

Job Action Sheet: Medical Screener

Version: 11/12/2009

Position Summary

Will answer medical questions for those members of the public whose questions could not be answered by General Screeners. Will also be asked to assess persons who may have contraindications or precautions to vaccination based on initial screening responses.

Supervised by

Screener Leader

Qualifications

Currently or formerly licensed RN, LPN, MD, or DO who is well versed in principles of vaccination, and technical information regarding influenza vaccine types, indications, contraindications, precautions, risks and risk-benefit analysis.

Responsibilities

Prior to assigned clinic

1. Review this Job Action Sheet and the following references prior to your first shift.
 - a. [Overview of Mass Vaccination Clinic](#)
 - b. Vaccine Information Statements ([H1N1 Inactivated](#), [H1N1 Live/attenuated](#))
 - c. Screening questionnaires for [Inactivated](#) and [Live/attenuated](#) vaccines (vaccine recipients will fill out the [Registration Form](#) screening questions, not these questionnaires, but they are excellent reference documents.
 - d. Questions & Answers: 2009 H1N1 Nasal Spray Vaccine
http://www.cdc.gov/h1n1flu/vaccination/nasalspray_qa.htm
 - e. CDCs "[Top 10 Frequently Asked Questions on Use of Influenza H1N1 Vaccines](#)"
2. Other useful background information:
 - a. General Questions and Answers on Thimerosal
http://www.cdc.gov/h1n1flu/vaccination/thimerosal_qa.htm
 - b. General Questions and Answers on Guillain-Barré syndrome (GBS)
http://www.cdc.gov/h1n1flu/vaccination/gbs_qa.htm
 - c. CDCs "[2009 H1N1 Influenza Shots and Pregnant Women](#)"
 - d. [Use of Influenza A \(H1N1\) 2009 Monovalent Vaccine](#), MMWR 8/28/2009.
 - e. [Vaccine Formulations](#) that may be dispensed at clinics and their package inserts ([Afluria](#), [Fluvirin](#), [Fluzone](#), [FluMist](#)) and list of [Components in Vaccines](#).
 - f. Clinic Layout ([The Ranch](#), [Lincoln Middle School](#), [Thompson Valley High School](#))
 - g. [CDC H1N1 Vaccination web page](#)

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3. If unfamiliar with the Incident Command System consider reviewing the FEMA on-line training course ICS 100.a (<http://training.fema.gov/emiweb/is/is100a.asp>).
4. If you have to cancel or change your shift, contact Jen Ramsey at 530-2738. If you have questions about this Job Action Sheet, contact Bruce Cooper, MD, bcooper@healthdistrict.org.
5. Arrive at the clinic site on time. The first hour will include check-in and briefing by your supervisor.

During clinic

1. Receive on-site briefing from supervisor.
2. Interview persons referred to the Medical Consultation Area by the General Screeners and by Registration Clerks to establish suitability for vaccination today and determine if those who requested LAIV may receive it.
 - a. Persons indicating they are ill today will be referred to Medical Screening from Late Registration or from General Screening stations. Note: Since they will be triaged directly to you before completing screening, you will need to complete the entire screening process if you determine that they should be vaccinated today.
 - i. Recommend they wear a surgical mask while in clinic area if indicated.
 - ii. Evaluate illness history and triage to home, urgent/emergency care, or recommend that individual can receive vaccination today.
 - iii. If they are to be vaccinated today, complete the screening process as follows:
 1. Check that they have no contraindications (Registration Form Questions #1, 2 and 4 are marked "NO"). If any are marked "YES, inform them that they cannot be vaccinated in this setting. Note your recommendation on their registration form and save it to give to your supervisor.
 2. Note if the person to be vaccinated has listed any allergies in the "Allergies" field on Registration Form or if Question 2 is marked "YES". If yes, determine whether any of these are components of influenza vaccines (reference: [Components in Vaccines](#)). If listed allergies are not components of vaccine, write "Cleared for vaccination" in "Allergies" field on Registration Form and initial. If they list any component as an allergy, evaluate and recommend whether or not they can receive a vaccination in this clinic, and which vaccine product they can receive, in consultation with your supervisor. If uncertain, do not vaccinate and recommend they discuss with their personal physician. Document your

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recommendation on their registration form and save it to give to your supervisor.

3. If the first part of Question #14 is marked "YES", i.e., they want FluMist, review responses and confirm the individual may receive the live/attenuated vaccine.
 - a. To receive FluMist a person must meet the following criteria: age between 2 and 49 years, not pregnant (#6 marked "NA" or "NO"), healthy (#9-13 and for children #16 marked "NO"), received no live vaccine recently (no seasonal LAIV or other live vaccines e.g., MMR, Varicella in past 28 days) and no seasonal LAIV earlier today. Note: if doses of inactivated vaccine are in short supply, the incident commander may permit you to allow a shorter interval between seasonal and H1N1 FluMist. Your supervisor will inform you if this is the case.
 - b. If person to be vaccinated meets eligibility criteria, circle "Flu Mist" in the upper right margin of the registration form and initial it. If they have contraindications or otherwise do not meet criteria for FluMist, cross out "Flu Mist" in upper right corner, write "Shot" and initial. Mark a line through the "YES" next to Question #14, write "NO" in the margin and initial.
4. Document any exceptions you make to the standard contraindications or precautions to vaccination on "Special Cases" form. That will allow us to follow-up with patients or their primary care physicians if indicated.
5. Ask if they have read the VIS and if they have any questions after reading it. Answer their questions.
6. Have them read and sign the consent. Assure signed consent by parent/guardian for any person less than 18 years of age.
7. Give the patient's registration form to them and direct them to the appropriate line in the vaccination area. Families go to family lines, adults go to adult lines.
 - b. Determine suitability for LAIV for patients referred from General Screeners. Among those wanting FluMist, the General Screeners will refer the following to you: all parents of young children age 2-4 (issue: rule out recurrent wheezing illnesses), all persons who have received other vaccines in the past 30 days (issue: rule out recent live vaccine), and

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all those with other questions about LAIV to you. Follow procedure outlined in (a)(iii) above.

3. Answer technical questions from clients referred by General Screener. After you have answered questions to their satisfaction, check that screening process outlined in (a)(iii) above has been completed, complete it if not, and direct them to the appropriate line in the vaccination area.
4. Report any security/safety issues immediately to your supervisor or security staff. Document incidents appropriately.
5. Inform your supervisor if you need additional forms or other supplies.
6. Your supervisor will provide rest periods and relief for you and other staff.

After clinic

Return your vest, name badge and equipment or materials you were issued and check out at the staffing check-in/check-out area before leaving the clinic.

Patient name: _____ Date of birth: ____/____/____
 (mo.) (day) (yr.)

Screening Questionnaire for Injectable Influenza Vaccination

For adult patients as well as parents of children to be vaccinated: The following questions will help us determine if there is any reason we should not give you or your child injectable influenza vaccination today. If you answer “yes” to any question, it does not necessarily mean you (or your child) should not be vaccinated. It just means additional questions must be asked. If a question is not clear, please ask your healthcare provider to explain it.

	Yes	No	Don't Know
1. Is the person to be vaccinated sick today?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Does the person to be vaccinated have an allergy to eggs or to a component of the vaccine?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Has the person to be vaccinated ever had a serious reaction to influenza vaccine in the past?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Has the person to be vaccinated ever had Guillain-Barré syndrome?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Form completed by: _____ Date: _____

Form reviewed by: _____ Date: _____

Information for Health Professionals about the Screening Questionnaire for Injectable Influenza Vaccination

Are you interested in knowing why we included a certain question on the Screening Questionnaire? If so, read the information below. If you want to find out even more, consult the sources listed at the bottom of this page.

1. Is the person to be vaccinated sick today?

There is no evidence that acute illness reduces vaccine efficacy or increases vaccine adverse events. Persons with an acute febrile illness usually should not be vaccinated until their symptoms have improved. Minor illnesses with or without fever do not contraindicate use of influenza vaccine. Do not withhold vaccination if a person is taking antibiotics.

2. Does the person to be vaccinated have an allergy to eggs or to a component of the vaccine?

Allergic reactions to any vaccine component can occur. The majority of reactions probably are caused by residual egg protein. Although current influenza vaccines contain only a limited quantity of egg protein, this protein can induce immediate allergic reactions among persons who have severe egg allergy. If a person can eat eggs, they can receive inactivated influenza vaccine. However, persons who have experienced an anaphylactic reaction (e.g., hives, swelling of the lips or tongue, acute respiratory distress, or collapse) after eating eggs should consult a physician for appropriate evaluation to help determine if vaccine should be administered. Persons who have documented immunoglobulin E (IgE)-mediated hypersensitivity to eggs, including those who have had occupational asthma or other allergic responses to egg protein, might also be at increased risk for allergic reactions to influenza vaccine. Consultation with a physician should be considered. Protocols have been published for safely administering influenza vaccine to persons with egg allergies (see source 3).

