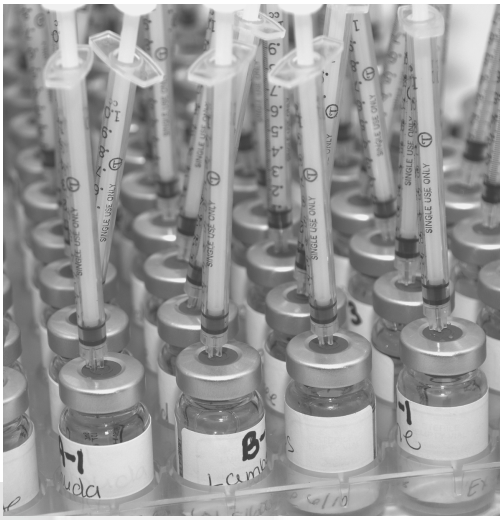
AAOA



PRACTICE RESOURCE TOOL KIT

WWW.AAOALLERGY.ORG

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

The American Academy of Otolaryngic Allergy

AAOA Practice Resource Tool Kit

The American Academy of Otolaryngic Allergy (AAOA) Practice Resource Tool Kit is intended as a guide to help AAOA members integrate allergy into their otolaryngology practice and to continually improve on this integration as new information, regulations, and resources become available.

While these tools are meant as resources, we highly recommend seeking input from your practice counsel and local/state medical associations and regulatory authorities, as rules vary between states. Our intention is to offer insights by sharing what others within AAOA do. These are not meant as recommendations.

Our goal is to continually add new content where appropriate. Because these resources are developed for use by our members, we encourage member feedback. By understanding the challenges our members face, we can better support the specialty. Below is the Table of Contents for the full compendium. You have the choice of downloading the full compendium or downloading those resources specific to your needs.

We would like to thank our workgroup who put in tremendous amounts of time to help develop this tool kit.

Practice Resource Tool Kit Workgroup:

Douglas Dawson, MD, Chair
Dole Baker, MD
Paul Fass, MD
Melissa Hertler, MD
Steve Houser, MD
Ayesha Khalid, MD, MBA
Adrienne Laury, MD
Andrea Lewis, MD
Alpen Patel, MD
Keith Sale, MD
Kristin Seiberling, MD
Farrah Siddiqui, MD
Robert Stachler, MD
Wesley VanderArk, MD
Christopher Vickery, MD
Kevin Wilson, MD

Table of Contents:

Otolaryngic Allergy Start Up Checklist

- **Physical space in your office**
  - A room in which testing can be performed (which can be tied up for 30-60 minutes at a time)
    - furniture
      - chair for the patient, ideally one that reclines in case of syncope or reaction, that has arm rests or a tray
      - sitting stool for the provider administering and reading the tests
      - extra chair(s) for family members or caregivers
      - desk space for paper or computer record keeping
      - counter space for testing trays and supplies (a rolling trolley cart may be useful if testing in more than one room or to keep testing supplies close at hand)
  - Space to administer immunotherapy injections (may be the testing room, exam room(s), or alternative)
  - Extra waiting room space, possibly separated from general ENT waiting area, in which staff can monitor patients for a reaction during their 20-30 minute wait after injection
  - A space which can be used for mixing, which ideally includes ample counter space, a sink, room for a refrigerator and area for paper or computer record keeping (see USP <797> resources)
- **Allergy personnel**
  - The MD is the primary allergy caregiver and decision maker
  - Highly variable additional staff requirement in individual practices
  - MA/Allergy Technician, LPN, RN, NP, PA or MD to perform skin testing and administer injections
  - Existing support/administrative staff

- **Choose an allergy antigen supplier**
  - do your research on which company best suits your practice, and region
  - do more research on what to include in your panel(s)
  - order antigen in sufficient quantities to avoid rapid turnover to new lots
  - order supplies in addition to antigen, including diluent(s), histamine, glycerin, vial racks, measuring cards for skin testing

- **Choose a vendor** for other allergy supplies and order them as well, including syringes (mixing and injection) and (if using) skin prick testing devices (both of which may be available from allergy vendor), alcohol and cotton balls, alcohol wipes, band aids, individual packets of hydrocortisone cream for after testing, sharps containers

- **Decide on how allergy record keeping** is going to take place (paper charts, direct documentation in EMR, hybrid model), and if dedicated allergy software makes sense in your practice
- **Make an "anaphylaxis kit"** stocked with emergency supplies, and a way to track expiration dates and restock when needed.
    - Anaphylaxis kit essentials
        - Medications
            - Epinephrine 1:1000
                - either auto-injectors, or at least 2 prefilled syringes with 0.1 ml for pediatrics, 0.3 ml for adults in an easily accessible location or top of kit
            - albuterol MDI (may stock disposable spacers)
            - H1 blocker (po, iv)
            - H2 blocker (po, iv)
            - corticosteroid (po, iv)
            - consider dopamine
        - Airway management supplies
            - suction (yankauer and flexible for ETT), can use suction on SMR cart or need machine
            - O2 tank with nasal cannula(s), mask(s)
            - Ambu-bag, mask(s)
            - Oral airways of various sizes
            - Intubating laryngoscope
            - ETTs in various sizes
            - cricothyrotomy and/or tracheostomy supplies
        - IV access supplies
            - Angiocatheters
            - tubing
            - fluids (NS or LR)
            - tape
            - iv pole
        - Access to AED?
        - Anaphylaxis treatment recording sheets

Staffing Considerations

Staff engagement and satisfaction is directly tied to physician and patient experience in our clinics. One of the most effective ways to ensure staff engagement is to balance the workload among your staff. By carefully evaluating the effort put forth by your team, by aligning roles and responsibilities, and by creating standard operating procedures according to those roles, you can optimize your clinic's efficiency while simultaneously improving staff and physician experiences.

As with the addition or expansion of any new line of service, consideration of staffing resources is key. As with many medical services, time is a key determining factor. Many consider the staff time required for mixing, testing, treating (shots), and board preparation.

Step 1: Consider the following:
Number of calls, emails, clinic time, EMR time, etc

Step 2: Consider how time calculated above compares to the volume of patients/week

Step 3: Use the above data to determine overall "staffing to workload" needs

Step 4: Considering your staffing to workload needs and your projected patient volume specifically for allergy (next 12 mo) and the projected time required for mixing, testing, treating, and board preparation will help determine what your specific staffing resource needs are to support allergy management. Keep in mind, adding any new service has an impact on clinical, ancillary, front office, and business operations staff.

Step 5: What are your state requirements re level of training necessary. There are many resources to help determine what your state requirements are. Several to consider are your state medical society, Medical Group Management Association (MGMA at https://www.mgma.com/resources), state nursing board, etc. The American Academy of Nurse Practitioner offers some resources on its website at www.aanp.org to help determine the level of training needed for various levels of patient care.
The American Academy of Physician Assistants (www.aapa.org) and the Society for PAs in Otolaryngology (SPAO at https://entpa.org/page-1842456) are additional resources to consider.

Step 6: Job descriptions help not only in the hiring process, but also in outlining expectations and roles of authority. Again, there are several resources. ASCENT: Administrator Support Community for ENT (formerly Association of Otolaryngology Administrators) offers several tools specific to otolaryngology available on its website at https://www.askascent.org/

Step 7: Define staff role within your Standard Operating Procedures (SOP). Who will be responsible for what. Within this specific to allergy, who is responsible for all the sterile compounding (USP General Chapter <797> and FDA guidance) compliance training, documentation, and related requirements.

The following pages outline supervision requirements and "incident to" requirements that pertain to allergy testing and treatment.

Staffing Considerations: Supervision

- All diagnostic tests are assigned a level of supervision
  - *General:* Physician does not need to be on premise, but have management responsibility for staff who does the test
  - *Direct:* Physician needs to be in the office suite, but does not need to be in the room when the test is done
  - *Personal:* Physician needs to be in the room when the test is performed

- Allergy tests are under ***Direct Supervision***
- Vial Preparation is under ***Direct Supervision***
- Allergy shots are also under ***Direct Supervision***

Ancillary Staff: Scope of Practice

- Nurse practice laws and regulations are specific to each state.
- AANP offers quick reference guide for licensure and regulatory requirements, as well as practice environment details, for all 50 states and the U.S. Territories. Downloadable State Regulatory Map available at www.aanp.org
- AAPA's webstore offers "PA State Laws and Regulations" includes all 50 states and the District of Columbia. www.AAPA.org offers a synopsis of each state's PA practice act, including scope of practice, prescribing and supervision, among other topics that cover PA practice.
- Recommend checking with state nursing board to confirm scope of practice and whether an NP/PA can supervise another staff member testing or treating
- Medical assistant and Nurse laws are specific to each state.
- For medical assistants, refer to the CAAHEP Standards for the Accreditation of Educational Programs in Medical Assisting. Appendix B contains the Core Curriculum. This delineates what medical assisting students in CAAHEP-accredited programs must know and be able to do in order to complete the program. It varies between states and can change so please refer to the above for your state regulations.
- For examples, see below:

  - New York and Connecticut laws do not permit physicians to delegate to medical assistants any administration of medication, including by means of injection.

  - The laws of Washington, California, Florida, Maryland, and South Dakota are fairly specific. They do permit physicians to delegate to medical assistants the administration of IM, subq, and ID injections. There is no language in the laws of these states that forbids medical assistants from being delegated the administration of allergy injections.

  The laws of some states require the delegating provider to verify the dosage and identity of the medication before it is administered by the medical assistant.

- The American Academy of Nursing has a "Policy and Advocacy" section on their website www.aannet.org/ . Regulations may also be hospital specific as some hospitals only employ RNs and do not have LPNs.

As an example, NP Scope of Practice is defined as:

- Full Practice: Evaluate patients, diagnose, order and interpret tests, initiate and manage treatments under the exclusive licensure authority of the state nursing board
- Reduced Practice: Reduces the ability to engage in at least one element of NP practice (above) and requires collaborative agreement with an outside health discipline for the NP to provide patient care
- Restricted Practice: Restricts the ability to engage in at least one element of NP practice (above) and state requires supervision, delegation, or team-management by an outside health discipline in order to provide patient care.

All personnel performing shots or testing should have formal allergy training, as well as training in anaphylaxis management. All allergy test interpretation, dose calculation, and vial preparation should be performed in conjunction with a physician practicing otolaryngic allergy.

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.

