

H1N1 Vaccination Program Frequently Asked Questions*

H1N1 VACCINE

How many H1N1 flu vaccines have been FDA-approved?

Four vaccines have been FDA approved:

Injectable Vaccines:

Influenza A (H1N1) 2009 Monovalent Vaccine (CSL Limited) – 6 months and older

Influenza A (H1N1) 2009 Monovalent Vaccine (Novartis Vaccines and Diagnostics Limited) - 4 years and older

Influenza A (H1N1) 2009 Monovalent Vaccine (Sanofi Pasteur, Inc.) - 6 months and older

Intranasal Vaccines:

Influenza A (H1N1) 2009 Monovalent Vaccine (MedImmune LLC) – 2-49 years (healthy and not pregnant)

Does the H1N1 vaccine contain an adjuvant?

No. The H1N1 vaccine being used in the US does not contain an adjuvant.

Which H1N1 vaccine is better: nasal mist or injectable?

On the basis of clinical trials performed to date, both types of vaccines provide sufficient protection against 2009 H1N1 influenza. The injectable is approved for use in people older than 6 months, including healthy people and people with chronic medical conditions (such as asthma, diabetes, or heart disease). The nasal mist is approved for use in healthy people 2-49 years of age who are not pregnant.

How long after I get a flu vaccine will I be immune to the flu virus?

Flu vaccines cause antibodies to develop in the body. These antibodies provide protection against infection with the viruses that are in the vaccine. Once you get vaccinated, your body makes protective antibodies in about two weeks. In the meantime, you are still at risk for getting the flu. In addition, children younger than 10 years old who are being vaccinated against 2009 H1N1 flu for the first time need a second dose 4 or more weeks later in order to be protected. While some protection is offered after the first dose, maximum protection is reached within two weeks after the second dose.

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

The seasonal flu vaccine and 2009 H1N1 flu vaccine are available as both live (nasal mist) and killed (injectable) vaccines.

Doses of seasonal nasal mist (live) flu vaccine and 2009 H1N1 nasal mist (live) flu vaccine CANNOT be given at the same time. They must be separated by a minimum of 14 days. [Note: Other live virus vaccines must be separated by 28 days.] Seasonal injectable (killed) flu vaccine can be given at the same time as 2009 H1N1 nasal mist (live) flu vaccine. The opposite is true as well: Seasonal nasal mist (live) flu vaccine can be given at the same time as 2009 H1N1 injectable (killed) flu vaccine. Tell your health care provider if you received any other vaccines within the past month or plan to get any within the next month.

Can flu vaccines be given at the same time as other vaccines?

Seasonal or 2009 H1N1 nasal mist (live) flu vaccines can be given at the same time as other killed vaccines (including injectable flu vaccine).

Seasonal or 2009 H1N1 nasal mist (live) flu vaccines and other live vaccines should be separated by at least 4 weeks.

Tell your health care provider if you received any other vaccines within the past month or plan to get any within the next month.

Will two doses of vaccine be required?

The U.S. Food and Drug Administration (FDA) has approved the use of one dose of 2009 H1N1 flu vaccine for persons 10 years of age and older. Children under 10 years will need two doses. Infants younger than 6 months of age are too young to get the 2009 H1N1 and seasonal flu vaccines. NOTE: For seasonal flu, children under 9 years of age need two doses.

What will be the recommended interval between the first and second doses of 2009 H1N1 flu vaccine for children under 10 years of age?

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

My child is due for a 2nd dose and I'm being told that he has to wait because the limited amount of vaccine needs to go to other children who have not yet had their 1st dose. If my child gets the 2nd dose more than 4 weeks after the 1st one, how does that affect his protection against the flu? Is my child protected against the flu with just one dose?

The span of 4 weeks between doses is a minimum time. The 2nd dose can be given after 4 weeks and still result in the same level of protection for your child. With just one dose, your child is partially protected against the flu. It is recommended that your child obtains the 2nd dose when it becomes available.

Will it be necessary for the first and second dose to be given by the same provider?

No. But please note that if you are using two different providers, when you go to get your second dose, bring information on your flu vaccination history to the second provider. Otherwise, information should be accessible through the NJ H1N1 Vaccine System.

Can the first dose be nasal mist and the second dose be injectable (and vice versa)?

Yes, but when feasible, the same brand and type of vaccine (live attenuated or inactivated) should be used.

Who should NOT get the injectable flu vaccine?

The flu shot is approved for use in people 6 months of age and older, including healthy people, people with chronic medical conditions and pregnant women. The following people should NOT get the injectable flu vaccine:

- People with 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.
- People who have had a life-threatening allergic reaction after a dose of seasonal flu vaccine.
- Infants younger than 6 months of age.

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 the health care provider if you ever had Guillain-Barre syndrome (a severe paralytic illness also called GBS).

