



Complete Summary

GUIDELINE TITLE

Allergen immunotherapy: a practice parameter.

BIBLIOGRAPHIC SOURCE(S)

Allergen immunotherapy: a practice parameter. American Academy of Allergy, Asthma and Immunology. Ann Allergy Asthma Immunol 2003 Jan;90(1 Suppl 1):1-40. [210 references] [PubMed](#)

COMPLETE SUMMARY CONTENT

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INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT

CATEGORIES

IDENTIFYING INFORMATION AND AVAILABILITY

SCOPE

DISEASE/CONDITION(S)

IgE-mediated conditions, such as:

- Allergic rhinitis
- Allergic asthma
- Hymenoptera sensitivity

GUIDELINE CATEGORY

Assessment of Therapeutic Effectiveness
Management
Treatment

CLINICAL SPECIALTY

Allergy and Immunology
Family Practice

Internal Medicine
Pediatrics

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

- To increase the appropriate use of allergen immunotherapy; and reduce the underuse, overuse, and misuse of allergen immunotherapy
- To establish guidelines for the safe and effective use of allergen immunotherapy, while reducing unwanted and unneeded variation in allergen immunotherapy practice

TARGET POPULATION

Children, adolescents and adults with allergic rhinitis, allergic asthma, or hymenoptera sensitivity

INTERVENTIONS AND PRACTICES CONSIDERED

Treatment/Management

1. Immunotherapy
 - Identify specific allergen vaccines
 - Establish starting dose and immunotherapy schedule
 - Management of adverse reactions, as needed
2. Patient education regarding risks and benefits
3. Maintenance immunotherapy

MAJOR OUTCOMES CONSIDERED

- Efficacy of immunotherapy
 - Symptom improvement (e.g., clinical symptom scores)
 - Reduction in medication
 - Reduction in bronchial hyperresponsiveness (e.g., pulmonary function testing)
- Safety of immunotherapy (e.g., rates of adverse events)

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

A comprehensive search of the medical literature was conducted with various search engines, including PubMed; immunotherapy, allergic rhinitis, asthma, stinging insect allergy, and related search terms were used.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Category of Evidence

Ia Evidence from meta-analysis of randomized controlled trials

Ib Evidence from at least 1 randomized controlled trial

IIa Evidence from at least 1 controlled study without randomization

IIb Evidence from at least 1 other type of quasi-experimental study

III Evidence from nonexperimental descriptive studies, such as comparative studies, correlation studies, and case-control studies

IV Evidence from expert committee reports or opinions or clinical experience of respected authorities, or both

LB Evidence from laboratory-based studies

METHODS USED TO ANALYZE THE EVIDENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Published clinical studies were rated by category of evidence and used to establish the strength of a clinical recommendation. Laboratory-based studies were not rated.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Strength of Recommendations

- A. Directly based on category I evidence
- B. Directly based on category II evidence or extrapolated from category I evidence
- C. Directly based on category III evidence or extrapolated from category I or II evidence
- D. Directly based on category IV evidence or extrapolated from category I, II, or III evidence
- E. Directly based on category LB evidence
- F. Based on consensus of the Joint Task Force on Practice Parameters

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

A working draft of the guideline document was reviewed by a large number of experts in immunotherapy, allergy, and immunology. These experts included reviewers appointed by the American College of Allergy, Asthma and Immunology (ACAAI), American Academy of Allergy, Asthma, and Immunology (AAAAI), and Joint Council of Allergy, Asthma and Immunology. More than 1,000 copies of the working draft were distributed at the ACAAI annual meeting in the fall of 2001. The authors carefully considered additional comments from these reviewers. The draft summary statements were distributed and presented at a symposium during the 2002 AAAAI annual meeting. Approximately 1,000 physicians attended this symposium. The authors reviewed comments from these participants also. The revised final document was approved by the sponsoring organizations and represents an evidence-based, broadly accepted consensus opinion.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Guideline recommendations are presented in the form of summary statements. After each statement is a letter in parentheses that indicates the strength of the recommendation. Grades of recommendations are defined at the end of the Major Recommendations field.

