Complete Summary

GUIDELINE TITLE

Using live, attenuated influenza vaccine for prevention and control of influenza: supplemental recommendations of the Advisory Committee on Immunization Practices (ACIP).

BIBLIOGRAPHIC SOURCE(S)

Harper SA, Fukuda K, Cox NJ, Bridges CB. Using live, attenuated influenza vaccine for prevention and control of influenza: supplemental recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR Recomm Rep 2003 Sep 26;52(RR-13):1-8. [24 references] PubMed

GUIDELINE STATUS

This is the current release of the guideline.

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SCOPE

DISEASE/CONDITION(S)

Influenza

GUIDELINE CATEGORY

Prevention

CLINICAL SPECIALTY

Allergy and Immunology
Family Practice
Infectious Diseases
Internal Medicine
Pediatrics
Pharmacology
Preventive Medicine

INTENDED USERS

Advanced Practice Nurses
Health Care Providers
Health Plans
Hospitals
Nurses
Physician Assistants
Physicians
Public Health Departments

GUIDELINE OBJECTIVE(S)

- To summarize recommendations by the Advisory Committee on Immunization Practices (ACIP) for using intranasally administered, trivalent, cold-adapted, live, attenuated influenza vaccine (LAIV)
- To supplement the 2003 ACIP recommendations regarding prevention and control of influenza (Centers for Disease Control. Prevention and Control of Influenza: Recommendations of the Advisory Committee on Immunization Practices [ACIP]. MMWR 2003;52[No. RR-8]:1–36.)

TARGET POPULATION

Healthy persons, aged 5–49 years, who want to avoid influenza infection and are not at high risk for complications from influenza infection

INTERVENTIONS AND PRACTICES CONSIDERED

1. Annual intranasal administration of trivalent, cold-adapted, live, attenuated influenza vaccine (LAIV) (FluMist™)
2. The 2003-2004 vaccine contains the following antigens (identical to the inactivated influenza vaccine):
    - A/Moscow/10/99 (H3N2)-like (manufacturers will use the antigenically equivalent A/Panama/2007/99 [H3N2] virus)
    - A/New Caledonia/20/99 (H1N1)-like
    - B/Hong Kong/330/2001-like strains (manufacturers will use either B/Hong Kong/330/2001 or the antigenically equivalent B/Hong Kong/1434/2002)

MAJOR OUTCOMES CONSIDERED

- Efficacy and effectiveness of live, attenuated influenza vaccine
- Person-to-person transmission of vaccine viruses

- Stability of vaccine viruses
- Side effects and adverse reactions

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases
Searches of Unpublished Data

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

Not stated

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

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

Not applicable

COST ANALYSIS

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

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not stated

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Notice from the National Guideline Clearinghouse (NGC) and the Centers for Disease Control and Prevention Advisory Committee on Immunization Practices (CDC, ACIP): Live, attenuated influenza vaccine (LAIV) was approved for use in the United States on June 17, 2003 (FluMist™, produced by MedImmune, Inc., Gaithersburg, Maryland). These recommendations supplement the 2003 ACIP recommendations regarding prevention and control of influenza (CDC. Prevention and Control of Influenza: Recommendations of the Advisory Committee on Immunization Practices [ACIP]. MMWR 2003;52[No. RR-8]:1-36).

Recommendations for Inactivated Influenza Vaccine

Recommendations for inactivated influenza vaccination have targeted specific groups for annual immunization, including persons aged ≥6 months who are at high risk for complications from influenza because of age or presence of certain medical conditions, persons who are in close contact with those at high risk, persons aged 50 to 64 years, and close contacts of infants aged 0 to 6 months. Vaccination with inactivated influenza vaccine is also encouraged when feasible for children aged 6 to 23 months and their close contacts and caregivers. In addition, physicians should administer inactivated influenza vaccine to any person who wishes to reduce the likelihood of becoming ill with influenza. Recommendations for use of inactivated influenza vaccine are located at CDC Web site.

