State of Nevada
Health and Human Services
Health Division
Immunization Program

2009 Novel H1N1
Welcome Packet

www.flu.nv.gov

STATE OF NEVADA

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
HEALTH DIVISION
Bureau of Child, Family & Community Wellness
Immunization Program
4150 Technology Way, Suite 210
Carson City, Nevada 89706
Telephone (775) 684-5900 · Fax (775) 684-8338

September 21, 2009

Dear Nevada H1N1 Provider:

On behalf of the State Health Division, I would like to thank you for enrolling to be a H1N1 provider for your patients and/or your local community. Your participation in the H1N1 vaccination campaign will ensure Nevadans have many options to access H1N1 vaccine. Please take the time to read the enclosed H1N1 Welcome Packet.

As an H1N1 provider there are a few mandatory items that you must comply with on a daily and weekly basis. All H1N1 providers will be required to report data to the Immunization Program. This is due to the state being mandated to report aggregate (target population and age) data to the CDC. This packet will explain all these mandatory items.

It is important to remember that the CDC has identified target groups that will be vaccinated first. The five target groups are broken down by "Initial Target Groups." The Nevada State Health Division will determine if the target groups need to be expanded or contracted based on vaccine supply in consultation with the CDC guidelines.

Initial Target Groups

- Pregnant women
- Persons who live with or provide care for infants less than 6 months old (e.g., parents, siblings, daycare providers)
- Healthcare and emergency medical services personnel
- Persons aged 6 months – 24 years old
- Persons aged 25 – 64 years who have medical conditions that put them at higher risk for influenza-related conditions.

Please remember that the H1N1 vaccine is free to everyone. You cannot charge for this vaccine. Private providers may charge a vaccine administrative fee (regional Medicare rate) of $21.34 per vaccine administered. Private providers may ask for this in cash from the patient or try and bill the patient's private health insurance. All public health providers cannot charge a patient for this fee, but may bill their private health insurance.

The Immunization Program is holding weekly H1N1 provider calls to explain the process and to answer questions. This weekly call is held on Wednesday's from 12:30 – 1:30 PM. Please call:

(866) 434-5269 – Access Code: 2669775

Or if line is full: (888) 422-7128 – Access Code: 123962

Thank you for becoming an H1N1 provider. Your willingness to participate in this vital task will help protect the health and lives of Nevada residents.

Please visit the Nevada flu website at www.flu.nv.gov. If you have any questions or concerns please call us at (775) 684-5900 or email at nviz@health.nv.gov.

Sincerely,

Christine N. Smith

Christine N. Smith
State of Nevada Immunization Program Manager

Table of Contents

H1N1 Information Resources

Requesting H1N1 Vaccine (including reporting requirements)

- Hilary Smith, Vaccine Requests, NSIP
  (775) 684-4139
  hasmith@health.nv.gov

- Vivian Lawrence, Vaccine Requests, NSIP
  (775) 684-4043
  vlawrence@health.nv.gov

Adverse Event Reporting

- Linda Platz, Vaccine Manager, NSIP
  (775) 684-5913
  lplatz@health.nv.gov

- Vaccine Adverse Events Reporting System website
  www.vaers.hhs.gov
  1-800-822-7967

Paper Reporting Forms (vaccination event documentation for Non-WebIZ providers)

- Erin Seward, Nevada WebIZ Manager, NSIP
  (775) 684-3209
  eseward@health.nv.gov

- Amanda (Mandy) Harris, Nevada WebIZ Help Desk Manager, NSIP
  (775) 684-4258
  asharris@health.nv.gov

Priority Groups

- Pam Forest, Provider Quality Assurance, NSIP
  (775) 684-5903
  pforest@health.nv.gov

- Linda Platz, Vaccine Manager, NSIP
  (775) 684-5913
  lplatz@health.nv.gov

Storage and Handling of Vaccines

- Linda Platz, Vaccine Manager, NSIP
  (775) 684-5913
  lplatz@health.nv.gov

- Pam Forest, Provider Quality Assurance, NSIP
  (775) 684-5903
  pforest@health.nv.gov

Vaccine Administration

- Linda Platz, Vaccine Manager, NSIP
  (775) 684-5913
  lplatz@health.nv.gov

- Pam Forest, Provider Quality Assurance, NSIP
  (775) 684-5903
  pforest@health.nv.gov

Nevada WebIZ Immunization Registry

- Nevada WebIZ Help Desk
  (775) 684-5954
  1-877-NV-WebIZ (toll-free for long distance)
  (689-3249)
  izit@health.nv.gov

Helpful Websites

State of Nevada Influenza Information
www.flu.nv.gov

CDC Influenza Information
www.flu.gov

CDC General Vaccination Information
www.cdc.gov/vaccines

Nevada Immunization Coalition
www.immunizenevada.com

Immunization Action Coalition
www.immunize.org

Vaccine Adverse Events Reporting System
www.vaers.hhs.gov

NSIP = Nevada State Immunization Program
CDC = Centers for Disease Control & Prevention

FEDERAL INFLUENZA A (H1N1) MONOVALENT VACCINE VACCINE PROVIDER AGREEMENT ADMINISTERED BY

STATE OF NEVADA HEALTH DIVISION

Immunization Program ▪ 4150 Technology Way ▪ Suite 210 ▪ Carson City ▪ Nevada ▪ 89706

Federal H1N1 Program
2009-2010 Agreement to Participate

Business/Clinic Name (Assigned PIN Number)

Vaccine Shipping Contact: _____
(Person responsible for the vaccines)

Physical/Shipping Address: _____
Street Address (No Post Office Box) City State Zip Code

Mailing Address: _____
(May be the same as the shipping) City State Zip Code

Direct Phone Number/Ext: _____ Back Office Number: _____

Fax Number: _____ E-mail address (please include): _____

IMPORTANT – Days and times the clinic is open to accept delivery of vaccines:

DAY OF THE WEEK	OPEN TIME	LUNCH TIME	CLOSED TIME
MONDAY			
TUESDAY			
WEDNESDAY			
THURSDAY			
FRIDAY			
Notify the Nevada State Immunization Program (in writing) of any changes, i.e. clinic closures or changes in hours of operation.			

To participate in the FEDERAL H1N1 program and receive federally supplied vaccine provided to my facility at no cost, I agree to the following conditions, on behalf of myself and all the practitioners, and others associated with the medical office, group practice, managed care organization, community/migrant/rural clinic, health department, or health delivery facility of which I am the physician-in-chief or equivalent:

Your participation in the 2009 Influenza A (H1N1) monovalent vaccine vaccination effort is greatly appreciated as a vital service that will protect individuals and the public against 2009 H1N1 Influenza. The 2009 Influenza A (H1N1) monovalent vaccine has been purchased by the federal government as a means of protecting the public against 2009 H1N1 Influenza. It is being made available to immunization providers working in partnership with state and local public health departments to vaccinate individuals for whom the vaccine is recommended. This Provider Agreement specifies the conditions of participation in the 2009 Influenza A (H1N1) monovalent vaccine vaccination effort in the U.S. and must be signed and submitted to the Nevada Immunization Program prior to receipt of the vaccine.

The immunization provider agrees to:

Physician in Chief to initial all:

_____1. Administer the 2009 Influenza A (H1N1) monovalent vaccine according to the recommendations of CDC's Advisory Committee on Immunization Practices as adopted by the Centers for Disease Control and Prevention. http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5810a1.htm
_____2. Store and handle the vaccine in accordance with the package insert provided with the vaccine including in compliance with cold chain requirements. Review the Checklist for Safe Vaccine Handling and Storage and the Vaccine Storage Unit "Things to Consider" as well as the enclosed "Handling Instructions for 2009 H1N1 Vaccine."
_____3. Provide a current Vaccine Information Statement to each individual before vaccination, and answer questions about the benefits and risks of vaccination, including different indications for live versus inactivated vaccines. http://www.cdc.gov/vaccines/pubs/vis/default.htm
_____4. Record in the patient's medical record or in an office log the date of administration, the site of administration, the vaccine type and lot number, and the name of the immunization provider for each individual vaccinated. The record must be kept for a minimum of three years following vaccination.
_____5. Report moderate and severe adverse events following vaccination to the Vaccine Adverse Event Reporting System (1-800-822-7967, http://vaers.hhs.gov/contact.htm).

In addition, the provider:

_____6. Cannot charge patients, health insurance plans, or other third party payers for the vaccine, the syringes or the needles as these are provided at no cost to the provider. The provider/facility is also prohibited from selling H1N1 vaccine, syringes or needles.
_____7. May charge a fee for the administration of the vaccine to the patient, their health insurance plan, or other third party payer. The administration fee cannot exceed the regional Medicare ($21.34) vaccine administration fee. If the administration fee is billed to Medicaid, the amount billed cannot exceed the state Medicaid administration fee. http://www.cms.hhs.gov/MLNMattersArticles/downloads/SE0920.pdf
_____8. May either administer the 2009 Influenza A (H1N1) monovalent vaccine for free to individuals who cannot afford the administration fee, or refer these individuals to a public health department clinic or affiliated public health provider for vaccination.
_____9. Must report the number of doses of 2009 Influenza A (H1N1) monovalent vaccine administered to individuals as requested by the state or local public health department.
____10. Must report to the state health division the number of doses of vaccine that were not able to be used because the vaccine expiration date was exceeded or the vaccine was wasted for other reasons. These doses must be disposed of in accordance with state regulations for biological waste.
____11. Are strongly encouraged to provide an immunization record card to the vaccine recipient or parent/guardian to provide a record of vaccination, to serve as an information source if a Vaccine Adverse Event Reporting System report is needed, and to serve as a reminder of the need for a second dose of vaccine (if necessary). Immunization cards will be included in each shipment of vaccine.
____12. Must report to the State Health Division on a weekly basis aggregate H1N1 doses administered and comply with NRS 439.265 (*reporting child H1N1 vaccines to the immunization registry – Nevada WebIZ*). The Nevada Immunization Program will notify H1N1 vaccine providers of this process.

Receipt of H1N1 vaccine shall constitute acceptance of the terms of this agreement.

Agreed to on behalf of the above-named providers and facilities:

(Signed or electronic submission) _____

Printed Name Physician in Chief (authorized to prescribe vaccines under Nevada State Law) **Medical License #**

Physician in Chief (authorized to prescribe vaccines under Nevada State Law) Signature **Date**

LIST OF EACH PRESCRIBING PHYSICIAN:

- Print the names of all providers who possess a medical license and prescription writing privileges.
- It is not necessary to include the names of all staff within this facility that may administer vaccine, but rather, only those who possess a medical license or are authorized to write prescriptions. Hospitals may just include the "Physician in Chief"

CURRENT MEDICAL LICENSE NUMBER DESIGNATING MD,DO,APN,PA	LAST NAME	FIRST NAME

(attach another sheet if additional space is needed)

CLINIC NAME:	PIN NUMBER:	CONTACT NAME:	PHONE NUMBER:

PROVIDER PROFILE: complete the table below to designate the number of H1N1 **doses** you would anticipate administering during the Influenza Season to the various "Initial Target Groups" as well as "All Other Groups".