Mechanisms of Immunotherapy

Summary Statement 1. Immunologic changes during immunotherapy are complex. Successful immunotherapy is often associated with a shift from TH₂ to TH₁ CD4+ lymphocyte immune response to allergen. (A)

Summary Statement 2. Successful immunotherapy is also associated with immunologic tolerance, defined as a relative decline in allergen-specific responsiveness. (A)

Summary Statement 3. The relationship between immunotherapy efficacy and specific IgE antibody levels is variable. (A)

Summary Statement 4. Increases in allergen-specific IgG blocking antibody titer are not predictive of the duration and degree of efficacy of immunotherapy. (A)

Allergen Extracts (Vaccines)

Summary Statement 5. Whenever possible, standardized extracts (vaccines) should be used to prepare vaccine treatment sets. (A)

Summary Statement 6. Nonstandardized extracts (vaccines) may vary widely in biologic activity. (B)

Summary Statement 7. In choosing the components for a clinically relevant vaccine, the physician should be familiar with local and regional aerobiology and indoor and outdoor allergens, paying special attention to potential allergens in the patient's own environment. (D)

Summary Statement 8. Knowledge of allergen cross-reactivity is important in the selection of allergens for immunotherapy, because limiting the number of allergens in a treatment vial is necessary to attain optimal therapeutic doses for the individual patient. (B)

Efficacy of Immunotherapy

Summary Statement 9. Immunotherapy is effective for treatment of allergic rhinitis, allergic asthma, and stinging insect hypersensitivity. Therefore, immunotherapy merits consideration in patients with these disorders. (A)

Summary Statement 10. Clinical studies to date do not support the use of allergen immunotherapy for food hypersensitivity, chronic urticaria, and/or angioedema. Therefore, allergen immunotherapy for patients with these conditions is not recommended. (B)

Summary Statement 11. Clinical parameters, such as symptom scores and medication use, may be useful measures of the efficacy of immunotherapy in a clinical setting. Routine periodic skin testing or in vitro IgE antibody testing of patients receiving immunotherapy is not recommended. (A)

Safety of Immunotherapy

Summary Statement 12. In the United States severe systemic reactions are rare after appropriately administered allergen immunotherapy. (C)

Summary Statement 13. Because most systemic reactions that result from allergen immunotherapy occur 20 to 30 minutes after an injection, patients should remain in the physician's office at least 20 to 30 minutes after an injection. (C)

Summary Statement 14. Patients taking beta-adrenergic blocking agents may be at increased risk when receiving allergen immunotherapy, because beta-receptor blockade can make treatment of anaphylaxis more difficult. Therefore, beta-adrenergic blocking agents are relative contraindications for immunotherapy. (C)

Summary Statement 15. Medical conditions that reduce the patient's ability to survive a systemic reaction are relative contraindications for allergen immunotherapy. Examples include severe asthma uncontrolled by pharmacotherapy and significant cardiovascular disease. (F)

Summary Statement 16. Allergen immunotherapy should be administered in a setting where procedures that can reduce the risk of anaphylaxis are in place and where the prompt recognition and treatment of anaphylaxis are assured. (D)

Patient Selection

Summary Statement 17. Allergen immunotherapy should be considered for patients who have demonstrable evidence of specific IgE antibodies to clinically relevant allergens. The decision to begin allergen immunotherapy depends on the degree to which symptoms can be reduced by avoidance and medication, the amount and type of medication required to control symptoms, and the adverse effects of medications. Patients who wish to avoid or reduce the long-term use of medications are good candidates for immunotherapy. (A) A complete list of clinical indications for immunotherapy can be found in Table 5 in the original guideline document.

Summary Statement 18. Patients with severe, poorly controlled asthma are at higher risk for systemic reactions to immunotherapy injections. (C)

Summary Statement 19. Venom immunotherapy should be strongly considered in patients with a history of a systemic reaction to a Hymenoptera sting (especially if the reaction was associated with respiratory or cardiovascular symptoms) and patients with demonstrable evidence of specific IgE antibodies. (A)

Summary Statement 20. Patients selected for immunotherapy should be cooperative and compliant. (A)

Allergen Selection and Handling

Summary Statement 21. The components of a clinically relevant vaccine (and therefore a vaccine that is most likely to be effective) should be selected on the basis of a careful history of relevant symptoms, knowledge of possible environmental exposures, and correlation with positive tests for specific IgE antibodies. (A)

Summary Statement 22. The immunotherapy vaccine should contain only clinically relevant allergens. (A)

Summary Statement 23. Immediate-type skin testing has been the primary diagnostic tool in clinical studies of allergen immunotherapy. Therefore, in most patients, skin testing should be used to determine whether the patient has specific IgE antibodies. Appropriately interpreted and well performed in vitro tests for specific IgE antibodies may also be used. (A)

