

Allergy Immunotherapy in the Primary Care Setting

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Issues in Primary Care Practice

- Indications for allergy immunotherapy
- Mechanism of action
- Contraindications
- Administration in general practice setting
- Safety
- Treatment of anaphylaxis

Indications for Immunotherapy

Effective for:

- Allergic rhinoconjunctivitis
- Allergic asthma
- Venom allergy

Not indicated for:

- Atopic dermatitis
- Food allergy
- Chronic urticaria
- Angioedema

Allergic Rhinoconjunctivitis

- High disease burden-- 5-22% of population
- Medications often fail to control sx (in up to 40% of patients)
- AIT improves symptom score, reduces medication requirements
- Long term efficacy to minimize future medication usage
- Treatment in children may help prevent onset of asthma

AIT for Allergic Asthma

- Improves asthma symptoms
- Improves PFTs
- Protects against bronchial challenge
- Decreases medication requirements
- Benefit equal to inhaled steroids, but has advantage of long term efficacy

Stinging Insect Hypersensitivity

- Venom AIT effective for reducing risk of anaphylactic reactions
- Stings lead to life-threatening reactions in 0.4-0.8% of children and 3% of adults
- Estimated 40 deaths/year
- Large, local reactions to stings have not been shown to benefit from AIT

Mechanism of Action of AIT

- Shift from allergic T-lymphocyte (TH2) response to “non-allergic” TH1 response
- TH1 response causes increased production of IgG4 which blocks IgE
- Seasonal increase in IgE is blunted
- Increased IL-10 suppresses mast cells/eos

AIT Dosing

- Allergens for mixtures selected by testing
- Build-up phase
 - 1000-10,000 times less potent than maintenance dose
 - Frequency of injections and dosing advances depend on the patient and the protocol
- Maintenance phase
 - Final dose reached , and injections occur every 2-6 weeks
 - Clinical response can take 1 year
 - Duration of therapy from 3-5 years
- “Rush” or “cluster” schedules

Patient Selection for AIT

- Positive immediate hypersensitivity skin test results
- Serum-specific IgE test results
- Uncontrolled symptoms despite medications and avoidance of triggers
- Intolerance to medications
- Desire to avoid long term medications
- Systemic reactions after insect sting

Contraindications to AIT

- Medical conditions that reduce the patient's ability to survive a serious allergic reaction
 - Heart disease, beta blockers
- Poorly controlled asthma $FEV_1 < 70\%$
- Patients who are unable to communicate clearly (children < 5)
- AIT not initiated during pregnancy

Immunotherapy in General Practice

- The preferred location for administration is the prescribing physician's office, especially for high risk patients
- AIT should be initiated and monitored by an allergist
- Pts. may receive AIT at another health care facility **if the physician and the staff are equipped to recognize and manage systemic reactions**
- Full, clear, detailed immunotherapy schedule must be present
- Constant, uniform labeling system for extracts, dilutions and vials
- Procedures to avoid clerical/nursing errors (i.e. pt. photo ID)

Review Health Status Before Injections

- Current asthma symptoms, ?measurement of PEF
- Current allergy symptoms and medication use
- New medications (beta blockers, ACE-I)
- Delayed reactions to previous injections
- Compliance with injection schedule
- New illness (fever), pregnancy
- Consultation with allergist as needed

Patient Responsibility

- Patient must wait 20-30 minutes in office
- Those with prior systemic or delayed reactions should wait longer
- Compliance with injection schedule
- Report any reactions to PCP and allergist
- Epi-Pen kits for self treatment

Immunotherapy Safety

- Incidence of fatalities has not changed much in the last 30 years in the US
- From 1990-2001 fatal reactions occurred at a rate of 1 per 2.5 million injections
- Average 3.4 deaths per year
- Most occur during maintenance phase or “rush”
- Poorly controlled asthmatics at greatest risk
- Many deaths associated with **a delay in administering epinephrine or not giving it at all**

