics may have OIT schedules built into their normal office workflow. The clinical director must decide which approach works best for his or her individual clinic. Practitioners should be mindful of the time requirements of OIT because this can affect office workflow and examination room availability.

As stated above, it is we recommend that patients on active OIT protocols do not exceed clinic capacity limits. Each OIT clinic should determine its maximum capacity before initiation of OIT protocols and schedule patients accordingly. Consideration should be given to scheduling new food allergy consultations as well as how and when to handle the increased demand for oral food challenges so that these patients can be seamlessly integrated into the office workflow. Patients with food allergies are introduced to foods at doses below the threshold that induces a severe reaction are strongly recommended. Initial dose escalation appointments require between 3 and 6 hours of clinic time. In addition, OIT clinics should consider that patients will be up dosed every 1–2 weeks, depending on which protocol is initiated. The clinic can expect ~45–60 minute appointments per patient updose. The number of up doses to reach a clinical end point varies per protocol and also how a patient responds to the therapy. However, an OIT clinic can expect ~6 months of up dosing per patient.

ON-CALL SERVICE

Also, it is our recommendation that patients on OIT have 24-hour access to a provider in case questions or concerns arise. How an on-call service is arranged is at the discretion of the clinical director. OIT clinics may take calls in a shared system, as long as patient confidentiality laws are not violated. This system requires detailed documentation to ensure that sound clinical judgments are made. It is recommended that, in the case of an emergency, patients call 911 and initiate an action plan, which may include administration of epinephrine before contacting the on-call provider.

CLINICAL PEARLS

- Proper office planning with staffing and scheduling, and with office space will help with OIT delivery to patients.
- Preparation ahead of time will enhance office efficiency and patient safety.

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