FluZone (sanofi pasteur) contains gelatin as a stabilizer; therefore a history of anaphylactic reaction to gelatin is a contraindication. Some inactivated influenza vaccines contain thimerosal as a preservative. Most persons with sensitivity to thimerosal, such as that found in contact lens solution, do not experience reactions to thimerosal administered as a component of vaccines. Check the package insert at www.immunize.org/packageinserts for a list of the vaccine components (i.e., excipients and

culture media) used in the production of the vaccine, or go to www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf.

3. Has the person to be vaccinated ever had a serious reaction to influenza vaccine in the past?

Patients reporting a serious reaction to a previous dose of inactivated influenza vaccine should be asked to describe their symptoms. Immediate—presumably allergic—reactions are usually a contraindication to further vaccination against influenza.

Fever, malaise, myalgia, and other systemic symptoms most often affect persons who are first-time vaccinees. These mild-to-moderate local reactions are not a contraindication to future vaccination. Also, red eyes or mild upper facial swelling following vaccination with inactivated injectable influenza vaccine is most likely a coincidental event and not related to the vaccine; these persons can receive injectable vaccine without further evaluation.

4. Has the person to be vaccinated ever had Guillain-Barré syndrome?

It is prudent to avoid vaccinating persons who are not at high risk for severe influenza complications but who are known to have developed Guillain-Barré syndrome (GBS) within 6 weeks after receiving a previous influenza vaccination. As an alternative, physicians might consider using influenza antiviral chemoprophylaxis for these persons. Although data are limited, the established benefits of influenza vaccination for the majority of persons who have a history of GBS, and who are at high risk for severe complications from influenza, justify yearly vaccination.

Sources:

1. CDC. *Epidemiology & Prevention of Vaccine-Preventable Diseases*, WL Atkinson et al., editors, at www.cdc.gov/vaccines/pubs/pinkbook.
2. CDC. "General Recommendations on Immunization: Recommendations of the Advisory Committee on Immunization Practices (ACIP)" at www.cdc.gov/vaccines/pubs/ACIP-list.htm.
3. CDC. "Prevention and Control of Influenza—Recommendations of ACIP" at www.cdc.gov/flu/professionals/vaccination.

2009 H1N1 INFLUENZA VACCINE

INACTIVATED (the “flu shot”)

WHAT YOU NEED TO KNOW

Many Vaccine Information Statements are available in Spanish and other languages. See <http://www.immunize.org/vis>.

1 What is 2009 H1N1 influenza?

2009 H1N1 influenza (also called Swine Flu) is caused by a new strain of influenza virus. It has spread to many countries.

Like other flu viruses, 2009 H1N1 spreads from person to person through coughing, sneezing, and sometimes through touching objects contaminated with the virus.

Signs of 2009 H1N1 can include:

- Fatigue
- Fever
- Sore Throat
- Muscle Aches
- Chills
- Coughing
- Sneezing

Some people also have diarrhea and vomiting.

Most people feel better within a week. But some people get pneumonia or other serious illnesses. Some people have to be hospitalized and some die.

2 How is 2009 H1N1 different from regular (seasonal) flu?

Seasonal flu viruses change from year to year, but they are closely related to each other.

People who have had flu infections in the past usually have some immunity to seasonal flu viruses (their bodies have built up some ability to fight off the viruses).

The 2009 H1N1 flu is a new flu virus. It is very different from seasonal flu viruses.

Most people have little or no immunity to 2009 H1N1 flu (their bodies are not prepared to fight off the virus).

3 2009 H1N1 influenza vaccine

Vaccines are available to protect against 2009 H1N1 influenza.

- These vaccines are made just like seasonal flu vaccines.
- They are expected to be as safe and effective as seasonal flu vaccines.
- They will not prevent “influenza-like” illnesses caused by other viruses.
- They will not prevent seasonal flu. *You should also get seasonal influenza vaccine, if you want to be protected against seasonal flu.*

Inactivated vaccine (vaccine that has killed virus in it) is injected into the muscle, like the annual flu shot. **This sheet describes the inactivated vaccine.**

A **live, intranasal** vaccine (the nasal spray vaccine) is also available. It is described in a separate sheet.

Some inactivated 2009 H1N1 vaccine contains a preservative called thimerosal to keep it free from germs. Some people have suggested that thimerosal might be related to autism. In 2004 a group of experts at the Institute of Medicine reviewed many studies looking into this theory, and found no association between thimerosal and autism. Additional studies since then reached the same conclusion.

4 Who should get 2009 H1N1 influenza vaccine and when?

WHO

Groups recommended to receive 2009 H1N1 vaccine first are:

- Pregnant women
- People who live with or care for infants younger than 6 months of age
- Health care and emergency medical personnel
- Anyone from 6 months through 24 years of age
- Anyone from 25 through 64 years of age with certain chronic medical conditions or a weakened immune system

As more vaccine becomes available, these groups should also be vaccinated:

- Healthy 25 through 64 year olds
- Adults 65 years and older

The Federal government is providing this vaccine for receipt on a voluntary basis. However, state law or employers may require vaccination for certain persons.

WHEN

Get vaccinated as soon as the vaccine is available.

Children through 9 years of age should get **two doses** of vaccine, about a month apart. Older children and adults need only one dose.

5 Some people should not get the vaccine or should wait

You should not get 2009 H1N1 flu vaccine if you have a **severe (life-threatening) allergy to eggs**, or to **any other substance in the vaccine**. *Tell the person giving you the vaccine if you have any severe allergies.*

Also tell them if you have ever had:

- a life-threatening allergic reaction after a dose of seasonal flu vaccine,
- Guillain Barré Syndrome (a severe paralytic illness also called GBS).

These may not be reasons to avoid the vaccine, but the medical staff can help you decide.

If you are moderately or severely ill, you might be advised to wait until you recover before getting the vaccine. If you have a mild cold or other illness, there is usually no need to wait.

Pregnant or breastfeeding women can get inactivated 2009 H1N1 flu vaccine.

Inactivated 2009 H1N1 vaccine may be given at the same time as other vaccines, including seasonal influenza vaccine.

6 What are the risks from 2009 H1N1 influenza vaccine?

A vaccine, like any medicine, could cause a serious problem, such as a severe allergic reaction. But the risk of any vaccine causing serious harm, or death, is extremely small.

The virus in inactivated 2009 H1N1 vaccine has been killed, so you cannot get influenza from the vaccine.

The risks from inactivated 2009 H1N1 vaccine are similar to those from seasonal inactivated flu vaccine:

Mild problems:

- soreness, redness, tenderness, or swelling where the shot was given
- fainting (mainly adolescents)
- headache, muscle aches
- fever
- nausea

If these problems occur, they usually begin soon after the shot and last 1-2 days.

Severe problems:

- Life-threatening allergic reactions to vaccines are very rare. If they do occur, it is usually within a few minutes to a few hours after the shot.
- In 1976, an earlier type of swine flu vaccine was associated with cases of Guillain-Barré Syndrome (GBS). Since then, flu vaccines have not been clearly linked to GBS.

7 What if there is a severe reaction?

What should I look for?

Any unusual condition, such as a high fever or behavior changes. Signs of a severe allergic reaction can include difficulty breathing, hoarseness or wheezing, hives, paleness, weakness, a fast heart beat or dizziness.

What should I do?

- **Call** a doctor, or get the person to a doctor right away.
- **Tell** the doctor what happened, the date and time it happened, and when the vaccination was given.
- **Ask** your provider to report the reaction by filing a Vaccine Adverse Event Reporting System (VAERS) form. Or you can file this report through the VAERS website at <http://www.vaers.hhs.gov>, or by calling **1-800-822-7967**.

VAERS does not provide medical advice.

8 Vaccine injury compensation

If you or your child has a reaction to the vaccine, your ability to sue is limited by law.

However, a federal program has been created to help pay for the medical care and other specific expenses of certain persons who have a serious reaction to this vaccine. For more information about this program, call **1-888-275-4772** or visit the program's website at: <http://www.hrsa.gov/countermeasurescomp/default.htm>.

9 How can I learn more?

- Ask your provider. They can give you the vaccine package insert or suggest other sources of information.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
 - Call **1-800-232-4636 (1-800-CDC-INFO)** or
 - Visit CDC's website at <http://www.cdc.gov/h1n1flu> or <http://www.cdc.gov/flu>
- Visit the web at <http://www.flu.gov>



DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION



Patient name: _____ Date of birth: ____/____/____
 (mo.) (day) (yr.)

Screening Questionnaire for Intranasal Influenza Vaccination

For adult patients as well as parents of children to be vaccinated: The following questions will help us determine if there is any reason we should not give you or your child intranasal influenza vaccine (FluMist) today. If you answer “yes” to any question, it does not necessarily mean you (or your child) should not be vaccinated. It just means additional questions must be asked. If a question is not clear, please ask your healthcare provider to explain it.