Local Reactions Are Common

- Redness, swelling, warmth at site
- Large, local, delayed reactions do not predict the development of severe systemic reactions
- Local reactions don't affect dosing schedule

Systemic Reactions

- Incidence of systemic reactions ranges from 0.05% to 3.2% per injection
- Risk factors include:
 - Dosing errors
 - Symptomatic asthma
 - High degree of allergy hypersensitivity
 - Use of beta blockers/ACE-I
 - New vials
 - Injections during the allergy season

Recognition of Systemic Reactions

- Most reactions occur in 20-30 minutes of vaccine
- Late phase (8-12 hrs) reactions possible
- Prompt recognition of potentially life threatening reactions by staff and patients
- Urticaria/angioedema are the most common initial symptoms--but they may be absent or delayed

Symptoms of Systemic Reactions

- Any allergic symptom that occurs at a location other than the site of the injection
 - Chest congestion or wheezing
 - Angioedema-swelling of lips, tongue, nose, or throat
 - Urticaria, itching, rash at any other site
 - Abdominal cramping, nausea, vomiting
 - Light-headedness, headache
 - Feeling of impending doom, decrease in level of consciousness

AIT in the PCP Office

- Preparedness plan in each office
- Prompt recognition of signs and symptoms of anaphylaxis
- Appropriate, aggressive treatment of systemic reactions
- If there is any doubt—give epinephrine!

Preparedness of the PCP Office

- Established medical protocols and treatment records posted
- Stock and maintain equipment/supplies
- Physicians and staff maintain “clinical proficiency” in anaphylaxis recognition and management
- Consideration of drills tailored to assess skills, response, and preparedness of office staff
- Tailor drill to consider access to local EMS-response times vary by location

Recommended Equipment

- Stethoscope, BP cuff
- Tourniquet, large bore IV needles, IV set-up
- Aqueous epinephrine 1:1000
- O2 and mask/nasal cannula
- Oral airway
- Diphenhydramine (oral and injection)
- Albuterol nebulized
- Glucagon
- IV corticosteroids
- ? IV Vasopressors
- ?AED

Initial Assessment of Anaphylaxis

- Level of consciousness
- Hemodynamic stability
- Oxygenation
- Upper and lower airway signs
- Cardiovascular system
- Skin
- GI symptoms
- Other sx possible

Immediate Intervention

- Assess ABC's
- **Administer epinephrine ASAP!** There is no contraindication
- Fatalities usually result from **delayed administration of epinephrine--with respiratory, and cardiovascular complications**
- Subsequent care based on response to epinephrine

Epinephrine

- 1:1000 dilution, 0.3 mg. dose administered IM or SQ q5 minutes as needed to control BP and other symptoms
 - Tourniquet above injection site
 - Pt can use their Epi-pen
- Effect of epi can be blunted by beta-blockers, with severe, prolonged sx including bronchospasm, bradycardia, and hypotension
- Glucagon can be used to reverse beta blockers

IM vs. SQ Epinephrine

- Both routes of injection appear in the literature
- IM injections into the thigh have been reported to provide more rapid absorption and higher plasma levels than IM or SQ injections into the arm.
- Studies directly comparing different routes have not been done

Interventions continued...

- Establish/maintain airway
- Give O₂/check pulse ox
- IV access, hang IV fluids with NS
- Consider:
 - Diphenhydramine 25-50 mg. IM
 - Albuterol nebulized
 - Glucagon
 - Ranitidine, steroids—not helpful acutely
- Transfer to ED

Summary/Questions

- No mention of ACLS certification in literature, but staff and physicians must be able to demonstrate proficiency in protocols
- Preparedness drills may be helpful at each office
- Posting of protocols and treatment logs to minimize confusion
- Do we need ETT or AED?

