



Complete Summary

GUIDELINE TITLE

Prevention of influenza: recommendations for influenza immunization of children, 2007-2008.

BIBLIOGRAPHIC SOURCE(S)

American Academy of Pediatrics Committee on Infectious Diseases. Prevention of influenza: recommendations for influenza immunization of children, 2007-2008. Pediatrics 2008 Apr;121(4):e1016-31. [106 references] [PubMed](#)

GUIDELINE STATUS

This is the current release of the guideline.

All clinical reports and policy statements from the American Academy of Pediatrics automatically expire 5 years after publication unless reaffirmed, revised, or retired at or before that time.

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory information has been released:

- [April 02, 2008, Relenza \(zanamivir\)](#): GlaxoSmithKline informed healthcare professionals of changes to the warnings and precautions sections of prescribing information for Relenza. There have been reports (mostly from Japan) of delirium and abnormal behavior leading to injury in patients with influenza who are receiving neuraminidase inhibitors, including Relenza.
- [March 4, 2008, Tamiflu \(oseltamivir phosphate\)](#): Roche and the U.S. Food and Drug Administration (FDA) informed healthcare professionals of neuropsychiatric events associated with the use of Tamiflu, in patients with influenza. Roche has updated the PRECAUTIONS section of the package insert to include the new information and guidance under the Neuropsychiatric Events heading.

COMPLETE SUMMARY CONTENT

** REGULATORY ALERT **

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SCOPE

DISEASE/CONDITION(S)

Influenza

GUIDELINE CATEGORY

Prevention

CLINICAL SPECIALTY

Family Practice
Infectious Diseases
Pediatrics
Preventive Medicine

INTENDED USERS

Advanced Practice Nurses
Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

To update the current recommendations for routine use of influenza vaccine in children

TARGET POPULATION

- Healthy children 6 through 59 months of age
- Children at high risk and adolescents with underlying medical conditions
- Household contacts and out-of-home caregivers of children younger than 5 years and children who are at risk of all ages
- Children who required regular medical follow-up or hospitalization during the preceding year because of chronic metabolic diseases, such as diabetes mellitus, renal dysfunction, hemoglobinopathies, or immunodeficiency caused by medication or by human immunodeficiency virus infection
- Any female who will be pregnant during influenza season

INTERVENTIONS AND PRACTICES CONSIDERED

Immunization with trivalent inactivated influenza vaccine or live-attenuated influenza vaccine, based on specified criteria

MAJOR OUTCOMES CONSIDERED

- Incidence and prevalence of influenza virus infection in children and adolescents
- Incidence and prevalence of hospitalization from influenza virus in children and adolescents
- Incidence and prevalence of influenza-related death in children and adolescents
- Adverse effects associated with influenza vaccine

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

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

Definitions Grades of Evidence

- A. Well-designed randomized, controlled trials or diagnostic studies performed on a population
- B. Similar to the guideline's target population
- C. Randomized, controlled trials or diagnostic studies with minor limitations; overwhelmingly consistent evidence from observational studies
- D. Observational studies (case-control and cohort design)
- E. Expert opinion, case reports, or reasoning from first principles (bench research or animal studies)

METHODS USED TO ANALYZE THE EVIDENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Guideline Definitions for Evidence-Based Statements

Statement Type	Definition	Implication
Strong Recommendation	The subcommittee believes that 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).	Clinicians should follow a strong recommendation unless a clear and compelling rationale for an alternative approach is present.
Recommendation	The subcommittee believes that the benefits exceed the harms (or that the harms 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 on	Clinicians also should generally follow a recommendation but remain alert to new information and sensitive to patient preferences.

Statement Type	Definition	Implication
	the basis of lesser evidence when high-quality evidence is impossible to obtain and the anticipated benefits outweigh the harms.	
Option	Either the quality of evidence that exists is suspect (grade D) or well-performed studies (grade A, B, or C) show little clear advantage to one approach versus another.	Clinicians should be flexible in their decision making in regards to appropriate practice, although they may set boundaries on alternatives; patient preference should play a substantial influencing role.
No Recommendation	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 versus harm; patient preference should play a substantial influencing role.

COST ANALYSIS

The hospitalization costs for influenza among children in the United States are estimated to be \$55 million per year. Several studies have suggested that the costs and benefits of immunizing children produce significant savings from health care and societal perspectives. In 1 study, the savings per immunized child