Key Impactors of Patient Flow

1. Scheduling
2. Office processes and staffing
3. Clinic layout
4. Technology

Understanding the foundations of patient flow

1. Demand and supply
    - Clinic consult, testing, and office procedure slots needed per day can be inferred from the number of appointments scheduled per day
    - Level loading appointment slots throughout the day and across the days of the week can help improve day to day flow
2. Scheduling to your demand
    - Creating schedules that accommodate your daily demand can improve patient flow
    - When unable to meet daily demand you can consider adding extra slots, hours, or days to accommodate demand
    - You may also need to consider adding APP support or new providers when your schedules are full and demand remains unmet

Developing a workflow that works for your practice

1. Previsit work
    - Pre-visit documentation completion by the patient can reduce staff check-in and rooming time
    - Nursing pre-visit evaluation and prep can expedite the exam process
    - Pre-procedure or pre-testing authorizations can be done ahead of time
2. Check in and registration
    - Standardize documentation and questionnaires
    - Consider automating self-check in via phone, online, or in office tablets/kiosks
    - Having a standard policy for managing late arrivals can reduce backlogs in clinic and facilitate clear expectations amongst patients and staff
3. Rooming
    - Shifting as much work out of the rooming process and into the pre-visit process can significantly reduce the patient's rooming time
    - Developing a consistent rooming process enhances your roomer's efficiency and can reduce the time to room a patient
4. Clinical evaluation or testing
    - EMR optimization and in-room documentation can reduce re-work
    - The addition of scribes (in-room, virtual, AI) can improve patient flow and potentially increase supply
5. Patient education
    - Templated or standard patient education materials that are integrated into the EMR can reduce the need the find and/or print materials
6. Checkout
    - Having dedicated checkout staff may reduce a bottleneck at the front desk where staff are trying to perform two functions

Optimizing clinic layout to meet your workflow

1. Consider separate waiting rooms for allergy and other patients
    - Separation allows for easier monitoring of shot patients for their observation period
2. Understand the movements of your patients and your team
3. Physician/Nurse/MA workspace
    - Creating a centralized location where the providers and staff work together can improve communication and help providers complete multiple tasks
    - Reducing steps between exam rooms and the centralized team space may improve provider flow
4. Room allocations
    - Proximity of allocated exam rooms and testing/treatment rooms may improve workflows and aid in patient flow

Using technology to gain efficiency in patient flow

1. Patient portals
    - Reduce phone calls and in-office education
    - Protect clinic exam slots by managing routine issues virtually
2. Automation
    - Pre-visit texting/emails
    - Pre-testing reminders

Patient Flow

Patient flow impacts a clinic's efficiency and correlates with patient, staff, and physician satisfaction. Some key factors include scheduling, office processes and staffing, clinic layout, and technology.

Foundations

Developing a clear understanding of your patient demand for clinic visits, allergy tests, and immunotherapy treatments serves as the foundation to patient flow. Practices that track the volume of scheduled visit types per day can use this information to predict the number and type of visits needed. These visits can then be spaced throughout the day and week to help minimize patient congestion in testing, treatment, or exam areas. Trending of this information can also be used to guide staffing throughout the day as well as predict the need to add new providers. In the example image below which shows the number of patients getting a practice manager could use the information to identify peak times of day and peak days of the week to prepare for higher volumes of allergy shot patients.

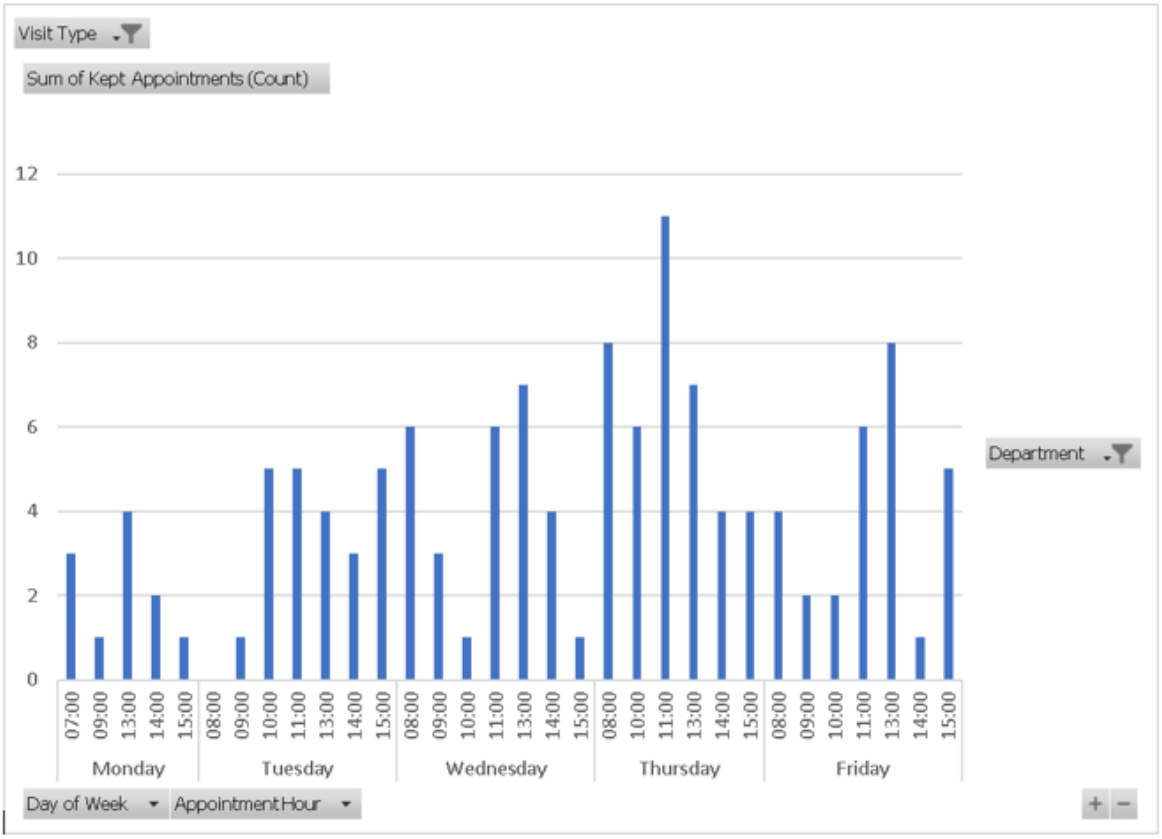
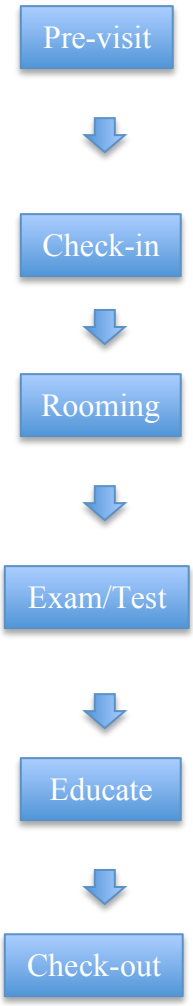


Figure 1. Number of patients receiving allergy shots per hour and by day of the week at one practice location.

Mapping Flow

Mapping your patient's experience and understanding how each component of the patient visit impacts flow will inform the practice management where improvement opportunities exist. Typically, a patient's visit experience includes pre-visit work, check-in/registration, rooming, clinical evaluation/testing, patient education, and checkout. To optimize your practice you may want to delineate workflows for standard clinic visits, allergy visits, allergy testing, and allergy shots.



For your registration staff, having patients fill out registration information, pre-visit screenings tools, and check-in documentation prior to their arrival shifts this work out of the clinic and expedites the patient's preparation for the examination. When possible, pre-certification for testing or procedures should also be done before the patient's arrival. Likewise, having a standard policy for managing late arrivals can reduce backlogs in your clinic and facilitate clear expectations amongst patients and staff.

Developing consistent patient questionnaires and pre-exam assessments reduces variability and streamlines in-office processes. You might also consider automating the check-in process either by phone, online, or in the office (kiosk, tablet, etc) to reduce front desk congestion and enhance patient flow through the registration process.

For your clinical staff, creating a consistent rooming process and optimizing in-room documentation can reduce re-work while also minimizing the roomer's time in the exam room. Utilization of drop down menus, smart phrases, or templates are great ways to create efficiency of process while generating trackable data.

For physicians and APPs, direct entry or utilization of scribes (in-person, virtual, or AI) may enhance the patient experience and help decrease your time spent in the electronic medical record. Keep in mind that the added cost of a scribe should be evaluated against the improvement in provider lifestyle and/or against the number of "extra" patients per day needed to offset that expense.

For education, adding templated information into the EMR and/or standardizing printed education materials for distribution at checkout can speed up the discharge process. Having such standardized materials for your patients to review will help your staff create a consistent education experience and reduce follow up phone calls.

Once the clinical component of the visit is complete the checkout process may be more efficient if there are staff dedicated only to check out: scheduling follow up, scheduling additional testing, and handing out important documentation. When check in and check out functions are performed by the same personnel in a busy practice it may lead to a backlog at your front desk.

Clinic Space Utilization

First, consideration should be given to separate waiting rooms for your allergy patients and for your other clinic patients. Having a dedicated waiting room for your allergy shot patients will allow your staff to more easily monitor patients and identify potential reactions.

Second, LEAN methodology adopted from Toyota suggests that the ideal operational cell flow is that of a "U". Check in, then loop around to include waiting area, exam room, testing, then check out such that each patient continues forward progress and there is no doubling back. If you can optimize your clinical space it may be helpful to assess the movements of your patients, staff, and providers as they manage patients in your clinic. By identifying how your team moves throughout the clinic, you can then move personnel or re-design your facilities to improve efficiencies. When the ideal is not possible, allocating rooms and provider workspace in such way as to accomplish minimal steps by the patient, staff, and providers will help patients flow through your practice more efficiently while also minimizing staff and provider non-value-added time.

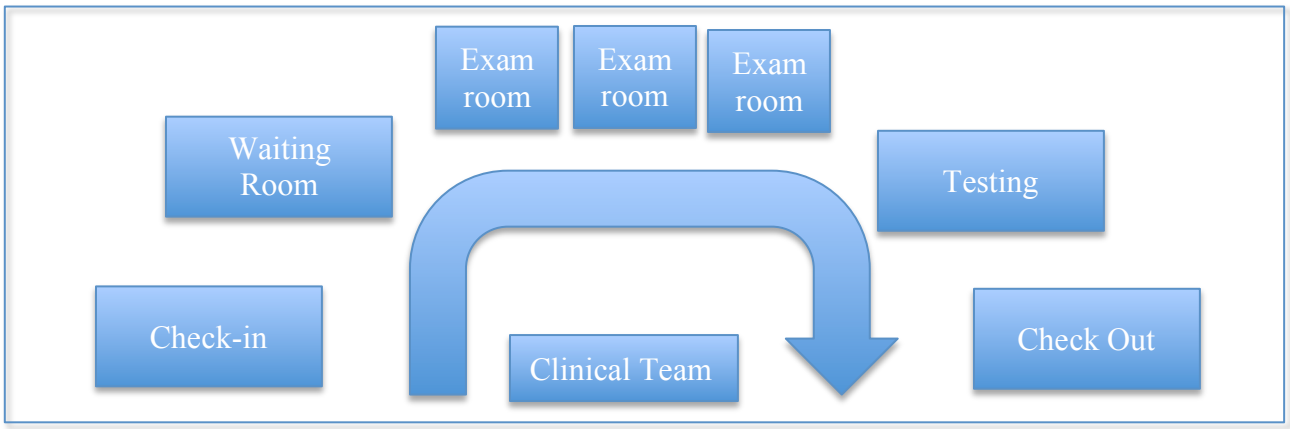


Figure 2. LEAN methodology suggests that the ideal operational cell flow is a U shape.