The Future of AIT

- Being studied for food allergies, atopic dermatitis, and other, less standardized allergens (dog, mold)
- Investigational studies
 - high dose sublingual IT
 - Anti-IgE therapy (omalizumab) given with standard AIT
 - novel vaccine delivery systems

Increase administration safety

- Detailed instructions from allergist
- Develop own step by step process for giving injections
- Standardize forms to document injections
- Standardize treatment for systemic reaction
- Agreement form for student compliance
- All staff mock systemic reaction drill

Patient History

<p>20 yr old male PMH: ASTHMA</p> <p>Meds: Singular, Albuterol inhaler</p>	<p>Began injections 09/13/2005 Only one injection at allergist office</p> <ol style="list-style-type: none"> 1. Trees, grass, weeds 2. Mites, cat, dog, mold 	<p>Per allergist instructions:</p> <p>Peak flow before and after injections</p> <p>Range: mid to high 600's</p>	<p>First late dose on 01/05/06</p>
<p>First hold for late reaction (> 24 hours) 03/02/2006</p> <p>Dose given 0.10 Red 1/500</p> <p>Peak flow: 720/ 730</p>	<p>Reduced due to late reaction 03/16/2006</p> <p>Dose dropped to 0.1 (had received 0.2 on 03/09)</p> <p>Peak flow 690/ 750</p>	<p>c/o itching at site 03/30/06, next injection began needle change</p>	<p>04/14/2006</p> <p>Systemic Reaction</p> <p>Peak flow before: 720</p>

Allergy Injection given

Patient returns c/o
Mouth feeling "funny"
SOB, had his inhaler
In hand

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Patient brought to exam room

Inhaler used
Lungs assessed, clear
Given benedryl 50mg po
Face becomes flushed

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Epi 0.3 cc given left arm

Patient feels better but
Still c/o SOB
Flushing subsides

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Patient begins to feel “funny” again

Complains of
Throat swelling, itching
Throat feeling smaller
Facial flushing returns

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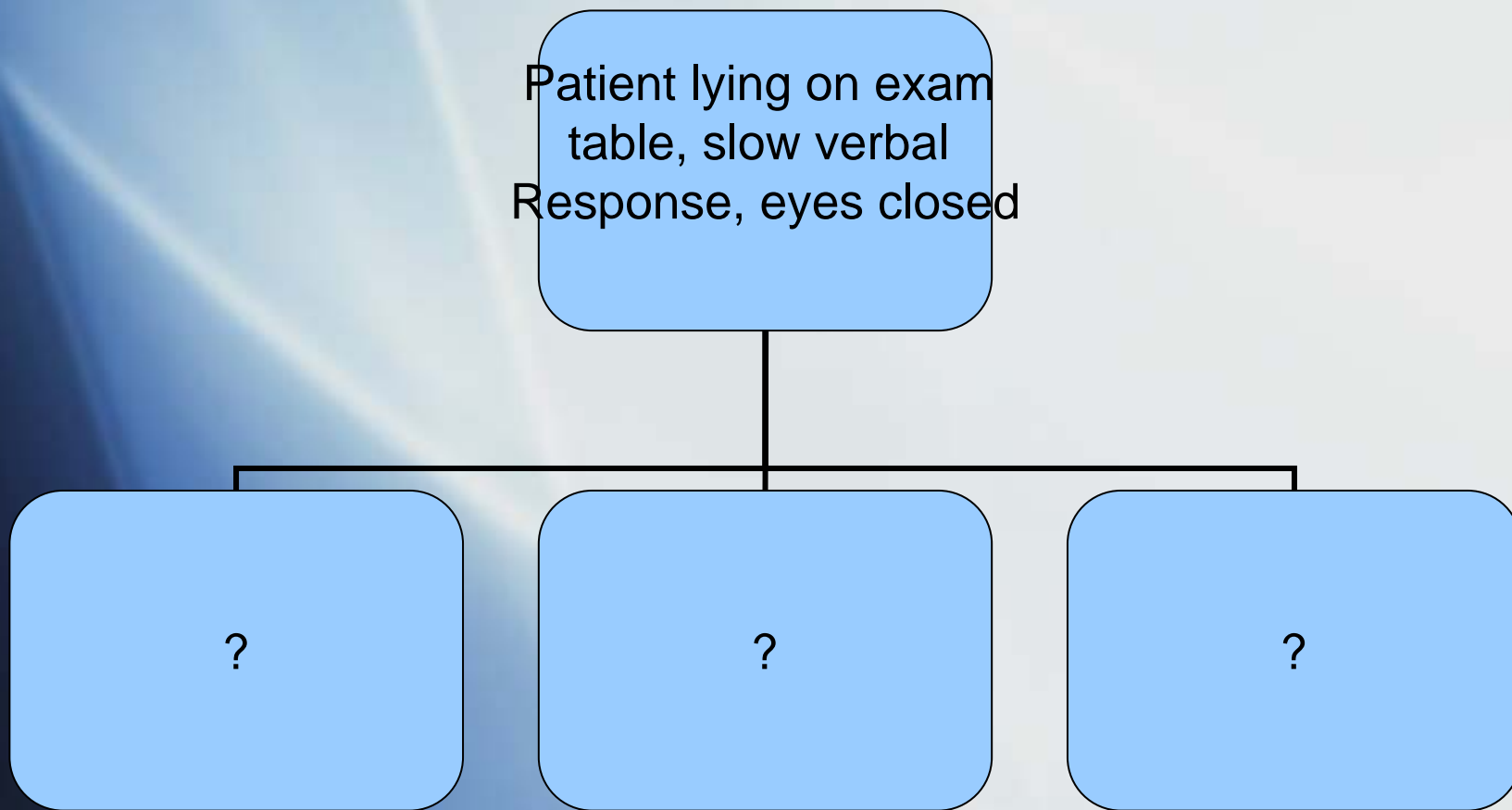
Epi repeated