ranged from \$7.23 to \$15.98 in any program of children up to 13 years of age, and an investment of \$2,156,109 in immunization of children younger than 5 years was predicted to result in an estimated savings yield of \$3,424,409 in health care costs, even with an assumed vaccine efficacy of only 60%. Other cost analyses have documented the considerable cost burden of illness among children. In a study of 727 children at a single medical center during 2000 to 2004, the mean total cost of hospitalization for influenza-related illness was \$13,159 (\$39,792 for patients admitted to an intensive care unit (ICU) and \$7030 for patients cared for exclusively on the wards). Strategies that focus on immunizing children with medical conditions that confer a higher risk of influenza complications seem to be more cost-effective than a strategy of immunizing all children. The expenses of immunizing children of varying ages were estimated, comparing the costs between using trivalent inactivated vaccine (TIV) with those of live-attenuated influenza vaccine (LAIV); costs per quality-adjusted life-year saved increased with age for both vaccines. In 2003 dollars per quality-adjusted life-year, costs for routine immunization using TIV were \$12,000 for healthy children 6 to 23 months of age and \$119,000 for healthy adolescents 12 to 17 years of age, compared with \$9,000 and \$109,000 using LAIV, respectively. Other studies demonstrated that influenza immunization of young children generates considerable savings from a societal perspective, especially if the total costs of immunization are less than \$30 per child and if immunizations can be administered in after-hours or weekend group settings so as to help parents not miss work for their children's immunization.

A recent review of research on the costs and benefits of immunizing children, household contacts, and those at high risk of morbidity and mortality from influenza complications suggests that the immunization of children has the potential to protect others in their homes and communities. However, because of limitations in the design or execution of several analyzed studies, this finding remains inconclusive. Results from a public survey on the cost associated with influenza disease provided the following estimates: when asked about their willingness to pay to prevent a hypothetical child from having an uncomplicated case of influenza, the median willingness-to-pay amount was \$100 for a child 14 years of age and \$175 for a child 1 year of age.

METHOD OF GUIDELINE VALIDATION

Not stated

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not applicable

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Definitions for the grades of evidence (A-D) and guideline definitions for evidence-based statements can be found at the end of the "Major Recommendations" field.

Recommendations

Influenza immunization is recommended for the following groups:

- Healthy children 6 through 59 months of age (recommendation; evidence Grade B).
- Children at high risk and adolescents with underlying medical conditions, including: asthma or other chronic pulmonary diseases, such as cystic fibrosis (recommendation; evidence grade B).
- Hemodynamically significant cardiac disease.
- Immunosuppressive disorders or therapy.
- Human immunodeficiency virus (HIV) infection.
- Sickle cell anemia and other hemoglobinopathies.
- Diseases requiring long-term aspirin therapy, such as juvenile idiopathic arthritis or Kawasaki disease (trivalent inactivated vaccine [TIV] only).
- Chronic renal dysfunction.
- Chronic metabolic disease, such as diabetes mellitus.
- Any condition that can compromise respiratory function or handling of secretions or can increase the risk of aspiration, such as cognitive dysfunction, spinal cord injuries, seizure disorders, or other neuromuscular disorders.
- Household contacts and out-of-home caregivers of children younger than 5 years and children who are at risk of all ages. Immunization of close contacts of children younger than 6 months may be particularly important, because these infants cannot be immunized (recommendation; evidence grade B).
- Children who required regular medical follow-up or hospitalization during the preceding year because of chronic metabolic diseases, such as diabetes mellitus; renal dysfunction; hemoglobinopathies; or immunodeficiency caused by medication or by HIV infection.
- Any female who will be pregnant during influenza season (TIV only).

In addition, immunization with either TIV or live-attenuated influenza vaccine (LAIV) is recommended for the following individuals to prevent transmission of influenza to those at risk, unless contraindicated:

- Individuals 5 years and older.
- Healthy contacts and caregivers of other children or adults at high risk of developing complications from influenza infection (recommendation; evidence grade B).
- Close contacts of immunosuppressed individuals (TIV only if severely immunosuppressed).
- Health care workers or volunteers.

Information about influenza surveillance is available through the Centers for Disease Control and Prevention Voice Information System (influenza update, 888-232-3228) or at www.cdc.gov/flu.influenza infection.

Definitions

Definitions Grades of Evidence

- A. Well-designed randomized, controlled trials or diagnostic studies performed on a population similar to the guideline's target population

- B. Randomized, controlled trials or diagnostic studies with minor limitations; overwhelmingly consistent evidence from observational studies
- C. Observational studies (case-control and cohort design)
- D. Expert opinion, case reports, or reasoning from first principles (bench research or animal studies)

Guideline Definitions for Evidence-Based Statements

Statement Type	Definition	Implication
Strong Recommendation	The subcommittee believes that 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).	Clinicians should follow a strong recommendation unless a clear and compelling rationale for an alternative approach is present.
Recommendation	The subcommittee believes that the benefits exceed the harms (or that the harms 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 on the basis of lesser evidence when high-quality	Clinicians also should generally follow a recommendation but remain alert to new information and sensitive to patient preferences.

Statement Type	Definition	Implication
	evidence is impossible to obtain and the anticipated benefits outweigh the harms.	
Option	Either the quality of evidence that exists is suspect (grade D) or well-performed studies (grade A, B, or C) show little clear advantage to one approach versus another.	Clinicians should be flexible in their decision making in regards to appropriate practice, although they may set boundaries on alternatives; patient preference should play a substantial influencing role.
No Recommendation	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 versus harm; patient preference should play a substantial influencing role.