Recommendations for Using Live, Attenuated Influenza Vaccine (LAIV)

- **Persons Who Should Not Be Vaccinated with LAIV**

  The following populations should not be vaccinated with LAIV:

  - persons aged <5 years or those aged ≥ 50 years[â□]
  - persons with asthma, reactive airways disease or other chronic disorders of the pulmonary or cardiovascular systems; persons with other underlying medical conditions, including such metabolic diseases as diabetes, renal dysfunction, and hemoglobinopathies; or persons with known or suspected immunodeficiency diseases or who are receiving immunosuppressive therapies[â□]
  - children or adolescents receiving aspirin or other salicylates (because of the association of Reye syndrome with wild-type influenza infection)[â□]
  - persons with a history of Guillain-Barré syndrome
  - pregnant women[â□]

- persons with a history of hypersensitivity, including anaphylaxis, to any of the components of LAIV or to eggs

  â These persons should receive inactivated influenza vaccine.

- **Close Contacts of Persons at High Risk for Complications from Influenza**

  Close contacts of persons at high risk for complications from influenza should receive influenza vaccine to reduce transmission of wild-type influenza viruses to persons at high risk. No data are available assessing the risk for transmission of LAIV from vaccine recipients to immunosuppressed contacts. In the absence of such data, use of inactivated influenza vaccine is preferred for vaccinating household members, health-care workers, and others who have close contact with immunosuppressed persons because of the theoretical risk that a live, attenuated vaccine virus could be transmitted to the immunosuppressed person and cause disease. Otherwise, no preference is given to either inactivated influenza vaccine or LAIV for vaccination of healthy persons aged 5 to 49 years in close contact with all other groups at high risk.

- **Timing of LAIV Administration**

  Administration of LAIV is not subject to tiered timing recommendations because it is not approved for use among populations at high risk. The optimal time to vaccinate is usually in October and November, but providers can begin vaccinating with LAIV as soon as vaccine supplies are available. Children aged 5 to 8 years who have never received influenza vaccine should receive LAIV for the first time in October or earlier because they need a second dose 6 to 10 weeks after the initial dose.

- **Dosage, Administration, and Storage**

  LAIV Dosage

  LAIV is intended for intranasal administration only and should not be administered by the intramuscular, intradermal, or intravenous route. LAIV must be stored at −15Â°C or colder. LAIV should not be stored in a frost-free freezer (because the temperature might cycle above −15Â°C), unless a manufacturer-supplied freezer box is used. LAIV must be thawed before administration. This can be accomplished by holding an individual sprayer in the palm of the hand until thawed, with subsequent immediate administration. Alternatively, the vaccine can be thawed in a refrigerator and stored at 2Â°C to 8Â°C for <24 hours before use. Vaccine should not be refrozen after thawing. LAIV is supplied in a prefilled singleuse sprayer containing 0.5 mL of vaccine. Approximately 0.25 mL (i.e., half of the total sprayer contents) is sprayed into the first nostril while the recipient is in the upright position. An attached dose-divider clip is removed from the sprayer to administer the second half of the dose into the other nostril. If the vaccine recipient sneezes after administration, the dose should not be repeated.

LAIV should be administered annually according to the following schedule:

- Children aged 5 to 8 years previously unvaccinated at any time with either LAIV or inactivated influenza vaccine should receive 2 doses of LAIV separated by 6 to 10 weeks (Note: one dose equals 0.5 mL, divided equally between each nostril).
- Children aged 5 to 8 years previously vaccinated at any time with either LAIV or inactivated influenza vaccine should receive 1 dose of LAIV. They do not require a second dose.
- Persons aged 9 to 49 years should receive 1 dose of LAIV.

LAIV can be administered to persons with minor acute illnesses (e.g., diarrhea or mild upper respiratory tract infection with or without fever). However, if clinical judgment indicates nasal congestion is present that might impede delivery of the vaccine to the nasopharyngeal mucosa, deferral of administration should be considered until resolution of the illness.

