



**2009 H1N1 Vaccine**  
**Questions and Answers Document for Healthcare Providers**  
Updated: October 23, 2009

**General Questions:**

- **If someone was laboratory confirmed as a case of novel H1N1, does that person need to be vaccinated against novel H1N1 influenza?**
  - Most people in the general public won't know if they are lab confirmed (rapid tests do not confirm novel H1N1) as having H1N1 influenza, so the Centers for Disease Control and Prevention (CDC) recommends vaccination of people, even if they think they had lab confirmed H1N1 influenza. If a healthcare facility knows that a healthcare worker was confirmed by the North Dakota Department of Health (NDDoH) Division of Laboratory Services as having H1N1, then the healthcare facility may make the decision not to vaccinate.
- **Children ages 6 months through 8 years receiving seasonal influenza vaccination for the first time are recommended to receive 2 doses. However, children ages 6 months through 9 years are recommended to receive 2 doses in the prescribing information for 2009 H1N1 vaccines. Does CDC recommend that clinicians follow the recommendation in the 2009 H1N1 vaccine package inserts, or use the standard seasonal vaccine recommendations?**
  - The recommendations for use of seasonal vaccine are unchanged. Using the 2009 H1N1 vaccine schedule presented in the prescribing information is recommended (6 months through 9 years receive 2 doses). However, if considered necessary for consistency, vaccination providers can also follow the guidance for the seasonal vaccines for both vaccines, pending additional data from ongoing studies. The ongoing vaccine immunogenicity studies might provide additional information on which children should receive 2 doses, but these data are not yet available.
- **If a child is 9 years of age when receiving the first dose of H1N1 vaccine, but will turn 10 by the time the child needs the second dose of H1N1 vaccine, should the second dose be administered?**
  - No. Two doses of H1N1 vaccine are only recommended for children 9 and younger.
- **The influenza A (H1N1) 2009 monovalent inactivated vaccine trials that are currently underway have often used a 21 day (3 week) interval between doses. Is a 21 day interval acceptable?**
  - CDC recommends that the two doses of 2009 H1N1 vaccines be separated by 28 or more days (4 weeks). However, trials of the inactivated 2009 H1N1 vaccines have often used a 21 day interval. Administering the two doses of a 2009 H1N1 inactivated vaccine at least 21 days apart is safe. Therefore, if the second dose of

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

- **How effective is the first dose of the 2009 H1N1 vaccine in children ages nine and younger?**
  - In clinical trials, only 36% of children ages 3 to 9 that received one 15 milligram dose of H1N1 vaccine experienced an immune response that would be protective against the virus, and only 25% of children ages 6 to 35 months old showed a strong immune response after a single 15 milligram dose of H1N1 vaccine. This response in younger children is similar to what is seen with seasonal flu vaccination.
- **Can the seasonal inactivated vaccine (trivalent inactivated vaccine or TIV) and the 2009 H1N1 inactivated vaccine be given at the same time?**
  - Yes.
- **Can a child who requires 2 doses of a 2009 H1N1 vaccine and who received the first dose with a inactivated 2009 H1N1 vaccine complete the series with the 2009 H1N1 Flumist®, or vice versa?**
  - When feasible, the same type of vaccine (live attenuated or inactivated) should be used in a two dose schedule, but mixed schedules are preferable to not completing the series. A 28 day interval between doses is recommended, but 21 days is acceptable. There are limited data on mixed schedules.
- **Can 2009 H1N1 vaccines be used outside the age range approved by the Food and Drug Administration?**
  - Whenever possible, vaccines should be administered in accordance with FDA-approved labeling. Vaccines approved for an age group will have undergone the required testing for that age group. There are no known safety concerns with use of inactivated vaccines in appropriate doses outside their labeled age indications. Data on vaccine effectiveness for influenza vaccines use outside of labeled age indications are limited.
  - Flumist® should not be used outside the approved age indications (ages 2 years through 49 years).
  - Inactivated influenza vaccines should not be given to infants younger than 6 months.
  - However, clinicians may use inactivated 2009 H1N1 vaccines for persons 6 months and older outside their labeled age range if a vaccine licensed for use in a particular age group is not available, and the need to provide vaccination is urgent. For instance, an inactivated 2009 H1N1 influenza vaccine licensed for people 18 years and older (e.g., CSL H1N1 vaccine) may be used for a child younger than 18 years if no other vaccine is available, and the alternative would be for the child to not receive a 2009 H1N1 influenza vaccine at that visit. Similarly, an inactivated 2009 H1N1 vaccine labeled for use in older children or