H1N1 NASAL MIST VACCINE

What is a nasal mist flu vaccine?

Nasal mist flu vaccine is sprayed into the nostrils rather than injected into the muscle. This is also called an intranasal influenza vaccine. This vaccine is a weakened live virus vaccine.

Can I get sick from the nasal mist flu vaccine?

No, the virus used in the nasal mist flu vaccine is weakened and is not able to produce influenza illness in a healthy person or to people they come into contact with. The nasal mist vaccine should only be given to healthy individuals.

Who can get the nasal mist flu vaccine?

The nasal mist flu vaccine is FDA approved for healthy children and adults from 2 through 49 years of age who are not pregnant.

Why is nasal mist flu vaccine limited to individuals 2-49 years old?

In order to license a vaccine for a particular age group, the company must present data to the FDA demonstrating safety and effectiveness. Studies with FluMist showed that it was effective in people 2-49. It was also tested in individuals 50-64 and did not demonstrate effectiveness. As with any vaccine, FluMist may not protect 100% of individuals receiving the vaccine.

Can breastfeeding mothers use the 2009 H1N1 nasal mist flu vaccine?

Yes, it is safe for breastfeeding mothers. People in contact with infants and newborns can receive the nasal mist vaccine.

Since the nasal mist flu vaccine contains a live virus, can the people who receive it infect others?

Although the package insert states that a person can shed (release) the vaccine virus, shedding alone should not be equated with person-to-person transmission. Studies have found that transmission is very rare. People who receive the nasal mist can have contact with everyone except the more severely immunocompromised (e.g., bone marrow transplant in a protective environment). This includes nasal mist administered in the school setting. Pregnant women, infants under six months of age and individuals of any age with lesser degrees of immunosuppression (diabetes, asthma, cancer on chemotherapy but not needing a protective environment, steroid or other immunosuppressive therapy, HIV/AIDS) may be in contact with people who have received the nasal mist. Pregnant women and individuals with lesser degrees of immunosuppression can work in the vaccination clinics and administer the vaccine even if they themselves are not candidates for this vaccine.

Can health care workers with direct patient care duties use the 2009 H1N1 nasal mist flu vaccine?

Most health care workers with direct patient care duties can safely use the nasal mist vaccine. Only the contacts of people with severely weakened immune systems (such as patients with bone marrow transplants who require a protective environment) should not receive the nasal mist vaccine. If they do receive the nasal mist vaccine, they should be restricted from contact with the immunosuppressed individual for 7 days after vaccination. Contacts of people with lesser degrees of immunosuppression (such as diabetes, cancer on chemotherapy not requiring a protective environment, HIV infections, elderly, steroid therapy) can receive the nasal mist and not be restricted.

Who should NOT get the nasal mist flu vaccine?

The following people should NOT get nasal mist flu vaccine. Anyone in these groups should contact their health care provider.

- People with 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.
- Pregnant women
- Children younger than 2 and adults 50 years and older
- Children younger than 5 years with asthma or one or more episodes of wheezing during the past year
- Children or adolescents on long-term aspirin treatment.

- Anyone with a weakened immune system
- 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)
- Anyone with a long-term health problem such as:
 - Heart disease
 - Lung disease
 - Asthma
 - Kidney or liver disease
 - Metabolic disease such as diabetes
 - Anemia and other blood disorders
- Anyone with certain muscle or nerve disorders (such as cerebral palsy) that can lead to breathing or swallowing problems

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-Barre 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.

H1N1 VACCINE SAFETY

Is the 2009 H1N1 influenza vaccine be safe?

According to the CDC, the 2009 H1N1 influenza vaccine is expected to be just as safe as seasonal flu vaccines.

Is the 2009 H1N1 influenza vaccine be made differently than the seasonal influenza vaccine?

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

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

Injectable vaccine:

- 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.

Nasal mist vaccine:

- Runny nose, nasal congestion
- cough
- Fever
- Headache and muscle aches
- Wheezing
- Abdominal pain or occasional vomiting or diarrhea
- Sore throat
- Chills
- Tiredness or weakness

Life-threatening allergic reactions are very rare. If they do occur, it is usually within a few minutes to a few hours after the shot.

Is there a possibility of Guillain-Barre Syndrome (GBS) cases following the 2009 H1N1 influenza vaccine?

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. On very rare occasions, people may develop GBS in the days or weeks after receiving certain vaccinations.

How do you know that GBS isn't related to vaccination? And what about miscarriages?

Adverse events - such as sudden deaths, spontaneous abortions, and Guillain-Barré syndrome - will occur in the population. These adverse events will happen regardless of whether people have been vaccinated for H1N1. In the context of vaccine safety monitoring, we call these naturally occurring events “background rates.” Background rates are helpful as a tool to assess vaccine safety by comparing the expected rate of adverse events to the actual/observed rate in any given timeframe once vaccination begins.