	Yes	No	Don't Know
1. Is the person to be vaccinated sick today?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Does the person to be vaccinated have an allergy to eggs or to a component of the influenza vaccine?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Has the person to be vaccinated ever had a serious reaction to intranasal influenza vaccine (FluMist) in the past?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Is the person to be vaccinated younger than age 2 years or older than age 49 years?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Does the person to be vaccinated have a long-term health problem with heart disease, lung disease, asthma, kidney disease, neurologic or neuromuscular disease, liver disease, metabolic disease (e.g., diabetes), or anemia or another blood disorder?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. If the person to be vaccinated is a child age 2 through 4 years, in the past 12 months, has a healthcare provider ever told you that he or she had wheezing or asthma?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Does the person to be vaccinated have a weakened immune system because of HIV/AIDS or another disease that affects the immune system, long-term treatment with drugs such as high-dose steroids, or cancer treatment with radiation or drugs?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Is the child or teen to be vaccinated receiving aspirin therapy or aspirin-containing therapy?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. Is the person to be vaccinated pregnant or could she become pregnant within the next month?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. Has the person to be vaccinated ever had Guillain-Barré syndrome?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. Does the person to be vaccinated live with or expect to have close contact with a person whose immune system is severely compromised and who must be in a protective isolation (such as in a hospital room with reverse air flow)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. Has the person to be vaccinated received any other vaccinations in the past 4 weeks?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Form completed by: _____ Date: _____
 Form reviewed by: _____ Date: _____

Technical content reviewed by the Centers for Disease Control and Prevention, September 2009. www.immunize.org/catg.d/p4067.pdf • Item #P4067 (9/09)

Information for Health Professionals about the Screening Questionnaire for Intranasal Influenza Vaccination

Are you interested in knowing why we included a certain question on the Screening Questionnaire? If so, read the information below. If you want to find out even more, consult the sources listed at the bottom of this page.

1. Is the person to be vaccinated sick today?

There is no evidence that acute illness reduces vaccine efficacy or increases vaccine adverse events. Persons with an acute febrile illness usually should not be vaccinated until their symptoms have improved. Minor illnesses with or without fever do not contraindicate use of influenza vaccine. Do not withhold vaccination if a person is taking antibiotics.

2. Does the person to be vaccinated have an allergy to eggs or to a component of the influenza vaccine?

History of anaphylactic reaction—such as hives, wheezing, or difficulty breathing, or circulatory collapse or shock (not fainting)—after eating eggs or receiving any component of the intranasal live attenuated influenza vaccine (LAIV, tradename FluMist) is usually a contraindication for further doses. Check the package insert (at www.immunize.org/packageinserts) for a list of the vaccine components (i.e., excipients and culture media) used in the production of the vaccine, or go to www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/b/excipient-table-2.pdf.

3. Has the person to be vaccinated ever had a serious reaction to intranasal influenza vaccine (FluMist) in the past?

Patients reporting a serious reaction to a previous dose of LAIV should be asked to describe their symptoms. Immediate—presumably allergic—reactions are usually a contraindication to further vaccination with LAIV.

4. Is the person to be vaccinated younger than age 2 years or older than age 49 years?

LAIV is not licensed for use in persons younger than age 2 years or older than age 49 years.

5. Does the person to be vaccinated have a long-term health problem with heart disease, lung disease, asthma, kidney disease, neurologic or neuromuscular disease, liver disease, metabolic disease (e.g., diabetes), or anemia or another blood disorder?

Persons with any of these health conditions should not be given the LAIV. Instead, they should be vaccinated with the inactivated injectable influenza vaccine.

6. If the person to be vaccinated is a child age 2 through 4 years, in the past 12 months, has a healthcare provider ever told you that he or she had wheezing or asthma?

LAIV is not recommended for a child this age if their parent or guardian answers yes to this question or if the child has a history of asthma or recurrent wheezing. Instead, they should be given the inactivated injectable influenza vaccine.

7. Does the person to be vaccinated have a weakened immune system because of HIV/AIDS or another disease that affects the immune system, long-term treatment with drugs such as high-dose steroids, or cancer treatment with radiation or drugs?

Persons with weakened immune systems should not be given the LAIV. Instead, they should be given the inactivated injectable influenza vaccine.

8. Is the child or teen to be vaccinated receiving aspirin therapy or aspirin-containing therapy?

Because of the theoretical risk of Reye's syndrome, children and teens on aspirin therapy should not be given LAIV. Instead they should be vaccinated with the inactivated injectable influenza vaccine.

9. Is the person to be vaccinated pregnant or could she become pregnant within the next month?

Pregnant women or women planning to become pregnant within a month should not be given LAIV. All pregnant women should, however, be vaccinated with the inactivated injectable influenza vaccine.

10. Has the person to be vaccinated ever had Guillain-Barré syndrome?

It is prudent to avoid vaccinating persons who are not at high risk for severe influenza complications but who are known to have developed Guillain-Barre syndrome (GBS) within 6 weeks after receiving a previous influenza vaccination. As an alternative, physicians might consider using influenza antiviral chemoprophylaxis for these persons. Although data are limited, the established benefits of influenza vaccination for the majority of persons who have a history of GBS, and who are at high risk for severe complications from influenza, justify yearly vaccination.

11. Does the person to be vaccinated live with or expect to have close contact with a person whose immune system is severely compromised and who must be in a protective isolation (such as in a hospital room with reverse air flow)?

Inactivated injectable influenza vaccine is preferred for persons who have close contact with severely immunosuppressed persons during periods in which the immunosuppressed person requires care in protective isolation (e.g., an isolation room of a bone marrow transplant unit). Either the inactivated injectable influenza vaccine or LAIV may be used in persons who have close contact with persons having lesser degrees of immunosuppression.

12. Has the person to be vaccinated received any other vaccinations in the past 4 weeks?

Persons who were given an injectable live virus vaccine (e.g., MMR, MMRV, varicella, yellow fever) in the past 4 weeks should wait 28 days before receiving LAIV. Separate the seasonal LAIV and H1N1 LAIV vaccines by at least 4 weeks because of concerns about competition between the 2 vaccine viruses. There is no reason to defer giving LAIV if persons were vaccinated with an inactivated vaccine or if they have recently received blood or other antibody-containing blood products (e.g., IG).

Sources:

1. CDC. *Epidemiology & Prevention of Vaccine-Preventable Diseases*, WL Atkinson et al., editors, at www.cdc.gov/vaccines/pubs/pinkbook.
2. CDC. "General Recommendations on Immunization: Recommendations of the Advisory Committee on Immunization Practices (ACIP)" at www.cdc.gov/vaccines/pubs/ACIP-list.htm.
3. CDC. "Prevention and Control of Influenza—Recommendations of ACIP" at www.cdc.gov/flu/professionals/vaccination.



You MUST bring this form to the clinic. Location: _____ Date _____ Time _____

Larimer County Health Dept. - H1N1 Influenza Vaccine Consent Form

First Name:	Last Name:	Age:	Date of Birth:
E-mail:		Phone #:	
Medicaid #: (if on Medicaid)		Allergies:	

Check The Box That Applies:

- 1. Has this person ever had an allergic reaction to eggs? NO YES
 - 2. Has this person ever had an allergic reaction to Thimerosal? NO YES
 - 3. Has this person ever had an allergic reaction to a flu shot? NO YES
 - 4. Does this person have a history of Guillain-Barré Syndrome? NO YES
 - 5. Does this person live with or care for a child under 6 months of age? NO YES
 - 6. Is this person pregnant? Not Applicable NO YES
 - 7. Is this person a health care worker? NO YES
 - 8. Is this person an emergency medical services (EMS) worker? NO YES
 - 9. Does this person have heart disease or stroke (except high blood pressure)? NO YES
 - 10. Does this person have a chronic health condition such as asthma, diabetes, or kidney disease? NO YES
 - 11. Does this person have a neuromuscular or neurological condition such as multiple sclerosis, seizure disorder, epilepsy, cerebral palsy, etc ? NO YES
 - 12. Does this person have a condition that weakens the immune system, such as cancer or HIV? NO YES
 - 13. Does this person have a blood disorder such as sickle cell anemia? NO YES
 - 14. Does this person want the nasal spray flu vaccine? (For healthy people age 2- 49 years of age. Note that nasal spray vaccine may be restricted or unavailable). NO YES
- If yes, has this person received any other vaccines in the last 30 days? NO YES
Date vaccine was received: _____

FOR CHILDREN ONLY:

- 15. Has this child already received a first dose of H1N1 (swine) flu vaccine? NO YES
Date: _____ Shot Nasal Spray
- 16. Is this child on long term aspirin therapy? NO YES

TO BE COMPLETED THE DAY OF THE CLINIC:

- 17. Are you feeling ill today? NO YES

I have read or had explained to me the information on the vaccine information statement form about influenza and influenza vaccine. I have had a chance to ask questions which were answered to my satisfaction. I believe I understand the benefits and risks of influenza vaccine and request that the vaccine be given to me or to the person named above for whom I am authorized to make this request.

I have reviewed and agree to the LCDHE consent for the purposes of treatment, payment and health care operations.