Whether concurrent administration of LAIV with other vaccines affects the safety or efficacy of either LAIV or the simultaneously administered vaccine is unknown. In the absence of specific data indicating interference, following the ACIP general recommendations for immunization is prudent (Centers for Disease Control [CDC], 2002). Inactivated vaccines do not interfere with the immune response to other inactivated vaccines or to live vaccines. An inactivated vaccine can be administered either simultaneously or at any time before or after LAIV. Two live vaccines not administered on the same day should be administered >4 weeks apart when possible.

LAIV Administration and Use of Influenza Antiviral Medications

The effect on safety and efficacy of LAIV coadministration with influenza antiviral medications has not been studied. However, because influenza antivirals reduce replication of influenza viruses, LAIV should not be administered until 48 hours after cessation of influenza antiviral therapy, and influenza antiviral medications should not be administered for 2 weeks after receipt of LAIV.

LAIV Storage

LAIV must be stored at –15Â°C or colder. LAIV should not be stored in a frost-free freezer because the temperature might cycle above –15Â°C, unless a manufacturer-supplied freezer box or other strategy is used. LAIV may be thawed in a refrigerator and stored at 2Â°C to 8Â°C for ≤24 hours before use. It should not be refrozen after thawing. Additional information is available at Wyeth Product Quality (1-800-411-0086) or at www.FluMist.com.

- **Side Effects and Adverse Reactions**

  Refer to the "Potential Harms" field for information on side effects and potential adverse reactions.

  Serious Adverse Events

  Serious adverse events among healthy children aged 5 to 17 years or healthy adults aged 18 to 49 years occurred at a rate of <1%. Surveillance should continue for adverse events that might not have been detected in previous studies.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is not specifically stated for each recommendation.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Possible advantages of live, attenuated influenza vaccine (LAIV) include its potential to induce a broad mucosal and systemic immune response, its ease of administration, and the acceptability of an intranasal rather than intramuscular route of administration.

Efficacy Among Healthy Children

A randomized, double-blind, placebo-controlled trial among 1,602 healthy children initially aged 15 to 71 months assessed the efficacy of the trivalent LAIV against culture-confirmed influenza during two seasons (Influenza seasons usually occur October to May.). Refer to the original guideline document for study details. The vaccine was 92% efficacious in preventing culture-confirmed influenza during the two-season study. Other results included a 27% reduction in febrile otitis media and a 28% reduction in otitis media with concomitant antibiotic use. Receipt of LAIV also resulted in decreased fever and otitis media among vaccine recipients who experienced influenza.

Effectiveness and Efficacy Among Healthy Adults

A randomized, double-blind, placebo-controlled trial among 4,561 healthy working adults aged 18 to 64 years assessed multiple endpoints, including reductions in illness, absenteeism, health-care visits, and medication use during peak and total influenza outbreak periods. Refer to the original guideline document for study

details and subgroup analyses. During peak outbreak periods, no difference was identified between LAIV and placebo recipients experiencing any febrile episodes. However, vaccination was associated with fewer days of illness, fewer days of work lost, fewer days with health-care provider visits, and reduced use of prescription antibiotics and over-the-counter medications.

Another randomized, double-blind, placebo-controlled challenge study among 92 healthy adults (LAIV, n = 29; placebo, n = 31; inactivated influenza vaccine, n = 32) aged 18–41 years assessed the efficacy of both LAIV and trivalent inactivated vaccine. The overall efficacy of LAIV and inactivated influenza vaccine in preventing laboratory documented influenza from all three influenza strains combined was 85% and 71%, respectively, on the basis of experimental challenge by viruses to which study participants were susceptible before vaccination. The difference between the two vaccines was not statistically significant.

POTENTIAL HARMS

Person-to-Person Transmission of Vaccine Viruses

Because live, attenuated influenza vaccine (LAIV) contains live influenza viruses, a potential exists for transmission of these viruses from vaccinees to other persons. Vaccinated immunocompetent children can shed vaccine viruses for $\leq$ 3 weeks. Refer to the original guideline document for details.

