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Practice Parameters

Administration of influenza vaccines to egg allergic recipients: A practice parameter update 2017☆

Matthew Greenhawt, MD, MBA, MSc; Paul J. Turner, BM, BcH, FRACP, PhD; John M. Kelso, MD

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Reprints: Matthew Greenhawt, MD, MBA, MSc, Section of Allergy and Clinical Immunology, Children's Hospital Colorado, University of Colorado School of Medicine, 13123 East 16th Avenue, Box 518, Anschutz Medical Campus, Aurora, CO 80045; E-mail: Matthew.Greenhawt@childrenscolorado.org.

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Contributors: The Joint Task Force on Practice Parameters has made a concerted effort to acknowledge all contributors to this parameter. If any contributors have been excluded inadvertently, the Task Force will ensure that appropriate recognition of such contributions is made subsequently. Workgroup Chair: Matthew Greenhawt, MD, MBA, MSc, Department of Pediatrics, Children's Hospital of Colorado, Section of Allergy and Immunology, University of Colorado School of Medicine, Aurora, Colorado. Joint Task Force on Practice Parameter Members: David I. Bernstein, MD, Department of Clinical Medicine and Environmental Health, Division of Immunology, Allergy, and Rheumatology, University of Cincinnati College of Medicine, Cincinnati, Ohio; Joann Blessing-Moore, MD, Department of Immunology, Stanford University Medical Center, Palo Alto, California; Chitra Dinakar, MD, Stanford University School of Medicine, Allergy & Asthma Clinical Chief, Stanford Health Care, Division of Pulmonary and Critical Care Medicine, Department of Medicine, Stanford University, Stanford, California; Matthew Greenhawt, MD, MBA, MSc, Department of Pediatrics, Children's Hospital of Colorado, Section of Allergy and Immunology, University of Colorado School of Medicine, Aurora, Colorado; Caroline Horner, MD, Department of Pediatrics, Division of Allergy, Immunology and Pulmonary Medicine, Washington University School of Medicine, St Louis, Missouri; David A. Khan, MD, Department of Internal Medicine, Division of Allergy and Immunology, University of Texas Southwestern Medical Center, Dallas, Texas; David M. Lang, MD, Department of Medicine, Department of Allergy and Clinical Immunology, and the Allergy and Immunology Fellowship Training Program, Cleveland Clinic Foundation, Cleveland, Ohio; John Oppenheimer, MD, Department of Internal Medicine, New Jersey Medical School, Morristown, New Jersey; Jay M. Portnoy, MD, Section of Allergy, Asthma & Immunology, The Children's Mercy Hospital, University of Missouri-Kansas City School of Medicine, Kansas City, Missouri; Christopher C. Randolph, Center for Allergy, Asthma and Immunology, Yale Hospitals, Waterbury, Connecticut; Matthew Rank, MD, Division of Allergy, Asthma, and Clinical Immunology, Mayo Clinic School of Medicine, Scottsdale, Arizona; Dana Wallace, MD, Department of Medicine, Nova Southeastern University, Davie, Florida. Parameter Workgroup Members: Matthew Greenhawt, MD, MBA, MSc, Department of Pediatrics, Children's Hospital of Colorado, Section of Allergy and Immunology, University of Colorado School of Medicine, Aurora, Colorado; John M. Kelso, MD, Division of Allergy, Asthma and Immunology, Scripps Clinic, San Diego, California; Paul J. Turner, BM, BCh, FRACP, PhD, Imperial College London and Imperial College Healthcare NHS Trust & Royal Brompton & Harefield NHS Foundation Trust, London, United Kingdom, and Department of Paediatrics, University of Sydney, Sydney, Australia. Invited Society Reviewers: Raghava Charya, MD, Bethesda, Maryland; Kathryn Convers, MD, Valrico, Florida; Sunita Kanumury, MD, Denville, New Jersey; Sangeetha Kodoth, MD, Knoxville, Tennessee; James T. Li, MD, Rochester, Minnesota; and Jim Parkerson, MD, Fort Wayne, Indiana.