Signature:	Date:
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DO NOT WRITE BELOW THIS LINE

Manufacturer/Lot #:	Site: RT LT RA LA Nasal	Dose: 0.25cc I.M. 0.50cc I.M. 0.1cc/nostril	Date: ____/____/____ Vaccinator Signature:
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Instructions for “Larimer Fights the Flu” clinics

- Adults and children getting shots - please wear a short sleeve shirt as your bottom clothing layer or a shirt with sleeves that can be easily rolled up above the shoulder. Infants and toddlers should wear something that gives easy access to their upper thigh.
- Please eat something before you come to the clinic. People who haven't eaten all day are more likely to feel faint when they get a shot.
- The document you printed out when you registered and/or that was e-mailed to you is your “ticket” to the vaccination clinic and consent form.
- You must bring your printed pre-registration ticket with you to be admitted to the clinic. If you were unable to print your pre-registration form you must have your registration confirmation ID number (on the top of the form to the right of the “zebra-stripe” code.) Adults should bring driver's license or photo ID with proof of residence in Larimer County. Health care workers in Larimer county, please bring work ID.
- Please arrive during the 15-minute appointment period specified on your pre-registration ticket. **DO NOT COME EARLY.** If you come at another time we may not be able to admit you into the clinic.
- Children under 18 must have a **parent or guardian** sign the consent in order to be vaccinated. Other adults or relatives may not give consent for a child under 18.
- Children/adolescents under 18 must be accompanied by a responsible adult.
- If you or your child has received any other immunizations in the past 30 days please bring your/ your child's immunization record to the clinic.
- If you are ill with flu like symptoms please stay home. These clinics are for H1N1 vaccinations only. There will be no medical care available for people with flu like illness.

Note that these flu vaccines are made by several different companies, and approved for several different age ranges. There is a chance that the vaccination clinic may not have the type of vaccine preferred or required for you or your child at your appointment date and time.

We'll do our best to give you your preferred option, but it's possible that the right vaccine type for each situation may not be available for every appointment slot. We have no control over which vaccines we receive, nor which vaccines the people seen earlier in the day will need.

Please accept our sincere apologies if we are unable to vaccinate you.

Components in 2009 H1N1 Influenza Vaccines

	<i>Fluvirin</i> TM (Novartis)	<i>Fluzone</i> TM (Sanofi Pasteur)	<i>Afluria</i> TM (CSL Biologics)	<i>FluMist</i> TM (Med- Immune)
Arginine				X
Betapropiolactone	X		X	
Egg proteins	X	X	X	X
Formaldehyde		X		
Gelatin		X		X
Gentamicin				X
Neomycin	X		X	
Nonylphenol ethoxylate	X			
Polymyxin	X		X	
Sodium taurodeoxycholate			X	
Thimerosal	X [†]	X*	X*	
Triton X-100 TM		X		

[†]The Thimerosal-reduced formulation in pre-filled syringes contains trace amounts of Thimerosal (<1 mcg)

*Available as a Thimerosal-free formulation in pre-filled syringes



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QUESTIONS & ANSWERS

2009 H1N1 Influenza Vaccine

November 5, 2009, 10:30 AM ET

2009 H1N1 Recommendations

Who will be recommended to receive the 2009 H1N1 vaccine?

CDC's Advisory Committee on Immunization Practices (ACIP) recommends that certain groups of the population receive the 2009 H1N1 vaccine first. These target groups include pregnant women, people who live with or care for children younger than 6 months of age, healthcare and emergency medical services personnel, persons between the ages of 6 months and 24 years old, and people ages of 25 through 64 years of age who are at higher risk for 2009 H1N1 because of chronic health disorders or compromised immune systems.

The Advisory Committee on Immunization Practices (ACIP) has issued separate recommendations on [Who Should Get Vaccinated Against Seasonal Flu](#).

Vaccine to protect against the 2009 H1N1 flu virus is available; however, initial supplies are limited. The Advisory Committee on Immunization Practices (ACIP) has recommended that the following groups receive the vaccine before others: pregnant women, people who live with or care for children younger than 6 months of age, health care and emergency medical services personnel with direct patient contact, children 6 months through 4 years of age, and children, especially those younger than 5 years of age and those who have high risk medical conditions are at increased risk of influenza-related complications. For a more detailed description of children at highest risk, read [Children with Developmental Disabilities and Chronic Medical Conditions](#)

The committee recognized the need to assess supply and demand issues at the local level. The committee further recommended that once the demand for vaccine for these target groups has been met at the local level, programs and providers should begin vaccinating everyone from ages 25 through 64 years. Current studies indicate the risk for infection among persons age 65 or older is less than the risk for younger age groups. Therefore, as vaccine supply and demand for vaccine among younger age groups is being met, programs and providers should offer vaccination to people over the age of 65.

Will two doses of vaccine be required?

The U.S. Food and Drug Administration (FDA) has approved the use of one dose of 2009 H1N1 flu vaccine for persons 10 years of age and older. This is slightly different from CDC's recommendations for seasonal influenza vaccination which states that children younger than 9 who are being vaccinated against influenza for the first time need to receive two doses. Infants younger than 6 months of age are too young to get the 2009 H1N1 and seasonal flu vaccines.

What will be the recommended interval between the first and second

dose for children 9 years of age and under?

CDC recommends that the two doses of 2009 H1N1 vaccine be separated by 4 weeks. However, if the second dose is separated from the first dose by at least 21 days, the second dose can be considered valid.

Do those that have been previously vaccinated against the 1976 swine influenza need to get vaccinated against the 2009 H1N1 influenza?

The 1976 swine flu virus and the 2009 H1N1 virus are different enough that it's unlikely a person vaccinated in 1976 will have full protection from the 2009 H1N1. People vaccinated in 1976 should still be given the 2009 H1N1 vaccine.

Can people who are allergic to eggs receive the 2009 H1N1 flu vaccine?

People who are allergic to eggs might be at risk for allergic reactions from receiving influenza vaccines, including the 2009 H1N1 vaccine. People who have had any of the following symptoms or experiences should consult with a doctor or other medical professional before considering any influenza vaccination:

- hives or swelling of the lips or tongue
- acute respiratory distress (trouble breathing) after eating eggs
- documented hypersensitivity to eggs, including those who have had asthma related to egg exposure at their workplace or other allergic responses to egg protein

Because children with severe asthma are at high risk of serious complications from influenza, a regimen has been developed for giving influenza vaccine to children with severe asthma and egg hypersensitivity.

Supply and Distribution

How do project areas know how much vaccine is available for them to order?

CDC sends project areas a weekly 2009 H1N1 allocation report each morning as it does for seasonal influenza vaccine. The report indicates how much of each formulation of 2009 H1N1 vaccine is available for them to order.

What is the number of doses “allocated” for ordering?

The number of doses "allocated" for ordering is the amount that is at the distribution depots and ready for states to order. The quantity of vaccine allocated is based on the project area's population size. As an example, if 6 million doses total (3 million doses of nasal spray vaccine AND 3 million doses of injectable vaccine) are ready for ordering nationally (as of today) and a state has 10% of the US population, then their allocation for today is 600,000 doses total (300,000 doses of the nasal spray vaccine and 300,000 doses of injectable vaccine).

How is vaccine shipped to project areas?

CDC's contractor for centralized distribution ships vaccine to hospitals, clinics, doctor's offices,

health departments, and other providers of vaccines that have been designated as vaccine-receiving sites by the Project Area (the project areas include all 50 states, the District of Columbia, 8 US Territories and freely associated states, and 3 large metropolitan health departments).

What kind of providers can be designated as vaccine recipients?

Providers that have the capability to receive, store and administer vaccine, including but not limited to provider offices, occupational health clinics, hospitals, local health departments, community vaccinators and pharmacies.

How many sites can a jurisdiction designate to receive vaccine?

There is a maximum of 150,000 sites to which vaccine can be shipped via centralized distribution. Project areas have received information about their allocation of sites.

What should project areas expect with respect to frequency of vaccine shipments?

Vaccine will be shipped as it becomes available, taking into account state allocations and orders. The process is modeled after that utilized by immunization programs to order seasonal influenza vaccine off the federal contract. Details about CDC's ordering/allocation process for seasonal influenza are described in the all-grantee message sent to immunization program grantees on 8/11/2009 (Grantee message for allocation).

What is the minimum dose order for shipments of 2009 H1N1 vaccine?

For each vaccine formulation (identified by its National Drug Code) the minimum dose order is 100 doses and all orders must be placed in increments of 100 doses. Each ancillary supply kit contains supplies to support 100 doses of vaccine, with different kits available for prefilled syringe products and for multi-dose vial products.

When and how much of the 2009 H1N1 vaccine will be available?

Both the flu shot (in the arm) and nasal spray form of 2009 H1N1 vaccines have now been produced and licensed by the Food and Drug Administration. The federal government has purchased a total of 250 million doses of 2009 H1N1 vaccine. The 2009 H1N1 vaccine first became available in early October and more doses are becoming available every week. Vaccine availability, however, depends on many factors so these numbers will be frequently updated. The first doses of live attenuated 2009 H1N1 flu vaccine were administered on October 5, 2009. Administration of the 2009 H1N1 flu shot began the week of October 12.

Will there be enough 2009 H1N1 flu vaccine for everyone who wants it?

It is expected that there will be enough 2009 H1N1 flu vaccine for anyone who chooses to get vaccinated. The US federal government has procured 250 million doses of 2009 H1N1 flu vaccine. This quantity of vaccine accounts for the National Institutes of Health (NIH) clinical trial data showing that children 6 months to 9 years of age will need two doses and persons 10 and older will need one dose. Limited amounts of 2009 H1N1 vaccine became available in early October, and more will continue to become available over the upcoming weeks.