Side Effects and Adverse Reactions

Twenty prelicensure clinical trials assessed the safety of the approved LAIV. In these combined studies, approximately 28,000 doses of the vaccine were administered to >20,000 subjects. A subset of these trials were randomized, placebo-controlled studies in which >4,000 healthy children aged 5 to 17 years and >2,000 healthy adults aged 18 to 49 years were vaccinated. The incidence of adverse events possibly complicating influenza (e.g., pneumonia, bronchitis, bronchiolitis, or central nervous system events) was not statistically different among LAIV and placebo recipients aged 5–49 years.

Children

Signs and symptoms reported more often among vaccine recipients than placebo recipients included runny nose or nasal congestion (20% to 75%), headache (2% to 46%), fever (0% to 26%), and vomiting (3% to 13%), abdominal pain (2%), and myalgias (0% to 21%). These symptoms were associated more often with the first dose and were self-limited. In a subset of healthy children aged 60–71 months from one clinical trial, certain signs and symptoms were reported more often among LAIV recipients after the first dose (n = 214) than placebo recipients (n = 95) (e.g., runny nose, 48.1% versus 44.2%; headache, 17.8% versus 11.6%; vomiting, 4.7% versus 3.2%; myalgias, 6.1% versus 4.2%), but these differences were not statistically significant. Unpublished data from a study including subjects aged 1 to 17 years indicated an increase in asthma or reactive airways disease in the subset aged 12 to 59 months. Because of this, LAIV is not approved for use among children aged <60 months (see Recommendations for Using Live, Attenuated Influenza Vaccine).

Adults

Among adults, runny nose or nasal congestion (28% to 78%), headache (16% to 44%), and sore throat (15% to 27%) have been reported more often among vaccine recipients than placebo recipients. In one clinical trial, among a subset of healthy adults aged 18–49 years, signs and symptoms reported more frequently among LAIV recipients (n = 2,548) than placebo recipients (n = 1,290) within 7 days after each dose included cough (13.9% versus 10.8%); runny nose (44.5% versus 27.1%); sore throat (27.8% versus 17.1%); chills (8.6% versus 6.0%); and tiredness/weakness (25.7% versus 21.6%).

Safety Among Groups at High Risk from Influenza-Related Morbidity

Until additional data are acquired, persons at high risk for experiencing complications from influenza infection (e.g., immunocompromised patients; patients with asthma, cystic fibrosis, or chronic obstructive pulmonary disease; or persons aged ≥ 65 years) should not be vaccinated with LAIV. Protection from influenza in these groups should be accomplished by using activated influenza vaccine.

Serious Adverse Events

Serious adverse events among healthy children aged 5 to 17 years or healthy adults aged 18 to 49 years occurred at a rate of <1%. Surveillance should continue for adverse events that might not have been detected in previous studies.

CONTRAINDICATIONS

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Persons Who Should Not Be Vaccinated with LAIV

The following populations should not be vaccinated with live, attenuated influenza vaccine (LAIV):

- persons aged <5 years or those aged ≥ 50 years*
- persons with asthma, reactive airways disease or other chronic disorders of the pulmonary or cardiovascular systems; persons with other underlying medical conditions, including such metabolic diseases as diabetes, renal dysfunction, and hemoglobinopathies; or persons with known or suspected immunodeficiency diseases or who are receiving immunosuppressive therapies*
- children or adolescents receiving aspirin or other salicylates (because of the association of Reye syndrome with wild-type influenza infection)*
- persons with a history of Guillain-Barré syndrome
- pregnant women*
- persons with a history of hypersensitivity, including anaphylaxis, to any of the components of LAIV or to eggs

*These persons should receive inactivated influenza vaccine.

QUALIFYING STATEMENTS

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Use of trade names and commercial sources is for identification only and does not imply endorsement by the U.S. Department of Health and Human Services.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Staying Healthy

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Harper SA, Fukuda K, Cox NJ, Bridges CB. Using live, attenuated influenza vaccine for prevention and control of influenza: supplemental recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR Recomm Rep 2003 Sep 26;52(RR-13):1-8. [24 references] PubMed

ADAPTATION

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

DATE RELEASED

2003 Sep 26

GUIDELINE DEVELOPER(S)

Centers for Disease Control and Prevention - Federal Government Agency [U.S.]