Patient lying on exam
table, slow verbal
Response, eyes closed

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What we learned

- Treat with epi at first sign of reaction
- Documentation after incident was difficult
- Treatment protocol for sustained reaction
- Need for drill for all staff, including receptionist (responsible for calling for ambulance, 911/security)

References

- Position Statement on the Administration of Immunotherapy Outside of the Prescribing Allergist Facility, ACAAI, October 1997.
- Rank MA, Li JTC. Allergen Immunotherapy. *Mayo Clin Proc.* 2007;82(9):1119-1123.
- Stokes JR, Casale TB. Allergy Immunotherapy for Primary Care Physicians. *AJM.* 2006;119(10):820-823.
- Lieberman P, Kemp SF, Oppenheimer J, et al. The diagnosis and management of anaphylaxis:an updated practice parameter. *J Allergy Clin Immunology* 2005;115:S483-523.
- Li JT, Lockey IL, Bernstein JM, et al. Allergen immunotherapy: a practice parameter. *Ann Allergy, Asthma & Immunology.*2003;90:1-40.

UHS-MCR=09A SYSTEMIC REACTIONS: Describe and underline in red. Report to allergist

*** Write comments on back**

REACTION E I
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University Health Service
ALLERGY INJECTION SERVICES

General Guidelines

- Allergy injections are given at the Medical Center Office, the River Campus Office, and the Eastman School Office. Times may vary per office. Appointments for allergy injections can be made by contacting any office.
- Patient's should decide at which office they want to receive their allergy injections and schedule appointments at that office each time.
- A UHS physician or nurse practitioner must be present in the University Health Service office when an allergy injection is given and for the designated waiting period of 20 minutes.

Appointments Not Kept:

- If a patient is unable to keep an appointment, the office must be notified prior to the scheduled time and date so that the appointment can be rescheduled.
- If the appointment is not kept and UHS is not notified prior to the appointment time, the patient *may* be required to pay a "No Show" fee before receiving the next injection.
- If the patient is late for a scheduled appointment, the patient may be unable to receive his/her injection. The decision is at the discretion of the allergy injection nurse.