Designate the number of DOSES you anticipate for the entire H1N1 Influenza Season

Maximum number of doses your vaccine storage unit can hold

H1N1 VACCINE PRESENTATIONS	PF Prefilled syringes 0.25	PF Single dose vials 0.25	PF Prefilled syringes 0.5	PF Single dose vials 0.5	Multi-dose vials 5.0	Nasal sprayer 2-49 years	TOTAL FOR H1N1 SEASON
INITIAL TARGET GROUPS							
Pregnant women							
Persons who live with or provide care for infants aged <6months (e.g., parents, siblings, and daycare providers)							
Health-care and emergency medical services personnel (who have direct contact with patients or infectious material)							
Persons aged 6 months—24 years							
Persons aged 25-64 years who have medical conditions that put them at higher risk for influenza-related complications							
ALL OTHER GROUPS							

Manufacturer Quality Control Office Telephone Numbers

Manufacturer/Distributor	Telephone Number	Product
MedImmune www.medimmune.com	877-633-4411	Nasal Spray
GlaxoSmithKline www.gsk.com	866-475-8222 or 888-825-5249	Adjuvant
CSL www.csl.com.au/	1-610-878-4000	Unknown
Sanofi Pasteur www.sanofipasteur.us	800-822-2463	Preloaded Syringes
Novartis www.novartis-vaccine.com	800-244-7668	Multi-Dose Vials

Vaccine Storage & Handling

Instructions: Place an "X" in the box that corresponds with the temperature. *The shaded zones represent unacceptable temperature ranges. If the temperature recorded is in the shaded zone:* 1. **Store the vaccine** under proper conditions as quickly as possible, 2. Call Linda Platz, RN at the Immunization Program at (775) 684-5913 for instructions, 3. Call the vaccine manufacturer(s) to determine whether the viability of the vaccine(s) has been affected, and 4. **Document the action taken** on the Vaccine Incident Report and fax the form to (775) 684-8338.

PIN #:	**Provider Name:**	**Month/Year Reported:**

Day of Month:		1		2		3		4		5		6		7		8		9		10		11		12		13		14		15		16		17		18		19		20		21		22		23		24		25		26		27		28		29		30		31	
Time of day:																																																											
Temp F°	**Temp C°**	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM
Refrigerator Temp		**PLEASE FAX WITH YOUR VACCINE ORDER**																																																										
≥ 49	≥ 9.5																																																										
48	9.0																			*Take immediate action if temperature falls in the shaded area*																																										
47	8.5																																																										
46	8.0																																																										
45	7.5																																																										
44	7.0																																																										
43	6.5																																																										
42	6.0																																																										
41	5.5																																																										
40	5.0																																																										
39	4.5																																																										
38	4.0																																																										
37	3.5																																																										
36	3.0																																																										
35	2.0																																																										
34	1.5																																																										
33	0.5																																																										
32	0.0																																																										
31	-0.5																			*Take immediate action if temperature falls in the shaded area*																																										
30	-1.0																																																										
29	-1.5																																																										
≤ 28	≤ -2.0																																																										
Freezer Temp																																																										
≥ 8	≥ -13																																																										
7	-14.0																			*Take immediate action if temperature falls in the shaded area*																																									
6	-14.5																																																										
5	-15.0																																																										
4	-15.5																																																										
≤ 3	≤ -16																																																									
or colder																																																										
Room Temp																																																										
Staff Initials																																																										

Vaccine storage unit(s) has/have been cleaned this month: Y / N

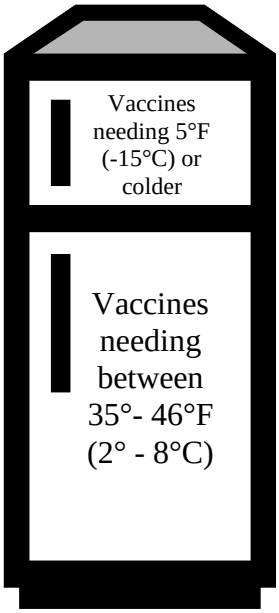
VACCINE STORAGE UNIT …Things to Consider!

In preparation for H1N1 you may want to ensure your vaccine storage unit is CDC acceptable. This will assure that your H1N1 vaccines, as well as your privately purchased vaccines and medications are stored in a manner to assure viability. In addition, certified, calibrated thermometers are required.

For more information on vaccine storage go to: http://www2a.cdc.gov/vaccines/ed/shtoolkit/

In evaluating or choosing your vaccine storage unit look for:

- Is it able to maintain required vaccine storage temperatures year-round (35-46º F),
- Is it large enough to hold the year's largest inventory (without crowding or touching the sides or back of the unit),
- Is it dedicated to the storage of vaccines and medications (no food allowed), and
- Does it have certified/calibrated thermometers?



Reminder: vaccines are not to be stored in the crisper drawers or in the doors

Acceptable Vaccine Storage Units Are:

- Commercial or lab styles are the most reliable but may be costly.
- Combination refrigerator/freezer unit sold for home use (not apartment size or smaller) are very reliable and moderately priced ($600-$700) and are acceptable as long as the refrigerator and freezer compartments each have a separate external door and separate temperature controls.
- Counter high refrigerators only are acceptable if they are lab style.
- Single thermostat units- Household-style refrigerators with a single thermostat are strongly discouraged. This type of refrigerator/freezer is acceptable only if storing vaccine in refrigerator *or* freezer, but not both. A single thermostat makes it difficult to maintain recommended temperatures in both sections. Do not purchase one of these. If you currently have a regular size combination refrigerator/freezer with only one control it may be reliable for refrigerator only storage.

Unacceptable Vaccine Storage Units Are:

The following units are unacceptable for vaccine storage at any time or duration, including daily use:

- "Dorm-style" or household-grade under-the-counter units provide poor temperature control and often freeze vaccines that require refrigeration, resulting in immediate and irreversible damage.
- "Dorm-style" units are defined as small refrigerator/freezer combination units with a single external door and an evaporator plate or cooling coil that forms a small freezer compartment within the unit or is pulled across the internal back wall of the unit.
- Counter high *refrigerator only* household grades are unacceptable.
- Any household refrigerator unit over 10 years old.

For questions call: Linda Platz RN, 775-684-5913

Vaccine Incident Report

Nevada State Immunization Program
4150 Technology Way, Suite 210, Carson City, Nevada 89706
phone: 775.684.5900 fax: 775.684.8338

Clinic/Facility/Practice Name: _____Provider (PIN) # _____

Reported by: _____ Telephone # _____ Date Reported: _____

Current temperature of refrigerator: _____F or _____C Max/min temperature reached: _____F or _____C

Current temperature of freezer: _____ F or _____C Max/min temperature reached: _____F or _____C

Temperature of Refrigerator at time of discovery of incident: _____ F or_____ C

Date and time of last recorded temp (which was within the recommended range): _____at ____AM/PM ___ F or____ C

Amount of time the temperature was outside normal range: refrigerator _____ freezer _____

Vaccines were moved to a working refrigerator/freezer post event: Yes/No

Description of incident: DO NOT THROW OUT AFFECTED VACCINES- (do not assume vaccines are not viable)*

What steps will be taken to prevent this from happening in the future?

Report of viability from manufacturer:

Complete section below for all vaccines affected by the event: (use another page if needed)

Vaccine Brand Name	Manufacturer	Lot No.	Exp Date	No. of doses	Vial Open or Closed	Disposition Per manufacturer i.e.: wasted, exp date changed, etc

HANDLING INSTRUCTIONS FOR 2009 H1N1 VACCINE

VACCINE RECEIPT INFORMATION:

Upon receipt of the package, the below steps should be followed:

- Inspect the package and contents for damage.
- Review the temperature monitor card in the package IMMEDIATELY.
- If package is damaged or if there are any concerns about vaccine integrity, please call McKesson Customer Service at 877-TEMP123 (877-836-7123) or your state/local immunization program right away.
- If the contents are in satisfactory condition, receive and process documents in accordance with the following procedures.
    - Count vials/product and place vaccine in monitored refrigerator immediately.
    - If the doses that you have received do not match the packing list, please contact your state/local immunization program right away.

Note: If multiple boxes are received, segregate the vaccine by box. Annotate box and temperature monitors/indicators to identify which temperature monitors belong to which box of vaccine (each box will contain a cold monitor and a warm monitor). The purpose of this is to be able to identify which vials or sprayers were affected if one of the boxes has become compromised in shipment.

VACCINE STORAGE INFORMATION:

- 2009 H1N1 vaccine must be maintained at a temperature of 2 to 8 degrees Celsius (35.6 to 46.4 degrees Fahrenheit). The vaccine must be kept at this temperature at all times.
- The vaccine **MUST NOT BE EXPOSED TO FREEZING TEMPERATURES!** The temperature monitoring device in your refrigerator must have a temperature reading capability to ensure the efficacy of the vaccine prior to administration. Temperature monitoring devices should be appropriately calibrated and methods used for calibration should have stated traceability to National Institute of Standards and Technology (NIST) standards. For more information on NIST traceability, open the following link. http://ts.nist.gov/Traceability/SupplMatls/suppl_matls_for_nist_policy_rev.cfm#FAQ_General. It is the receiving provider's responsibility to maintain proper storage temperature until vaccine administration.
- Any refrigerator used for vaccine storage must be dedicated to storage of biologics (i.e., food or beverages should not be stored in vaccine storage units). Refrigerators should have sufficient usable space to store the largest number of vaccine doses expected at one time without overloading. Vaccines stored in combination refrigerator/freezer units should NEVER be stored in areas directly underneath air vents, in deli-crispers/vegetable bins, or in the doors. Bottles of water can be added to these areas to create thermal mass, thus stabilizing refrigerator temperature. **Dorm-style refrigerator units (freezer and refrigerator with shared exterior door) provide poor temperature control and often freeze vaccines, therefore should not be used to store vaccines any longer than the length of a clinic for a particular clinical day (i.e., vaccines should not be stored overnight in dorm-style refrigerators).**
- The refrigerator storage unit must be electronically alarmed or manually monitored; temperatures should be recorded at a minimum of every 12 hours.
- A record of these readings should be maintained at the location of the vaccine storage unit, for example on the door. Refer to the Centers for Disease Control and Prevention's Vaccine Storage and Handling Toolkit for further guidance. This site can be accessed at the following link: http://www2a.cdc.gov/vaccines/ed/shtoolkit/pages/resources.htm.

Vaccine Storage and Handling Toolkit

National Center for Immunization and Respiratory Diseases

Vaccine Shipments

Disclaimer: State or local health department immunization programs may recommend or require different vaccine shipment and transport practices from those described here. The information presented here is meant to provide general guidelines only. Contact the state or local health department immunization program for details.

Standard Operating Procedures

Vaccine may be transported by either hand-carrying or shipping to another site. In both cases, the cold chain must be maintained. It is important to establish a routine, systematic process for handling vaccine shipments and vaccine transport. Each facility should develop its own written standard operating procedures (SOPs), covering every aspect of vaccine shipping: receiving, storing, packing, and transportation. Written SOPs are useful for reference, training, and evaluation of staff performing the work and should be included in the Routine Vaccine Storage and Handling Plan (see section on Storage and Handling Plans).

The SOP should specify that the vaccine is attended at all times during transport, that it is promptly placed into appropriate storage units upon arrival, and that it is transported in the minimum needed quantity to avoid unnecessary loss of expensive vaccine.