adults (e.g., Novartis, CSL, or some Sanofi Pasteur formulations) can be given to an infant or younger child if the alternative would be for the child to not receive any influenza vaccine at that visit. For children ages 6 months through 35 months, a half dose (0.25 mL) of a vaccine licensed for older children or adults should be used. If possible, children who require 2 doses should receive at least 1 dose in a formulation approved for their age. Use of vaccines outside approved indications is a temporary measure that applies only to the special circumstances faced during the 2009 H1N1 pandemic, and should be avoided if possible.

### **Flumist®:**

- **Can Flumist® be administered to someone with active asthma or a history of asthma?**
  - The ACIP does not define asthma, so any report of asthma should be a contraindication to Flumist®.
- **Do antivirals interfere with the effectiveness of Flumist®?**
  - Yes, antivirals can affect the Flumist®. Flumist® should not be administered until 48 hours after antiviral use has been completed. Antivirals should not be prescribed (unless medically necessary) until 2 weeks after the administration of Flumist®.
- **Can the Flumist® vaccine interfere with a lab test?**
  - The live attenuated influenza vaccine viruses in Flumist® (seasonal vaccine and 2009 H1N1 monovalent vaccine) can cause a positive result on a rapid influenza diagnostic test. The tests are designed to detect influenza viruses and cannot differentiate between live attenuated and wild-type influenza viruses. A positive test in a person who recently (in the previous 7 days) received LAIV and who also has an influenza-like illness could be caused by either LAIV or wild-type influenza virus.
- **If seasonal Flumist® and 2009 H1N1 Flumist® are given at the same visit, do either or both doses need to be repeated, and if so, when?**
  - Seasonal Flumist® and 2009 H1N1 Flumist® should not be administered at the same visit. There are no data from studies in humans on the administration of seasonal and H1N1 2009 monovalent live attenuated vaccines at the same visit. Use of the 2 types of Flumist® at the same time could result in reduced immunogenicity for one vaccine, according to some experts. However, if both types of Flumist® are inadvertently administered at the same visit neither vaccine needs to be repeated.
- **What is the minimum interval between doses of seasonal Flumist® and 2009 H1N1 Flumist®?**
  - There are no data on sequential administration of the two types of Flumist® (seasonal and 2009 H1N1). The ACIP General Recommendations on live attenuated vaccines indicates that 28 days (4 weeks) is the recommended minimum interval, and can be applied to use of a seasonal Flumist® and a 2009 H1N1 Flumist®, because these are considered 2 different vaccines. The ACIP recommendations were developed based on data from studies using attenuated live virus vaccines such as measles, mumps and rubella vaccine that are injected. However, based on previous studies of Flumist® replication and immune response, as little as 14 days (2 weeks) might be sufficient to allow for an

appropriate immune response to both vaccines. Therefore, an interval between the two types of Flumist® of 2 weeks or more may be acceptable, although an interval of 28 days is preferred.