Where will the vaccine be available?

Every state is developing a vaccine delivery plan. Vaccine will be available in a combination of settings such as vaccination clinics organized by local health departments, healthcare provider offices, schools, and other private settings, such as pharmacies and workplaces. For more information, see [State/Jurisdiction Contact Information for Health Care Providers Interested in Providing H1N1 Vaccine](#).

For information on seasonal vaccine supply and distribution, visit [Seasonal Influenza Vaccine Supply for the U.S. 2009-2010 Influenza Season](#).

Seasonal and H1N1 Vaccine

Will the seasonal flu vaccine also protect against the 2009 H1N1 flu?

The seasonal flu vaccine will not protect you against 2009 H1N1 flu. For more information about the seasonal flu vaccine, read [Key Facts About Seasonal Flu Vaccine](#).

Will this vaccine be made differently than the seasonal influenza vaccine?

No. This vaccine will be made using the same processes and facilities that are used to make the currently licensed seasonal influenza vaccines.

Can the seasonal vaccine and the 2009 H1N1 vaccine be given at the same time?

Inactivated 2009 H1N1 vaccine can be administered at the same visit as any other vaccine, including pneumococcal polysaccharide vaccine. Live 2009 H1N1 vaccine can be administered at the same visit as any other live or inactivated vaccine EXCEPT seasonal live attenuated influenza vaccine.

Prior Illness

Should I get vaccinated against 2009 H1N1 if I have had flu-like illness since the Spring of 2009?

The symptoms of influenza (flu-like illnesses) are similar to those caused by many other viruses. Even when influenza viruses are causing large numbers of people to get sick, other viruses are also causing illnesses. Specific testing, called “RT-PCR test,” is needed in order to tell if an illness is caused by a specific influenza strain or by some other virus. This test is different from rapid flu tests that doctors can do in their offices. Since most people with flu-like illnesses will not be tested with RT-PCR this season, the majority will not know whether they have been infected with 2009 H1N1 flu or a different virus.

Therefore, if you were ill but do not know if you had 2009 H1N1 infection, you should get vaccinated, if your doctor recommends it. So, most people recommended for 2009 H1N1 vaccination should be vaccinated with the 2009 H1N1 vaccine regardless of whether they had a flu-like illness earlier in the year. If you have had 2009 H1N1 flu, as confirmed by an RT-PCR test, you should have some immunity against 2009 H1N1 flu and can choose not to get the

2009 H1N1 vaccine. However, vaccination of a person with some existing immunity to the 2009 H1N1 virus will not be harmful. For more information on flu tests, see [Influenza Diagnostic Testing During the 2009-2010 Flu Season](#).

Any immunity from 2009 H1N1 influenza infection or vaccination will not provide protection against seasonal influenza. All people who want protection from seasonal flu should still get their seasonal influenza vaccine.

Prevention

Are there other ways to prevent the spread of illness?

Take everyday actions to stay healthy.

Cover your nose and mouth with a tissue when you cough or sneeze. Throw the tissue in the trash after you use it.

Wash your hands often with soap and water, especially after you cough or sneeze. If soap and water are not available, use an alcohol-based hand rub.*

Avoid touching your eyes, nose or mouth. Germs spread that way.

Stay home if you get sick. CDC recommends that you stay home from work or school and limit contact with others to keep from infecting them.


Follow public health advice regarding school closures, avoiding crowds and other social distancing measures. These measures will continue to be important after a 2009 H1N1 vaccine is available because they can prevent the spread of other viruses that cause respiratory infections.

What about the use of antivirals to treat 2009 H1N1 infection?

CDC has issued [interim guidance for the use of antiviral drugs](#) for this season. CDC also has published [Questions & Answers related to the use of antiviral drugs](#) for this season.

Are natural remedies (also referred to as “complementary” or “alternative” medicine) recommended to prevent the 2009 H1N1 flu virus?

The first and most important step to prevent the flu is to get vaccinated. Vaccination stimulates an immune response using a killed or weakened virus that uses the body’s own defense mechanisms to prevent infection. CDC's current recommendations to protect against 2009 H1N1 virus do not include natural remedies as a sole prevention method. If you want to use a natural remedy to reduce symptoms, CDC recommends that you talk to your healthcare provider about options.

Alternative medicine should not be used as a replacement for proven conventional care, or to postpone seeing a doctor about a medical problem. The National Institutes of Health (NIH) provides information at <http://health.nih.gov/topic/AlternativeMedicine>  on specific alternative options, including scientific information, potential side effects, and cautions for each.

The Federal Trade Commission (FTC) warns consumers to be cautious about products that claim to prevent, treat, or cure 2009 H1N1 influenza, specifically products like pills, air filtration devices, and cleaning agents can kill or eliminate the virus.

Canadian Study Reponse

I heard that getting a seasonal flu vaccine increases a person's chances of getting the 2009 H1N1 flu virus. Is this true?

CDC has reviewed data from studies done in the United States, and these studies along with a published study from Australia found that receipt of seasonal influenza vaccine neither increased nor decreased the risk of getting 2009 H1N1 influenza. In contrast, a small published study from Mexico found that seasonal vaccine provided some protection against 2009 H1N1. There has been recent media coverage about research conducted in Canada that suggests getting a season flu vaccination increases a person's chances for becoming infected with the 2009 H1N1 flu virus. No other country has reported that seasonal vaccine has any positive or negative effect on the risk of getting 2009 H1N1 influenza. CDC is continuing to review the data as it becomes available.

Should I still get a seasonal flu vaccination?

All influenza viruses may cause serious illness and vaccination is the first and most important step in protecting against flu. CDC recommends seasonal flu vaccination for anyone who wants to reduce their chances of getting seasonal flu.

What groups are recommended for seasonal flu vaccine?

Vaccination is particularly important for people who are at high risk of having serious seasonal flu-related complications or people who live with or care for those at high risk for serious seasonal flu-related complications, including:

- Children aged 6 months up to their 19th birthday
- Pregnant women
- People 50 years of age and older
- People of any age with certain chronic medical conditions
- People who live in nursing homes and other long-term care facilities
- People who live with or care for those at high risk for complications from flu, including:
 - Health care workers
 - Household contacts of persons at high risk for complications from the flu
 - Household contacts and out of home caregivers of children less than 6 months of age (these children are too young to be vaccinated)

Additional information on the Canadian studies can be found at <http://www.cdc.gov/media/pressrel/2009/s091007.htm>

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Questions & Answers: 2009 H1N1 Nasal Spray Vaccine

October 7, 2009, 6:30 PM ET

Influenza A (H1N1) Monovalent Nasal-Spray Flu Vaccine (Live Attenuated Influenza Vaccine [LAIV])

What is the nasal spray flu vaccine?

What is the nasal spray flu vaccine? There are two types of flu vaccine: the flu shot and the nasal spray vaccine. Both types of vaccine are being made against 2009 H1N1. The nasal spray flu vaccine (sometimes called LAIV for Live Attenuated Influenza Vaccine) is a vaccine made with live, weakened viruses that cannot grow at normal body temperature and is given via a nasal sprayer. This vaccine was approved for seasonal influenza viruses in 2003 and tens of millions of doses of the vaccine have been given in the United States.

How is the 2009 H1N1 nasal spray vaccine different from the seasonal nasal spray vaccine?

The 2009 H1N1 nasal spray vaccine is being made in the same way as the seasonal nasal spray vaccine, but instead of containing three weakened live flu viruses, it only contains weakened 2009 H1N1 virus. (That is why it's called a "monovalent" vaccine.). The recommendations for who can get the 2009 H1N1 nasal spray vaccine are the same as for seasonal nasal spray vaccine. LAIV is recommended for use in healthy* people 2 years to 49 years of age who are not pregnant.

Who can be vaccinated with the 2009 H1N1 nasal-spray flu vaccine (LAIV)?

The 2009 H1N1 nasal spray vaccine is recommended for use in healthy people 2 years Through 49 years of age who are not pregnant. See below

Can health care providers get the live attenuated influenza vaccine?

Yes. LAIV is a very good option for most health care providers who are healthy, younger than 50 years old, and not pregnant. However, health care providers should not get LAIV if they are providing medical care for patients who require special environments in the hospital because they are profoundly immunocompromised (e.g., those who work in bone marrow transplant units). Although no immunocompromised patient has been shown to be harmed by use of LAIV among health care workers, the recommendation against the use of LAIV in health care workers with this type of patient contact is intended as an extra precaution for fragile

immunocompromised patients. Health care workers with this type of patient contact can get LAIV, but if they do, they should wait 7 days after being vaccinated before returning to duties that include care of severely immunocompromised patients in special environments.

Can health care personnel in a neonatal intensive care unit (NICU) get LAIV (live attenuated influenza vaccine)?