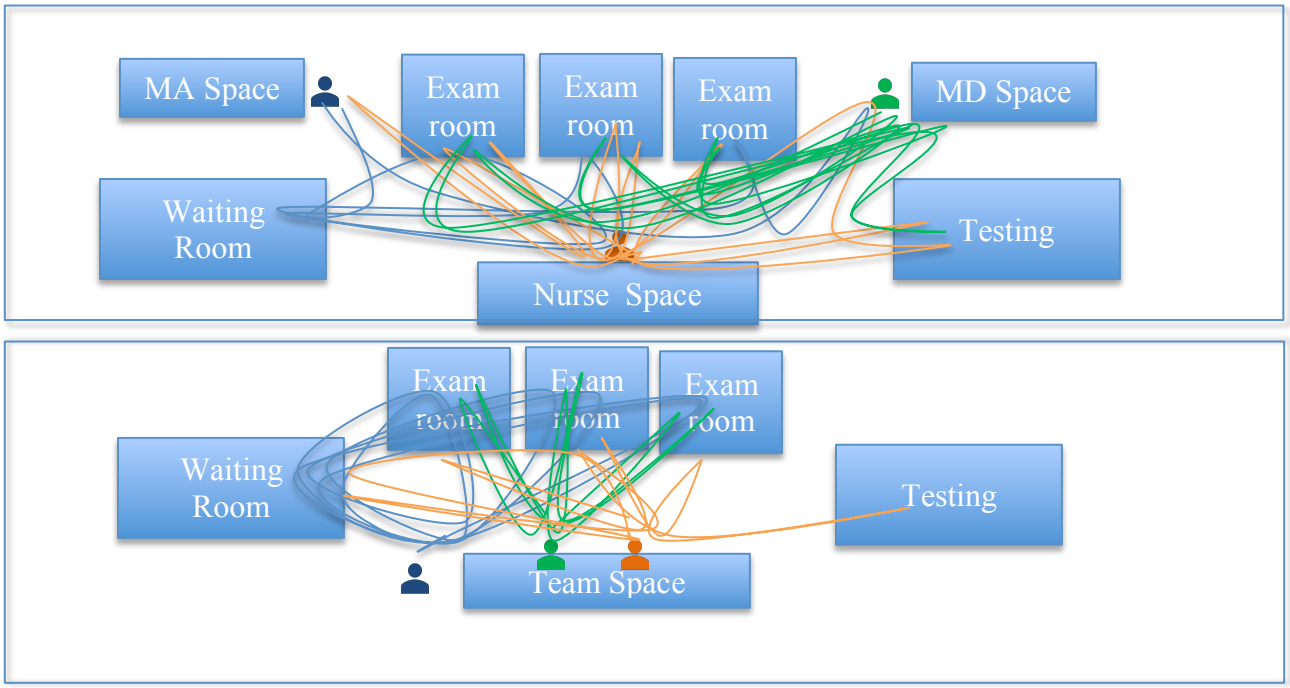


Figure 3. Tracking your staff and physician movement around the clinic can help identify ways to improve flow.

Technology

Lastly, technologic advances in EMR portals and clinic automation may serve as way to improve patient flow. By taking advantage of your EMR's secure messaging tools and using third party services that provide phone or texting reminders you may be able to reduce late arrivals, delays in registration, or incomplete pre-visit documentation. In addition, some insurance carriers now cover electronic visits. If your office is able to support such visits it may prevent routine patient care issues from taking up valuable slots in your clinic schedules. In addition, there are some vendors that offer tools to enhance allergy practice management including registration, check-in, safe mixing practices, inventory management, and analytics. Companies like Audigy, Fuel Medical, or Xtract may allow you to digitize portions of your patient experience and improve flow through automation.

Tip Sheet on Evaluating Payor Contracts & Policies

For most Medicare plans, allergy and allergy testing is a covered service and requires no precertification. Commercial plans do vary and this can generally easily be checked on-line by checking eligibility and benefits for the patient's particular plan. Many plans allow the actual CPT codes to be checked for a specific patient and will list the particular benefits.

By checking the actual CPT codes, the staff can ensure there are no limitations on the type of allergy tests being performed (ie. prick, RAST, intradermal). In addition to checking eligibility and benefits for individual patients, it can be very informative for the practice to check the 'official' Medical Policy of their main payers'. This can usually be done online by searching the insurers medical policy for allergy immunotherapy, allergy testing, or allergy services. Here you will be able to see the policy for covered services and exclusions (such as for example sublingual therapy, acupuncture for allergies, homeopathy for allergies, etc.). Additional issues to consider are if the insurer requires documentation of pharmacological or environmental treatment failures prior to testing and/or immunotherapy. Most, if not all, insurers do not cover sublingual immunotherapy as a covered service.

If a specific indication is not addressed in the online materials then you should call for pre-authorization and inquire. The staff member calling should notate the date, time and who they talked with to obtain authorization. This is especially important when seeing a patient for a second opinion (or a patient changing allergists) and they patient may require a repeated or second allergy test within the same year. Some practices also routinely pre-certify many of their commercially insured's allergy tests much as they would surgery.

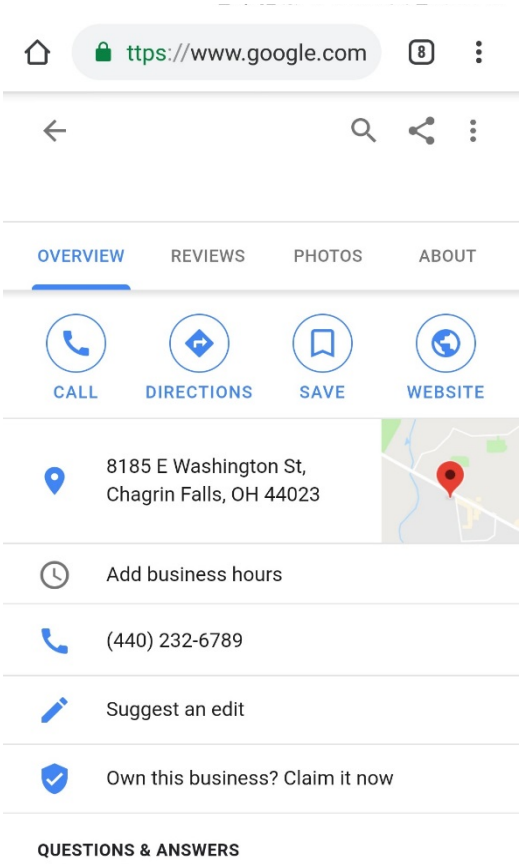
Once a patient has been tested and you are recommending subcutaneous immunotherapy, you should check the patient's specific benefits for immunotherapy and be prepared to inform the patient of their estimated costs and responsibility (co-pay, deductible, etc.). This is also a good time to check the insurer's policy and the patient's benefits for limitations on number of vials/doses per month or quarter, dollar amount maximums, treatment duration limitations.

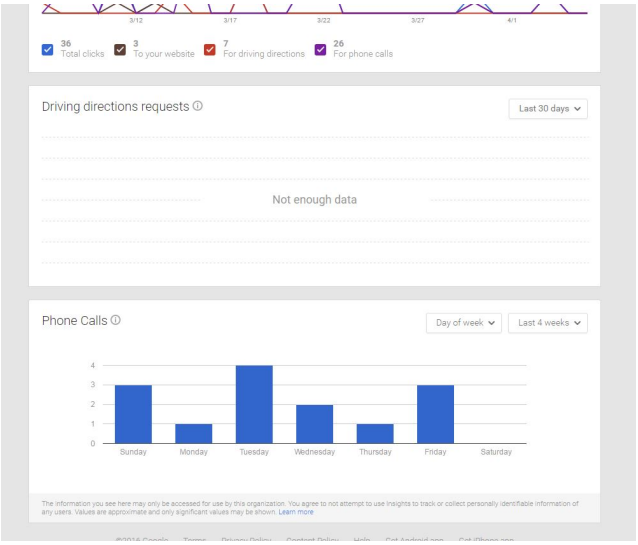
An important consideration is that your reimbursement for each of your insurers/payors covers your actual immunotherapy costs. You should develop an estimate of your costs of preparing treatment vials and your costs of providing allergy injection services (supplies, staff time, your supervisory time, general overhead) and compare this to your payment from various payors. A spreadsheet can be a helpful way to analyze this information.