Payment:

- Fee-for-service payment will be collected each week when indicated, with appropriate records maintained by the office staff.

Information from Patient's Allergist: (*See the Antigen Information Request Form*)

- Individuals requesting that allergy injections be administered by the University Health Service staff are required to provide the following written information from their personal allergist:
 - a. Vials properly labeled with patient's name, contents, and expiration date.
 - b. Date and amount of last injection. (Initial injections must be administered in an allergist's office.)
 - c. Any previous reactions.
 - d. Dosage and schedule.
 - e. Changes to be made in case of lateness, new injection material, or local reaction with previous injection.

Maintenance of Allergy Schedules:

- Individuals are expected to maintain the schedules as instructed by their allergist. Allergy injections must be given according to these specific time intervals. This is necessary for both the safety and success of the allergy program.
- When injections are not on schedule, it is the responsibility of the **individual** to have their allergist call, mail, or fax UHS with instructions. When instructions are called to the UHS nurse by the allergist, written instructions must follow in order to continue the injections. Documentation of orders should include name and title of person giving the order.
- Special instructions that deviate from routine procedure will be referred to the UHS Director, or his designee.

Discarding of Injection Material

- Injection material in UHS will be discarded upon expiration date. This information (including expiration date) should be documented in the allergy record.
- UHS shares the responsibility with the individual for ordering an adequate supply of injection material. UHS will assist with ordering only if the order form is provided.

Allergy Serum Mailing

- If a student needs to have his/her serum mailed to them (i.e., leaving UR for semester or graduation), the serum needs to be sent via Express Mail. The charge will be placed on the student's tuition bill if applicable, or UHS will indicate "Bill recipient." on the Express Mail form.
- In no case will UHS assume financial responsibility for mailing/sending of allergy serum to the patient.

Orientation of New Allergy Patients:

- Prior to the first injection (given by the UHS nurse) the patient must review the UHS policy and procedures and the allergist's orders with a UHS nurse.
- Information from this visit is transferred to the UHS Allergy Treatment Record. All orders are copied, with the original order sent to the UHS Medical Center Office to be filed in the patient's chart. The copy is placed in the Allergy Log.
- In the initial visit the nurse will:
 - a. Explain the UHS allergy policy and procedures to the patient. The patient will be offered a copy of the policy.
 - b. Have the patient read and sign the Allergy Agreement and the No-Show Policy Agreement.
 - c. Explain the appointment schedule.
 - d. Offer the patient the "Allergy Injection Services at the University Health Service" information card.

ALLERGY MEDICATION STORAGE

ACCEPTING ALLERGY SERUM:

- If allergy serum comes to UHS by mail or is dropped off at receptionists' desk, give the serum to an RN to document receiving and then refrigerate.
- Log serum onto Allergy Serum Register and *note on patients record in RED "New Serum Received"*
- Label the end of the box with the patient's name and DOB.
- Check name and compare contents of vials with enclosed order sheet. If new solutions are not used immediately, apply tape to the top of the vial.
- Place solutions in designated box in the refrigerator and store alphabetically by the patient's last name.

RELEASING ALLERGY SERUM:

- Remove serum from the refrigerator. Check two patient identifiers (Name & DOB) Have patient identify solution.
- Review instructions for storage and transportation with the patient.
- Make copies of current orders and treatment record. Give a copy to the patient.
- Record "solutions and copies taken by patient" on dated entry on documentation sheet.
- If someone other than the patient will be picking up the allergy serum, written permission from the patient is required and must be kept in the patient's medical chart.
- It is the patient's responsibility to make arrangements for picking up their allergy serum.