Yes. Either the inactivated injectable influenza vaccine or the LAIV can be given to health care personnel working in a neonatal intensive care unit (NICU). Nearly all healthy, non-pregnant health care workers, including those who come in contact with newborn infants, pregnant women, persons with a solid organ transplant, persons receiving chemotherapy (not in preparation for a bone marrow transplant), and persons with HIV/AIDS, may receive LAIV if otherwise eligible. However, LAIV should not be used for health care personnel who care for patients undergoing bone marrow transplantation (i.e., patients who require a protected environment).

No special precautions (e.g., masks or gloves) are necessary for health care personnel who have been vaccinated with the LAIV and who do not work with patients undergoing bone marrow transplantation. However, for health care personnel that were vaccinated with LAIV and who work with patients undergoing bone marrow transplantation, the ACIP recommends, as a precautionary measure, that those health care personnel avoid providing care for such patients for 7 days after vaccination.

Who should *not* be vaccinated with the 2009 H1N1 nasal-spray flu vaccine LAIV?

Certain people should not get a nasal spray flu vaccine, including the 2009 H1N1 nasal spray vaccine. This includes:

- People younger than 2 years of age;
- Pregnant women;
- People 50 years of age and older;
- People with a medical condition that places them at higher risk for complications from influenza, including those with chronic heart or lung disease, such as asthma or reactive airways disease; people with medical conditions such as diabetes or kidney failure; or people with illnesses that weaken the immune system, or who take medications that can weaken the immune system;
- Children younger than 5 years old with a history of recurrent wheezing;
- Children or adolescents receiving aspirin therapy;
- People who have had Guillain-Barré syndrome (GBS), a rare disorder of the nervous system, within 6 weeks of getting a flu vaccine,
- People who have a severe allergy to chicken eggs or who are allergic to any of the nasal spray vaccine components.

Should the nasal-spray flu vaccine be given to patients with chronic diseases other than those specifically listed above?

No. The nasal-spray flu vaccine is approved for use only in healthy* people 2 years to 49 years of age who are *not* pregnant.

Are there any contraindications to giving breastfeeding mothers the

2009 H1N1 vaccine?

Breastfeeding is not a contraindication for the nasal spray flu vaccine. Women who are breastfeeding can get the nasal spray vaccine, including 2009 H1N1 vaccine.

Can pregnant women be in contact with someone who has gotten the nasal spray vaccine (LAIV)?

Yes. A pregnant woman can be in close contact with someone who has gotten the nasal spray flu vaccine (LAIV). A pregnant woman can also administer (give) a nasal spray vaccine (LAIV). Because the viruses in the nasal spray vaccine are attenuated or weakened, vaccine viruses are unlikely to cause any illness symptoms, even if an unvaccinated person inadvertently gets vaccine viruses in their nose. The nasal spray vaccine against seasonal influenza viruses has been used in millions of school children and healthy adults since it was licensed, and there have been no reports of pregnant women becoming ill after exposure to their vaccinated children or other family members.

While it's OK for her contacts to get the nasal spray vaccine, this vaccine should not be given to pregnant women. While LAIV is not known to be a safety risk for pregnant women, there have not been studies of LAIV among pregnant women to assess safety and effectiveness for use in this group. LAIV can be given to women after they have delivered, even if they are nursing.

CDC recommends that pregnant women get both the 2009 H1N1 flu shot and the seasonal flu shot. Flu shots are made with a killed virus, and have not been shown to cause harm to pregnant women or their babies.

Can the nasal-spray flu vaccine be given to patients when they are ill?

The nasal-spray flu vaccine can be given to people with minor illnesses (e.g., diarrhea or mild upper respiratory tract infection with or without fever). However, if nasal congestion is present that might limit delivery of the vaccine to the nasal lining, then delaying of vaccination until the nasal congestion is reduced should be considered.

Can people receiving the nasal-spray flu vaccine LAIV pass the vaccine viruses to others?

In clinical studies, transmission of vaccine viruses to close contacts occurred only rarely. The current estimated risk of getting infected with vaccine virus after close contact with a person vaccinated with the nasal-spray flu vaccine is low (0.6%-2.4%). Because the viruses are weakened, infection is unlikely to result in influenza illness symptoms since the vaccine viruses have not been shown to change into typical or naturally occurring influenza viruses.

Can contacts of people with weakened immune systems get the nasal-spray flu vaccine?

People who are in contact with others with severely weakened immune systems when they are being cared for in a protective environment (for example, people with hematopoietic stem cell transplants), should not get the nasal spray vaccine, including the 2009 H1N1 nasal spray vaccine if they will come into contact with the severely immunocompromised person within 7 days of vaccination. People who have contact with others with lesser degrees of immunosuppression (for example, people with diabetes, people with asthma taking

corticosteroids, or people infected with HIV) can get the nasal spray vaccine.

What side effects are associated with the nasal-spray flu vaccine?

In children, side effects can include runny nose, headache, wheezing, vomiting, muscle aches, and fever. In adults, side effects can include runny nose, headache, sore throat, and cough. Fever is not a common side effect in adults receiving the nasal spray flu vaccine.

How effective is the nasal-spray seasonal flu vaccine?

In one large study among children aged 15-85 months, the seasonal nasal-spray flu vaccine reduced the chance of influenza illness by 92% compared with placebo. In a study among adults, the participants were not specifically tested for influenza. However, the study found 19% fewer severe febrile respiratory tract illnesses, 24% fewer respiratory tract illnesses with fever, 23-27% fewer days of illness, 13-28% fewer lost work days, 15-41% fewer health care provider visits, and 43-47% less use of antibiotics compared with placebo. A recent study suggested that seasonal LAIV may not be as effective as seasonal inactivated vaccine in adults, but more data are needed to confirm if one is better than the other. Both vaccines are expected to be effective against 2009 H1N1.

When should the 2009 H1N1 nasal-spray flu vaccine be given?

Flu vaccination should begin as soon as vaccine is available and continue throughout the influenza season, into December, January, and beyond. By early October 2009, extensive 2009 H1N1 flu activity was being reported in the United States. It's possible that there may be waves of 2009 H1N1 activity during the 2009-2010 flu season that hit communities more than once over the course of the influenza season, which typically peaks in January or February but can last as late as May.

How many doses of nasal spray vaccine are needed?

In adults, only one dose of 2009 H1N1 vaccine, including the 2009 H1N1 nasal spray vaccine, is needed for protection.

All children 2 through 9 years of age getting a 2009 H1N1 vaccine will need two doses of 2009 H1N1 vaccine (either the 2009 H1N1 flu shot or the 2009 H1N1 nasal spray vaccine). The first dose should be given as soon as vaccine becomes available. The second dose should be given 28 or more days after the first dose. The first dose "primes" the immune system; the second dose provides immune protection. Children who only get one dose of vaccine when they need two doses may have reduced or no protection. Be sure to follow up to get your child a second dose if they need one. It usually takes about two weeks after the second dose for protection to begin.

Can people who got the flu shot last year get the nasal-spray flu vaccine LAIV this year?

Yes, people who got inactivated influenza vaccine (the flu shot) last year can get the nasal-spray flu vaccine this year.

Can the nasal-spray flu vaccine be given at the same time as other vaccines?

The nasal spray flu vaccine can be given at the same time or around the same time as an

inactivated (killed) vaccine or any other live vaccine except for the seasonal nasal spray vaccine. (The seasonal nasal spray vaccine and the 2009 H1N1 nasal spray vaccine *should not be given at the same time.*) The 2009 H1N1 flu shot (inactivated 2009 H1N1 vaccine) can be given at the same visit as any other vaccine, including pneumococcal polysaccharide vaccine.

Can the 2009 H1N1 nasal spray vaccine and the seasonal nasal spray vaccine be given at the same time to the same person?

No. The seasonal nasal spray vaccine and the 2009 H1N1 nasal spray vaccine *should not be given at the same time.* This is because the nasal spray vaccines might not be as effective if given together. It is fine to receive the 2009 H1N1 nasal spray at the same time as the seasonal influenza (flu) shot, or the seasonal flu nasal spray at the same time as the 2009 H1N1 flu shot vaccine.

Can the nasal-spray flu vaccine be used together with influenza antiviral medications?

If a person is taking an influenza antiviral drug (including Tamiflu® or Relenza®), then the nasal spray flu vaccine should not be given until 48 hours after the last dose of the influenza antiviral medication was given. If a person takes antiviral drugs within two weeks of getting the nasal spray flu vaccine, that person should get revaccinated. (The antiviral drugs will have killed the vaccine viruses that are supposed to cause the immune response against those viruses.)

Antiviral drugs can be taken with the inactivated (i.e. killed) flu vaccine.

If a child under the age of 9 years is getting seasonal influenza vaccine for the first time and requires 2 doses, does the same type of vaccine have to be used for both doses?

Ideally the same type of vaccine should be used for both doses as we know a series of two doses of the same type of vaccine has worked in clinical trials. No information is available about how effective a series of two different vaccines might be. If different types of vaccine are used for the first and second doses, however, there is no need to revaccinate a child. The doses should be separated by at least one month (28 days).

How is the nasal-spray flu vaccine stored?

The nasal-spray flu vaccine, including both the seasonal and 2009 H1N1 nasal spray vaccines, must be stored in a refrigerator at 2-8°C (35-46°F).