- **If seasonal and H1N1 Flumist® are not administered on the same day, but are separated by less than 14 days (2 weeks), do either or both doses need to be repeated, and if so, when?**
  - Seasonal Flumist® and 2009 H1N1 Flumist® should not be administered at the same visit, and should be separated by at least 14 days and ideally by at least 28 days based on previous studies of attenuated influenza vaccine virus replication and immune response. If the interval between administration of seasonal Flumist® and 2009 H1N1 Flumist® is from 1-13 days, the vaccine more recently administered should be repeated.
- **Can Flumist® be given at the same time as an inactivated influenza vaccine (e.g., seasonal Flumist® and 2009 H1N1 inactivated vaccine, or 2009 H1N1 Flumist® and seasonal trivalent inactivated influenza vaccine [TIV])?**
  - Yes, these two types of vaccines can be given at the same time, based upon ACIP's General Immunization recommendations. Any interval between the two types of vaccines is also acceptable.
- **Can healthcare providers get Flumist®?**
  - Yes. Flumist® is a very good option for most healthcare providers who are healthy, younger than 50 years old, and not pregnant. However, healthcare providers should not get Flumist® if they are providing medical care for patients who require special environments in the hospital because they are profoundly immunocompromised (e.g., those who work in bone marrow transplant units). Although no immunocompromised patient has been shown to be harmed by use of Flumist® among healthcare workers, the recommendation against the use of Flumist® in healthcare workers with this type of patient contact is intended as an extra precaution for fragile immunocompromised patients. Healthcare workers with this type of patient contact can get Flumist®, but if they do, they should wait 7 days after being vaccinated before returning to duties that include care of severely immunocompromised patients in special environments.
- **Who should not be vaccinated with the 2009 H1N1 nasal-spray flu vaccine Flumist®?**
  - Certain people should not get a nasal spray flu vaccine, including the 2009 H1N1 nasal spray vaccine. This includes:
    - People younger than 2 years of age;
    - Pregnant women;
    - People 50 years of age and older;
    - People with a medical condition that places them at higher risk for complications from influenza, including those with chronic heart or lung disease, such as asthma or reactive airways disease; people with medical conditions such as diabetes or kidney failure; or people with illnesses that weaken the immune system, or who take medications that can weaken the immune system;
    - Children younger than 5 years old with a history of recurrent wheezing;
    - Children or adolescents receiving aspirin therapy;

- People who have had Guillain-Barré syndrome (GBS), a rare disorder of the nervous system, within 6 weeks of getting a flu vaccine,
  - People who have a severe allergy to chicken eggs or who are allergic to any of the nasal spray vaccine components.
- **Can people receiving the nasal-spray flu vaccine Flumist® pass the vaccine viruses to others?**
  - In clinical studies, transmission of vaccine viruses to close contacts occurred only rarely. The current estimated risk of getting infected with vaccine virus after close contact with a person vaccinated with the nasal-spray flu vaccine is low (0.6% - 2.4%). Because the viruses are weakened, infection is unlikely to result in influenza illness symptoms since the vaccine viruses have not been shown change into typical or naturally occurring influenza viruses.
- **Can contacts of people with weakened immune systems get the nasal-spray flu vaccine?**
  - People who are in contact with others with severely weakened immune systems when they are being cared for in a protective environment (for example, people with hematopoietic stem cell transplants), should not get the nasal spray vaccine, including the 2009 H1N1 nasal spray vaccine if they will come into contact with the severely immunocompromised person within 7 days of vaccination. People who have contact with others with lesser degrees of immunosuppression (for example, people with diabetes, people with asthma taking corticosteroids, or people infected with HIV) can get the nasal spray vaccine.
- **Can healthcare workers who cannot receive the nasal spray vaccine (e.g., pregnant women, older adults, persons with chronic medical conditions) administer this vaccine to others?**
  - Yes. Healthcare workers who cannot get the nasal spray vaccine themselves can administer the vaccine to others.
- **Can H1N1 influenza vaccine allocated from the NDDoH be used for out-of-state residents?**
  - Yes. Providers may vaccinate their usual patients, even if they are out-of-state residents.