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Chief Editors: Matthew Greenhawt, MD, MBA, MSc; Paul J. Turner, FRACP, PhD; John M. Kelso, MD.
Members of the Joint Task Force on Practice Parameters: David Bernstein, MD; Joann Blessing-Moore, MD; Chitra Dinakar, MD; Matthew Greenhawt, MD; Caroline Horner, MD; David Khan, MD; David Lang, MD; John Oppenheimer, MD; Jay Portnoy, MD; Christopher Randolph, MD; Matt Rank, MD; and Dana Wallace, MD.
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Classification of Recommendations and Evidence

Recommendation Rating Scale

Statement	Definition	Implication
Strong recommendation (StrRec)	A strong recommendation means the benefits of the recommended approach clearly exceed the harms (or that the harms clearly exceed the benefits in the case of a strong negative recommendation) and that the quality of the supporting evidence is excellent (grade A or B).* In some clearly identified circumstances, strong recommendations may be made based on lesser evidence when high-quality evidence is impossible to obtain and the anticipated benefits strongly outweigh the harms.	Clinicians should follow a strong recommendation unless a clear and compelling rationale for an alternative approach is present.
Recommendation (Rec)	A recommendation means the benefits exceed the harms (or that the harms clearly exceed the benefits in the case of a negative recommendation), but the quality of evidence is not as strong (grade B or C).* In some clearly identified circumstances, recommendations may be made based on lesser evidence when high-quality evidence is impossible to obtain and the anticipated benefits outweigh the harms.	Clinicians should also generally follow a recommendation but should remain alert to new information and sensitive to patient preferences.
Option (Opt)	An option means that either the quality of evidence that exists is suspect (grade D)* or that well-done studies (grade A, B, or C)* show little clear advantage to one approach vs another.	Clinicians should be flexible in their decision making regarding appropriate practice, although they may set bounds on alternatives; patient preference should have a substantial influencing role.
No recommendation (NoRec)	No recommendation means there is both a lack of pertinent evidence (grade D)* and an unclear balance between benefits and harms.	Clinicians should feel little constraint in their decision making and be alert to new published evidence that clarifies the balance of benefit vs harm; patient preference should have a substantial influencing role.

Category of Evidence

- Ia Evidence from meta-analysis of randomized controlled trials
- Ib Evidence from at least one randomized controlled trial
- IIa Evidence from at least one controlled study without randomization
- IIb Evidence from at least one other type of quasiexperimental study
- III Evidence from nonexperimental descriptive studies, such as comparative studies
- IV Evidence from expert committee reports or opinions or clinical experience of respected authorities or both

*Strength of Recommendation**

- A Directly based on category I evidence
- B Directly based on category II evidence or extrapolated recommendation from category I evidence
- C Directly based on category III evidence or extrapolated recommendation from category I or II evidence
- D Directly based on category IV evidence or extrapolated recommendation from category I, II, or III evidence
- LB Laboratory based
- NR Not rated

How This Practice Parameter Update Was Developed

The Influenza Vaccine and Egg Allergy Practice Parameter Workgroup was commissioned by the Joint Task Force on Practice Parameters (JTFPP) to develop practice parameters that address the administration of influenza vaccines to egg allergic recipients. Workgroup members invited to participate in the parameter development are considered experts in the field. Workgroup members have been vetted for financial conflicts of interest by the JTFPP, and their conflicts of interest have been listed in this document and are posted on the JTFPP website at https://www.allergyparameters.org/. Where a potential conflict of interest is present, the potentially conflicted workgroup member was excluded from discussing relevant issues. The charge to the workgroup was to use a systematic literature review, in conjunction with consensus expert opinion and workgroup-identified supplementary documents, to develop a practice parameter that provides a comprehensive approach for the administration of influenza vaccines to egg allergic recipients based on the current state of the science.

Preface

Annual seasonal influenza vaccination remains the most effective means of protection against contracting influenza illness and preventing spread of the disease among the population.[1] Influenza infection is a significant source of morbidity and mortality in the United States. During the 2015–2016 influenza season, an estimated 308,232 persons were hospitalized in the United States because of influenza, including 15,389 hospitalizations of children younger than 5 years.[2] It is estimated that 23,607 deaths occur each year in the United States as a result of influenza, including approximately 124 children.[3] Egg allergy affects as many as 2% of US children,[4] and of these, 29% also have asthma.[5] Therefore, egg allergic children are a subgroup who may be at higher risk for influenza-related complications. However, because most influenza vaccines are grown in embryonated chicken eggs and may contain residual egg protein (ovalbumin),[1] they were contraindicated in those with egg allergy until recently.[6]

New Developments

A large number of studies have reported inactivated influenza vaccine (IIV) to be safe for egg allergic recipients, including those with a history of anaphylaxis to egg, with low rates of minor reactions among egg allergic recipients that are no greater than those incurred by non–egg allergic recipients.[7] Furthermore, these studies have demonstrated that special precautions, such as prevaccine skin testing or stepwise challenge, are unnecessary for risk stratification.[7] Moreover, the ovalbumin content in all IIV available in the United States is less than 1 μg per dose,[1] an amount considered highly unlikely to cause reactions even in the most severely egg allergic recipients. Two non–egg-based influenza vaccines have been introduced. One (ccIIV4) is grown in cell culture and in theory could contain 50 fg of ovalbumin (1 fg equals 1^{e-9}μg).[1] It is approved for recipients 4 years and older. The other (RIV, available both as trivalent RIV3 and quadrivalent RIV4) uses recombinant hemagglutinin protein produced in an insect cell line and does not contain egg protein.[1] It is approved for patients 18 years and older.