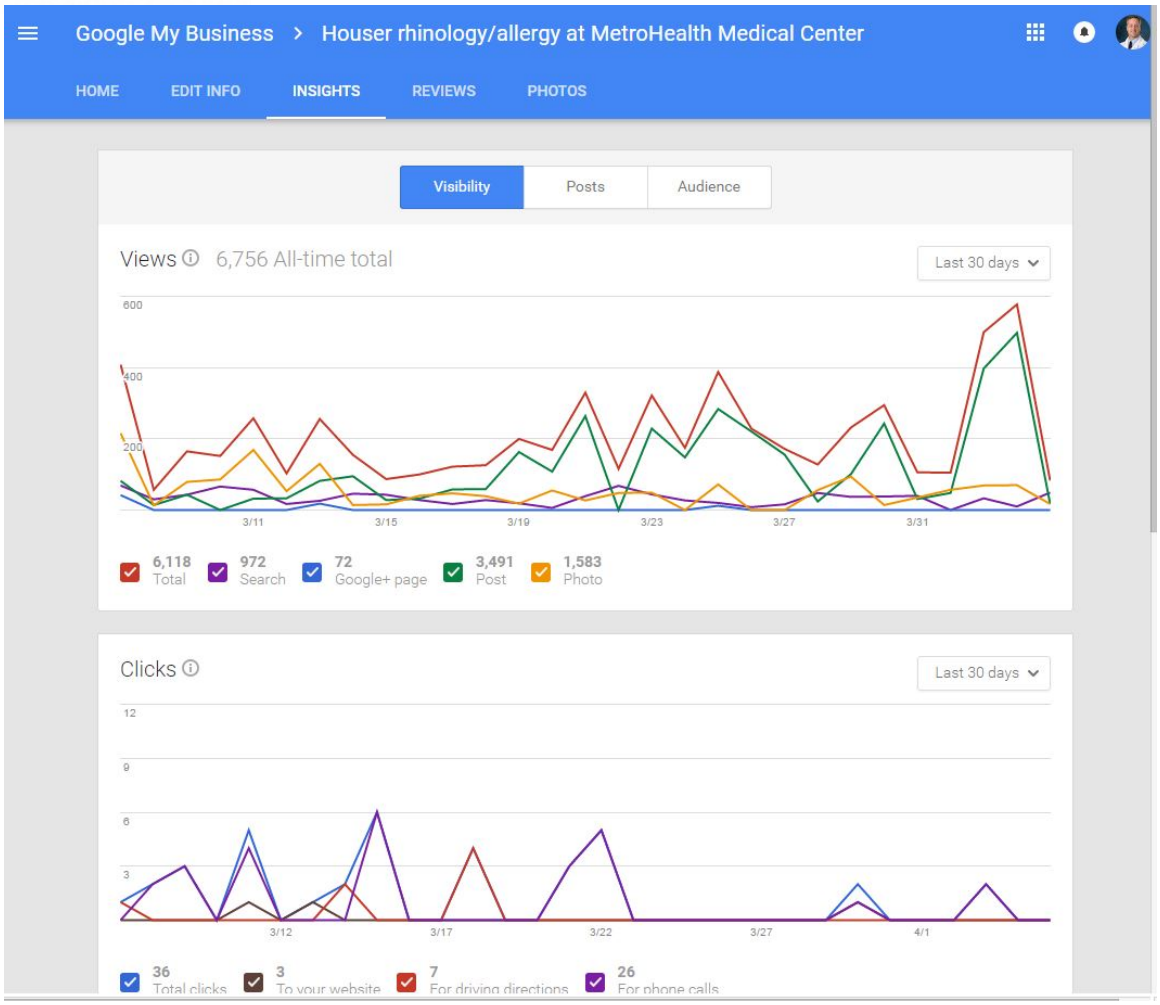
Marketing Your Practice

Google listing

- Patients will use google to find physicians
- Google creates a listing for all businesses in a geographic area
- You need to "claim your listing" by searching the area on Google, finding the listing, and clicking on "claim it now"
    - Follow the instructions that will involve either a call to your practice (alert your desk staff it is coming), or a postcard with a 4 digit code mailed out to you within 5 business days.
    - Once the listing is officially claimed, then you can edit it and add in more data, such as hours and photos from the practice.
    - Fleshing out the Google listing will cause your listing to bubble up higher in the search algorithms, allowing more patients to find you
    - As Google is very location specific, you may wish to create an entry for each practice location – each needs to be "claimed" as above. Google does not like duplicate practice names, so you may wish to name it "ENT/Allergy Associates in X community." It becomes a bit cumbersome, and frankly Google is always refining the process, so it will no doubt change over time.
    - The googlemybusiness site will email with data as to web traffic heading your way, as well as calls and direction requests. See below.







Practice Websites

- Patients today will see you on the web before seeing you in person, and your web presence is an extension of your practice.
- You can consider using a local office to manage your site; this allows maximal interaction and massaging of the site to suite your needs. Basically, you get what you pay for, so you should assess your area for competitiveness, etc. to decide how much $$ to sink into the project. A good website becomes a valuable/necessary practice expense in today's market. SEO is vitally important here as well – ask your web designer what they plan to do for its maximization.
- Some sites will allow patient intake forms to speed up their visit once they show up in the office. Some sites steer patients to your practice, and allow them to make an appointment with you: zocdoc is such a service with a $3K per year fee; they claim to be able to bring in 100 new patients per week.
- If you are in need of a logo, or other smaller work, check out https://www.fiverr.com/ You can inexpensively contract with an online artist, etc. for such pieces.
- Patient testimonials end up being one of the most powerful agents to convince patients to see you (think of the reviews on Amazon products that you peruse…). Ask a satisfied patient if you can use their image, or at least a statement, as to their care through your practice.

Public interest messages

- A great way to increase exposure is through public lecturing and writing. While lecturing to a group of providers gathers referrals, speaking directly to the public will generate direct patient self-referrals. Your message can get directly to potential patients via community talks, or articles you author.
- For the former, seek out your hospital-community liaison to inquire as to speaking possibilities. Your talk would need to be geared toward a less educated audience than PCPs.
- Be prepared for the "professional patients" that attend to seek out a free visit by dominating the question session with their own detailed history – learn to halt their domination through offering to speak to them after the session is over, and offer them your card and a visit.
- Be sure to bring many cards and/or flyers for folk to grab as they leave. Many attendees will be under another's care, but perhaps not satisfied, so they want to "check you out" before they make the plunge into a visit.
- Writing public interest pieces can be very brief blurbs, or more detailed pieces. Your hospital may have a community newsletter that would be a fantastic way to reach patients. Topical stories are often of interest, e.g., seasonal allergy 3 tier approach discussions during grass season.
- Month/week/day awareness for a particular disease state are an excellent time to provide a message on your website, or newsletter. ENT related issues are listed in the following table. One practice's website that used monthly awareness messages is: http://entandsleep.com/blog/

Month	Awareness issues
January	Thyroid health awareness
February	Kids ENT health; World Cancer day (2/4)
March	Sleep awareness week
April	Oral cancer awareness; Facial protection
May	Better speech and hearing; Allergy and Asthma awareness; Better sleep; Trauma awareness; Food allergy awareness week; No tobacco day
June	Migraine and Headache awareness; Cancer survivors day
July	
August	Children's Health day
September	Thyroid Cancer awareness; Fall awareness; Food safety education
October	Audiology Awareness
November	GERD awareness week
December	

Physician rating websites

- If you Google any doctor, you will discover half a dozen websites that all attempt to grade physicians to aid patients in selecting a doctor. Google does this on their map searches, and you will also see: healthgrades, vitals.com, md.com, doximity, doctor.webmed.com, zocdoc.com, linkedin.com, angieslist.com, sharecare.com, ratemds.com.
- Keep in mind that your computer savvy patients that found you online, are also more likely to be the ones that post a review online as well.
- Some of these sites allow you to "claim your profile" which allows you to flesh out an entry that a potential patient may see. You may also then be able to respond to reviews if you so desire.

- Negative reviews are bound to occur, and sadly they cannot really be eliminated. For example: a one star review as the poster stated the listed phone number was incorrect, so they were unable to make an appt. – the doctor responded with an apology and updated the data, but the negative review remained.
- You should never go tit-for-tat against patient reports, but either apologize and offer a solution, or simply ignore it. A good article discussing this phenomenon is here:
- https://www.groovehq.com/support/deal-with-bad-online-reviews

Social Media

- **Twitter** is a busy online tool that allows you to post messages that may be seen to those following you immediately, but also remain for others to search and find later.
- Practice specific data, such as a new associate or employee, are helpful. A new service, or location are good to broadcast. It is best to keep a purely professional Twitter profile, and avoid political, or other issues, that may turn off some patients.
- Overall, Twitter is worth having, as it is free, but it is unlikely to recruit many patients.
- **Facebook** allows the creation of pages that potential patients can find and read.
- Essentially, your practice website can be duplicated onto Facebook, to maximize exposure.
- Facebook is more than happy to sell targeted ads to you, to direct potential new patients your way. Their effectiveness is unclear.

Garnering referrals from PCPs/NPs/PAs

ENT new patient visits are a mix of patient-initiated, and referrals. Word of mouth (most powerful agent, but out of your control – just provide good care and leave your patients to help your practice) and your web presence will facilitate patient-initiated visits as above).

What of referrals from providers? If a patient praises you to their PCP, then that PCP will send more patients your way. Providing feedback (letters, perhaps a call) to PCPs as to your common patient's treatment course will bolster a good relationship.

Educating PCPs as to medical conditions via community talks is a powerful way to develop a referral network – your hospital may arrange these, or through drug reps. The ability to place a name with a face, and seeing a specialist as a regular person, can build trust. Allergy management is a topic of interest to most every primary provider. Never fear that you will educate them to the point that they need not send you patients – the patients will still come, but their work ups may be partially done (meds tried, RAST, etc.), and the complaints will be more appropriate for your care (e.g., tension headache patients might not be sent your way, as not allergy nor sinus related).

Interacting directly with nurse practitioners and physician assistants can also be of immense value in practice building. These folks are often acting as the primary provider for patients, so the issues above all apply. NPs and PAs are often eager to learn more and are receptive to any teaching you can pass on; they often realize that their training is somewhat of a "survey course" and they want more education. These providers may need more shaping though, to direct referrals appropriately (e.g., TMJ pain to dentists, not ENT). These providers will have their own meetings, distinct from MDs and DOs that offer opportunities to interact with them and develop treatment partnerships. Often, these folk do not have the financial support to travel though, so they accrue continuing education credits online, or through local meetings – hospital granted CEUs for a talk you would deliver is a win-win for you and them.

Allergy Coding

Common Allergy Codes — Testing (AMA CPT Codes)**:**

95004	Skin Prick Test	1 stick/antigen
95024	Intradermal Test	1 stick/antigen
95027	Intradermal Dilutional Testing	Multiple sticks/antigen
86003	In Vitro Test	Only billable if performed in office; cannot bill lab work
95017	Venoms—*New*	Any combination of percutaneous (scratch, puncture, prick) & intracutaneous sequential and incremental, immediate test reaction
95018	Biologicals & Drugs—*New*	Any combination of percutaneous (scratch, puncture, prick) & intracutaneous sequential and incremental, immediate test reaction

Allergy CPT Testing Codes:

95004

- CPT Definition:
  Percutaneous tests, (scratch, puncture, prick) with allergenic extracts, immediate-type reaction, including test interpretation and reported by a physician, specify number of tests
- CPT 2008 revised guideline to support that history and physical services are not included in this code and that an E/M service should not be reported separately for the interpretation and report.
  - *"including test interpretation and report by a physician" added to descriptor*
- An E/M can be billed in addition *only* if a separate and distinct service is performed

95024

- CPT Definition:
  Intracutaneous (intradermal) tests, with allergenic extracts for ***airborne*** allergens, immediate-type reaction, including test interpretation and report by a physician, specify number of tests
- CPT 2008 revised guideline to support that history and physical services are not included in this code and that an E/M service should not be reported separately for the interpretation and report.
  - *"including test interpretation and report by a physician" added to descriptor*
- An E/M can be billed in addition ***only*** if a separate and distinct service is performed
- Intradermal Codes **(95024/95027)** do ***not*** cover foods; Airborne only

95027

- CPT Definition:
  Intracutaneous (intradermal) tests, sequential and incremental, with allergenic extracts for ***airborne allergens***, immediate-type reaction, including test interpretation and report by a physician, specify number of tests

- CPT 2008 revised guideline to support that history and physical services are not included in this code and that an E/M service should not be reported separately for the interpretation and report.
  - *"including test interpretation and report by a physician" added to descriptor*
- An E/M can be billed in addition ***only*** if a separate and distinct service is performed
- If >1 dilution/antigen; must use 95027
- Do not refer to as SET or Skin Endpoint Titration
- Terms SET & Rinkel = NonCoverage by many carriers
- Intradermal Codes **(95024/95027)** do ***not*** cover foods; Airborne only