Can health care workers who cannot receive the nasal spray vaccine (e.g., pregnant women, older adults, persons with chronic medical conditions) administer this vaccine to others?

Yes. Health care workers who cannot get the nasal spray vaccine themselves can administer the vaccine to others.

What personal protective equipment is recommended for health care workers who are giving the 2009 H1N1 nasal spray vaccine?

Personal protective equipment (gloves and masks) are not needed when administering the

nasal spray vaccine, including the 2009 H1N1 nasal spray vaccine.

Does the nasal spray flu vaccine contain thimerosal?

No, neither the seasonal nor the 2009 H1N1 nasal-spray flu vaccines contain thimerosal or any other preservative.

Can the nasal spray flu vaccine give you the flu?



Unlike the flu shot, the nasal spray flu vaccine does contain live viruses. **However, the viruses are attenuated (weakened) and cannot cause flu illness.** The weakened viruses are cold-adapted, which means they are designed to only cause infection at the cooler temperatures found within the nose. The viruses cannot infect the lungs or other areas where warmer temperatures exist. Some children and young adults 2 years to 17 years of age have reported experiencing mild reactions after receiving seasonal nasal spray flu vaccine, including runny nose, nasal congestion or cough, chills, tiredness/weakness, sore throat and headache. Some adults 18 years to 49 years of age have reported runny nose or nasal congestion, cough, chills, tiredness/weakness, sore throat and headache. These side effects are mild and short-lasting, especially when compared to symptoms of influenza infection.

Who makes the nasal spray vaccine?

The nasal spray vaccine for use in the United States is being made by MedImmune, the same company that makes the seasonal nasal spray vaccine called "FluMist®." The 2009 H1N1 nasal spray vaccine is being made using the same manufacturing process that has been used since 2003 to make the seasonal nasal spray vaccine.

* "Healthy" indicates persons who do not have an underlying medical condition that predisposes them to influenza complications.

More Information About Flu Vaccine

[2009 H1N1 Nasal Spray: Vaccine Information Statement \(VIS\)](#) 
[Seasonal Nasal Spray: Vaccination Information Statement \(VIS\)](#)
[2009 H1N1 Flu Shot: Vaccine Information Statement \(VIS\)](#) 
[Seasonal Flu Shot: Vaccination Information Statement \(VIS\)](#)

Additional Resources for on the Use of Nasal Spray Vaccines in Health Care Settings

Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices (ACIP), 2009.

<http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5808a1.htm>

Influenza Vaccination of Health-Care Personnel: Recommendations of the Healthcare Infection Control Practices Advisory Committee (HICPAC) and the Advisory Committee on Immunization Practices (ACIP).

<http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5502a1.htm>

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Frequently asked questions on use of influenza A(H1N1) 2009 monovalent vaccines (2009 H1N1 vaccines): Practical considerations for immunization programs and providers

November 3, 2009, 11:00 AM ET

Two different influenza vaccines are available this influenza season, and many people will be recommended to receive both the seasonal influenza vaccine and the 2009 influenza A (H1N1) 2009 monovalent vaccine (referred to in this document as 2009 H1N1 vaccine). Below are some practical considerations for use of influenza vaccines. They are only intended to address the current pandemic situation and might change as the situation unfolds. They are not intended to be applied to routine use during future seasonal influenza vaccination efforts.

1. Two Doses for Children

Children ages 6 months through 8 years receiving seasonal influenza vaccination for the first time are recommended to receive 2 doses. However, children ages 6 months through 9 years are recommended to receive 2 doses in the prescribing information for 2009 H1N1 vaccines. Does CDC recommend that clinicians follow the recommendation in the 2009 H1N1 vaccine package inserts, or use the standard seasonal vaccine recommendations?

The recommendations for use of seasonal vaccine are unchanged. Using the 2009 H1N1 vaccine schedule presented in the prescribing information is recommended (6 months through 9 years receive 2 doses). However, if considered necessary for consistency, vaccination providers can also follow the guidance for the seasonal vaccines for both vaccines, pending additional data from ongoing studies. The ongoing vaccine immunogenicity studies might provide additional information on which children should receive 2 doses, but these data are not yet available.

2. Definition of 1 Month Interval

The interval between doses stated in the 2009 H1N1 vaccine prescribing information is "approximately 1 month". What does "approximately 1 month" mean?

CDC recommends that the two doses of 2009 H1N1 vaccines be separated by 28 days (4 weeks).

3. Acceptable Interval for 2009 H1N1 Inactivated Vaccines

The influenza A (H1N1) 2009 monovalent inactivated vaccine trials that are currently underway have often used a 21 day (3 week) interval between doses. Is a 21 day interval acceptable?

CDC recommends that the two doses of 2009 H1N1 vaccines be separated by 28 or more days (4 weeks). However, trials of the inactivated 2009 H1N1 vaccines have often used a 21 day interval. Administering the two doses of a 2009 H1N1 inactivated vaccine at least 21 days apart

is safe. Therefore, if the second dose of an inactivated 2009 H1N1 vaccine is separated from the first dose by at least 21 days, the second dose can be considered valid. If the interval separating the doses is less than 21 days, the second dose should be repeated 28 or more days after the first dose (21 days acceptable). Trials of 2009 H1N1 live attenuated vaccines have used a 28 day interval between doses and therefore 28 days is the appropriate valid interval. Additional information about intervals for both types of 2009 H1N1 vaccines (inactivated and live attenuated) from the ongoing clinical trials will be considered when available.

4. Using Seasonal Inactivated Influenza Vaccine and 2009 H1N1 Inactivated Vaccine at the Same Time

Can the seasonal inactivated vaccine (trivalent inactivated vaccine or TIV) and the 2009 H1N1 inactivated vaccine be given at the same time?

Yes.

5. Use of Seasonal Live Attenuated Influenza Vaccine (LAIV) and 2009 H1N1 LAIV at the Same Visit

If seasonal LAIV and 2009 H1N1 LAIV are given at the same visit, do either or both doses need to be repeated, and if so, when?

Seasonal LAIV and 2009 H1N1 LAIV should not be administered at the same visit. There are no data from studies in humans on the administration of seasonal and H1N1 2009 monovalent live attenuated vaccines at the same visit. Use of the 2 types of LAIV at the same time could result in reduced immunogenicity for one vaccine, according to some experts. However, if both types of LAIV are inadvertently administered at the same visit neither vaccine needs to be repeated.

6. Minimum Interval between Different LAIV Formulations

What is the minimum interval between doses of seasonal LAIV and 2009 H1N1 LAIV?

There are no data on sequential administration of the two types of LAIV (seasonal and 2009 H1N1). The ACIP General Recommendations on live attenuated vaccines indicates that 28 days (4 weeks) is the recommended minimum interval, and can be applied to use of a seasonal LAIV and a 2009 H1N1 LAIV, because these are considered 2 different vaccines. The ACIP recommendations were developed based on data from studies using attenuated live virus vaccines such as measles, mumps and rubella vaccine that are injected. However, based on previous studies of LAIV replication and immune response, as little as 14 days (2 weeks) might be sufficient to allow for an appropriate immune response to both vaccines. Therefore, an interval between the two types of LAIV of 2 weeks or more may be acceptable, although an interval of 28 days is preferred.

7. Repeating Doses when Seasonal LAIV and 2009 H1N1 LAIV are Used in Shorter Intervals than is Accepted (between 1 and 13 days)

If seasonal and H1N1 LAIV are not administered on the same day, but are separated by less than 14 days (2 weeks), do either or both doses need to be repeated, and if so, when?

Seasonal LAIV and 2009 H1N1 LAIV should not be administered at the same visit, and should be separated by at least 14 days and ideally by at least 28 days based on previous studies of attenuated influenza vaccine virus replication and immune response. If the interval between administration of seasonal LAIV and 2009 H1N1 LAIV is from 1-13 days, the vaccine more recently administered should be repeated.

8. Using an Inactivated Vaccine and a Live Attenuated Vaccine at the Same Time

Can a live attenuated vaccine be given at the same time as an inactivated influenza vaccine (e.g., seasonal LAIV and 2009 H1N1 inactivated vaccine, or 2009 H1N1 LAIV and seasonal trivalent inactivated influenza vaccine [TIV])?

Yes, these two types of vaccines can be given at the same time, based upon ACIP's General Immunization recommendations. Any interval between the two types of vaccines is also acceptable.

9. Using an Inactivated 2009 H1N1 Vaccine and a Live Attenuated 2009 H1N1 Vaccine in the Same Series

Can a child who requires 2 doses of a 2009 H1N1 vaccine and who received the first dose with a inactivated 2009 H1N1 vaccine complete the series with the 2009 H1N1 LAIV, or vice versa?

When feasible, the same type of vaccine (live attenuated or inactivated) should be used in a two dose schedule, but mixed schedules are preferable to not completing the series. A 28 day interval between doses is recommended, but 21 days is acceptable. There are limited data on mixed schedules.

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General Questions and Answers on Thimerosal

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What is thimerosal?

Thimerosal is a mercury-based preservative that has been used for decades in the United States in multi-dose vials (vials containing more than one dose) of some vaccines to prevent the growth of microorganisms, such as bacteria and fungi, which may contaminate them.