Without SOPs there can be no assurance that proper procedures will be followed or that problems will be identified, reported, and corrected. You may want to test various materials and packing configurations to find out what works best for your situation before developing your SOPs.

The SOP should specify that the vaccine is:	
1	Attended at all times during transport.
2	Promptly placed into appropriate storage units upon arrival
3	Transported in the minimum needed quantity to avoid unnecessary loss of expensive vaccine.

Receiving and Unpacking Vaccine Shipments

Receiving Vaccine Shipments

Arrange for vaccine deliveries to be made only when the vaccine coordinator or backup person is on duty. All staff members who accept vaccine deliveries must be aware of the importance of maintaining the cold chain and of the need to **immediately notify** the vaccine coordinator or backup person of the arrival of the vaccine shipment so that it can be handled and stored appropriately.

All staff members who accept vaccine deliveries must be aware of the importance of maintaining the cold chain and of the need to immediately notify the vaccine coordinator or backup person upon arrival.

Picking Up Vaccine Shipments

In some states, providers pick up vaccine from public depots and might be required to supply their own coolers for vaccine transport. In this case, the state health department immunization program will provide guidance regarding the appropriate coolers. When picking up vaccine shipments, do not place vaccine in the trunk of the vehicle. The temperature inside the trunk cannot be regulated and could become too hot or too cold for the vaccine. Deliver the vaccine directly to the facility and unpack and store it upon arrival (see Checking the Condition of a Shipment in this section).

When transporting vaccine in ordinary vehicles use the passenger compartment-not the trunk.

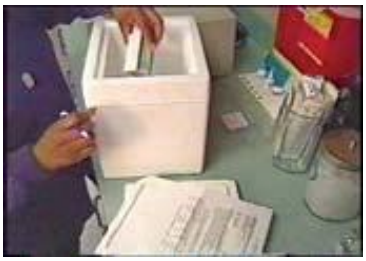
Checking the Condition of a Shipment

When you receive your vaccine shipment, it should be examined immediately.

- Examine the shipping container and its contents for any signs of physical damage.
- Determine if the shipping time was less than 48 hours. If the interval between shipment from the supplier and arrival of the product at the provider's office was more than 48 hours, the vaccine could have been exposed to excessive heat or cold that might have altered its integrity.

Examine the shipping container and its contents for any signs of physical damage.

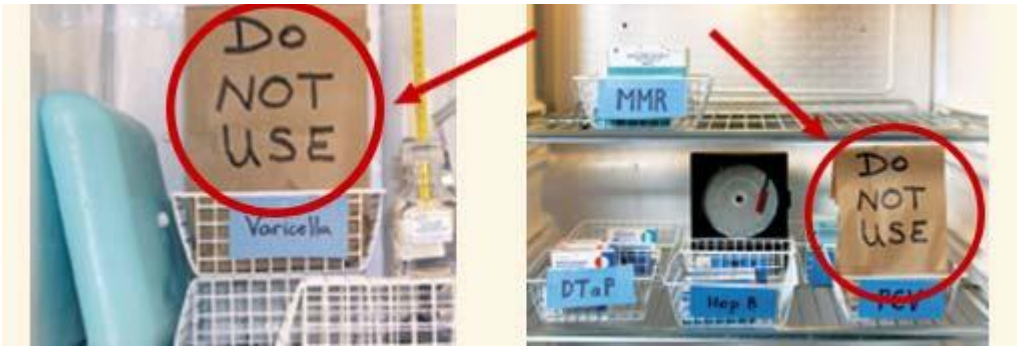
- Crosscheck the contents with the packing slip to be sure they match.
- Check the vaccine expiration dates to ensure that you have not received any vaccine or diluent that is already expired or that has a short expiration date (see Expiration Dates in the Vaccine Inventory Management section for details).
- Check that lyophilized (freeze-dried) vaccine has been shipped with the correct type and quantity of diluent for reconstitution.



Crosscheck the contents with the packing slip to be sure they match.

- Examine the vaccine and diluent for heat or cold damage
  - Check the cold chain monitor(s) (CCM) to see if the vaccine or diluent has been exposed to temperatures outside the recommended range during transport.
  - Check that inactivated vaccines are cold but not frozen. Refrigerated packs should still be cold. Frozen packs can be melted but the package should still be cold. Vaccines should not be in direct contact with refrigerated/frozen packs. There should be an insulating barrier between the vaccine and the refrigerated/frozen packs, such as crumpled brown packing paper, bubble wrap, or some other barrier.
  - Check that measles/mumps/rubella (MMR) vaccine is cold or frozen.
  - Check that MMRV, varicella, and zoster vaccines are frozen and that dry ice is present in the shipping container. Dry ice must be handled carefully (see Handling Dry Ice in the Resources section for details).
  - Check that diluent is cool or at room temperature. Diluent should not be in direct contact with refrigerated/frozen packs. There should be an insulating barrier between the diluent and the refrigerated/frozen packs, such as crumpled brown packing paper, bubble wrap, or some other barrier. The diluent for varicella vaccine may be shipped with its vaccine but should not be placed in the container with the dry ice.

If there are any discrepancies with the packing slip or concerns about the shipment, immediately notify the primary vaccine coordinator (or the backup person), mark the vaccine and diluent as "DO NOT USE," and store them in proper conditions apart from other vaccine supplies until the integrity of the vaccine and diluent is determined.



If there are any discrepancies with the packing slip or concerns about the shipment, immediately mark the vaccine and diluent as "DO NOT USE," and store them in proper conditions.

Contact the vaccine manufacturer and the state health department immunization program for further guidance (see Handling Inappropriate Vaccine Storage Conditions [Light and Temperature] in the Storage Troubleshooting section for details).

Storing and Documenting Vaccine Shipments Upon Arrival

After the vaccine shipment has been checked according to the procedures described in this section (see Checking the Condition of a Shipment), immediately store the vaccine and diluents at the recommended temperatures and record the arrival for each vaccine and diluents noting all the details as outlined in the stock records (see section on Vaccine Inventory Management). Do not leave the shipment unattended. The vaccines inside might warm to inappropriate temperatures and become unusable. All staff who may accept packages for the clinic must be aware that vaccine shipments require **immediate attention**. Staff who do not routinely handle vaccines but who accept vaccine shipments should alert the primary vaccine coordinator (or the designated backup person) as soon as vaccine shipments arrive so that they may be stored properly.

All staff who may accept packages for the clinic must be aware that vaccine shipments require immediate attention

Transporting Vaccine to Off-Site Clinics

General Recommendations

The best assurance of vaccine efficacy is to minimize the number of times vaccines are handled and transported. If vaccine transportation to another location is required, it is critical that vaccine potency is protected by maintaining the cold chain at all times.

If vaccine transportation to another location is required, it is critical that vaccine potency is protected by maintaining the cold chain at all times

When a multidose vial is used, Food and Drug Administration (FDA) regulations require that it be used only by the provider's office where it was first opened. A partially used vial may be transported to or from off-site clinics operated by the same provider as long as the cold chain is properly maintained. However, such a vial may not be transferred to another provider or transported across state lines. While there is no defined limit to the number of times vaccine may be transported to different clinic sites, multiple transport increases the risk that vaccine will be exposed to inappropriate storage conditions.

Transporting Varicella-Containing Vaccines

Varicella-containing vaccines should be transported on dry ice in a frozen state to maintain potency. If these vaccines must be transported to off-site clinics and dry ice is not available, single-antigen varicella vaccine and MMRV may be transported at 35° to 46° F (2° to 8° C); however, this will greatly reduce the shelf life of these vaccines. Single-antigen varicella vaccine and MMRV that are stored at 35° to 46° F (2° to 8° C) must be discarded 72 hours after removal from the freezer. Single-antigen varicella vaccine and MMRV that are removed from the freezer and transported at 35° to 46° F (2° to 8° C) must be labeled with the **date and time** they were removed from the freezer. Only **single-antigen** varicella vaccine and MMRV

may be transported and stored at 35° to 46° F (2° to 8° C). Zoster vaccine must be maintained at +5° F (-15° C) at all times, and must be transported on dry ice. Once removed from the freezer, none of these vaccines may be refrozen. Because of the risk of vaccine wastage, the National Center for Immunization and Respiratory Diseases, Centers for Disease Control and Prevention strongly discourages transport of these vaccines to off-site clinics. Consult your state health department immunization program for advice and details.

Transporting Diluent

Diluent should travel with its corresponding vaccine at all times to ensure that there are always equal numbers of vaccine vials and diluent vials for reconstitution. Additionally, the diluent must always be of the correct type and from the same manufacturer as the vaccine it accompanies.

Diluent should travel with its corresponding vaccine at all times to ensure that there are always equal numbers of vaccine vials and diluent vials for reconstitution

Diluent may be transported or shipped at room temperature or inside the same insulated cooled container as its corresponding vaccine. If transported inside cooled containers, diluent must not be in direct contact with refrigerated/frozen packs because of the potential for freezing. Refrigerate diluent in advance if it is to be carried in the insulated transport container so that it does not raise the temperature of the refrigerated vaccines.

Diluent for MMR, MMRV, varicella, and zoster vaccines may be transported at room temperature at 68° to 77°F (20° to 25°C), but must never be transported inside a container with dry ice.

Packing Vaccine for Transport to Off-Site Clinics

Different state health department immunization programs may recommend or require different vaccine transport practices and procedures. Contact your state health department immunization program for specific policies regarding vaccine transport, details on how to pack vaccine and diluent for transport, and procedures for maintaining the cold chain in the field.

The following are general guidelines for packing vaccine:

1. Use properly insulated containers to transport vaccine. These containers should be validated to ensure that they are capable of maintaining the vaccine at the correct temperatures. You may use the shipping containers the vaccines arrived in from the manufacturer. Alternatively, you may use hard-sided plastic insulated containers or Styrofoam coolers with at least 2-inch thick walls.

Use properly insulated containers to transport vaccine.

Thin-walled Styrofoam coolers, such as those purchased at grocery stores to hold beverages, are not acceptable.

Thin-walled Styrofoam coolers, such as those purchased at grocery stores to hold beverages, are not acceptable.

2. Pack enough refrigerated/frozen packs to maintain the cold chain. Do not use loose or bagged ice. The number and placement of refrigerated/frozen packs inside the container will depend on container size and outside temperature. For detailed instructions, see Chart of Refrigerated/Frozen Needs for Different Climates in the Resources Section.

3. Be sure to place an insulating barrier (e.g., bubble wrap, crumpled brown packing paper, Styrofoam peanuts) between the refrigerated/frozen packs and the vaccines to prevent accidental freezing. A layer of toweling is not sufficient as a barrier. The contents of the container should be layered as follows: refrigerated/frozen packs, barrier, vaccine, thermometer, another layer of barrier, and additional refrigerated/frozen packs.
4. Pack vaccines in their original packaging on top of the barrier. Do not remove vaccine vials from boxes, and do not draw up vaccine in advance.
5. Use a properly placed thermometer near the vaccine to assess whether the cold chain has been broken. The thermometer should be place next to the vaccine and should not come in contact with the refrigerated/frozen packs.
6. Attach labels to the outside of the container to clearly identify the contents as being valuable and fragile vaccines.