Coding Vignettes

Note: Each practice is responsible for confirming coverage, coding, and payment parameters for those payers that affect the practice. *These vignettes are cited as examples only*

- All codes are billed using the number of sticks or tests/antigen
- Many carriers have strict interpretations of how testing codes differ
- For ID testing,
  - if only perform 1 stick/test per antigen considered straight intradermal = **95024**
  - Two or more sticks/tests per antigen considered intradermal dilutional testing = **95027**

For each antigen/same day,

- You ***can*** bill
  95004 + 95024 or 95004 + 95027

- You ***cannot*** bill
  95004, 95024, + 95027 or 95024 + 95027

- Billing audits are based on correct code usage

- Carriers have limits on the number of tests:
  - Billed at one time
  - Billed within a certain time (year)

- Billing in excess of carrier limits may restrict payment or be flagged for audit

- Recommend requesting current allergy payment practices from carriers

Sample Billing for 14 Allergen Test Battery

- Percutaneous (Prick) Testing — **95004** X 14 units
- Intradermal Testing (ID) — **95024** X 14 (1 test/antigen)
- Intradermal Dilutional Testing (IDT) — **95027** X 42 units (*assumes 3 dilutions/antigen*)

In Vitro Testing

- Most Medicare carriers and private payers currently cover IVT as a second line option to skin prick testing
- Key to check for policy updates; Some may have defined restrictions
- Billing is under CPT Code **86003**
- IVT must be performed in the physician's office to bill
- If lab performs test, only bill blood draw

Supervision

- All diagnostic tests are assigned a level of supervision
  - *General:* Physician does not need to be on premise, but have management responsibility for staff who does the test
  - *Direct:* Physician needs to be in the office suite, but does not need to be in the room when the test is done.
  - *Personal:* Physician needs to be in the room when the test is performed

- Allergy tests are under ***Direct Supervision***

Ancillary Staff: Scope of Practice

- Nurse practice laws and regulations are specific to each state.
- AANP offers quick reference guide for licensure and regulatory requirements, as well as practice environment details, for all 50 states and the U.S. Territories. Downloadable State Regulatory Map available at www.aanp.org
- AAPA's webstore offers "PA State Laws and Regulations" includes all 50 states and the District of Columbia. www.AAPA.org offers a synopsis of each state's PA practice act, including scope of practice, prescribing and supervision, among other topics that cover PA practice.
- Recommend checking with state nursing board to confirm scope of practice and whether an NP/PA can supervise another staff member testing or treating

As an example, NP Scope of Practice is defined as:

- Full Practice: Evaluate patients, diagnose, order and interpret tests, initiate and manage treatments under the exclusive licensure authority of the state nursing board
- Reduced Practice: Reduces the ability to engage in at least one element of NP practice (above) and requires collaborative agreement with an outside health discipline for the NP to provide patient care
- Restricted Practice: Restricts the ability to engage in at least one element of NP practice (above) and state requires supervision, delegation, or team-management by an outside health discipline in order to provide patient care.

Common Allergy Codes — Immunotherapy (Treatment) (AMA CPT Codes)**:**

95004	Skin Prick	1 stick/antigen
95024	lntradermal	1 stick/antigen
95027	IDT	Multiple sticks/antigen
95115	Single Shot	Single Injection lmmunotherapy Single shot from single vial
95117	Multiple Shot	Two or more lmmunotherapy Injections Single shot from multiple vial; no X's
95165	Vial Preparation	Bill X #units Medicare exception: Dose defined as 1 cc regardless of actual dosage delivered
95144	Vial Preparation	Single dose vial

Immunotherapy Codes

Administration

- **CPT Code: 95115**
  Professional services for allergen immunotherapy not including provision of allergenic extracts; single injection

- **CPT Code: 95117**
  Professional services for allergen immunotherapy not including provision of allergenic extracts; two or more injections

  Report either 95115 or 95117 during a single patient encounter. If one injection is given, report 95115 (only). If two or more injections are given, report 95117 (only).

Preparation

- **CPT Code: 95165**
  Professional services for the supervision of preparation and provision of antigens for allergy immunotherapy; single or multiple antigens (specify number of doses)

- **CPT Code: 95165**
  Describes the preparation of the antigen, the antigen extract itself, and the physician's assessment and determination of the concentration and volume to use based on the patient's history and results of previous skin testing.
  These codes require that the number of doses be specified.

Coding Vignettes

- **CPT Code: 95165**
  Professional services for the supervision of preparation and provision of antigens for allergen immunotherapy; single or multiple antigens (specify number of doses)

  - 95165 X units
  - Units = doses for non-Medicare carriers
  - Units = cc for Medicare
  - Note: *Several private payers have adopted Medicare interpretation*

- Non-Medicare Clinical Example:
  - Physician prepares 10-dose multidose 5 cc vial for a patient. Same encounter, 1 dose is administered via 1 injection
  - 95165 X 10 in units box and 1 injection code: 95115

- Medicare Clinical Example
  - Physician prepares 10-dose multidose 5 cc vial for a patient. Same encounter, 1 dose is administered
  - 95165 X 5 in units box and 95115

- CMS interprets the unit as a "billable dose,"
  not a clinical dose.

- CMS billable dose is equal to 1 cc
  – 5 cc vial = 5 units no matter how many doses

- **CPT Code: 95144**
  Professional services for the supervision of preparation and provision of antigens for allergen immunotherapy, single dose vials(s) (specify number of vials)

- **CPT Code: 95144**
  Describes the preparation and provision of extract furnished in a single dose vial(s) by the allergist/otolaryngologist for administration by another physician. Single dose vials contain a single dose of antigen that is administered in one injection.

- **CPT Code: 95144**
  Describes the preparation and provision of single-dose vials of antigens to be administered by another physician.
  - Single dose vials contain one dose of antigen to be administered in a single injection.
  - Vials are designed for use when there is concern about the accuracy of measurement of doses from a multidose vial by a non-allergist.
  - Number of single dose vials prepared and provided should be specified when reporting this code.

Coding Vignettes

- **95144 Vignette**
  - You prepare two single-dose vials of allergenic extract for a patient who plans to travel to another city within his state during the time his two different allergy injections are due.
  - Your staff packages the vials along with relevant storage and other information and gives them to the patient.
  - Several weeks later, a primary care physician in another city administers the two allergy injections from the single dose vials.

  - You report **code 95144** with the number **2 in the units field** of the claim, specifying, according to the code, the number of vials prepared and provided.

The primary care physician reports **code 95117** with the number **1 in the units field** of the claim, indicating that two or more injections, exclusive of the supply of antigen, were administered at that visit.

Per CPT Guidelines (2005 Edits):

*"Office visit codes may be used in addition to allergen immunotherapy**, if** other identifiable services are provided at that time"*

NCCI Procedure to Procedure (PTP) edits

- Focus: Codes 95115-95180 (allergen immunotherapy) with Codes 95004-95079 (allergy testing & ingestions challenge
- Assumptions: Testing precedes immunotherapy by at least one day
- CMS will allow use of NCCI-associated modifiers for the "uncommon" scenario where a patient needs to be tested for reactions to additional allergens on same day of service
- Physicians may perform intradermal testing when a new vial is used (e.g., vial test).
- This is ***NOT*** separately reportable with an allergy testing code since CMS considers this quality control (safety check) to be an inherent component of immunotherapy
- Vial Testing: NCCI Policy Manual states:

"*Physicians should not report allergy testing CPT codes for allergen potency (safety) testing prior to administration of immunotherapy. Confirmation of the appropriate potency of an allergen vial for immunotherapy administration is an inherent component of immunotherapy*"

Supervision

- **Code 95165 & 95144** describe the supervision and provision of antigens for allergy immunotherapy, whether single or multiple antigens
- Supervision refers to direct supervision, meaning the physician *needs* to be in the office suite, but does not need to be in the room.
- Immunotherapy services are "incident to", requiring direct supervision within the office suite
- **Nurse practice laws and regulations are specific to each state.**
  - AANP offers quick reference guide for licensure and regulatory requirements, as well as practice environment details, for all 50 states and the U.S. Territories. Downloadable State Regulatory Map available at www.aanp.org
  - AAPA's webstore offers "PA State Laws and Regulations" includes all 50 states and the District of Columbia. www.AAPA.org offers a synopsis of each state's PA practice act, including scope of practice, prescribing and supervision, among other topics that cover PA practice.
  - Recommend checking with state nursing board to confirm scope of practice and whether an NP/PA can supervise another staff member testing or treating

As an example, NP Scope of Practice is defined as:

- Full Practice: Evaluate patients, diagnose, order and interpret tests, initiate and manage treatments under the exclusive licensure authority of the state nursing board
- Reduced Practice: Reduces the ability to engage in at least one element of NP practice (above) and requires collaborative agreement with an outside health discipline for the NP to provide patient care
- Restricted Practice: Restricts the ability to engage in at least one element of NP practice (above) and state requires supervision, delegation, or team-management by an outside health discipline in order to provide patient care.

References:

1. CMS Manual http://cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf
2. AMA CPT 2005 Professional Edition, page 374
3. AMA CPT 2008 Changes: An Insider's View
4. NCCI Policy Manual, Chapter 11, Section K, 4
5. http://www.aanp.org/legislation-regulation/state-legislation/state-practice-environment
6. http://www.aapa.org

Note: AMA CPT Editorial Panel maintains CPT. A new version of the CPT Book is issued annually.