Summary Statement 24. Immunotherapy is effective for pollen, fungi (molds), animal dander, dust mite, cockroach, and Hymenoptera sensitivity. Therefore, immunotherapy should be considered as part of the management program in patients who have symptoms related to exposure to these allergens and in whom the presence of specific IgE antibodies has been established. (A)

Summary Statement 25. In the mixing of an allergen vaccine, the following factors must be considered: (1) the crossreactivity of the allergens, (2) the optimal dose of each constituent, and (3) enzymatic degradation of the allergens. (E)

Summary Statement 26. The selection of allergens for immunotherapy should be based in part on the cross-reactivity of clinically relevant allergens. Many related pollen contain allergens that are cross-reactive. When pollen allergens are substantially cross-reactive, selection of a single pollen within the cross-reactive genus or subfamily may suffice. When pollen allergens are not substantially cross-reactive, testing for and treatment with multiple locally prevalent pollen may be necessary. (B)

Summary Statement 27. The efficacy of immunotherapy depends on achieving an optimal therapeutic dose of each of the clinically relevant constituents in the vaccine. (A)

Summary Statement 28. Separation of aqueous extracts (vaccines) with high proteolytic enzyme activities (e.g., fungi, dust mites, cockroach, and insect venoms) from other extracts (vaccines) is recommended. (E)

Summary Statement 29. Extracts (vaccines) should be stored at 4 degrees C to reduce the rate of potency loss. Dilute concentrations are more sensitive to temperature and lose potency more rapidly than do more concentrated preparations. The expiration date for dilute concentrations should reflect their shorter shelf life. (E)

Immunotherapy Schedules and Doses

Summary Statement 30. A commercially available allergen extract (vaccine) may be used alone or combined to prepare a customized allergen mixture for an individual patient. (F)

Summary Statement 31. The highest concentration of a vaccine projected as the therapeutically effective dose is called the maintenance concentrate. (F)

Summary Statement 32. The maintenance concentrate should be selected to deliver a dose considered to be a therapeutically effective dose for each of its constituent components. (A)

Summary Statement 33. Serial dilutions of the maintenance concentrate should be made in preparation for the buildup phase of immunotherapy. (F)

Summary Statement 34. Use of a consistent, uniform labeling system for dilutions from the maintenance concentrate may reduce errors in administration. (F)

Summary Statement 35. The maintenance concentrate and serial dilutions, whether a single vaccine or a mixture of vaccines, should be prepared and labeled for each patient. (F)

Summary Statement 36. The starting dose for buildup is usually a 1,000- or 10,000-fold dilution of the maintenance concentrate, although a lower starting dose may be advisable for highly sensitive patients. (A)

Summary Statement 37. During the buildup phase, the usual frequency of vaccine administration is one to two injections per week, at least 2 days apart. (A)

Summary Statement 38. If immunotherapy is continued after a systemic reaction, the dose of vaccine should be appropriately reduced. (D)

Summary Statement 39. It is usual practice to reduce the dose of vaccine when the interval between injections is prolonged. (F)

Summary Statement 40. With cluster immunotherapy, two or more injections are administered per visit to achieve a maintenance dose more rapidly than with conventional schedules. (A)

Summary Statement 41. Rush schedules can achieve a maintenance dose more quickly than weekly schedules, but are associated with an increased risk of systemic reaction. Premedication can reduce the rate of systemic reaction. (B)

Summary Statement 42. Routine premedication before allergen immunotherapy injections administered on a conventional schedule is not necessary and may mask the early signs of systemic reaction. (F)

Summary Statement 43. When the patient has reached a maintenance dose, the interval between injections can often be progressively increased as tolerated to 4 to 6 weeks. (A)

Summary Statement 44. Clinical improvement usually is observed within 1 year after the patient reaches a maintenance dose. (A)

Summary Statement 45. Patients should be evaluated at least every 6 to 12 months while they receive immunotherapy. (F)

Summary Statement 46. A decision to continue or stop immunotherapy should be made after 3 to 5 years. (A)

Summary Statement 47. The vaccine contents, informed consent for immunotherapy, and administration of vaccines should be carefully documented. (F)

Special Considerations in Immunotherapy

Summary Statement 48. The preferred location for the administration of allergen immunotherapy is the office of the physician who prepared the patient's vaccine. (D)