Refrigerated/frozen packs

Place bubble wrap, crumpled brown packing paper, or Styrofoam peanuts between the refrigerated/frozen packs and the vaccines.

Place a thermometer next to the vaccine but not in contact with the refrigerated/frozen packs.

Attach the appropriate labes to the outside of the container.

7. Record vaccine type(s), quantity, date, time, and originating facility on a label on the outside of the container.

You may also see Maintaining the Cold Chain During Transport in the Resources section for general guidelines.

Monitoring Temperatures During Off-Site Clinics

If vaccine must be maintained in an insulated cooler during an off-site clinic, keep the cooler closed as much as possible. At a minimum, vaccine temperatures be checked and recorded **hourly.**

If vaccine must be maintained in an insulated cooler during an off-site clinic, keep the cooler closed as much as possible. A thermometer must be kept in the cooler with the vaccines, and temperatures should be checked and recorded periodically to ensure that the cold chain is not broken. The National Center for Immunization and Respiratory Diseases, Centers for Disease Control and Prevention recommends that, at a minimum, vaccine temperatures be checked and recorded **hourly.**

Shipping Vaccine to State Health Departments or Vaccine Manufacturers

Shipping Vaccine with a Short Expiration Date or Other Usable Vaccine

Occasionally, providers may need to return vaccine with a short expiration date or other usable publicly purchased vaccine to the immunization program. Contact the state health department immunization program for detailed instructions on returning these vaccines. Some state health department immunization programs may permit the transfer of vaccine with a short expiration date or other usable vaccine to another provider. Consult your immunization program for specific policies regarding vaccine transfers.

Shipping Unusable Vaccine

Expired vaccine, wasted vaccine, and vaccine that has lost its potency because of inappropriate storage conditions may be returned to the vaccine manufacturer or to the state health department immunization program under certain circumstances. Contact the vaccine supplier, which may be the vaccine manufacturer or the state health department immunization program, for detailed instructions on returning these vaccines. If the vaccines are publicly purchased, contact the state health department immunization program for instructions on returning vaccines for excise tax credit. In general, expired, wasted or mishandled vaccine may be shipped via the U.S. mail or by other available modes of shipment (e.g., UPS ™, FedEx®). Do not return loose vials in an envelope. Pack the vials in a box with packing material to avoid breakage.

Returned unusable vaccine is not considered to be hazardous material, so no special warning signs or special handling notices are necessary.

Centers for Disease Control and Prevention

Checklist for Safe Vaccine Handling and Storage

Here are the 20 most important things you can do to safeguard your vaccine supply. Are you doing them all? Reviewing this list can help you improve your clinic's vaccine management practices.

YES	NO	
		1. We have a designated person in charge of the handling and storage of our vaccines.
		2. We have a back-up person in charge of the handling and storage of our vaccines.
		3. A vaccine inventory log is maintained that documents: _____ Vaccine name and number of doses received _____ Date the vaccine was received _____ Arrival condition of vaccine _____ Vaccine manufacturer and lot number _____ Vaccine expiration date.
		4. Our refrigerator for vaccines is either household-style or commercial-style, NOT dormitory-style. The freezer compartment has a separate exterior door. Alternatively, we use two storage units: a free-standing refrigerator and a separate, free-standing freezer.
		5. We do NOT store any food or drink in the refrigerator or freezer.
		6. We store vaccines in the middle of the refrigerator or freezer, and NOT in the door.
		7. We stock and rotate our vaccine supply so that the newest vaccine of each type (with the longest expiration date) is placed behind the vaccine with the shortest expiration date.
		8. We check vaccine expiration dates and we first use those that will expire soonest.
		9. We post a sign on the refrigerator door showing which vaccines should be stored in the refrigerator and which should be stored in the freezer.
		10. We always keep a thermometer in the refrigerator.
		11. The temperature in the refrigerator is maintained at 35-46°F (2-8°C).
		12. We keep extra containers of water in the refrigerator to help maintain cold temperatures.
		13. We always keep a thermometer in the freezer.
		14. The temperature in the freezer is maintained at +5°F (-15°C) or colder.
		15. We keep ice packs and other ice-filled containers in the freezer to help maintain cold temperatures.
		16. We post a temperature log on the refrigerator door on which we record the refrigerator and freezer temperatures twice a day – first thing in the morning and at clinic closing time – and we know whom to call if the temperature goes out of range.
		17. We have a "Do Not Unplug" sign next to the refrigerator's electrical outlet.
		18. In the event of a refrigerator failure, we take the following steps: _____ We assure that the vaccines are placed in a location with adequate refrigeration _____ We mark exposed vaccines and separate them from undamaged vaccines _____ We note the refrigerator or freezer temperature and contact the vaccine manufacturer or state health department to determine how to handle the affected vaccines _____ We follow the vaccine manufacturer's or health department's instructions as to whether the affected vaccines can be used, and, if so, we mark the vials with the revised expiration date provided by the manufacturer or health department.
		19. We have obtained a detailed written policy for general and emergency vaccine management from our local or state health department.
		20. If all above answers are "YES," we are patting ourselves on the back. If not, we have assigned someone to implement needed changes!

WARNING

Do not unplug the refrigerator/
freezer or break circuit.
Expensive vaccine in storage.

In event of electrical problem, immediately contact:

WARNING

Do not unplug the refrigerator/
freezer or break circuit.
Expensive vaccine in storage.

In event of electrical problem, immediately contact:

WARNING

Do not unplug the refrigerator/
freezer or break circuit.
Expensive vaccine in storage.

In event of electrical problem, immediately contact:

Appendices

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MMWR

Recommendations and Reports

August 28, 2009 / 58(RR10);1-8

Use of Influenza A (H1N1) 2009 Monovalent Vaccine

Recommendations of the Advisory Committee on Immunization Practices (ACIP), 2009

Prepared by

National Center for Immunization and Respiratory Diseases, CDC

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Summary

This report provides recommendations by CDC's Advisory Committee on Immunization Practices (ACIP) regarding the use of vaccine against infection with novel influenza A (H1N1) virus. Information on vaccination for seasonal influenza has been published previously (CDC. Prevention and control of seasonal influenza with vaccines: recommendations of the Advisory Committee on Immunization Practices [ACIP], 2009. MMWR 2009;58[No. RR-8]). Vaccines against novel influenza A (H1N1) virus infection have not yet been licensed; however, licensed vaccine is expected to be available by mid-October 2009. On July 29, 2009, ACIP reviewed epidemiologic and clinical data to determine which population groups should be targeted initially for vaccination. ACIP also considered the projected vaccine supply likely to be available when vaccine is first available and the expected increase in vaccine availability during the following 6 months. These recommendations are intended to provide vaccination programs and providers with information to assist in planning and to alert providers and the public about target groups comprising an estimated 159 million persons who are recommended to be first to receive influenza A (H1N1) 2009 monovalent vaccine. The guiding principle of these recommendations is to vaccinate as many persons as possible as quickly as possible. Vaccination efforts should begin as soon as vaccine is available. State and local health officials and vaccination providers should make decisions about vaccine administration and distribution in accordance with state and local conditions. Highlights of these recommendations include 1) the identification of five initial target groups for vaccination efforts (pregnant women, persons who live with or provide care for infants aged <6 months, health-care and emergency medical services personnel, children and young adults aged 6 months--24 years, and persons aged 25--64 years who have medical conditions that put them at higher risk for influenza-related complications), 2) establishment of priority for a subset of persons within the initial

target groups in the event that initial vaccine availability is unable to meet demand, and 3) guidance on use of vaccine in other adult population groups as vaccine availability increases. Vaccination and health-care providers should be alert to announcements and additional information from state and local health departments and CDC concerning vaccination against novel influenza A (H1N1) virus infection. Additional information is available from state and local health departments and from CDC's influenza website (http://www.cdc.gov/flu).

Introduction

In April 2009, a new influenza A (H1N1) virus, novel influenza A (H1N1) virus, was determined to be the cause of influenza illness in two children in the United States during March and April 2009 (1,2) and the cause of outbreaks of respiratory illness in Mexico (3). This virus was transmitted in communities across North America within weeks and was identified in many areas of the world by May 2009 (4,5). On June 11, 2009, the World Health Organization (WHO) declared a worldwide pandemic, indicating uncontained community-level transmission of the novel influenza A (H1N1) virus in multiple areas of the world (5). Worldwide transmission of the novel influenza A (H1N1) virus has continued since June in both the Northern and Southern Hemispheres (6). Transmission is likely to persist and might increase in the Northern Hemisphere during fall and winter. In contrast to seasonal influenza, current evidence indicates that relatively few severe cases of novel influenza A (H1N1) virus infection have occurred among older persons, and the highest hospitalization rates for illness caused by this virus have been among persons aged <65 years (7). The signs and symptoms of novel influenza A (H1N1) virus infection are similar to those of seasonal influenza, and specific diagnostic testing is required to distinguish novel influenza A (H1N1) virus from seasonal influenza virus (7; CDC, unpublished data, 2009).

Influenza vaccination is the most effective method for preventing influenza and influenza-related complications. However, current seasonal influenza vaccines are not likely to provide protection against novel influenza A (H1N1) virus (8). Specific vaccines against the novel influenza A (H1N1) virus are being manufactured, and licensed vaccine is expected to be available in the United States by mid-October 2009 (9). However, the initial supply of these vaccines might not be enough to meet the demand for vaccine. For this reason, CDC's Advisory Committee on Immunization Practices (ACIP) recommends that certain groups at highest risk for infection or influenza-related complications should be the initial targets for vaccination. Highlights of these recommendations include 1) the identification of five initial target groups for vaccination efforts (pregnant women, persons who live with or provide care for infants aged <6 months, health-care and emergency medical services personnel, children and young adults aged 6 months--24 years, and persons aged 25--64 years who have medical conditions that put them at higher risk for influenza-related complications), 2) establishment of priority for a subset of persons within the initial target groups in the event that initial vaccine availability is unable to meet demand, and 3) guidance on use of vaccine in other adult population groups as vaccine availability increases. Because novel influenza A (H1N1) virus is continuing to cause illness in the United States and worldwide, the primary focus of vaccination efforts should be to vaccinate as many persons as possible in the recommended target groups as quickly as possible once vaccine becomes available. As vaccine availability increases, additional groups are recommended for vaccination. ACIP will review new epidemiologic and clinical data as they become available and might revise these recommendations.

Methods

ACIP provides recommendations to CDC for the prevention and control of vaccine-preventable diseases in the U.S. civilian population. During April--July 2009, the ACIP Influenza Working Group met frequently by teleconference to discuss new information on the spread of novel influenza A (H1N1) virus. In the process of developing vaccination recommendations for consideration by the full ACIP, members considered the

evolving burden of illness caused by the virus, the age and risk groups most affected, progress in developing vaccines, anticipated vaccine supply, and various possible vaccination strategies. ACIP's deliberations were informed by consultation with other federal agencies and a review of vaccine allocation guidance developed as part of influenza prepandemic planning during 2007--2008 (10).

The full committee's initial discussions related to novel influenza A (H1N1) virus took place during a public ACIP session held on June 25--26, 2009. At a subsequent public meeting held on July 29, 2009, ACIP made recommendations for use of the influenza A (H1N1) 2009 monovalent vaccine currently in production for the U.S. market. Information presented at these meetings is available at http://www.cdc.gov/vaccines/recs/acip/slides-jun09.htm and http://www.cdc.gov/vaccines/recs/acip/slides-july09-flu.htm.