CPT Coding Guidance

Allergen Testing:

Code	Baseline Info	Requirements	Pearls
95004	Skin prick test	1 prick/antigen - Requires physician direct physician supervision	- If doing more than 1, must specify the number in the units field - Includes interpretation and evaluation of results - E/M billed separately if distinct service performed
95024	Intradermal test	Airborne allergens only 1 test/antigen - Requires physician direct supervision	- If doing more than 1, specify the number - Cannot be combined with 95027
95027	Intradermal dilutional testing	Airborne allergens only Multiple dilutions/antigen - Requires physician direct supervision	- When doing more than 1, specify number - Cannot be combined with 95024
95028	Intradermal dilutional – delayed reaction	Delayed reaction - Requires physician direct supervision	- When doing more than 1, specify number
95044	Patch testing	Requires physician direct supervision	- When doing more than 1, specify number - Separate E/M level when returning for interpretation and removal of patches
95076	Ingestion Challenge Testing		- Covers the first 120 of ingestion challenge (not face-to-face time) - Stops when interventional therapy is applied
95079	Additional 60 min for Ingestion Challenge Testing		- Added to 95076 when you go above the original 120 min - Cannot be coded alone
86003	In vitro testing	Must be performed in physician's office If performed in lab, only bill for blood draw	- If doing more than 1, specify the number
95017	Venoms – any testing type		- If doing more than 1, specify number of tests - Can include prick, intradermal, and dilutional testing
95018	Drugs – any testing type		- If doing more than 1, specify number of tests - Can include prick, intradermal, and dilutional testing

Asthma Testing:

Code	Baseline Info	Requirements	Pearls
94010	PFT alone		
94060	PFT with pre and post bronchodilator		
94664	Demonstration	Demonstration or evaluation of patient using an inhaler	
95070	Methacholine test	Must use compounds that cause a bronchial challenge - Must have personal supervision of the physician during testing	
99070	Bronchodilator supply		

ANTIGEN TESTING MUST PRECEDE IMMUNOTHERAPY BY AT LEAST ONE DAY

Antigen Preparation:

*** Require the physician to have direct supervision – ie. Be in the office suite
*** Must follow USP 797 guidelines

1. Before beginning compounding activities, personnel perform a thorough hand-cleansing procedure by removing debris from under the fingernails, using a nail cleaner under warm water, followed by vigorous hand and arm washing to the elbows for at least 30 seconds, with soap and water
2. Compounding personnel don hair covers, facial hair covers, gowns and face masks
3. Compounding personnel perform antiseptic hand cleansing with an alcohol-based surgical hand scrub with persistent activity
4. Compounding personnel don powder-free gloves that are compatible with 70% isopropyl alcohol (IPA) before beginning compounding manipulations
5. Compounding personnel disinfect their gloves intermittently with 70% IPA when preparing multiple allergen extracts as CSP's
6. Ampul necks and vial stoppers on packages of manufactured sterile ingredients are disinfected by careful wiping with sterile 70% IPA swabs to ensure that the critical sites are wet for at least 10 seconds and allowed to dry before they are used to compound allergen extracts as CSP'
7. The aseptic compounding manipulations minimize direct contamination (e.g. from glove fingertips, blood, nasal and oral secretions, shed skin and cosmetics, other nonsterile materials) of critical sites (e.g. needles, opened ampuls, vial stoppers)
8. Single-dose allergen extracts as CSP's shall not be stored for subsequent additional use
9. The label of each multiple dose vial (MDV) of allergen extracts as CSP's lists the name of one specific patient and a BUD and storage temperature range that is assigned based on manufacturers' recommendations or peerreviewed publications.
10. Skin Test materials do not need to be for one patient –verbal communication from FDA

Code	Baseline Info	Requirements	Pearls
95144	Single dose vial preparation	Professional service for preparation of single dose vial to be administered as 1 shot	- Intention is for use while traveling so that correct SCIT dose can be administered elsewhere - Must specify the number of vials you are preparing; gone for 4 weeks – you prepare 4 vials
95165	Vial Preparation	- Professional services for the preparation of single or multi-dose antigen vial - Physician must sign off on vial prep	- Specify number of units - Definition of units varies depending on the payor; ie Medicare units = ml and non-Medicare units = doses

Documentation recommendation for continuation of AIT (renewal of 95165)

1. Current medication use (prescriptions and OTC)
2. Response to AIT
3. Reactions?
4. Antigen content of vials
5. If AIT for >5 years, document justification for continuation

Antigen Administration:

Code	Baseline Info	Requirements	Pearls
95115	Single allergen shot	- Must be signed off on by a physician	
95117	Two or more allergen shots	- Must be signed off on by a physician	

Counseling and observation:

Code	Baseline Info	Requirements	Pearls
99211	Nurse visit for counseling along with observation of first SLIT dose (aqueous or tablet)	- Must include counseling and education and must document this	- Cannot just use for SLIT observation without counseling that is also documented

SLIT Cost Calculator
Instructions

Members will need to log in to have access to the SLIT Cost Calculator. The AAOA will NOT be keeping any data entered by the member.
Disclaimer: This calculator can and should be customized for use in your practice. The amount charged for SLIT vials can vary from practice to practice. SLIT dosing schedules can also vary. Please note the number & amount of drops can impact the duration of a SLIT vial.

Answer the first five questions:

Questions	Note
How many patients do you have on SLIT?	Enter the current number of patients on SLIT.
How many days does your typical SLIT vial last?	Enter the number of days your typical SLIT vial last. This can be an estimate or an average.
How much do you charge for this SLIT vial ($USD)?	Enter the monetary value (in US dollars) that you charge for a SLIT vial. This number should be a monetary value based on an estimate, or an average based on the charged amount for previous SLIT vials in your practice.
How many ml of concentrate do you add on average per allergen?	Enter the number of ml of concentrate generally added per allergen. Numbers with decimals will be rounded up or down.
How much does 1 ml of concentrated extract cost on average ($USD)?	Enter your average cost for 1 ml of concentrated extract. This number should be a monetary value.

Complete the estimated percentage of allergen section: In this section, please enter the estimated percentage of SLIT vials that have 1 allergen, 2 allergens, 3 allergens, etc. until you reach a total of a 100%.

Complete the operating expenses/overhead section:

Questions	Note
Salary of the person calculating and mixing vial ($/hr)	Enter the salary cost per hour of the person mixing the vial. If there is more than one person involved in that process, create your average cost based on their level of involvement, frequency and average it out. This number should be a monetary value.
Please estimate this person's time directly spent on one vial (min)?	Enter the estimated number of minutes the person calculating and mixing vial spends on one vial.
Please estimate the physician's time directly spent on one vial (min)?	Enter the estimated number of minutes the physician spends on one vial.
Monthly cost of supplies/equipment/ staff/rent/utilities ($USD)	Enter the monthly cost of overhead that can be allocated to SLIT in US dollars. This cost generally range from $10 to $30.

Explaining the numbers obtained:
As you enter your numbers, the SLIT Cost Calculator will populate below based on the number of extracts and give you the following numbers:

- Your average cost of extracts.
- The cost of staff time; the cost of the person calculating and mixing the vial and the cost of the physician based on time directly spent on one vial.
- The total cost to the physician based on the cost of extracts, staff time, and overhead expenses. This cost is a monthly cost per each SLIT patient.
- The average monthly payment that the SLIT patient should be charged based on your charge per vial and vial span based on usage.
- The monthly profit/loss based on revenue and expense per SLIT patient.
- Profit/loss per SLIT patient based on 4 years of treatment.
- Profit/loss for all your patients currently on SLIT in the practice over 4 years.
- Profit/loss for all your patients currently on SLIT in the practice over 1 year.

Disclosure
The SLIT Cost Calculator was developed in 2016 by Dr. Williams R. Reisacher, a valued AAOA Fellow member, faculty, and IFAR reviewer. The SLIT Cost Calculator was presented at the 2017 AAOA Annual Meeting in Chicago, IL, on September 8, 2017.

SLIT Cost Calculator
Example

How many patients do you have on SLIT? 100

How many days does your typical SLIT vial last? 50

How much do you charge for this SLIT vial ($USD)? $ X

How many ml of concentrate do you add on average per allergen? 1

How much does 1 ml of concentrated extract cost on average ($USD)? $4.00

Please estimate what percentage of your vials have (total 100%):

1 allergen:	0.00%
2 allergens:	0.00%
3 allergens:	2.00%
4 allergens:	5.00%
5 allergens:	10.00%
6 allergens:	15.00%
7 allergens:	20.00%
8 allergens:	25.00%
9 allergens:	15.00%
10 allergens:	8.00%
Total:	100.00%

Salary of the person calculating and mixing vial ($/hr)? $60.00

Please estimate this person's time directly spent on one vial (min)? 30

Please estimate the physician's time directly spent on one vial (min)? 5

Monthly cost of supplies/equipment/staff/rent/utilities ($USD): $30.00
Note: This cost can be estimated to be between $10 -$30.

Analysis for each SLIT user per month of therapy

Number of extracts:	1	2	3	4	5	6	7	8	9	10
Average cost of extracts:	$2.40	$4.80	$7.20	$9.60	$12.00	$14.40	$16.80	$19.20	$21.60	$24.00
Cost of nurse's time:	$14.00	$15.00	$16.00	$17.00	$18.00	$19.00	$20.00	$21.00	$22.00	$23.00
Cost physician time: *(estimated at $8/min)*	$24.00	$24.00	$24.00	$24.00	$24.00	$24.00	$24.00	$24.00	$24.00	$24.00
Cost of supplies/equipment / staff/rent/utilities:	$30.00	$30.00	$30.00	$30.00	$30.00	$30.00	$30.00	$30.00	$30.00	$30.00
Total cost to physician: *(extract + non-extract)*	$70.40	$73.80	$77.20	$80.60	$84.00	$87.40	$90.80	$94.20	$97.60	$101.00
Payment from SLIT pt:	$ 0.6X	$ 0.6X	$ 0.6X	$ 0.6X	$ 0.6X	$ 0.6X	$ 0.6X	$ 0.6X	$ 0.6X	$ 0.6X
Monthly profit/loss:	[CALCULATE BY SUBSTRACTING TOTAL COST FROM SLIT PAYMENT]									
Profit/loss per SLIT pt for 4 years:	[MULTIPLY MONTHLY PROFIT/LOSS x 48 MONTHS]									
1 year profit/loss for all SLIT pts in the practice:	$ Y [BASED ON % VIALS WITH SPECIFIC NUMBER OF EXTRACTS]									
4 year profit/loss for all SLIT pts in the practice:	[MULTIPLY $ Y x 4 YEARS]									

USP General Chapter <797> Pharmaceutical Compounding — Sterile Preparations: Not Too Early to Work toward Compliance

While is has been many years of effort, are you prepared for the implementation of the new "pending" USP General Chapter <797> Pharmaceutical Compounding — Sterile Preparations?

Yes. Recently the USP announced a postponement due to its appeal process. While the implementation date of December 1, 2019 has been postpone, we fully expect the existing proposed update to be implemented. So, as an otolaryngologist compounding allergenic extracts for allergy immunotherapy in your office, what do you need to do to prepare for compliance? There are several key components to consider. First, and foremost, the USP website is your best resource for the latest guidelines. We also will keep our website (www.aaoallergy.org) up-to-date with the latest.

In the meantime, use the information below to help you and your staff prepare.

Annual Compliance Criteria:
What you need to document annually to comply with the *pending* USP General Chapter <797> Pharmaceutical Compounding — Sterile Preparations

Annually, all compounding personnel must complete and document the following 3 key sterile compounding compliance criteria:

1. Personnel must demonstrate knowledge and proficiency in the principles and skills for sterile compounding. This proficiency can be achieved through the AAOA's Allergen Extract Sterile Compounding Compliance module. These are single user modules, and you can register online at https://aaoa.cloud-cme.com/default.aspx?EID=193&P=3000&CaseID=42.

   All personnel training and competency must be documented annually.