What are preservatives and why are they used in vaccines?

In vaccines, preservatives are used to prevent the growth of bacteria and fungi in the event that they get into the vaccine. This may occur when a syringe needle enters a vial as a vaccine is being prepared for administration. Contamination by germs in a vaccine could cause serious illness or death. In some vaccines, preservatives are added during the manufacturing process to prevent microbial growth.

Will the 2009 H1N1 influenza vaccine contain thimerosal?

The 2009 H1N1 influenza vaccines that FDA is licensing (approving) will be manufactured in several formulations. Some will come in multi-dose vials and will contain thimerosal as a preservative. Multi-dose vials of seasonal influenza vaccine also contain thimerosal to prevent potential contamination after the vial is opened.

Some vaccine manufacturers will be producing 2009 H1N1 influenza vaccine in single-dose units, which will not require the use of thimerosal as a preservative. In addition, the live-attenuated version of the vaccine, which is administered intranasally (through the nose), is produced in single-units and will not contain thimerosal.

I have concerns about the use of thimerosal. Is thimerosal still being used?

People have a right to expect the vaccines they receive are safe and effective. CDC and FDA also hold vaccines to the highest standards of safety. That is why CDC and FDA continually evaluate new scientific information about the safety of vaccines. Since 2001, no new vaccine licensed by FDA for use in children has contained thimerosal as a preservative, and all vaccines routinely recommended by CDC for children under six years of age have been thimerosal-free, or contain only trace amounts, except for multi-dose formulations of influenza vaccine. This was done as a precautionary step and not because there was evidence confirming that thimerosal-containing vaccines were causing health problems. The most recent and rigorous scientific research does not support the hypothesis that thimerosal-containing vaccines are harmful.

Thimerosal is an important preservative that protects vaccines against potential microbial contamination, which may occur in opened multi-dose vials of vaccine. Such contamination could cause serious illness or death. Since seasonal influenza vaccine is produced in large quantities for annual immunization campaigns, some of the vaccine is produced in multi-dose vials, and contains thimerosal to safeguard against possible contamination of the vial once it is opened.

Three leading federal agencies (CDC, FDA, and NIH) have reviewed the published research on thimerosal and found it to be a safe product to use in vaccines. Three independent

organizations [The National Academy of Sciences' Institute of Medicine, Advisory Committee on Immunization Practices (ACIP), and the American Academy of Pediatrics (AAP)] reviewed the published research and also found thimerosal to be a safe product to use in vaccines. The scientific community supports the use of thimerosal in influenza vaccines.

Is thimerosal safe when used as a preservative in vaccines?

CDC places a high priority on vaccine safety, surveillance, and research. CDC is aware that the presence of the preservative thimerosal in vaccines and suggestions of a relationship to autism has raised concerns. These concerns make the decisions surrounding vaccinations confusing and difficult for some people, especially parents. Numerous studies have found no association between thimerosal exposure and autism. Since 2001, no new vaccine licensed by FDA for use in children has contained thimerosal as a preservative and all vaccines routinely recommended by CDC for children under six years of age have been thimerosal-free, or contain only trace amounts, except for some formulations of influenza vaccine. Unfortunately, we have not seen reductions in the numbers of children identified with autism indicating that the cause of autism is not related to a single exposure such as thimerosal.

The federal government is committed to assuring the safety of vaccines. This is achieved by FDA oversight of rigorous pre-licensure trials and post-licensure monitoring by CDC and FDA. This commitment not only stems from our scientific and medical dedication, it is also personal – for most of us who work at CDC are also parents and grandparents. We too, place tremendous value on the health and safety of children.

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General Questions and Answers on Guillain-Barré syndrome (GBS)

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What is Guillain-Barré syndrome (GBS)?

Guillain-Barré syndrome (GBS) is a rare disorder in which a person's own immune system damages the nerve cells, causing muscle weakness and sometimes paralysis. GBS can cause symptoms that last for a few weeks or several months. Most people recover fully from GBS, but some people have permanent nerve damage. In rare cases, people have died of GBS, usually from difficulty with breathing. In the United States, for example, an estimated 3,000 to 6,000 people develop GBS each year on average, whether or not they received a vaccination. This is about 1 to 2 cases of GBS per 100,000 people.



What causes GBS?

Scientists do not fully understand what causes GBS, but it is believed that stimulation of the body's immune system may play a role in its development. Here's what scientists know for sure: About two-thirds of people who develop GBS symptoms do so several days or weeks after they have been sick with a diarrheal or respiratory illness. Infection with the bacterium Campylobacter jejuni is one of the most common risk factors for GBS. People can also develop GBS after having the flu or other infections (such as cytomegalovirus and Epstein Barr virus). On very rare occasions, they may develop GBS in the days or weeks following receiving a vaccination.

Who is at risk for developing GBS?

Anyone can develop GBS, but it is more common among adults than children. The incidence of GBS increases with age, and people over age 50 are at greatest risk for developing GBS. Each year, on average, about 3,000 to 6,000 people in the United States develop GBS whether or not they received a vaccination – that's 1 to 2 people out of every 100,000 people.

Do vaccines cause GBS?

It is not fully understood why some people develop GBS, but it is believed that the nerve cells are damaged by a person's own immune system. Many types of infections, and in very rare cases vaccines, may activate the immune system to cause damage to the nerve cells.

How common is GBS, and how common is it after people are vaccinated for seasonal influenza?

GBS is rare. Each year, about 3,000 to 6,000 people in the United States develop GBS whether or not they received a vaccination – that's 1 to 2 people out of every 100,000 people. This is referred to as the background rate.

In 1976, there was a small risk of GBS following influenza (swine flu) vaccination (approximately 1 additional case per 100,000 people who received the swine flu vaccine). That number of GBS cases was slightly higher than the background rate for GBS. Since then,

numerous studies have been done to evaluate if other flu vaccines were associated with GBS. In most studies, no association was found, but two studies suggested that approximately 1 additional person out of 1 million vaccinated people may be at risk for GBS associated with the seasonal influenza vaccine. It is important to keep in mind that severe illness and possible death can be associated with influenza, and vaccination is the best way to prevent influenza infection and its complications.

What happened in 1976 with GBS and the swine flu vaccine?

Scientists first reported a suspected link between GBS and vaccinations in 1976, during a national campaign to vaccinate people against a swine flu virus. The investigation found that vaccine recipients had a higher risk for GBS than those who were not vaccinated (about 1 additional case occurred per 100,000 people vaccinated). Given this association, and the fact that the swine flu disease was limited, the vaccination program was stopped.

Since then, numerous studies have been done to evaluate if other flu vaccines were associated with GBS. In most studies, no association was found, but two studies suggested that approximately 1 additional person out of 1 million vaccinated people may be at risk for GBS associated with the seasonal influenza vaccine.


Why did some people develop GBS after they received the 1976 swine flu vaccine?

The Institute of Medicine (IOM) conducted a thorough scientific review in 2003 and concluded that people who received the 1976 swine influenza vaccine had a slight increased risk for developing GBS. Scientists have multiple theories on why this increased risk may have occurred, but the exact reason for this association remains unknown.

Do you expect that the 2009 H1N1 vaccine will be associated with GBS?

We expect the 2009 H1N1 vaccine to have a similar safety profile as seasonal flu vaccines, which have very good safety track records. The seasonal influenza vaccine has not been consistently associated with GBS.

How will public health authorities investigate cases of GBS?

Ensuring the safety of vaccines is a high priority for CDC. CDC and its partners have an aggressive plan to actively monitor the 2009 H1N1 vaccine to ensure its safety. Several systems are in place to monitor vaccine safety. One of these systems is the [Vaccine Adverse Event Reporting System \(VAERS\)](#) .

CDC and FDA co-manage VAERS, which serves as an early warning system to collect voluntary reports about possible side effects that people experience following vaccinations. CDC and FDA scientists review all VAERS reports and store the information in a computerized database that is monitored to detect new, unusual, or rare health events that could be possible side effects of vaccines.

In addition to the normal vaccine safety monitoring systems, CDC is proactively putting additional monitoring systems in place to ensure safety after licensing. Some of these systems include: actively observing persons in defined geographic areas, collaborating with professional organizations for reports of any adverse events after vaccination, and conducting thorough investigations when severe adverse events occur to determine whether they may have been associated with the vaccine. Through these numerous approaches, we will be able to detect any possible risk of GBS that might be associated with the 2009 H1N1 vaccine early in the vaccination campaign and take appropriate action.

How will the federal government determine whether people who receive the 2009 H1N1 vaccine have an increased risk for GBS?

GBS cases occur every year in the general population for many different reasons. To monitor whether people who receive the 2009 H1N1 vaccine have an increased risk for GBS, U.S. public health officials will determine if the number of GBS cases reported among people who receive the 2009 H1N1 vaccine is higher than the number of cases reported in the general population.

If there is an increase in the number of reported cases, public health officials will conduct intensive investigations. If any problems are detected with this 2009 H1N1 vaccine, they will be reported to health officials, healthcare providers, and the public, and health officials will take needed action to ensure the public's health and safety.

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