Background

Human infections with the novel influenza A (H1N1) virus were first identified in April 2009 (1), and infections with this virus have been reported worldwide (5). Because serologic studies suggest that a large majority of the population is susceptible to novel influenza A (H1N1) virus, substantial potential exists for widespread infection (2). The novel influenza A (H1N1) virus is antigenically and genetically distinct from other human influenza A (H1N1) viruses in circulation since 1977 (2). As of August 1, 2009, the novel influenza A (H1N1) viruses circulating worldwide appear to be antigenically similar (11).

Clinical Features

The signs and symptoms of novel influenza A (H1N1) virus infection are similar to those of seasonal influenza (7,12). Definitive diagnosis of novel influenza A (H1N1) virus infection requires specific testing for H1N1 viruses using real-time reverse transcriptase--polymerase chain reaction or viral culture (7,13). Rapid influenza diagnostic tests (RIDTs) for seasonal influenza sometimes can detect novel influenza A (H1N1) virus, but sensitivity has been estimated at 40%--70% (13,14). Negative RIDTs should not be used to exclude the diagnosis of novel influenza A (H1N1) virus infection (13).

The age distribution of confirmed illness, severity of illness, and prevalence of medical risk factors among persons with severe illness have been consistent among many countries and over time. As of July 31, 2009, the median age of persons with laboratory-confirmed infections in the United States was 12 years, and the highest infection incidence was among persons aged 5--24 years (7,11). The incidence of infection was lowest among persons aged ≥65 years. Similar findings have been reported in other countries (15).

A comparison of the age distribution of hospitalized persons with laboratory-confirmed novel influenza A (H1N1) also demonstrates a striking difference from seasonal influenza (Figure). As of July 31, 2009, the median age of hospitalized persons with laboratory-confirmed novel influenza A (H1N1) virus infection was 20 years, and the incidence of hospitalization was highest among young children aged <4 years (11; CDC, unpublished data, 2009). Only 282 (5%) of 5,514 hospitalizations and 29 (8%) of the 353 reported deaths had occurred among persons aged ≥65 years (CDC, unpublished data, 2009). The median age among persons who died with novel influenza A (H1N1) virus infection was 37 years. In contrast, in multiple studies of seasonal influenza, hospitalization and mortality rates have been highest among persons aged ≥65 years, and an estimated 90% of seasonal influenza-related deaths and 60% of seasonal influenza-related hospitalizations occurred among adults aged ≥65 years (16,17). As of July 31, 2009, only 282 (5%) of 5,514 hospitalizations and 29 (8%) of the 353 reported deaths attributed to novel influenza A (H1N1) virus infection had occurred among persons aged ≥65 years (CDC, unpublished data, 2009). Cumulative novel influenza A (H1N1) hospitalization rates for April--July 2009 approached or exceeded typical end-of-season cumulative rates for

seasonal influenza among school-aged children and adults aged 18--49 years in the Emerging Infections Program* (EIP) surveillance areas (11). However, among persons aged ≥65 years, these cumulative hospitalization rates are <20% of the rates typically observed during the winter among persons in this age group. The median age of hospitalized patients during the 2007--08 influenza season in EIP surveillance areas was 59 years, compared with a median age of 26 years for persons hospitalized in these areas during April--July 2009 (CDC, unpublished data, 2009). In addition, outbreaks attributable to novel influenza A (H1N1) viruses among older adults in long-term--care facilities have not been reported even when novel influenza A (H1N1) has been identified among health-care workers in these facilities who worked while ill.

Medical risk factors for severe infection are similar to those identified previously in studies of seasonal influenza (12). In one case series of 179 patients hospitalized with laboratory-confirmed novel influenza A (H1N1) virus infection, 117 (65%) patients had a medical risk factor previously associated with severe infection in studies of seasonal influenza (e.g., chronic heart, lung, renal, liver disease; cancer or immunosuppression; or pregnancy) (12,18; CDC, unpublished data, 2009). Deaths caused by novel influenza A (H1N1) have been reported among pregnant women. In one case series, the incidence of hospitalization for confirmed novel influenza A (H1N1) virus infection among pregnant women was four times higher than that of the general population (19). Obesity (defined as body-mass index [BMI] ≥30) or morbid obesity (BMI ≥40) has been noted among hospitalized patients in some case series (20,21). However, the majority of these patients had other medical risk factors, and investigations to determine whether obesity or morbid obesity is an independent risk factor for severe infection are underway.

Epidemiology and Transmission

The epidemiology of novel influenza A (H1N1) virus infection is under investigation, and epidemiologic characteristics might change as transmission continues. Outbreaks in settings in which young person's congregate (e.g., schools, colleges, and camps) have been a frequent source of community transmission (22,23). During spring and summer 2009, many schools and camps in the United States were dismissed temporarily as a result of outbreak concerns, causing considerable community impact (24).

The number of laboratory-confirmed infections underestimates the incidence of influenza illness caused by novel influenza A (H1N1) virus infection because laboratory testing has been focused on persons with more severe infection. Similar to clinical practice for seasonal influenza, many healthy persons with likely novel influenza A (H1N1) virus infections never are tested because their illness does not require medical intervention or specific diagnosis. Community surveys and population-based telephone surveys in areas with focal outbreaks of novel influenza A (H1N1) virus infection have identified self-reported influenza-like illness (ILI) among approximately 6% of the population in the areas surveyed (CDC, unpublished data, 2009). In June 2009, the New York City Health Department conducted a household survey that indicated that 7% of New Yorkers reported having ILI (fever accompanied by either cough or sore throat) during May 1--20, 2009; because other indicators of ILI (e.g., physician visits for respiratory illness) demonstrated continued and increasing community transmission within New York City, subsequent surveys are likely to indicate that even higher rates of self-reported ILI occurred during late May--June 2009 (25).

Transmission of novel influenza A (H1N1) virus infection in health-care settings has been reported. Among 11 health-care personnel (HCP) with probable or possible patient-to-HCP acquisition and available information on personal protective equipment use, only three HCP reported always using either a surgical mask or an N95 respirator in one case series (26). Acquisition of novel influenza A (H1N1) virus infection by HCP in community settings also has been identified, raising the possibility of introduction of novel influenza A (H1N1) viruses to patients in health-care settings by infected HCP (26).

Vaccination Against Novel Influenza A (H1N1) Virus Infection

Limited data from serologic studies of persons who received vaccination with seasonal influenza vaccines suggest that seasonal influenza vaccines will not provide protection against novel influenza A (H1N1) virus. Among adults, cross-reactive antibody to novel influenza A (H1N1) virus at titers that correlate with protection from illness in studies of seasonal influenza vaccine was detected in 6%--9% of those aged 18--64 years and in 33% of those aged >60 years. No children tested had cross-reactive antibody to novel influenza A (H1N1) virus. Titers of cross-reactive antibody to novel influenza A (H1N1) virus did not increase after administration of seasonal influenza vaccine (2,8).

Vaccines against novel influenza A (H1N1) virus infection are being produced using methods similar to those used for seasonal influenza vaccines. Licensure of vaccines against novel influenza A (H1N1) virus will be based on the same licensure standards used for seasonal influenza vaccines, as is done routinely each year when strains are changed in the seasonal vaccine. Both live, attenuated and inactivated influenza A (H1N1) 2009 monovalent vaccine formulations will be available initially; as with seasonal influenza vaccines, neither of these vaccines will contain adjuvants. The Food and Drug Administration (FDA) and WHO have selected A/California/07/2009 (H1N1) for use as the strain for the vaccines currently being manufactured.

In previously unvaccinated persons aged <9 years, 2 doses of seasonal influenza vaccine are required to induce immunity because young children typically have had limited exposure to influenza viruses and are not immunologically primed (i.e., they do not have preexisting antibodies) (12). The lack of preexisting antibody cross-reactive with the novel influenza A (H1N1) virus among children and younger adults raises the possibility that 2 doses of vaccine (typically separated by ≥21 days) also will be needed to provide protection for persons in these age groups. Ongoing studies will provide additional information about the immune response vaccine, including which groups might need 2 doses. Updated information will be published by CDC in MMWR or will be available at http://www.cdc.gov/flu.

Several vaccines containing an adjuvant also are being studied but probably will not be available initially. These vaccines likely will need to be used under an Emergency Use Authorization.† Additional guidance will be provided if adjuvanted vaccines are made available.

Recommended Use of Influenza A (H1N1) 2009 Monovalent Vaccine

ACIP recommends that vaccination efforts should focus initially on persons in five target groups (Box) whose members are at higher risk for influenza or influenza-related complications, are likely to come in contact with influenza viruses as part of their occupation and could transmit influenza viruses to others in medical care settings, or are close contacts of infants aged <6 months (who are too young to be vaccinated). In the event that vaccine availability is unable to meet initial demand, priority should be given to a subset of the five target groups (Box).

Initial Target Groups

When vaccine is first available, ACIP recommends that programs and providers administer vaccine to persons in the following five target groups (order of target groups does not indicate priority):

- pregnant women,
- persons who live with or provide care for infants aged <6 months (e.g., parents, siblings, and daycare providers),
- health-care and emergency medical services personnel,§

- persons aged 6 months--24 years, and
- persons aged 25--64 years who have medical conditions that put them at higher risk for influenza-related complications.¶

These five target groups comprise an estimated 159 million persons in the United States. This estimate does not accurately account for persons who might be included in more than one category (e.g., a health-care worker with a high-risk condition). Vaccination programs and providers should begin vaccination of persons in all these groups as soon as vaccine is available.

Subset of Target Groups During Limited Vaccine Availability

Current projections of initial vaccine supply indicate that establishment of a subset of the five initial target groups will not be necessary in most areas. However, demand for vaccination and initial supply might vary considerably across geographic areas. If the supply of the vaccine initially available is not adequate to meet demand for vaccination among the five target groups listed above, ACIP recommends that the following subset of the initial target groups receive priority for vaccination until vaccine availability increases (order of target groups does not indicate priority):

- pregnant women,
- persons who live with or provide care for infants aged <6 months (e.g., parents, siblings, and daycare providers),
- health-care and emergency medical services personnel who have direct contact with patients or infectious material,
- children aged 6 months--4 years, and
- children and adolescents aged 5--18 years who have medical conditions that put them at higher risk for influenza-related complications.

This subset of the five target groups comprises approximately 42 million persons in the United States. Vaccination programs and providers should give priority to this subset of the five target groups only if vaccine availability is too limited to initiate vaccination for all persons in the five initial target groups.

Expanding Vaccination Efforts Beyond Initial Target Groups

Decisions about expanding vaccination to include additional populations beyond the five initial target groups should be made at the local level because vaccine availability and demand might vary considerably by area. Once vaccination programs and providers are meeting the demand for vaccine among the persons in the five initial target groups, vaccination should be expanded to all persons aged 25--64 years. Decisions about expanding or establishing priorities for vaccination should be made in accordance with local circumstances based on the judgment of state and local health officials and health-care providers. CDC and other public health agencies will assess the vaccine supply on a continuing basis throughout the manufacturing period. CDC and state and local health authorities will inform providers and the general public if any indication exists of a substantial delay or an inadequate supply.