Summary Statement 49. Generally, patients at high risk of systemic reaction should receive immunotherapy in the office of the physician who prepared the patient's vaccine. (D)

Summary Statement 50. Regardless of location, allergen immunotherapy should be administered under the supervision of an appropriately trained physician and personnel. (D)

Summary Statement 51. Immunotherapy injections should not be administered at home because of the risk of inadequate recognition and treatment of systemic reactions. (F)

Summary Statement 52. Immunotherapy for children is effective and often well tolerated. Therefore, immunotherapy is appropriate (as is pharmacotherapy and allergen avoidance) in the management of children with allergic rhinitis, allergic asthma, and stinging insect hypersensitivity. Allergen immunotherapy may prevent the development of asthma in children with allergic rhinitis. (A)

Summary Statement 53. Children <5 years of age may have difficulty cooperating with an immunotherapy program. Therefore, the physician should carefully consider the benefits and risks of immunotherapy and individualize treatment in patients younger than 5 years of age. (A)

Summary Statement 54. Allergen immunotherapy may be continued in the pregnant patient, but it is customary to delay the commencement of allergen immunotherapy until the patient is no longer pregnant. (C)

Summary Statement 55. In older adults, medications and co-morbid medical conditions may increase the risk from immunotherapy. Therefore, special consideration must be given to the benefits and risks of immunotherapy in older adults. (D)

Summary Statement 56. Allergen immunotherapy can be considered in patients with immunodeficiency and autoimmune disorders. (D)

Summary Statement 57. High-dose sublingual-swallow, high-dose sublingual-spit, and oral immunotherapy are under clinical investigation. Efficacy has been demonstrated for high-dose sublingual-swallow therapy, but the results of oral immunotherapy are equivocal. Sublingual-spit therapy requires further study. These therapies are not currently in general use in the United States, and no vaccines intended for sublingual or oral use are available in the United States. (A)

Summary Statement 58. Intranasal immunotherapy is undergoing evaluation in children and adults with allergic rhinitis, but this modality is currently not used in the United States. (B)

Summary Statement 59. Low-dose immunotherapy, enzyme- potentiated immunotherapy and immunotherapy (parenteral or sublingual) based on provocation-neutralization testing are not effective and are not recommended. (D)

Summary Statement 60. If a patient receiving immunotherapy transfers from one physician to another, the new physician and the patient should decide whether to continue the immunotherapy program initiated by the previous physician or to prepare a new program. (F)

Summary Statement 61. If a patient transfers from one physician to another and no change is made in either the immunotherapy schedule or the vaccine, the risk of systemic reaction is not substantially increased. (F)

Summary Statement 62. A full, clear, and detailed documentation of the patient ´s immunotherapy schedule must accompany the patient when he or she transfers from one physician to another. Also, a record of previous responses to and compliance with the program should be communicated to the new physician. Finally, a detailed record of the results of the patient ´s specific IgE antibody tests (immediate-type skin tests or in vitro tests) should be provided. (F)

Summary Statement 63. An immunotherapy vaccine must be considered changed if there is any change in the constituents of the vaccine. This includes any change in the lot, manufacturer, vaccine type (e.g., aqueous, glycerinated, standardized, nonstandardized), components, or relative amounts of the components in the mixture. (E)

Summary Statement 64. If a patient transfers from one physician to another, there is an increased risk of systemic reaction if the immunotherapy vaccine is changed because of the marked variability in the content and potency of vaccines. The risk of systemic reaction with a different vaccine is greater with nonstandardized vaccines and with vaccines containing mixtures of allergens. (F)

Summary Statement 65. Immunotherapy with a different vaccine should be conducted cautiously. If there is inadequate information to support continuation of the previous immunotherapy program (including tests for specific IgE antibodies), reevaluation may be necessary and a new schedule and vaccine prepared. (F)

Definitions:

Strength of Recommendations

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- D. Directly based on category IV evidence or extrapolated from category I, II, or III evidence
- E. Directly based on category LB evidence
- F. Based on consensus of the Joint Task Force on Practice Parameters

Category of Evidence

Ia Evidence from meta-analysis of randomized controlled trials

Ib Evidence from at least 1 randomized controlled trial

IIa Evidence from at least 1 controlled study without randomization

IIb Evidence from at least 1 other type of quasi-experimental study

III Evidence from nonexperimental descriptive studies, such as comparative studies, correlation studies, and case control studies

IV Evidence from expert committee reports or opinions or clinical experience of respected authorities, or both

LB Evidence from laboratory-based studies

CLINICAL ALGORITHM(S)

An annotated clinical algorithm is provided in the original guideline document for allergen immunotherapy.