## **Pregnancy:**

- **Can a woman who is breastfeeding receive the H1N1 vaccine?**
  - Yes. Both seasonal flu and 2009 H1N1 influenza vaccines should be given to breastfeeding mothers. Breastfeeding is fully compatible with flu vaccination, and preventing maternal infection provides secondary protection to the infant. Maternal vaccination is especially important for infants less than 6 months old, who are ineligible for vaccination. In addition, transfer of vaccination-related antibodies by breastfeeding further reduces the infant's chances of getting sick with the flu.
- **Can the 2009 H1N1 flu vaccine be given at any time during pregnancy?**
  - Seasonal flu vaccine is recommended for all pregnant women at any time during pregnancy, and has not been shown to cause harm to a pregnant woman or her baby. The ACIP also recommends that 2009 H1N1 flu vaccine be given to all

pregnant women at any time during pregnancy.

## **Vaccine Safety:**

- **Will the 2009 H1N1 vaccines that are currently recommended contain adjuvants?**
  - No. An adjuvant is a substance added to a vaccine to improve the immune response so that less vaccine is needed. Only vaccines that do not contain adjuvants will be used in the United States during the 2009 flu season. This includes all of the 2009 H1N1 and seasonal influenza vaccines that will be available for children and adults in both the injectable and nasal spray formulations. None of these influenza vaccines contain adjuvants.
- **Will the 2009 H1N1 influenza vaccine contain thimerosal?**
  - The 2009 H1N1 influenza vaccines that U.S. Food and Drug Administration (FDA) is licensing (approving) will be manufactured in several formulations. Some will come in multi-dose vials and will contain thimerosal as a preservative. Multi-dose vials of seasonal influenza vaccine also contain thimerosal to prevent potential contamination after the vial is opened. Some 2009 H1N1 influenza vaccines will be available in single-dose units, which will not require the use of thimerosal as a preservative. In addition, the live-attenuated version of the vaccine, which is administered intranasally (through the nose), is produced in single units and will not contain thimerosal.
- **Is thimerosal safe when used as a preservative in vaccines?**
  - The U.S. Centers for Disease Control and Prevention (CDC) places a high priority on vaccine safety, surveillance, and research. CDC is aware that the preservative thimerosal in vaccines and suggestions of a relationship to autism have raised concerns. These concerns make the decisions surrounding vaccinations confusing and difficult for some people, especially parents. Numerous studies have found no association between thimerosal exposure and autism. Since 2001, no new vaccine licensed by FDA for use in children has contained thimerosal as a preservative. In addition, all vaccines recommended by CDC for children younger than 6 have been thimerosal-free or contain only trace amounts, except for some formulations of influenza vaccine. Unfortunately, there have not been reductions in the numbers of children identified with autism indicating that the cause of autism is not related to a single exposure such as thimerosal.
- **Will there be a possibility of Guillain-Barré syndrome cases following the 2009 H1N1 vaccine?**
  - Guillain-Barré syndrome (GBS) is a rare disease in which the body damages its own nerve cells, causing muscle weakness and sometimes paralysis. It is not fully understood why some people develop GBS, but it is believed that stimulation of the body's immune system may play a role in its development. Infection with the bacterium *Campylobacter jejuni*, which can cause diarrhea, is one of the most common risk factors for GBS. People can also develop GBS after having the flu or other infections (such as cytomegalovirus and Epstein Barr virus). On very rare occasions, they may develop GBS in the days or weeks following receiving a vaccination. In 1976, there was a small risk of GBS following influenza (swine flu) vaccination (approximately 1 additional case per 100,000 people who

received the swine flu vaccine). That number of GBS cases was slightly higher than what is normally seen in the population, whether or not people were vaccinated. Since then, numerous studies have been done to evaluate if other flu vaccines were associated with GBS. In most studies, no association was found, but two studies suggested that approximately 1 additional person out of 1 million vaccinated people may be at risk for GBS associated with the seasonal influenza vaccine. FDA and CDC will be closely monitoring reports of serious problems following the 2009 H1N1 influenza vaccines, including GBS.

- **How do I report a vaccine adverse event?**
  - Vaccine adverse events must be reported to the Vaccine Adverse Events Reporting System (VAERS). This may be done by filling out a VAERS form online at [vaers.hhs.gov/index](http://vaers.hhs.gov/index). Forms may also be printed from the website and faxed to the NDDoH or directly to VAERS. Adverse events can also be reported to VAERS through the North Dakota Immunization Information System (NDIIS).