Current studies indicate the risk for infection among persons aged ≥65 years is less than the risk for persons in younger age groups. Expanding vaccination recommendations to include adults aged ≥65 years is recommended only after assessment of vaccine availability and demand at the local level. Once demand for vaccine among younger age groups is being met, vaccination should be expanded to all persons aged ≥65 years. This recommendation might need to be reassessed as new epidemiologic, immunologic, or clinical trial data warrant and in the context of global need for vaccine.

ACIP makes the following additional recommendations about use of influenza A (H1N1) 2009 monovalent vaccine:

- The number of doses of vaccine required for immunization against novel influenza A (H1N1) has not been established. Because vaccine availability is expected to increase over time, vaccine should not be held in reserve for patients who already have received 1 dose but might require a second dose.
- Simultaneous administration of inactivated vaccines against seasonal and novel influenza A (H1N1) viruses is permissible if different anatomic sites are used. However, simultaneous administration of live, attenuated vaccines against seasonal and novel influenza A (H1N1) virus is not recommended.
- All persons currently recommended for seasonal influenza vaccine, including those aged ≥65 years, should receive the seasonal vaccine as soon as it is available. Recommendations for use of the 2009--10 seasonal influenza vaccine have been published previously (12).

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* CDC's Emerging Infections Program Influenza Project conducts surveillance for laboratory-confirmed, influenza-related hospitalizations in children (persons aged <18 years) and adults in 60 counties covering 12 metropolitan areas of 10 states (San Francisco, California; Denver, Colorado; New Haven, Connecticut; Atlanta, Georgia; Baltimore, Maryland; Minneapolis/St. Paul, Minnesota; Albuquerque, New Mexico; Las Cruces, New Mexico; Albany, New York; Rochester, New York; Portland, Oregon; and Nashville, Tennessee). Cases are identified by reviewing hospital laboratory and admission databases and infection-control logs for children and adults with a documented positive influenza test (viral culture, direct/indirect fluorescent antibody assay (DFA/IFA), real-time reverse transcription--polymerase chain reaction (rRT-PCR), or a commercial rapid antigen test) conducted as a part of routine patient care.

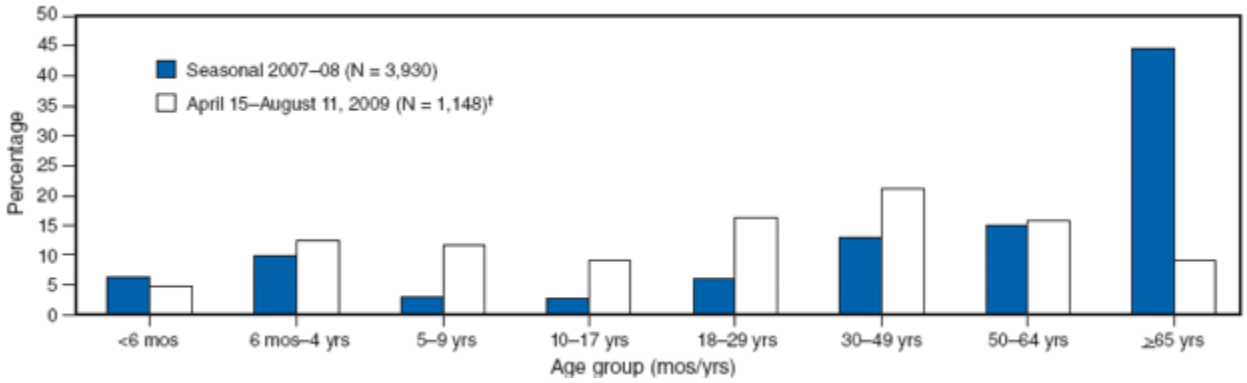
† If an emerging public health threat is identified for which no licensed or approved product exists, the Project BioShield Act of 2004 authorizes the Food and Drug Administration commissioner to issue and Emergency Use Authorization so promising countermeasures can be disseminated quickly to protect the safety of the U.S. population.

§ Health-care personnel (HCP) include all paid and unpaid persons working in health-care settings who have the potential for exposure to patients with influenza, infectious materials, including body substances, contaminated medical supplies and equipment, or contaminated environmental surfaces. HCP might include (but are not limited to) physicians, nurses, nursing assistants, therapists, technicians, emergency medical service personnel, dental personnel, pharmacists, laboratory personnel, autopsy personnel, students and trainees, contractual staff not employed by the health-care facility, and persons (e.g., clerical, dietary, housekeeping, maintenance, and volunteers) not directly involved in patient care but potentially exposed to infectious agents that can be transmitted to and from HCP. The recommendations in this report apply to HCP in acute-care hospitals, nursing homes, skilled nursing facilities, physicians' offices, urgent care centers, and outpatient clinics, and to persons who provide home health

care and emergency medical services (27). Emergency medical services personnel might include persons in an occupation (e.g., emergency medical technicians and fire fighters) who provide emergency medical care as part of their normal job duties.

¶ Chronic medical conditions that confer a higher risk for influenza-related complications include chronic pulmonary (including asthma), cardiovascular (except hypertension), renal, hepatic, cognitive, neurologic/neuromuscular, hematologic, or metabolic disorders (including diabetes mellitus) or immunosuppression (including immunosuppression caused by medications or by human immunodeficiency virus) (12).

FIGURE. Distribution by age group of persons hospitalized with laboratory-confirmed influenza,* --- United States, 2007--08 winter influenza season and April 15--August 11, 2009



Source: Emerging Infections Program, CDC.

* Evidence of a positive influenza test result by viral culture, direct fluorescent assay, immunoflourescence assay, real-time reverse--transcription polymerase chain reaction, rapid influenza diagnostic test, serology, or written note in the medical chart.

† Influenza subtype cannot be determined with some types of tests, and the proportion of positive influenza tests that were attributable to novel influenza A (H1N1) virus cannot be determined. However, national surveillance for influenza viruses indicates that >95% of viruses circulating during this time were novel influenza A (H1N1) virus.

Alternate Text: The figure contrasts the distribution by age group of persons hospitalized with laboratory-confirmed influenza for two periods, the 2007–08 winter influenza season, when ordinary seasonal influenza virus predominated, and April 15–August 11, 2009, when an estimated >95% of influenza cases were caused by novel influenza A (H1N1) virus. The data indicate that in contrast with seasonal influenza virus, which is highest among persons aged ≥65 years, incidence of infection with novel influenza A (H1N1) virus was lowest among persons aged ≥65 years.

BOX. Initial target groups for novel influenza A (H1N1) vaccination programs and a subset of these target groups to receive vaccine if initial vaccine availability is not sufficient to meet demand*

Initial target groups

ACIP recommends that programs and providers provide vaccine to all persons in the following five initial target groups as soon as vaccine is available (order of target groups does not indicate priority):

- pregnant women,
- persons who live with or provide care for infants aged <6 months (e.g., parents, siblings, and daycare providers),
- health-care and emergency medical services personnel,†
- children and young adults aged 6 months--24 years, and

- persons aged 25--64 years who have medical conditions that put them at higher risk for influenza-related complications.§

Subset of initial target groups

ACIP recommends that all persons in the following subset of the five initial target groups receive priority for vaccination if vaccine availability is not sufficient to meet demand (order of target groups does not indicate priority):

- pregnant women,
- persons who live with or provide care for infants aged <6 months (e.g., parents, siblings, and daycare providers),
- health-care and emergency medical services personnel who have direct contact with patients or infectious material,
- children aged 6 months--4 years, and
- children and adolescents aged 5--18 years who have medical conditions that put them at higher risk for influenza-related complications.§

* Priority should be given to persons in the subset of the five target groups only if initial vaccine availability is not sufficient to meet demand for all persons in the five target groups. As vaccine availability increases, vaccination programs should be expanded to include all members of the initial target groups. Vaccination of other adult populations is recommended as vaccine availability increases.

† Health-care personnel (HCP) include all paid and unpaid persons working in health-care settings who have the potential for exposure to patients with influenza, infectious materials, including body substances, contaminated medical supplies and equipment, or contaminated environmental surfaces. HCP might include (but are not limited to) physicians, nurses, nursing assistants, therapists, technicians, emergency medical service personnel, dental personnel, pharmacists, laboratory personnel, autopsy personnel, students and trainees, contractual staff not employed by the health-care facility, and persons (e.g., clerical, dietary, housekeeping, maintenance, and volunteers) not directly involved in patient care but potentially exposed to infectious agents that can be transmitted to and from HCP. The recommendations in this report apply to HCP in acute-care hospitals, nursing homes, skilled nursing facilities, physicians' offices, urgent care centers, and outpatient clinics, and to persons who provide home health care and emergency medical services. Emergency medical services personnel might include persons in an occupation (e.g., emergency medical technicians and fire fighters) who provide emergency medical care as part of their normal job duties.

§ Medical conditions that confer a higher risk for influenza-related complications include chronic pulmonary (including asthma), cardiovascular (except hypertension), renal, hepatic, cognitive, neurologic/neuromuscular, hematologic, or metabolic disorders (including diabetes mellitus) and immunosuppression (including immunosuppression caused by medications or by human immunodeficiency virus).

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VACCINE ADVERSE EVENT REPORTING SYSTEM

24 Hour Toll-Free Information 1-800-822-7967
P.O. Box 1100, Rockville, MD 20849-1100
PATIENT IDENTITY KEPT CONFIDENTIAL

For CDC/FDA Use Only
VAERS Number _____
Date Received _____

Patient Name:
Last First M.I.
Address
City State Zip
Telephone no. (____) _____

Vaccine administered by (Name):
Responsible Physician _____
Facility Name/Address
City State Zip
Telephone no. (____) _____

Form completed by (Name):
Relation to Patient ☐ Vaccine Provider ☐ Patient/Parent ☐ Manufacturer ☐ Other
Address *(if different from patient or provider)*
City State Zip
Telephone no. (____) _____

1. State	2. County where administered	3. Date of birth mm / dd / yy	4. Patient age	5. Sex ☐ M ☐ F	6. Date form completed mm / dd / yy

7. Describe adverse events(s) (symptoms, signs, time course) and treatment, if any

8. Check all appropriate:
☐ Patient died (date mm / dd / yy)
☐ Life threatening illness
☐ Required emergency room/doctor visit
☐ Required hospitalization (_____days)
☐ Resulted in prolongation of hospitalization
☐ Resulted in permanent disability
☐ None of the above

9. Patient recovered ☐ YES ☐ NO ☐ UNKNOWN

12. Relevant diagnostic tests/laboratory data

10. Date of vaccination mm / dd / yy
Time _____ AM PM

11. Adverse event onset mm / dd / yy
Time _____ AM PM

13. Enter all vaccines given on date listed in no. 10

	Vaccine (type)	Manufacturer	Lot number	Route/Site	No. Previous Doses
a.					
b.					
c.					
d.					

14. Any other vaccinations within 4 weeks prior to the date listed in no. 10

	Vaccine (type)	Manufacturer	Lot number	Route/Site	No. Previous doses	Date given
a.						
b.						