Beginning in 2011, the Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP) and the American Academy of Pediatrics (AAP) Committee on Infectious Diseases (COID) recommended that egg allergic patients receive annual IIV, with certain precautions. Those with a history of only hives after egg ingestion were recommended to receive the vaccine in a primary care setting and be observed for 30 minutes after vaccination, whereas those with a history of more severe reactions to egg were recommended to see an allergist for vaccination.[8,9]

An practice parameter on adverse reactions to vaccines was published in 2012,[10] with an update on influenza vaccination of eggallergic patients published in 2013,[11] which stated the following:

- All patients with egg allergy of any severity, including anaphylaxis, should receive IIV annually, using any age-approved brand of IIV in an age-appropriate dose. Such patients can receive the vaccine as a single dose without prior vaccine skin testing.
- For egg allergic patients 18 years and older, either egg-based or egg-free IIV can be used.
- Special precautions regarding medical setting and waiting periods after administration of IIV to egg allergic recipients beyond those recommended for any vaccine are not warranted.
- For IIV, language that describes egg allergic recipients as being at increased risk compared with non–egg allergic recipients or requiring special precautions should be removed from guidelines and product labeling.
- All practitioners were reminded to be aware that although anaphylactic reactions are rare after vaccination, their immediate onset and life-threatening nature require that all personnel and facilities providing vaccinations of any kind have procedures in place for anaphylaxis management.

In all the aforementioned guidelines, live attenuated influenza vaccine (LAIV) was not recommended for use in egg allergic recipients. This is because LAIV also contains a very low level of ovalbumin (<0.24 μg per 0.2-mL dose),[12] and at the time, no studies demonstrating its safety in egg allergic recipients had been published. Another concern raised regarded the possibility of increased risk for wheezing in patients with asthma after vaccine administration,[12] although the evidence base for this is limited.[13]

Since publication of the 2013 practice parameter update,[12] additional data have been published regarding the safety of both IIV and LAIV in egg allergic recipients. Two large multicenter, prospective cohort studies demonstrated the safety of LAIV in egg allergic individuals.[13,14] The CDC/ACIP and AAP/COID have updated their guidelines for the 2017–2018 influenza season,[1,15] largely adopting the recommendations made in the 2013 practice parameter.[11]

The AAP/COID guidelines now state the following[15]:

- "All children with an egg allergy of any severity can receive an influenza vaccine without any additional precautions beyond those recommended for any vaccine."
- "IIV administered in a single, age-appropriate dose is well tolerated by recipients with a history of egg allergy of any severity."
- "Special precautions for egg-allergic recipients of IIV are not warranted, because the rate of anaphylaxis after IIV administration is no greater in egg-allergic than in non–egg-allergic recipients or from other universally recommended vaccines."
- "Standard vaccination practice for all vaccines in children should include the ability to respond to rare acute hypersensitivity reactions"

The CDC/ACIP, in its guidance for the 2017–2018 influenza season,[1] also states that persons with egg allergy of any severity can receive any age-appropriate influenza vaccine but recommends that those who report having had reactions to egg that involve symptoms other than hives receive the vaccine in a medical setting supervised by a health care professional.

In addition, current guidelines from the Canadian National Advisory Committee on Immunization state, "Egg allergic individuals may be vaccinated against influenza using inactivated TIV or QIV, or LAIV without prior influenza vaccine skin test and with the full dose, irrespective of a past severe reaction to egg, and without any extraordinary precautions."[16]

Summary Statements

The purpose of this practice parameter update is to review new data pertaining to the safety of influenza vaccines in egg allergic individuals and provide recommendations regarding annual influenza vaccination in egg allergic individuals. This focused practice parameter answers the following focused questions: (1) Is IIV safe in egg allergic individuals, including those with a history of severe reactions to egg ingestion? (2) Are special precautions necessary to administer IIV to any egg allergic recipients? (3) Are non–egg-based IIV medically necessary in egg allergic patients in the age groups for which they are approved? and (4) Is LAIV safe to administer to egg allergic individuals, including those with a history of anaphylaxis to egg ingestion?

Summary Statement 1: Influenza vaccines should be administered to individuals with egg allergy of any severity, just as they would be to individuals without egg allergy. Strength of recommendation: strong. Evidence level: A/B.

