

AAOA



PRACTICE RESOURCE TOOL KIT

Physical Space & Equipment Needed for the Allergy Patient



Materials presented in this tool kit are intended as resource only and should not be construed as guidance

Physical Space & Equipment Needed for the Allergy Patient

Physical Space

Allergy services should have dedicated space within the ENT Office. Minimal requirements, there should space for a table or counter where the testing boards and treatment vials for immunotherapy can be prepared. The area should be well lit and clean. It should be away from the day-to-day activities of the office and it should be free of distractions (phone, TV, Internet etc).

It needs to comply with the USP General Chapter <797> Pharmaceutical Compounding — Sterile Preparation requirements. These include:

- ✓ An ISO Class 5 Primary Engineering Control (PEC) **OR** a dedicated Allergen Extracts Compounding Area (AECA)
- ✓ The PEC or AECA must be located away from unsealed windows, doors that connect to the outdoors, and traffic flow (all of which may adversely affect the air quality).
- ✓ Neither the PEC or AECA may be located where environmental control challenges (e.g., restrooms, warehouses, food preparation areas) could negatively affect the air quality.
- ✓ The PEC or AECA must be located at least 1 meter away from a sink.
- ✓ If used, a PEC must be certified every 6 months, and cleaned and disinfected daily and when surface contaminations is known or suspected. Apply sterile 70% IPA to the work surface between each prescription set
- ✓ An AECA must have a visible perimeter and meet the following conditions:
 - Access restricted to authorized personnel during compounding
 - No other activity permitted during compounding
 - All surfaces must be cleanable
 - No carpet allowed
 - Surfaces should be resistant to damage by cleaning and sanitizing agents
 - Surfaces must be smooth, impervious, non-shedding, and free from cracks or crevices to allow for easier cleaning
 - Dust-collecting overhangs (e.g., utility pipes, ledges, windowsills) should be minimized or must be easily cleaned
 - Designed and controlled to provide a well-lighted work environment, with temperature and humidity controls for the comfort of the compounding personnel wearing the required garb
 - Work surface must be cleaned and disinfected daily and when surface contamination is known or suspected
 - Apply sterile 70% IPA to the work surface between each prescription set
 - Walls, doors, and doorframes within the perimeter of the AECA must be cleaned and disinfected monthly and when surface contamination is known or suspected.
 - Ceiling must be cleaned and disinfected when visibly soiled.
- ✓ Vail stoppers on packages of conventionally manufactured sterile ingredients must be wiped with 70% IPA to ensure that the critical sites are wet and allowed to dry before they are used to compound allergenic extract prescription sets.

When work is being done in the allergy area, the door should be closed and a sign posted on the door stating that allergy work is being done and there is to be absolutely no interruptions of any sort for any reason, except the building is being evacuated. The allergy staff (NP, PA, RN, MA, etc) should avoid distractions. Many offices require staff to leave his or her phone in another room to prevent distractions as well. In most offices, an exam room will suffice to serve this purpose provided there is enough space to mix everything and to spread out all of the supplies needed to complete the allergy tasks. There needs to be a sink nearby, but at least 1 M away from the mixing area, to allow the staff to wash their hands and discard any liquids.

Refrigeration

A refrigerator needs to be purchased that is large enough to store the allergens, testing boards, treatment boards, and all of the prepared patient vials. This refrigerator is not to store any food products for personal consumption. Ideally, it is to have a temperature gauge with an alarm on it. Should the temperature change from the range, the alarm will go off. This will enable the practice to ensure that the antigens are preserved.



Testing Room

The testing room should be large enough for the allergy staff, patient, and a family member. It should contain a chair that can recline in the event of a vasovagal or anaphylaxis event. The room should have the equipment to do vitals if need be (BP cuff, Thermometer, Oxygen saturation monitor). The emergency cart should have oxygen, IV fluids, epinephrine, and any drugs that are needed for resuscitation. A timer is often helpful for monitoring the time to do the reading for the tests. It may be helpful to have a TV, internet access, reading material in the testing room to give the patient something to watch during the waiting period while testing.

Waiting Room

Ideally, a separate waiting area should be available for the allergy patients. This will allow allergy patients to come in easily for their shots without disrupting the rest of your practice flow. It should have 6 to 10 chairs, depending on how much allergy patient flow the office has. This area should be close to the testing and treatment areas for monitoring any reactions after the testing or shots. If a separate room is not available, designated areas in the lobby for the main practice should be set up, so ancillary staff can keep an eye on the patient. Current recommendations are to watch the patient for 30 minutes after the immunotherapy injections. The location of the allergy patients should be such that the staff can monitor them for the elected time period.

Different Flow for the Allergy Patient

The flow of the allergy patients will be different than the regular ENT patients. They will be coming into the practice and should have a different waiting period than the standard ENT patient. In a practice with a secondary lobby or waiting area, they can come in, get their shot, wait, and be out of the office through a separate door. Ideally, the allergy patient will have a different flow pattern than the average patient after they have been established. It is confusing for regular new patients to wait while other patients sign in, immediately go through the door to the back, have their shot, and leave all while they are waiting for their appointment.

Storage Area for the Supplies

The supplies need to be stored in an area that is regularly assessable and out of the way of the normal office activities. Usually a designated area can be assigned to store the testing supplies: the prick devices, syringes, measuring devices, diluent, gowns and gloves for mixing, and the appropriate records for the testing. It is best to define your allergy service protocols and create a standard operating procedures (SOP). Within your SOP, you should keep your testing, compounding, and refrigeration logs, as well as data for your allergen supplies, antigen lots, BUDs, etc.

Handouts for the Patients about the Testing Day

Handouts need to be prepared for the patient to make them aware of which medications and foods they will need to avoid prior to testing. A sheet describing the testing and the patient's responsibilities needs to be given to them prior to their testing.

Define your charge policy up front. For example, let patients know that missing the testing visit or a shot visit will result in a charge, if that is your protocol.

Explain the need for an autoinjectable epinephrine device as part of your testing and treatment protocol. Many use consent forms to help assure the patients comply with attaining the autoinjectable epinephrine. Up front counseling improves patient compliance not only with testing but also with immunotherapy.