15. Vaccinated at:
☐ Private doctor's office/hospital ☐ Military clinic/hospital
☐ Public health clinic/hospital ☐ Other/unknown

16. Vaccine purchased with:
☐ Private funds ☐ Military funds
☐ Public funds ☐ Other/unknown

17. Other medications

18. Illness at time of vaccination (specify)

19. Pre-existing physician-diagnosed allergies, birth defects, medical conditions (specify)

20. Have you reported this adverse event previously? ☐ No ☐ To health department ☐ To doctor ☐ To manufacturer

Only for children 5 and under

22. Birth weight _____lb. _____oz.

23. No. of brothers and sisters

21. Adverse event following prior vaccination (check all applicable, specify)

	Adverse Event	Onset Age	Type Vaccine	Dose no. in series
☐ In patient				
☐ In brother or sister				

Only for reports submitted by manufacturer/immunization project

24. Mfr./imm. proj. report no.

25. Date received by mfr./imm.proj.

26. 15 day report? ☐ Yes ☐ No

27. Report type ☐ Initial ☐ Follow-Up

Health care providers and manufacturers are required by law (42 USC 300aa-25) to report reactions to vaccines listed in the Table of Reportable Events Following Immunization. Reports for reactions to other vaccines are voluntary except when required as a condition of immunization grant awards.

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DIRECTIONS FOR COMPLETING FORM

(Additional pages may be attached if more space is needed.)

GENERAL

- Use a separate form for each patient. Complete the form to the best of your abilities. Items 3, 4, 7, 8, 10, 11, and 13 are considered essential and should be completed whenever possible. Parents/Guardians may need to consult the facility where the vaccine was administered for some of the information (such as manufacturer, lot number or laboratory data.)
- Refer to the Reportable Events Table (RET) for events mandated for reporting by law. Reporting for other serious events felt to be related but not on the RET is encouraged.
- Health care providers other than the vaccine administrator (VA) treating a patient for a suspected adverse event should notify the VA and provide the information about the adverse event to allow the VA to complete the form to meet the VA's legal responsibility.
- These data will be used to increase understanding of adverse events following vaccination and will become part of CDC Privacy Act System 09-20-0136, "Epidemiologic Studies and Surveillance of Disease Problems". Information identifying the person who received the vaccine or that person's legal representative will not be made available to the public, but may be available to the vaccinee or legal representative.
- Postage will be paid by addressee. Forms may be photocopied (must be front & back on same sheet).

SPECIFIC INSTRUCTIONS

Form Completed By: To be used by parents/guardians, vaccine manufacturers/distributors, vaccine administrators, and/or the person completing the form on behalf of the patient or the health professional who administered the vaccine.

Item 7: Describe the suspected adverse event. Such things as temperature, local and general signs and symptoms, time course, duration of symptoms, diagnosis, treatment and recovery should be noted.

Item 9: Check "YES" if the patient's health condition is the same as it was prior to the vaccine, "NO" if the patient has not returned to the pre-vaccination state of health, or "UNKNOWN" if the patient's condition is not known.

Item 10 and 11: Give dates and times as specifically as you can remember. If you do not know the exact time, please indicate "AM" or "PM" when possible if this information is known. If more than one adverse event, give the onset date and time for the most serious event.

Item 12: Include "negative" or "normal" results of any relevant tests performed as well as abnormal findings. Item 13: List ONLY those vaccines given on the day listed in Item 10.

Item 14: List any other vaccines that the patient received within 4 weeks prior to the date listed in Item 10.

Item 16: This section refers to how the person who gave the vaccine purchased it, not to the patient's insurance. Item 17: List any prescription or non-prescription medications the patient was taking when the vaccine(s) was given. Item 18: List any short term illnesses the patient had on the date the vaccine(s) was given (i.e., cold, flu, ear infection).

Item 19: List any pre-existing physician-diagnosed allergies, birth defects, medical conditions (including developmental and/or neurologic disorders) for the patient.

Item 21: List any suspected adverse events the patient, or the patient's brothers or sisters, may have had to previous vaccinations.
If more than one brother or sister, or if the patient has reacted to more than one prior vaccine, use additional pages to explain completely. For the onset age of a patient, provide the age in months if less than two years old.

Item 26: This space is for manufacturers' use only.

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?	☐	☐	☐
2. Does the person to be vaccinated have an allergy to eggs or to a component of the vaccine?	☐	☐	☐
3. Has the person to be vaccinated ever had a serious reaction to influenza vaccine in the past?	☐	☐	☐
4. Has the person to be vaccinated ever had Guillain-Barré syndrome?	☐	☐	☐

Form completed by: _____ Date: _____

Form reviewed by: _____ Date: _____

Technical content reviewed by the Centers for Disease Control and Prevention, September 2008.

www.immunize.org/catg.d/p4066.pdf • Item#P4066 (9/08

Nombre del paciente: _____ Fecha de nacimiento: ____/____/____
(mes) (día) (año)

Cuestionario de selección para la vacuna inyectable contra la gripe

Para pacientes adultos y para los padres de niños a los que se van a vacunar: Las siguientes preguntas nos ayudarán a determinar si hay algún motivo por el cual no deberíamos aplicar hoy la vacuna inyectable contra la influenza (la gripe) a usted o a su hijo. Si contesta "sí" a alguna de las preguntas, eso no siempre quiere decir que usted (o su hijo) no se debe vacunar. Simplemente quiere decir que hay que hacerles más preguntas. Si alguna pregunta no está clara, pida a su profesional de la salud que se la explique.

	Sí	No	No sabe
1. La persona que se va a vacunar, ¿está enferma hoy?	☐	☐	☐
2. La persona que se va a vacunar, ¿es alérgica a los huevos o a algún componente de la vacuna?	☐	☐	☐
3. La persona que se va a vacunar, ¿tuvo alguna vez una reacción seria a la vacuna contra la influenza (gripe)?	☐	☐	☐
4. La persona que se va a vacunar, ¿tuvo alguna vez el síndrome de Guillain-Barré?	☐	☐	☐

Formulario llenado por: _____ Fecha: _____

Formulario revisado por: _____ Fecha: _____

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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 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.

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.

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?			
2.	Does the person to be vaccinated have an allergy to eggs or to a component of the influenza vaccine?			
3.	Has the person to be vaccinated ever had a serious reaction to intranasal influenza vaccine (FluMist®) in the past?			
4.	Is the person to be vaccinated 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, metabolic disease (e.g., diabetes), anemia, or other blood disorders?			
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?			
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-terms treatment with drugs such as steroids, or cancer treatment with x-rays or drugs?			
8.	Is the person to be vaccinated receiving aspirin therapy or aspirin-containing therapy?			
9.	Is the person to be vaccinated pregnant or could she become pregnant within the next month?			
10.	Has the person to be vaccinated ever had Guillain-Barre' syndrome?			
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 environment (such as in a hospital room with reverse air flow)?			
12	Has the person to be vaccinated received any other vaccinations in the past 4 weeks?			

Form Completed by: Date:

Form Reviewed by: Date:

Nombre del paciente _____ Fecha de nacimiento:_____ / _____ / _____
(mes) (día) (año)

Cuestionario de selección para la vacuna intranasal contra la influenza

Para pacientes adultos y para los padres de niños a los que se van a vacunar: Las siguientes preguntas nos ayudarán a determinar si hay algún motivo por el cual no deberíamos aplicar hoy la vacuna intranasal contra la influenza (o gripe) (FluMist®) a usted o a su hijo. Si contesta "sí" a alguna de las preguntas, eso no siempre quiere decir que usted (o su hijo) no se debe vacunar. Simplemente quiere decir que hay que hacerles más preguntas. Si alguna pregunta no está clara, pida a su profesional de la salud que se la explique.

		SI	NO	No Sabe
1.	La persona que se va a vacunar, ¿está enferma hoy?			
2.	La persona que se va a vacunar, ¿es alérgica a los huevos o a algún componente de la vacuna?			
3.	La persona que se va a vacunar, ¿tuvo alguna vez una reacción seria a la vacuna contra la influenza (gripe)?			
4.	La persona que se va a vacunar, ¿tiene menos de 2 años o más de 49 años?			
5.	La persona que se va a vacunar, ¿tiene algún problema de salud a largo plazo de enfermedad del corazón, enfermedad de los pulmones, asma, enfermedad de los riñones, alguna enfermedad metabólica (por ejemplo, diabetes), anemia o alguna otra enfermedad de la sangre?			
6.	La persona que se va a vacunar, ¿es un niño de 2 a 4 años con antecedentes de sibilancias recurrentes o asma?			
7.	La persona que se va a vacunar, ¿tiene el sistema inmunológico débil debido al VIH/SIDA o a otra enfermedad que afecta el sistema inmunológico, tratamiento a largo plazo con medicamentos como esteroides, o tratamiento contra el cáncer con rayos X o medicamentos?			
8.	La persona que se va a vacunar, ¿recibe terapia con aspirinas o terapia que contenga aspirina?			
9.	La persona que se va a vacunar, ¿está embarazada o podría quedar embarazada en el próximo mes?			
10.	La persona que se va a vacunar, ¿ha tenido alguna vez el síndrome de Guillain-Barré?			
11.	La persona que se va a vacunar, ¿vive, o espera tener contacto cercano, con una persona que tiene el sistema inmunológico gravemente afectado y que tiene que estar en un ambiente protegido (como una habitación de hospital con flujo de aire invertido)?			
12	La persona que se va a vacunar, ¿ha recibido alguna otra vacuna en las últimas 4 semanas?			

Formulario llenado por : Date:

Formulario revisado por: Date:

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 con- traindication for further doses. Check the package insert 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 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, metabolic disease (e.g., diabetes), anemia, or other blood disorders?
Persons with any of these health conditions should not be given the LAIV. Instead, they should be vaccinated with the injectable influenza vaccine (TIV).

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 children at this age with possible reactive airways disease (e.g., history of asthma or recurrent wheezing or whose parent or guardian answers yes to this question). Instead, they should be given TIV.

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 steroids, or cancer treatment with x- rays or drugs?
Persons with weakened immune systems should not be given the LAIV. Instead, they should be given TIV.

8. Is the person 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 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 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 environment (such as in a hospital room with reverse air flow)?
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 a protective environment.

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. There is no reason to defer giving LAIV if they 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.

How to Administer Intramuscular (IM) Injections

Administer these vaccines by the intramuscular (IM) route: Diphtheria-tetanus (DT, Td) with pertussis (DTaP, Tdap); *Haemophilus influenzae* type b (Hib); hepatitis A (HepA); hepatitis B (HepB); human papillomavirus (HPV); inactivated influenza (TIV); meningococcal conjugate (MCV); and pneumococcal conjugate (PCV). Administer inactivated polio (IPV) and pneumococcal polysaccharide (PPSV) either IM or SC.

Patient age	Injection site	Needle size
Newborn (0–28 days)	Anterolateral thigh muscle	⅝"* (22–25 gauge)
Infant (1–12 months)	Anterolateral thigh muscle	1" (22–25 gauge)
Toddler (1–2 years)	Anterolateral thigh muscle	1–1¼" (22–25 gauge)
	Alternate site: Deltoid muscle of arm if muscle mass is adequate	⅝–1"* (22–25 gauge)
Children (3–18 years)	Deltoid muscle	⅝–1"* (22–25 gauge)
	Alternate site: Anterolateral thigh muscle	1–1¼" (22–25 gauge)
Adults 19 years and older	Deltoid muscle of arm	1–1½"*† (22–25 gauge)
	Alternate site: Anterolateral thigh muscle	1–1¼" (22–25 gauge)

*A ⅝" needle may be used only if the skin is stretched tight, the subcutaneous tissue is not bunched, and injection is made at a 90° angle.