2. Successful completion of the gloved fingertip and thumb sampling on both hands, no fewer than 3 separate times. Each fingertip and thumb evaluation must occur after performing separate and complete hand hygiene and garbing procedure. Successful completion of the initial gloved fingertip and thumb test is defined as zero (0) colony-forming units (cfu); Subsequent gloved fingertip and thumb sampling after media-fill testing is defined as ≤ 3cfu (total for both hands).

3. Successful completion of the media-fill test to demonstrate sterile technique must be evaluated every 12 months.

For more details read more on the USP General Chapter <797> Sterile Compounding criteria below or go to https://www.usp.org/compounding/general-chapter-797

USP General Chapter <797> Pharmaceutical Compounding — Sterile Preparations – 2019 Update Details

Under the new standards, in-office compounding of individual treatment sets for allergen immunotherapy, beginning Dec. 1 (**currently postponed until further noticed**), need to comply with the following:

Personnel Qualifications

- Designate one person with training and expertise in allergen immunotherapy to ensure all personnel who will be preparing allergen immunotherapy are trained, evaluated, and supervised.
- All personnel must complete training and be able to demonstrate knowledge of principles and skills for sterile compounding
- Annual personnel training and competency must be documented.
- Personnel must demonstrate proficiency in sterile compounding procedures by passing written or electronic testing before they can be allowed to compound allergenic extract prescription sets.
- All compounders must successfully complete gloved fingertip and thumb sampling on both hands, no fewer than 3 separate times. Each fingertip and thumb evaluation must occur after performing separate and complete hand hygiene and garbing procedure.

Hygiene and Garbing

- Before beginning allergen immunotherapy prescription set compounding, personnel must perform hand hygiene and garbing procedures according the facility Standard Operating Procedures (SOP).
- Minimum garb requirements:
    - sterile, powder-free gloves;
    - low-lint, sleeved garments that fit snugly around the wrists and enclose at the neck (e.g., gowns or coveralls);
    - low-lint, disposable head covers that cover hair, ears, and if applicable, facial hair
    - face mask

Facilities

- Compounding must occur in either (1) an ISO Class 5 Primary Engineering Control (PEC) **OR** (2) in a dedicated Allergenic 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., restroom, 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 contamination 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 is allowed.
- Surfaces should be resistant to damage by cleaning and sanitizing agents.
- Surfaces must be smooth, impervious, non-shedding, and free of 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 working environment, with temperature and humidity controls for the comfort of 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 door frames within the perimeter of the AECA must be cleaned and disinfected monthly and when surface contamination is known or suspected.
- Ceilings must be cleaned and disinfected when visibly soiled

- Vial 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.

Establishing BUDs

- The BUD for the prescription set must be no later than the earliest expiration date of any allergenic extract or any diluent that is part of the prescription set. The BUD must not exceed 1 year from the date the prescription set is mixed or diluted.

Labeling

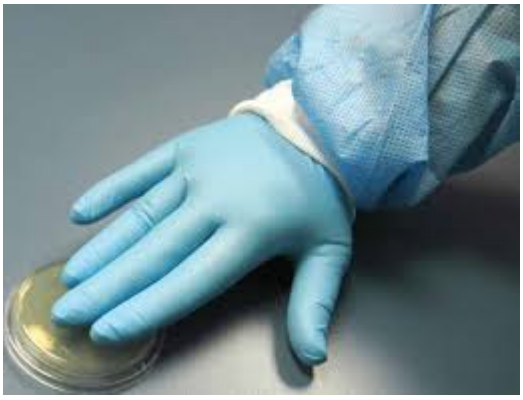
- The label of each vial of an allergenic extract prescription set must display the following prominently and understandably:
  - Patient name
  - Type and fractional dilution of each vial, with corresponding vial number
  - BUD
  - Storage conditions

Documentation

All facilities where allergenic extract prescription sets are prepared must have and maintain written or electronic documentation to include, but not limited to, the following:

- Standard Operating Procedures (SOPs) describing all aspects of the compounding process.
- Personnel training records, competency assessments, and qualification records, including corrective actions for any failures.
- Certification reports for PEC, if used, including any corrective actions for any failures.
- Temperature logs for refrigerator(s).
- Compounding records for individual allergenic extract prescription sets
  - Compounding records must include:
    - Name, concentration, volume, vendor or manufacturer, lot number, and expiration date for each component

  - Date and time of preparation of the allergenic extracts
  - Assigned internal identification number
  - Method to identify the individuals involved in the compounding process and verifying the final CSP
  - Total quantity compounded
  - Assigned BUD and storage requirements
  - Results of QC procedures (e.g., visual inspection, second verification of quantities)
- Information related to complaints and adverse events.
- Investigations and corrective actions



Latest Updates:

On September 23, 2019, the United States Pharmacopeia has announced that, due to appeals underway, the previously announced implementation date of December 1, 2019 for Chapter <797> on Pharmaceutical Compounding of Sterile Preparations is officially postponed. We do not know at this time what the new implementation deadline will be.

However, there is no reason to believe that any changes will be made to the updated standards for physician in-office compounding of allergen extract. For those of you have initiated changes to meet the updated standards for the compounding area, cleaning, staff training, and documentation, we encourage you to continue those efforts. For those of you who have not started, we strongly encourage you to proceed.

Visit our website at http://www.aaoallergy.org/ and watch out for email updates from the AAOA. We will keep you updated as soon as more information is available.

Media-Fill Test Resources

USP General Chapter <797> Pharmaceutical Compounding — Sterile Preparations defines the minimum standards to be followed when preparing compounded sterile drugs (compounded sterile preparations or CSPs). Within these, compounding personnel must have their sterile technique and related practices evaluated every 12 months as demonstrated by successful completion of a media-fill test. The media-fill test is a simulation used to qualify processes and personnel engaged in sterile compounding to ensure that the processes and personnel are able to prepare compounded sterile preparations (CSPs) without contamination.

To assist, below is a list of vendors who supply Media-Fill tests. Please note the requirements and procedures for each test may vary between manufacturers. We recommend assuring you purchase sampling devices that meet the USP General Chapter <797> requirements to demonstrate competency in CSP preparation. This list is not intended to be comprehensive nor does the American Academy of Otolaryngic Allergy (AAOA) recommend or endorse any specific company, manufacturer, or product. This list is intended solely for informational purposes.

Acute Care Pharmaceuticals
(888) 909-7700
http://www.pharma-choice.com

Hardy Diagnostics
(805) 346-2766 or (800) 266-2222
http://hardydiagnostics.com

Q.I.medical, Inc.
(530) 272-8700
http://www.qimedical.com

VALITEQ (Allerteq 1; Allerteq 4; Attack II Kit)
(800) 433-7698
http://www.valiteq.com

Note: Media-Fill Test difficulty level should be medium risk/complexity.

Gloved Fingertip and Thumb Sampling Resources

USP General Chapter <797> Pharmaceutical Compounding — Sterile Preparations defines the minimum standards to be followed when preparing compounded sterile drugs (compounded sterile preparations or CSPs). Within these, compounding personnel are required to successfully complete gloved fingertip and thumb sampling annually. This is part of the demonstration of competency in appropriate hand hygiene and garbing. The gloved fingertip and thumb sampling must be done on both hands no fewer than 3 times annually.

To assist, below is a list of vendors who supply gloved fingertip and thumb sampling devices. Please note the requirements and procedures for each test may vary between manufacturers. We recommend assuring you purchase sampling devices that meet the USP General Chapter <797> requirements to demonstrate competency in hand hygiene and garbing. This list is not intended to be comprehensive nor does the American Academy of Otolaryngic Allergy (AAOA) recommend or endorse any specific company, manufacturer, or product. This list is intended solely for informational purposes.

Acute Care Pharmaceuticals
Product Name: Tryptic Soy Agar (TSA) P34
(888) 909-7700
http://www.pharma-choice.com

Hardy Diagnostics
Product Name: Tryptic Soy Agar (TSA) P34
(805) 346-2766 or (800) 266-2222
http://hardydiagnostics.com

Q.I.medical, Inc.
Product Name: EnviroTest™ – ET1000
(530) 272-8700
http://www.qimedical.com

VALITEQ
Product Name: Contact Plates for Surface Microbial Sampling
(800) 433-7698
http://www.valiteq.com

Incubator Resources

USP General Chapter <797> Pharmaceutical Compounding — Sterile Preparations defines the minimum standards to be followed when preparing compounded sterile drugs (compounded sterile preparations or CSPs). Within these, compounding personnel are required to successfully complete media-fill tests and gloved fingertip and thumb sampling annually. While the manufacturers vary somewhat in how their products work, some require use of an incubator.

To assist, below is a list of incubator suppliers. This list is not intended to be comprehensive nor does the American Academy of Otolaryngic Allergy (AAOA) recommend or endorse any specific company, manufacturer, or product. This list is intended solely for informational purposes.

Being Instrument
(800) 278-1390
https://www.beinglab-usa.com/

Binder
(631) 318-6133
https://www.binder-world.com/us

BMT USA
(360) 863-2252
https://www.bmtusa.com/

CARON Products
(800) 648-3042
https://www.caronproducts.com/

HighRes Biosolutions
(781) 932-1912
https://highresbio.com/

Labnet International
(732) 417-0700
https://www.labnetinternational.com/

PHC Corporation of North America
(800) 858-8442
https://www.phchd.com/us/biomedical

SHEL LAB
(888) 227-1410
https://www.sheldonmanufacturing.com/

Thermo Fisher Scientific
(800) 556-2323
https://www.thermofisher.com/us/en/home.html

Torrey Pines Scientific
(866) 573-9104
https://www.torreypinesscientific.com/

Wheaton
(800) 225-1437
https://wheaton.com/

Yamato Scientific America
(800) 292-6286
https://yamato-usa.com/

Section 21. Compounding Allergenic Extracts from USP General Chapter <797> Pharmaceutical Compounding — Sterile Preparations

Excerpted below is section 21. Compounding Allergenic Extracts from USP General Chapter <797> Pharmaceutical Compounding — Sterile Preparations. For the full document, please go to www.usp.org

21. COMPOUNDING ALLERGENIC EXTRACTS

Licensed allergenic extracts are mixed and diluted into prescription sets for an individual patient, even though these allergenic extract combinations are not specified in the approved licenses for the licensed biological products [e.g., Biological License Applications (BLA)]. Because patients must be maintained on a maintenance dose of prepared concentrated allergenic extracts for a period of time longer than the BUDs specified for Category 1 and Category 2, longer BUDs are required for prescription sets to achieve effective therapy.