ADMINISTRATION OF ALLERGY INJECTIONS

1. Call patient by name (first and last) to verify name on injection record.
2. Check second patient identifier (DOB). Remove patient's serum from the refrigerator. Ask patient to identify serum.
3. Inquire about any reactions following previous injection.
 - Review any *early local* reactions, current health status, and medications.
 - Record any *delayed* reactions on treatment record. Adjust dose accordingly.
4. Check with UHS physician before giving allergy injection if:
 - Fever
 - Obvious wheezing or complaint of wheezing.
 - Hives or other rash of undetermined etiology.
 - Patient is on beta-blocker or MAO inhibitor medications
 - Newly reported pregnancy or illness.
5. Use disposable 26 or 27 gauge needles and disposable allergy syringes with 0.01 ml gradation.
6. Carefully check for the proper patient identity, the correct allergen vial, proper dose, and site:
 - Check:* Patient's identity using two identifiers, name and DOB.
Record's identity
Patient's allergist's orders
 - Check vial's:* Identity
Expiration date
Allergen label
Concentration
Cap color code, if applicable
 - Record:* The proper date, site, vial number, dose, RN initials, and time of injection on treatment record.
 - Administer:* Rinse syringe with medication as ordered (e.g., epinephrine).
Draw up proper dose.
Alternate arms, unless otherwise instructed.
Swab site with alcohol.
Administer injection.

Administration of Injection

7. Injection site is the outer aspect of the upper arm, midway between the shoulder and the elbow in the groove between the deltoid and triceps muscle.
8. Injections should be given subcutaneously ONLY, unless otherwise ordered.
9. Aspirate the syringe plunger before injection. If blood is aspirated, DO NOT inject. Withdraw immediately and discard. Draw up new dose and repeat the procedure.
10. Avoid rubbing the injected area to prevent rapid absorption.
11. Advise patient to:
 - Wait 20 minutes in the waiting room. Have a UHS registered nurse, nurse practitioner, or physician check the patient's injection site before leaving.
 - Call or return to UHS immediately if problems develop.
 - Avoid strenuous activity immediately (2 hours) after injection.
 - Note when next injection is due and schedule appointment at time of visit, if possible.
 - Schedule re-evaluation, if necessary.
 - Order new serum if needed.
12. At the end of the waiting period (20 minutes), the injection site will be checked by an available registered nurse, nurse practitioner, or physician. If no reaction, a check will be placed in the chart next to that date's recorded information. Any reactions will be documented on the treatment record.

Allergen Immunotherapy Record

Date	Comments:	Initials	Complete Signature

Systemic Reaction Record

Time of injection _____ am/pm. See front of form for extract strength, dose, site **TIME OF REACTION:** _____ am/pm

Circle reaction sx Multiple hives at injection site, Systemic urticaria, Pruritis, Flushing, SOB, Wheezing, Hypotension, rapid/weak pulse
 RCO/ESM CALL SECURITY AT x 13 FOR AMBULANCE

Treatment: Asses Airway, Results _____ Apply oxygen prn @ 4L NP Note time _____

Vital signs q 5 min: Time: _____ R _____ BP _____ P _____ Any change/increase sx: _____

Vital signs q 5 min: Time: _____ R _____ BP _____ P _____ Any change/increase sx: _____

Vital signs q 5 min: Time: _____ R _____ BP _____ P _____ Any change/increase sx: _____

Vital signs q 5 min: Time _____ R _____ BP _____ P _____ Any change/increase sx: _____

Vital signs q 5 min: Time _____ R _____ BP _____ P _____ Any change/increase sx: _____

Apply tourniquet above injection site: Time _____ Release after 10 minutes

Inject Epinephrine 1:1000 .03mL sq Time _____ Note Site R / L

Epinephrine 1:1000 .03mL sq Time _____ Note Site R / L

Epinephrine 1:1000 .03mL sq Time _____ Note Site R / L

Inject Diphenhydramine 25-50 mg IM. Time _____ Note dose _____ Note Site

Albuterol inhaler _____ Time _____ Via Nebulizer _____

Transfer to ED via ambulance: Time _____