†A ⅝" needle is sufficient in adults weighing <130 lbs (<60 kg); a 1" needle is sufficient in adults weighing 130–152 lbs (60–70 kg); a 1–1½" needle is recommended in women weighing 152–200 lbs (70–90 kg) and men weighing 152–260 lbs (70–118 kg); a 1½" needle is recommended in women weighing >200 lbs (>90 kg) or men weighing >260 lbs (>118 kg).

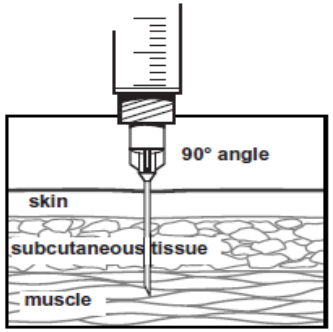
Needle insertion

Use a needle long enough to reach deep into the muscle.

Insert needle at a 90° angle to the skin with a quick thrust.

(Before administering an injection, it is not necessary to aspirate, i.e., to pull back on the syringe plunger after needle insertion.¶)

Multiple injections given in the same extremity should be separated by a minimum of 1", if possible.

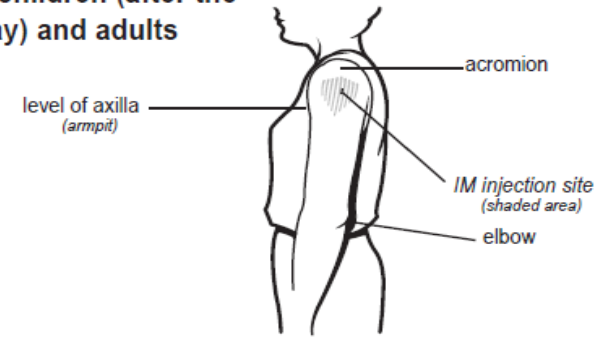


¶CDC. "ACIP General Recommendations on Immunization" at www.immunize.org/acip

IM site for infants and toddlers

Insert needle at a 90° angle into the anterolateral thigh muscle.

IM site for children (after the 3rd birthday) and adults



Insert needle at a 90° angle into thickest portion of deltoid muscle — above the level of the axilla and below the acromion.

Technical content reviewed by the Centers for Disease Control and Prevention, February 2009.

www.immunize.org/catg.d/p2020.pdf • Item #P2020 (2/09)

Immunization Action Coalition • 1573 Selby Ave. • St. Paul, MN 55104 • (651) 647-9009 • www.immunize.org • www.vaccineinformation.org • admin@immunize.org

It's federal law!

You must give your patients current Vaccine Information Statements (VISs)

As healthcare professionals understand, the risks of serious consequences following vaccination are many hundreds or thousands of times less likely than the risks associated with the diseases that the vaccines protect against. Most adverse reactions from vaccines are mild and self-limited. Serious complications are rare, but they can have a devastating effect on the recipient, family members, and the providers involved with the care of the patient. We must continue the efforts to make vaccines as safe as possible.

Equally important is the need to furnish vaccine recipients (or the parents/legal representatives of minors) with objective information on vaccine safety and the diseases that the vaccines protect against, so that they are actively involved in making decisions affecting their health or the health of their children. When people are not informed about vaccine adverse events, even common, mild events, they can lose their trust in healthcare providers and vaccines. Vaccine Information Statements (VISs) provide a standardized way to present objective information about vaccine benefits and adverse events.

What are VISs?

VISs are developed by the staff of the Centers for Disease Control and Prevention (CDC) and undergo intense scrutiny by panels of experts for accuracy. Each VIS provides information to properly inform the adult vaccine recipient or the minor child's parent or legal representative about the risks and benefits of each vaccine. VISs are not meant to replace interactions with healthcare providers, who should answer questions and address concerns that the recipient or the parent/legal representative may have.

Use of the VIS is mandatory!

Before a healthcare provider vaccinates a child or an adult with a dose of any vaccine containing diphtheria, tetanus, pertussis, measles, mumps, rubella, polio, hepatitis A, hepatitis B, *Haemophilus influenzae* type b (Hib), influenza, pneumococcal conjugate, meningococcal, rotavirus, human papillomavirus (HPV), or varicella (chickenpox) vaccine, the provider is required by the National Childhood Vaccine Injury Act (NCVIA) to provide a copy of the VIS to either the adult recipient or to the child's parent/legal representative.

VISs are also available for pneumococcal polysaccharide vaccine, as well as various vaccines used primarily for international travelers. The use of these VISs is recommended but not currently required by federal law.

An alternative VIS—the multi-vaccine VIS—is an option to providing single-vaccine VISs when administering one or more of these routine birth-through-6-month vaccines: DTaP, hepatitis B, Hib, pneumococcal (PCV), polio (IPV), or rotavirus (RV). The multi-vaccine VIS can also be used when giving combination birth-through-6-month vaccines (i.e., Pediarix, Pentacel, or Comvax) or when giving two or more routine birth-through-6-month vaccines together at other pediatric visits (e.g., 12–15 months or 4–6 years).

State or local health departments or individual providers may place the clinic name on the VISs, but any other changes must be approved by the director of CDC's National Center for Immunization and Respiratory Diseases.

What to do with VISs

Some of the legal requirements concerning the use of VISs are as follows:

1. Before an NCVIA-covered vaccine is administered to anyone (this includes adults!), you must give the patient or the parent/legal representative a copy of the most current VIS available for that vaccine. Make sure you give your patient time to read the VIS prior to the administration of the vaccine.
2. You must record in your patient's chart the date the VIS was given.
3. You must also record on the patient's chart the publication date of the VIS, which appears on the bottom of the VIS.

How to get VISs

All available VISs can be downloaded from the website of the Immunization Action Coalition at www.immunize.org/vis or from CDC's website at www.cdc.gov/vaccines/pubs/vis/default.htm. Ready-to-copy versions may also be available from your state or local health department.

Non-English language versions of VISs are not available from CDC; however, several state health departments have arranged for their translations. These versions do not require CDC approval. You can find VISs in more than 30 languages on the Immunization Action Coalition website at www.immunize.org/vis. To find VISs in alternative formats (e.g., audio, web-video), go to: www.immunize.org/vis/vis_audio.asp.

To obtain a complete set of current VISs in more than 30 languages, visit IAC's website at www.immunize.org/vis

Most current versions of VISs

As of May 2009, the most recent versions of the VISs are as follows:

DTaP/DT/DTP 5/17/07	PCV 12/9/08
hepatitis A 3/21/06	PPSV 4/16/09
hepatitis B 7/18/07	polio 1/1/00
Hib 12/16/98	rabies 1/12/06
HPV (H. papillomavirus) 2/2/07	rotavirus 8/28/08
influenza (LAIV) ... 7/24/08	shingles 9/11/06
influenza (TIV) 7/24/08	Td/Tdap 11/18/08
Japan. enceph. ... 5/11/05	typhoid 5/19/04
meningococcal 1/28/08	varicella 3/13/08
MMR 3/13/08	yellow fever 11/9/04

Multi-vaccine VIS 9/18/08
(for 6 vaccines given to infants/children: DTaP, IPV, Hib, Hep B, PCV, RV)

"We have an obligation to provide patients and/or parents with information that includes both the benefits and the risks of vaccines. This can be done with the Vaccine Information Statements that healthcare providers are required by law to provide prior to the administration of vaccines."

Walter A. Orenstein, MD, past director, National Immunization Program, CDC

Technical content reviewed by the Centers for Disease Control and Prevention, May 2009.

www.immunize.org/catg.d/p2027.pdf • Item #P2027 (5/09)

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 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 **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: **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 **www.cdc.gov/h1n1flu** or **www.cdc.gov/flu**
- Visit the web at **www.flu.gov**

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

Vaccine Information Statement
2009 H1N1 Inactivated Influenza Vaccine 10/2/09

2009 H1N1 INFLUENZA VACCINE

LIVE, ATTENUATED (the nasal spray vaccine)

WHAT YOU NEED TO KNOW

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

1 What is 2009 H1N1 influenza?

2009 H1N1 influenza (sometimes 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 virus is a new virus strain. 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 protection from seasonal flu.***

Live, attenuated intranasal vaccine (or **LAIV**) is sprayed into the nose. **This sheet describes the live, attenuated intranasal vaccine.**

An **inactivated** vaccine is also available, which is given as a shot. It is described in a separate sheet.

The 2009 H1N1 LAIV does not contain thimerosal or other preservatives. It is licensed for people from 2 through 49 years of age.

The vaccine virus is attenuated (weakened) so it will not cause illness.

4 Who should get 2009 H1N1 influenza vaccine and when?

WHO

LAIV is approved for people from 2 through 49 years of age who are not pregnant and do not have certain health conditions (see number 5 below). Groups recommended to receive 2009 H1N1 LAIV first are healthy people who:

- are from 2 through 24 years of age,
- are from 25 through 49 years of age and
  - live with or care for infants younger than 6 months of age, or
  - are health care or emergency medical personnel.

As more vaccine becomes available, other healthy 25 through 49 year olds should also be vaccinated.

> Note: While certain groups should not get LAIV – for example pregnant women, people with long-term health problems, and children from 6 months to 2 years of age – it is important that they be vaccinated . They should get the flu shot.

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 LAIV 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*.

2009 H1N1 LAIV should not be given to the following groups.

- children younger than 2 and adults 50 years and older
- pregnant women,
- anyone with a weakened immune system,
- anyone with a long-term health problem such as
  - heart disease
  - kidney or liver disease
  - lung disease
  - metabolic disease such as diabetes
  - asthma
  - anemia and other blood disorders
- children younger than 5 years with asthma or one or more episodes of wheezing during the past year,
- anyone with certain muscle or nerve disorders (such as cerebral palsy) that can lead to breathing or swallowing problems,
- anyone in close contact with a person with a *severely* weakened immune system (requiring care in a protected environment, such as a bone marrow transplant unit),
- children or adolescents on long-term aspirin treatment.

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.

Tell your doctor if you 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.

2009 H1N1 LAIV may be given at the same time as most other vaccines. Tell your doctor if you got any other vaccines within the past month or plan to get any within the next month. H1N1 LAIV and seasonal LAIV should not be given together.

6 What are the risks from 2009 H1N1 LAIV?

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 risks from 2009 H1N1 LAIV are expected to be similar to those from seasonal LAIV:

Mild problems:

Some children and adolescents 2-17 years of age have reported mild reactions, including:

- runny nose, nasal congestion or cough
- fever
- headache and muscle aches
- wheezing
- abdominal pain or occasional vomiting or diarrhea

Some adults 18-49 years of age have reported:

- runny nose or nasal congestion
- sore throat
- cough, chills, tiredness/weakness
- headache

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 vaccination.
- In 1976, an earlier type of inactivated swine flu vaccine was associated with cases of Guillain-Barré Syndrome (GBS). LAIV has not been 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 **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:
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 **www.cdc.gov/h1n1flu** or **www.cdc.gov/flu**
  - Visit the web at **www.flu.gov**

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

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