Allergenic extracts prescription sets must follow standards at least as stringent as those in this section:

Personnel Qualifications

1. A designated person with training and expertise in allergen immunotherapy is responsible for ensuring that personnel who will be preparing allergen immunotherapy are trained, evaluated, and supervised.
2. Before beginning to independently prepare allergenic extracts, all compounding personnel must complete training and be able to demonstrate knowledge of principles and skills for sterile compounding.
3. Annual personnel training and competency must be documented. Personnel must demonstrate proficiency in these procedures by passing written or electronic testing before they can be allowed to compound allergenic extract prescription sets.
4. Before being allowed to independently compound, all compounders must successfully complete gloved fingertip and thumb sampling on both hands (see Box 2-1 and Table 1), no fewer than 3 separate times. Each fingertip and thumb evaluation must occur after performing separate and complete hand hygiene and garbing procedure. After the initial competency evaluation, compounding personnel must successfully complete gloved fingertip and thumb sampling at least every 12 months thereafter.
5. Compounding personnel must have their sterile technique and related practices evaluated every 12 months as demonstrated by successful completion of a media-fill test (see Box 2-2).
6. Personnel who fail competency evaluations must successfully pass reevaluations in the deficient area(s) before they can resume compounding of allergenic extract prescription sets. The designated person(s) must identify the cause of failure and determine appropriate retraining requirements.
7. Personnel who have not compounded an allergenic extract prescription set in more than 6 months must be evaluated in all core competencies before resuming compounding duties.

Personnel Hygiene and Garbing

8. Before beginning compounding of allergen immunotherapy prescription sets, personnel must perform hand hygiene (see Box 3-1) and garbing procedures according to facility SOPs.
9. The minimum garb requirements include:
    - Low-lint garment with sleeves that fit snugly around the wrists and that is enclosed at the neck (e.g., gowns or coveralls)
    - Low-lint, disposable covers for head that cover the hair and ears and, if applicable, disposable cover for facial hair
    - Face mask

- Sterile powder-free gloves

10. Compounding personnel must rub sterile 70% IPA onto all surfaces of the gloves and allow them to dry thoroughly throughout the compounding process.

Facilities

11. The compounding process must occur in an ISO Class 5 PEC or in a dedicated allergenic extracts compounding area (AECA). The PEC or AECA used to compound prescription sets 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 a PEC nor an AECA may be located where environmental control challenges (e.g., restrooms, warehouses, or food preparation areas) could negatively affect the air quality. The PEC or the work surfaces in the AECA must be located at least 1 meter away from a sink. The impact of activities that will be conducted around or adjacent to the PEC or AECA must be considered carefully when designing such an area.
    - If used, the PEC must be certified every 6 months (see 5. Certification and Recertification).
    - If used, a visible perimeter must establish the boundaries of the AECA.
        - Access to the AECA during compounding must be restricted to authorized personnel.
        - During compounding activities, no other activity is permitted in the AECA.
        - The surfaces of walls, floors, fixtures, shelving, counters, and cabinets in the AECA must be cleanable.
        - Carpet is not allowed in the AECA.
        - Surfaces should be resistant to damage by cleaning and sanitizing agents.
        - The surfaces in the AECA upon which the allergenic extract prescription sets are prepared must be smooth, impervious, free from cracks and crevices, and non-shedding to allow for easy cleaning and disinfecting.
        - Dust-collecting overhangs such as utility pipes, ledges, and windowsills should be minimized. If overhangs or ledges are present, they must be easily cleanable.
        - The AECA must be designed and controlled to provide a well-lighted working environment, with temperature and humidity controls for the comfort of compounding personnel wearing the required garb.

Cleaning and Disinfecting

12. In a PEC, all interior surfaces of the PEC must be cleaned and disinfected daily and when surface contamination is known or suspected. Apply sterile 70% IPA to the horizontal work surface between each prescription set.
13. In an AECA, all work surfaces in the AECA where direct compounding is occurring must be cleaned and disinfected daily and when surface contamination is known or suspected. Apply sterile 70% IPA to the horizontal work surface between each prescription set.
    - If present, walls, doors, and door frames within the perimeter of the AECA must be cleaned and disinfected monthly and when surface contamination is known or suspected.
    - Ceilings within the perimeter of the AECA must be cleaned and disinfected when visibly soiled and when surface contamination is known or suspected.
14. Vial stoppers on packages of conventionally manufactured sterile ingredients must be wiped with sterile 70% IPA to ensure that the critical sites are wet and allowed to dry before they are used to compound allergenic extracts prescription sets.

Establishing BUDs

15. The BUD for the prescription set must be no later than the earliest expiration date of any allergenic extract or any diluent that is part of the prescription set, and the BUD must not exceed 1 year from the date the prescription set is mixed or diluted.

Labeling

16. The label of each vial of an allergenic extract prescription set must display the following prominently and understandably:
    - Patient name

- Type and fractional dilution of each vial, with a corresponding vial number
- BUD
- Storage conditions

Shipping and Transport

17. If shipping or transporting allergenic extract prescription sets, compounding personnel must select modes of transport that are expected to deliver properly packed prescription sets in an undamaged, sterile, and stable condition. Inappropriate transport can adversely affect the quality of allergenic extract prescription sets.
18. When shipping or transporting allergenic extract prescription sets that require special handling, personnel must include specific handling instructions on the exterior of the container.

Documentation

19. All facilities where allergenic extract prescription sets are prepared must have and maintain written or electronic documentation to include, but not limited to, the following:
    - SOPs describing all aspects of the compounding process
    - Personnel training records, competency assessments, and qualification records including corrective actions for any failures
    - Certification reports of the PEC, if used, including corrective actions for any failures
    - Temperature logs for the refrigerator(s)
    - Compounding records for individual allergenic extract prescription sets (see Box 21-1)
    - Information related to complaints and adverse events
    - Investigations and corrective actions

Box 21-1. Compounding Records for Individual Allergenic Extract Prescription Sets

Compounding Records must include at least the following information:

- Name, concentration, volume, vendor or manufacturer, lot number, and expiration date for each component
- Date and time of preparation of the allergenic extract
- Assigned internal identification number
- A method to identify the individuals involved in the compounding process and verifying the final CSP
- Total quantity compounded
- Assigned BUD and storage requirements
- Results of QC procedures (e.g., visual inspection, second verification of quantities)

Box 2-1. Gloved Fingertip and Thumb Sampling Procedures

- Use one sampling device per hand (e.g., plates, paddles, or slides) containing general microbial growth agar [e.g., trypticase soy agar (TSA)] supplemented with neutralizing additives (e.g., lecithin and polysorbate 80) as this agar supports both bacterial and fungal growth.
- Label each sampling device with a personnel identifier, whether it was from the right or left hand, and the date and time of sampling.
- Do not apply sterile 70% isopropyl alcohol (IPA) to gloves immediately before touching the sampling device because this could cause a false-negative result.
- Using a separate sampling device for each hand, collect samples from all gloved fingers and thumbs from both hands by rolling finger pads and thumb pad over the agar surface.
- Incubate the sampling device at a temperature of 30°–35° for no less than 48 hours and then at 20°–25° for no less than 5 additional days. Store media devices during incubation to prevent condensate from dropping onto the agar and affecting the accuracy of the cfu reading (e.g., invert plates).
- Record the number of cfu per hand (left hand, right hand).
- Determine whether the cfu action level is exceeded by counting the total number of cfu from both hands.

Table 1. Action Levels for Gloved Fingertip and Thumb Sampling*

Gloved Fingertip and Thumb Sampling	Action Levels (total number of cfu from both hands)
Initial sampling after garbing	>0
Subsequent sampling after media-fill testing (every 6 months)	>3

*Action levels are based on the total cfu count from both hands.

Box 2-2. Media-Fill Testing Procedures

- If all of the starting components are sterile to begin with, manipulate them in a manner that simulates sterile-to-sterile compounding activities, and transfer the sterile soybean–casein digest media into the same types of container–closure systems commonly used at the facility. Do not further dilute the media unless specified by the manufacturer.
- If some of the starting components are nonsterile to begin with, use a nonsterile soybean–casein digest powder to make a solution. Dissolve nonsterile commercially available soybean–casein digest medium in nonbacteriostatic water to make a 3% nonsterile solution. Manipulate it in a manner that simulates nonsterile-to-sterile compounding activities. Prepare at least 1 container as the positive control to demonstrate growth promotion, which is indicated by visible turbidity upon incubation.
- Once the compounding simulation is completed and the final containers are filled with the test media, incubate them in an incubator for 7 days at 20°–25° followed by 7 days at 30°–35° to detect a broad spectrum of microorganisms.
- Failure is indicated by visible turbidity or other visual manifestations of growth in the media in one or more container–closure unit(s) on or before 14 days.

Glossary*

Allergenic extract prescription set: Combinations of licensed allergenic extracts which would be mixed and diluted to provide subcutaneous immunotherapy to an individual patient, even though these allergenic extract combinations are not specified in the approved BLAs for the licensed biological products.

Allergenic extracts: Biological substances used for the diagnosis and/or treatment of allergic diseases such as allergic rhinitis, allergic sinusitis, allergic conjunctivitis, bee venom allergy, and food allergy.

Allergenic extracts compounding area (AECA): A designated, unclassified space, area, or room with a visible perimeter that is suitable for preparation of allergenic extract prescription sets.

Aseptic processing: A method by which separate, sterile components (e.g., drugs, containers, or closures) are brought together under conditions that maintain their sterility. The components can either be purchased as sterile or, when starting with nonsterile components, can be separately sterilized prior to combining (e.g., by membrane filtration, autoclave).

Aseptic technique: A set of methods used to keep objects and areas free of microorganisms and thereby minimize infection risk to the patient. It is accomplished through practices that maintain the microbe count at an irreducible minimum.

Compounding: The process of combining, admixing, diluting, pooling, reconstituting, repackaging, or otherwise altering a drug or bulk drug substance to create a sterile medication.

Garb: Items such as gloves, garments (e.g., gowns, coveralls), shoe covers, head and facial hair covers, masks, and other items designed to reduce particle-shedding from personnel and minimize the risk of contamination of CSP(s).

Gloved fingertip and thumb sampling: Process to evaluate a compounder's competency in correctly performing hand hygiene and garbing.

Media-fill test: A simulation used to qualify processes and personnel engaged in sterile compounding to ensure that the processes and personnel are able to prepare CSPs without contamination.

* Glossary descriptions extracted from the 2019 release of the USP General Chapter <797> Pharmaceutical Compounding -Sterile Preparations.

Patient Resources

Multiple patient education resources can be found at www.AAOAllergy.org. → Patient Resources page:

- What is Allergy?
- What is an Otolaryngic Allergist?
- Allergy Treatment
- Exercising and Allergies
- Allergies and Asthma
- Seasonal Allergies
- Pollen Maps
- A Brief History of Allergy Treatment
- What Are Allergies
- How to Prepare for Your Allergy Testing
- My Allergy Test Was Negative, So What Next?
- Types of Nasal Sprays
- Proper Way to Use a Nasal Spray
- Off to College: Tips for Managing Allergies in a New Environment

The Patient Recourses page is being constantly updated so check back for more patient education recourses.

AAOA

PRACTICE RESOURCE TOOL KIT

WWW.AAOALLERGY.ORG

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