### **Vaccine Storage and Handling:**

- **What temperatures does the 2009 H1N1 influenza vaccine need to be stored at?**
  - All 2009 H1N1 influenza vaccines must be stored at 35 – 46 degrees Fahrenheit (2 – 8 degrees Celsius).
- **What should a provider do if the temperature indicators in the vaccine shipments show that temperatures were out of range during shipping?**
  - Providers should place the vaccine in the refrigerator and not use it and contact the NDDoH immediately at 800.472.2180.

### **Billing:**

- **Can vaccination providers charge or bill for the 2009 H1N1 vaccine?**
  - No. 2009 H1N1 influenza vaccine and ancillary supplies (syringes, needles, sharps containers, and alcohol swabs) have been purchased by the federal government and provided free of charge to all providers participating in this voluntary vaccination effort. Therefore, it will not be permissible to charge for the 2009 H1N1 vaccine itself.
- **Can vaccination providers charge or bill for administration of the 2009 H1N1 vaccine to patients?**
  - Yes. While every effort is being made to ensure that cost is not a barrier for patient receipt of vaccine, providers may charge or bill for vaccine administration. Policies and procedures guiding this financial transaction are explained below.
  - Local public health units may not bill for the administration of the 2009 H1N1 vaccine.
- **How much can providers charge or bill for the administration fee?**
  - The maximum administration fee that may be charged to patients is \$18.45 (the regional Medicare Fee Cap).
  - Providers may bill customary charges to private third party payors. Providers should bill payers and insurance plans at their regular agreed-upon rates, and may accept whatever level of reimbursement is provided by a plan or payer for H1N1

vaccine administration. Providers participating with Blue Cross Blue Shield of North Dakota (BCBSND) will need to charge BCBSND members the same rate for administration of the H1N1 vaccine as those patients paying out of pocket to comply with their contracts. Thus, BCBSND will use the Medicare Regional Fee Cap (\$18.45) as the fee schedule amount for the administration of H1N1 influenza vaccine.

- **Will Medicare pay providers for administration of 2009 H1N1 vaccine?**
  - Yes, like the seasonal influenza vaccine, the 2009 H1N1 vaccine and its administration are covered under the Part B preventive services benefit for all Medicare beneficiaries with Part B coverage.
- **Will private providers be able to charge patients for vaccine administration if they are uninsured?**
  - Yes, private providers may charge a fee for the administration of the vaccine to the patient. Should they choose to charge an administration fee, the fee may not exceed \$18.45. If the patient is unable to pay, the provider may choose to administer the 2009 H1N1 vaccine for free or for a reduced fee. Providers are encouraged to ensure that cost is not a barrier to vaccination. Providers may also refer these patients to local public health units to be vaccinated.

### **NDIIS and Scanning:**

- **How do I know my facility's provider ID?**
  - Your facility's provider ID is the same as your Prevention Partnership Provider Number and is listed at the bottom left hand corner of the NDIIS. If you don't have access to NDIIS or are unsure contact the Immunization Program at 800.472.2180.
- **Our vaccine is being sent to our local public health unit (LPHU), do I use my provider ID on the scanning form or theirs?**
  - When scanning vaccine you'll use your provider ID even if your vaccine is shipped directly to the LPHU. The provider ID field is located on the bottom left hand corner of the scanning form. The provider ID field allows other providers to know where the vaccine was administered.
- **Does our facility have to scan into NDIIS and manually enter immunization data?**
  - No. If your facility is scanning immunization records into NDIIS you WON'T have to manually enter the information into NDIIS.
- **What should we do if a lot number isn't in our inventory when we administer a vaccine?**
  - It may take a couple of days for McKesson to send the shipping logs to the NDIIS. After receiving the vaccine, if your facility is scanning immunization records into NDIIS continue to scan the information. If your facility is manually entering vaccine and the lot numbers don't appear in your inventory after a couple of days contact the immunization program at 1-800-472-2180. Providers will not be able to enter vaccine into the NDIIS without a lot number.
- **Do providers need to keep the scanning form after scanning?**
  - Yes, providers will store the scanning form as they would the traditional vaccine administration record.

