SAFETY OF HOME-BASED IMMUNOTHERAPY

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Introduction

• Taking immunotherapy injections at home presents a greater risk from a medico legal standpoint than receiving injections in a physicians office.

• Systemic anaphylactic reaction is the most important risk assumed by patients who undergo allergy immunotherapy.
Systemic Anaphylactis

• Prevalence of severe systemic reactions of allergen immunotherapy ranges from <1% of patients receiving conventional immunotherapy
• 34% of patients in some studies of rush immunotherapy
• Percentage of systemic reactions per injection is 0.2%.

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# Immunotherapy Risk Factors

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Why Home Based Immunotherapy?

- Costs are lower.
- More convenient than visiting the physicians office.
  - Absent from work and/or school
  - Travel distance
- Inconvenience is a major reason for patients to abandon immunotherapy
Why Not Home-Based Immunotherapy?

- Medical Legal
- The American Academy of Allergy, Asthma, & Immunology (AAAAI) suggested that home therapy is less safe
- AAOA board endorsed AAAAI Parameters
Task Force Report: Allergen Immunotherapy: A Practice Parameter Objective:

• To optimize the practice of allergen immunotherapy for patients with allergic diseases.
• Establish guidelines for safe and effective use of allergen immunotherapy while reducing unnecessary variation in immunotherapy practice.
Location of Allergen Immunotherapy Administration:

Regardless of the location, allergen immunotherapy should be administered under the direct supervision on an appropriately trained physician, qualified physician extender (NP or PA) or both in a facility with the appropriate equipment, medication, and personnel to treat anaphylaxis.
Prescribing Physicians Office

• The *preferred* location for administration of allergen immunotherapy is in the office of the physician who prepared the patient’s allergen immunotherapy extract.
  • However, in many cases it may be necessary to administer the allergen immunotherapy extract in another physician’s office.

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Prescribing Physician’s Office cont.

- Patients at high risk of systemic reactions, where possible, should receive immunotherapy in the office of the physician who prepared the patient’s allergen immunotherapy extract.
  - Highly sensitive (brittle)
  - Severe symptoms
  - Comorbid conditions
  - History of recurrent systemic reactions

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Outside Medical Facilities:

- Home administration: In rare and exceptional cases when allergen immunotherapy cannot be administered in a medical facility and withholding this therapy would result in a serious detriment to the patient’s health (e.g., VIT for a patient living in a remote area) careful consideration of potential benefits and risks of at-home administration of allergen immunotherapy should be made on an individual basis.

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Outside Medical Facilities: cont.

• Home Administration: cont.
  • Potential benefits and risks involved in home immunotherapy.
  • Informed consent from the patients and appropriate family members.
  • Need another adult person trained to administer the injection and treat anaphylaxis.
  • The package insert approved by the FDA that accompanies all allergen extracts, including venom, implies that allergy injections should be administered in a clinical setting under the supervision of a physician.

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Is there any difference in safety when immunotherapy is given at home rather than at a physicians office?
Hurst, Gordon, and Fornadley’s Multicenter Prospective Study in in Otolaryngology-Head and Neck Surgery November 1999, Addresses the Question:

- AAOA Fellows
- 5-15 years in practice
- All practiced allergy according to AAOA guidelines
Prospective Study:

- 1 year period, 27 otolaryngic allergy practices
- Recorded all systemic reactions to immunotherapy
  - 635,600 patient visits
  - 1,144,000 injections
- 60% given at home
- Major systemic reactions observed after 0.005% of injections
- No hospitalizations or deaths
- 81% given during maintenance therapy
Risk Factors for Major Reactions

- Build-up phase of immunotherapy
- Active asthma
- First injection from a treatment vial
Other Risk Factors

• Injections given in Primary Care Setting
  • Had higher incidence of death than home immunotherapy.
    • Physicians not specifically trained and certified in allergy, but nevertheless prescribe and give their own immunotherapy, or who administer injections prepared by consulting allergist.
    • Lack of knowledge and inexperience are factors in cases where death resulted.
  • The allergist who consults the patient and furnishes the immunotherapy solutions to be administered by the patient’s primary care office has a duty to educate that physician in proper treatment of reactions to minimize risk.

Journal of Allergy Clinical Immunology 1989
Home and office injections had similar rates of total systemic reactions, but home-based had fewer major reactions.
Their Conclusion:

Allergy immunotherapy administered according to AAOA guidelines either in the home or at an office is very safe.
AAOA Survey 2010:

Practitioners that allow home SCIT

- Otolaryngologists 54% (n=57 of 104)
- Allergists/Immunologists 47% (n=27 of 58)
- Primary Care providers 61% (n=54 of 88)
- All respondents 55% (n=138 of 250)
Safety Related to:

- Strength of maintenance dose
- Patient selection
- Patient education and training
Patient Selection

- No history of systemic reactions
- At maintenance dose
- Non-asthmatic
- Not highly-sensitive (brittle)
- Not on beta-blocker
- >5 yrs
Patient Training

SCIT Home Treatment Checklist:
• Epinephrine, allergy needles and albuterol ordered by staff.
• Review PowerPoint with allergy staff.
• Understand the syringe measurements.
• Understand procedure to draw up correct dose.
• Understand aseptic technique.
• Understand where to inject.
• Understand how to inject.
• Understand proper disposal of sharps.
• Understand emergency procedures and feel confident in ability to execute same procedures.
• Practice injecting self w/ saline until comfortable with the procedure.
• Understands how to complete injection record, need to complete weekly and bring to each office appointment.
• Successfully complete the post-training test.
Alternatives to Home SCIT

- SLIT is accepted as a better home alternative despite lack of FDA Approval because it is less likely to cause adverse reactions.