SOURCE(S) OF FUNDING

United States Government

GUIDELINE COMMITTEE

Advisory Committee on Immunization Practices (ACIP)
ACIP Influenza Working Group

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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Liaison Representatives: American Academy of Family Physicians, Richard D. Clover, M.D., Louisville, Kentucky, and Martin Mahoney, M.D., Ph.D., Clarence, New York; American Academy of Pediatrics, Jon Abramson, M.D., Winston-Salem, North Carolina, and Carol Baker, M.D., Houston, Texas; American Association of Health Plans, Robert Scallettar, M.D., North Haven, Connecticut; American Collage

Health Association, James C. Turner, M.D., Charlottesville, Virginia; American College of Obstetricians and Gynecologists, Stanley Gall, M.D., Louisville, Kentucky; American College of Physicians, Kathleen M. Neuzil, M.D., Seattle, Washington; American Medical Association, Litjen Tan, Ph.D., Chicago, Illinois; American Pharmaceutical Association, Stephan L. Foster, Pharm.D., Memphis, Tennessee; Association of Teachers of Preventive Medicine, W. Paul McKinney, M.D., Louisville, Kentucky; Canadian National Advisory Committee on Immunization, Monica Naus, M.D., Vancouver, British Columbia, Canada; Healthcare Infection Control Practices Advisory Committee, Jane D. Siegel, M.D., Dallas, Texas; Infectious Diseases Society of America, Samuel L. Katz, M.D., Durham, North Carolina, and William Schaffner, M.D., Nashville, Tennessee; London Department of Health, David M. Salisbury, M.D., London, United Kingdom; National Association of County and City Health Officials, J. Henry Hershey, M.D., Christiansburg, Virginia; National Coalition for Adult Immunization, David A. Neumann, Ph.D., Bethesda, Maryland; National Immunization Council and Child Health Program, Mexico, Jose Ignacio Santos, M.D., Mexico City, Mexico; National Medical Association, Rudolph E. Jackson, M.D., Atlanta, Georgia; National Vaccine Advisory Committee, Georges Peter, M.D., Providence, Rhode Island; and Pharmaceutical Research and Manufacturers of America, and Geno Germano, St. Davids, Pennsylvania

ACIP Influenza Working Group

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Members: Kristin Lee Nichol, M.D., and Margaret B. Rennels, M.D., ACIP; Jon Abramson, M.D., American Academy of Pediatrics; Stanley A. Gall, M.D., American College of Obstetricians and Gynecologists; Linda C. Lambert, Ph.D., National Institutes of Health; Roland A. Levandowski, M.D., and ChrisAnna M. Mink, M.D., Food and Drug Administration; Kathleen M. Neuzil, M.D., American College of Physicians; Fred Ruben, M.D., Pharmaceutical Research and Manufacturers of America; William Schaffner, M.D., Infectious Diseases Society of America; Richard D. Clover, M.D., and Martin Mahoney, M.D., Ph.D., American Academy of Family Physicians; and Nancy J. Cox, Ph.D., Keiji Fukuda, M.D., Carolyn B. Bridges, M.D., Dennis J. O'Mara, and William W. Thompson, Ph.D., Centers for Disease Control and Prevention

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available from the Centers for Disease Control and Prevention (CDC) Web site:

- HTML Format

- Portable Document Format (PDF)

Print copies: Available from the Centers for Disease and Control Prevention, MMWR, Atlanta, GA 30333. Additional copies can be purchased from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402-9325; (202) 783-3238.

AVAILABILITY OF COMPANION DOCUMENTS

The following related guideline is available:

- Centers for Disease Control and Prevention. Prevention and control of influenza: recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR Recomm Rep 2003 Apr 25;52(RR-8):1-36.

PATIENT RESOURCES

None available

NGC STATUS

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