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified for each recommendation (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Effective management of allergic rhinitis, allergic asthma, and stinging insect hypersensitivity
- Allergen immunotherapy may prevent the development of asthma in children with allergic rhinitis

POTENTIAL HARMS

- Injections of allergen vaccine can cause local or systemic reactions. Serious systemic reactions (some fatal) can occur. Risk factors for serious systemic reactions include (1) a medical condition that reduces the ability to survive a

- systemic reaction, (2) compromised pulmonary function, (3) poorly controlled asthma, and (4) concurrent use of beta-adrenergic blocking agents
- Patients who are mentally or physically unable to communicate clearly may not be able to report signs and symptoms, especially early symptoms, suggestive of a systemic reaction

CONTRAINDICATIONS

CONTRAINDICATIONS

Relative contraindications include:

- Any medical condition that reduces the patient's ability to survive a systemic allergic reaction. Examples include patients with markedly compromised lung function (either chronic or acute), poorly controlled asthma, unstable angina, recent myocardial infarction, significant arrhythmia, uncontrolled hypertension, or failure of a major organ system
- Use of beta-adrenergic blocking agents

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- These clinical guidelines are designed to assist clinicians by providing a framework for the evaluation and treatment of patients and are not intended to replace a clinician's judgment or establish a protocol for all patients. Not all recommendations will be appropriate for all patients.
- Recognizing the dynamic nature of clinical practice and practice parameters, the recommendations in the guideline should be considered applicable for 3 years after publication.
- There are no data to support allergen immunotherapy as a treatment for non-IgE-mediated symptoms of rhinitis or asthma.
- There are no data on the effectiveness or risks associated with allergen immunotherapy in patients with immunodeficiency or autoimmune disorders. Concern about the increased risk of immunotherapy in such patients is largely theoretical.
- These guidelines are not designed for use by pharmaceutical companies in drug promotion.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

To improve the uniformity and standardization of immunotherapy practice, the guideline provides and recommends the use of standard vaccine prescription forms, vaccine content forms, and immunotherapy administration forms. Sample forms are found in the original guideline document. They are also available from the [Joint Council of Allergy, Asthma, and Immunology \(JCAAI\) Web site](#). According to the guideline developers, the routine use of these standardized forms should improve the quality of immunotherapy practice.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness
Staying Healthy

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Allergen immunotherapy: a practice parameter. American Academy of Allergy, Asthma and Immunology. *Ann Allergy Asthma Immunol* 2003 Jan;90(1 Suppl 1):1-40. [210 references] [PubMed](#)

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1996 (revised 2003 Jan)

GUIDELINE DEVELOPER(S)

American Academy of Allergy, Asthma and Immunology - Medical Specialty Society
American College of Allergy, Asthma and Immunology - Medical Specialty Society
Joint Council of Allergy, Asthma and Immunology - Medical Specialty Society

GUIDELINE DEVELOPER COMMENT

These guidelines were developed by the Joint Task Force on Practice Parameters for Allergy and Immunology, representing the American Academy of Allergy, Asthma, and Immunology, the American College of Allergy, Asthma, and Immunology and the Joint Council of Allergy, Asthma and Immunology.

SOURCE(S) OF FUNDING

Funded exclusively by the American Academy of Allergy, Asthma, and Immunology (AAAAI), the American College of Allergy, Asthma, and Immunology (ACAAI) and the Joint Council of Allergy, Asthma and Immunology (JCAAI).

GUIDELINE COMMITTEE

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

ENDORSER(S)

American Academy of Pediatrics - Medical Specialty Society

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Joint Council of Allergy, Asthma and Immunology. Practice parameters for allergen immunotherapy. J Allergy Clin Immunol 1996 Dec;98(6 Pt 1):1001-11.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the [Joint Council of Allergy, Asthma, and Immunology \(JCAAI\) Web site](#).

Print copies: Available from JCAAI, 50 N. Brockway, Ste 3-3 Palatine, IL 60067; E-mail: info@jcaai.org.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on October 1, 1998. The information was verified by the guideline developer on December 15, 1998. This summary was updated by ECRI on December 4, 2003.

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The logo for FIRST GOV, with "FIRST" in blue and "GOV" in red.