Data from 28 studies, covering 4,315 egg allergic patients, including 656 patients with severe egg allergy, describe uneventful administration of egg-based IIV without any reported cases of anaphylaxis.[7,17,18] Low rates of minor reactions such as hives have been noted to occur but at no greater rate than those occurring in non–egg allergic controls.[7] Ongoing analysis of the Vaccine Adverse Event Reporting System data after the 2011 CDC guidelines recommended the administration of influenza vaccine to egg allergic recipients has not demonstrated any increased reporting of allergic reactions, including anaphylaxis, in egg allergic individuals after influenza vaccination compared with the general population.[19] Similarly, the Canadian guidelines recommending no special precautions for influenza vaccination of egg allergic recipients have been in place since 2014, and no increase in adverse reactions have been observed.[20] Thus, all patients with egg allergy, irrespective of the severity, including those with a history of anaphylaxis after egg

ingestion, should receive influenza vaccine annually, using any age-approved brand of influenza vaccine in an age-appropriate dose. With respect to the current influenza vaccines in use in the United States, vaccine providers (eg, physician offices, health care system occupational/employee health sections, retail pharmacy chains providing vaccine services) do not need to inquire about egg allergy status of recipients before the administration of any influenza vaccine. Vaccine providers and screening questionnaires do not need to ask about the egg allergy status of recipients of influenza vaccine.

Summary Statement 2: No special precautions beyond those recommended for the administration of any vaccine to any patient are necessary for administration of influenza vaccine to egg allergic individuals. Strength of recommendation: strong. Evidence level: A/B.

Egg allergic patients can be vaccinated safely with influenza vaccines in the same manner as those without egg allergy.[11,15,16] Previously recommended precautions, such as choice of a specific vaccine based on ovalbumin content (at least in countries where the known ovalbumin content in all available IIV is <1 μg per dose), skin testing with the vaccine, and divided or graded dosing, are unnecessary.[11,21] Similarly, specific waiting periods or special medical settings for the administration of influenza vaccine to egg allergic recipients are unnecessary.[11,15,16]

Anaphylaxis can occur rarely after the administration of any vaccine to any patient at a rate of approximately 1 per million.[7] Therefore, as per ACIP general recommendations on immunization, providers should be aware that "although anaphylactic reactions are rare after vaccination, their immediate onset and life-threatening nature require that all personnel and facilities providing vaccinations have procedures in place for anaphylaxis management."[22] Furthermore, as with any vaccine, patients who have had an anaphylactic reaction to influenza vaccination itself, as opposed to a reaction to egg ingestion, should be evaluated by an allergist before subsequent vaccinations.[10]

Summary Statement 3: Use of non–egg-based influenza vaccines (ccIIV3, RIV3, or RIV4) in egg allergic individuals in the age groups for which they are approved is acceptable but not medically necessary or preferred. Strength of recommendation: moderate. Evidence level: C/D.

Non–egg-based influenza vaccines (ccIIV3, RIV3, or RIV4), which do not contain measurable quantities of egg protein, may be administered to egg allergic recipients. However, there is no medical reason to do so, and there is no preference for the use of these vaccines in egg allergic recipients over egg-based vaccines.[1] As with any vaccine, there are rare reports of anaphylactic reactions even to non–egg-based vaccines.[23]

Summary Statement 4: Live attenuated influenza vaccine (LAIV) may be administered to patients with egg allergy of any severity in the age group for which it is approved (ages 2–49 years), in particular, countries and seasons when LAIV is recommended as an agent (based on effectiveness in prior seasons). Strength of recommendation: strong. Evidence level: A/B.

Three recently published studies have demonstrated that LAIV is safe for use in egg allergic individuals of all ages, including those with anaphylaxis to egg ingestion.[13,14,24] These reports collectively describe 955 children with egg allergy, including 412 with a history of anaphylaxis with egg ingestion, who have been safely vaccinated with LAIV without developing any immediate systemic reactions. As with IIV, this is likely because of the low amount of egg protein in the vaccine (<0.24 μg of ovalbumin per dose).[12] CDC/ACIP and AAP/COID acknowledge the safety of LAIV in egg allergic recipients but recommend that it not be used in any population during the 2017–2018 season because of concerns regarding effectiveness.[1,15]

Conclusion

There is strong evidence that egg allergic individuals can safely receive IIV or LAIV if the latter vaccine is recommended for use once the concerns regarding efficacy have been resolved. Presence of egg allergy in an individual is not a contraindication to receive IIV or LAIV. Influenza vaccine recipients with egg allergy are at no greater risk for a systemic allergic reaction than those without egg allergy. Precautions, such as choice of a particular vaccine, special observation periods, or restriction of administration to particular medical settings, are not warranted and constitute an unnecessary barrier to immunization. Vaccine providers and screening questionnaires do not need to ask about the egg allergy status of recipients of influenza vaccine.

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