- **What types of pencils/pens can be used on the scanning form?**
  - The form will scan the best with dark pens. Pencil lead wears off the form and isn't ideal for storage of the form. Do not use red pens.
- **Can the scanning forms be folded?**
  - Providers should make every attempt to not fold the scanning forms. The NDDoH has tested the performance of scanning with folded forms and found that folding had no significant impact on scanning performance.
- **How can I get the scanning software?**
  - The Goscan Application is available for download and installation at [www.ndflu.com/goscan](http://www.ndflu.com/goscan). Providers should print off the instructions and follow them exactly. Be sure you do a test scan. There is a short video on the use of GoScan that is accessible from the above link.
- **Who should I call if I have questions about scanning?**
  - Please contact Barb Winking at 701.328.2297.
- **What type of scanner can we use for scanning H1N1 vaccine to NDIIS?**
  - All TWAIN compliant scanners are compatible with the scanning software. See your scanner's specs to determine whether it's TWAIN compliant. Most scanners are TWAIN compliant. These types of scanners are available at most local office supply stores.
- **What should we do if we need to transfer the 2009 H1N1 vaccine to another facility?**
  - If transferring the vaccine to another facility go to the lot distribution tab in NDIIS and select transfer. Mark the lot number that needs to be transferred and the facility the vaccine is being transferred to, print off the packing slip and send a copy of the packing slip with the vaccine. H1N1 vaccine can only be transferred to facilities that have signed the H1N1 provider agreement. Hospitals will need to do this if transferring vaccine to satellite clinics. Local public health units will need to do this if receiving vaccine for clinics in their county.
- **Will the NDDoH scan on behalf of clinics?**
  - No. If unable to conduct scanning, then doses will have to be manually entered into the NDIIS. Private providers may contact the local public health unit in their area to determine whether or not the local public health unit will scan on a provider's behalf.
- **Will the NDDoH purchase scanners for private providers?**
  - No. Most private providers should already have a compatible scanner, if not, the NDDoH will not be purchasing them for private providers.
- **Where can I get copies of the scanning form?**
  - A copy of the scanning form is available at [www.ndflu.com](http://www.ndflu.com). Scanning forms are also available for order at [hanassets.nd.gov/](http://hanassets.nd.gov/). Vaccine Information Statements (VIS) are also available for order on the same website.
- **Are providers required to report doses administered of H1N1 influenza vaccine to the NDIIS?**
  - Yes. All doses administered of H1N1 influenza vaccine must be reported to the NDIIS within one week of administration. This can be done by manual data entry or scanning.
- **Do providers need to report doses administered to the NDDoH separately from entering into the NDIIS?**

- No. Data entry into the NDIIS is sufficient. The NDDoH will be able to determine doses administered from the NDIIS.
- **Do providers have to use the NDDoH scanning form (vaccine administration record)?**
  - If a provider is planning on scanning data into the NDIIS, then they must use the NDDoH scanning form. If a provider is directly entering data into the NDIIS, then they do not have to use the scanning form, but must somehow obtain the information that is on the scanning form. This information is required in the NDIIS.
- **What is the second page of the NDDoH scanning form used for?**
  - This page is optional for providers to use. The first section are screening questions to determine if the patient is eligible to receive influenza vaccine. A guide to these screening questions is available at [www.immunize.org/catg.d/p4066.pdf](http://www.immunize.org/catg.d/p4066.pdf). The second section are screening questions used to determine if the patient is eligible to receive Flumist®. A guide to these screening questions is available at [www.immunize.org/catg.d/p4067.pdf](http://www.immunize.org/catg.d/p4067.pdf).

**Please contact the NDDoH Immunization Program with any additional questions at 701.328.2378 or toll-free at 800.472.2180.**