CLINICAL ALGORITHM(S)

A clinical algorithm, "Algorithm for determining recommended influenza immunization actions for children," is provided in the original guideline document.

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

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

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate use of the influenza vaccine in children for the 2007-2008 influenza season

POTENTIAL HARMS

- Consideration should be given to the potential risks and benefits of administering influenza vaccine to any child with known or suspected immunodeficiency. Precaution should also be taken when considering live-attenuated influenza vaccine (LAIV) administration to people with minor acute illness, such as a mild upper respiratory tract infection with or without fever. Although the vaccine can most likely be given in this case, LAIV should not be delivered if nasal congestion will impede the delivery of the vaccine to the nasopharyngeal mucosa, until the congestion-inducing illness is resolved. In addition, trivalent inactivated vaccine (TIV) is the influenza vaccine of choice for any child living with a family member or household contact who is severely immunocompromised (i.e., in a protected environment). The preference of TIV over LAIV for these individuals is because of the theoretic risk of infection in an immunocompromised contact of a LAIV-immunized child. As a precautionary measure, recently immunized people should restrict contact with severely immunocompromised (i.e., in a protected environment) patients for 7 days after LAIV immunization, although there have been no reports of LAIV transmission between these 2 groups.
- The most common symptoms associated with TIV administration are soreness at the injection site and fever.
- Postlicensure studies indicate that among children immunized for the first time, fever and stuffy nose are more common in recipients of LAIV than among recipients of TIV.
- If there is an association between seasonal influenza vaccine and Guillain-Barre' syndrome, the risk is very minimal, at no more than 1 to 2 cases per million doses.
- Because past reports are conflicting, the issue of safety of TIV immunization for children and adults with human immunodeficiency virus (HIV) infection is uncertain. However, experts generally believe that the benefits of TIV influenza immunization for children with HIV infection far outweigh the risks.

CONTRAINDICATIONS

CONTRAINDICATIONS

Children Who Should Not Be Immunized With Trivalent Inactivated Vaccine

- Children younger than 6 months.

- Children who have a moderate-to-severe febrile illness. Minor illnesses, with or without fever, do not contraindicate its use, particularly among children with mild symptoms of upper respiratory tract infection or allergic rhinitis.
- Children who have a history of hypersensitivity, including anaphylaxis, to eggs; to any previous influenza vaccine dose; or to any of the vaccine components.
- Children who have a history of Guillain-Barré syndrome (GBS) (recommendation; evidence grade C).

Children Who Should Not Be Immunized With Live-attenuated Influenza Vaccine

- Children younger than 2 years (recommendation; evidence grade B).
- Children who have a moderate-to-severe febrile illness.
- Children who received other live vaccines within the last 4 weeks.
- Children who have asthma, reactive airways disease, or other chronic disorders of the pulmonary or cardiovascular systems.
- Children who have underlying medical conditions, including metabolic disease, such as diabetes, renal dysfunction, and hemoglobinopathies.
- Children who have known or suspected immunodeficiency disease or are receiving immunosuppressive therapies.
- Children who are receiving aspirin or other salicylates.
- Children who have a history of GBS (recommendation; evidence grade C).
- Adolescents who are pregnant.
- Children who have a history of hypersensitivity, including anaphylaxis, to eggs; to any previous influenza vaccine dose; or to any of the vaccine components.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Clinical Algorithm

For information about [availability](#), see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Staying Healthy

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

American Academy of Pediatrics Committee on Infectious Diseases. Prevention of influenza: recommendations for influenza immunization of children, 2007-2008. Pediatrics 2008 Apr;121(4):e1016-31. [106 references] [PubMed](#)

ADAPTATION

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

DATE RELEASED

2007 Apr (revised 2008 Apr 1)

GUIDELINE DEVELOPER(S)

American Academy of Pediatrics - Medical Specialty Society

SOURCE(S) OF FUNDING

American Academy of Pediatrics

GUIDELINE COMMITTEE

Committee on Infectious Diseases

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

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GUIDELINE AVAILABILITY

Electronic copies: Available from the [American Academy of Pediatrics \(AAP\) Policy Web site](#).

Print copies: Available from American Academy of Pediatrics, 141 Northwest Point Blvd., P.O. Box 927, Elk Grove Village, IL 60009-0927.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI Institute on May 15, 2007. The information was verified by the guideline developer on May 23, 2007. This summary was updated by ECRI Institute on March 10, 2008 following the U.S. Food and Drug Administration (FDA) advisory on Tamiflu (oseltamivir phosphate). This summary was updated by ECRI Institute on April 9, 2008 following the U.S. Food and Drug Administration (FDA) advisory on Relenza (zanamivir). This summary was updated by ECRI Institute on May 16, 2008. The updated information was verified by the guideline developer on May 20, 2008.

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