What is the best source of information for the 2009 H1N1 influenza vaccine?

You should talk with your health care provider about the 2009 H1N1 influenza vaccine. There is also information on the CDC website at www.cdc.gov/H1N1flu. You can also check www.flu.gov. Both sites can be found on NJ’s website: www.nj.gov/health/flu/h1n1.

What should I do if I think I’m experiencing a bad side effect of the flu vaccine?

Serious side effects are rare. If you are having a bad side effect from a flu shot, contact your health care provider immediately. In addition, you or your health care provider can report the side effect to the federal government through the VAERS (Vaccine Adverse Event Reporting System) program, which has been set up to monitor vaccine safety. VAERS website: <http://vaers.hhs.gov/esub/index>.

THIMEROSAL

What is thimerosal?

Thimerosal is a mercury-based preservative that has been used since the 1930s in multi-dose vials (vials containing more than one dose) of some vaccines to prevent the growth of microorganisms, such as bacteria and fungi, which may contaminate them. Such contamination could cause serious illness or death.

Why is there concern about mercury?

Mercury is a naturally occurring element that is found in air, water and soil. Mercury in the air eventually settles into water or onto land where it can be washed into water. Once deposited, certain microorganisms can change it into [methylmercury](#), a highly toxic form that builds up in fish, shellfish and animals that eat fish. Fish and shellfish are the main sources of methylmercury exposure to humans. High levels of methyl mercury in the bloodstream may harm the body, particularly the nervous system.

Thimerosal contains a different form of mercury called ethylmercury. Studies comparing ethylmercury and methylmercury suggest that they are processed differently in the human body. Ethylmercury is broken down and excreted much more rapidly than methylmercury. Therefore, ethylmercury (the type of mercury in the influenza vaccine) is much less likely than methylmercury (the type of mercury in the environment) to accumulate in the body and cause harm.

Why was thimerosal removed from vaccines if there is no danger?

After long-standing interest in lessening human exposure to mercury, thimerosal was removed from most vaccines.

Does the 2009 H1N1 influenza vaccine contain thimerosal?

The FDA-approved vaccines 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 nasal mist version of the vaccine is produced in single-dose units and does not contain thimerosal.

How much thimerosal is in flu vaccine?

When used as a preservative, it is present in concentrations up to 0.01% (50 micrograms thimerosal per 0.5 mL dose or 25 micrograms mercury per 0.5 mL dose).

How much thimerosal-free vaccine will be available?

Thimerosal is a preservative. It is anticipated that enough thimerosal-free vaccine in pre-loaded syringes and single dose vials will be available for young children and pregnant women. You can consult your local health agency or health care provider for more information about this.

Is it safe for children and pregnant women to receive an influenza vaccine that contains thimerosal?

Yes. It is very important to protect children and pregnant woman against influenza since they are at risk for complications. Numerous studies have found no harmful effects from thimerosal.

Have any adverse reactions to thimerosal ever been reported?

When vaccines containing thimerosal have been administered in the recommended doses, allergic type reactions (hives, shock) have been noted on rare occasions. No other harmful effects have been reported. Numerous studies have found no association between thimerosal and autism.

H1N1 FLU CLINIC INFORMATION**Where can I get a 2009 H1N1 influenza vaccination?**

New Jersey can have over 4,000 sites that will have vaccine shipped directly from the CDC. But there will be many more locations throughout the state that will offer 2009 H1N1 vaccinations: health care providers' offices, community health centers, county and local health departments, and retail pharmacies.

H1N1 flu vaccine will be distributed to New Jersey (and across the country) in staggered shipments. Right now, it is very early in that process and a limited supply of vaccine is being delivered. We expect more later in November and December. Both the nasal mist and the injectable form of the vaccine will be available for several months and there is expected to be enough vaccine for everyone who wants to get vaccinated.

Providers will share specific information with their patients and some local health departments will be scheduling vaccination clinics. Check your local papers for public clinics being held for specific target groups. You can also check the NJ State website (<http://web.doh.state.nj.us/apps2/flu/fluschedules.aspx>) for public health locations in your area that will be vaccinating. This website is updated on an on-going basis. In addition, private physician offices, community health centers, employee health services, and pharmacies may also have vaccine supplies.

How do I use the online “Find A Flu Shot” locator?

1. Click on the Find a Flu Shot button on the NJDHSS website: <http://nj.gov/health/>
2. Click on **Flu Shot Clinics Sponsored by Local Health Departments**
3. Check the box for seasonal, H1N1 or both.
4. Click on the arrow and highlight county (can skip to see entire state)
5. Click on the arrow and highlight municipality (can skip to see entire county)
6. Click on the Search button
7. When you find a clinic, be sure to click on the text in the column labeled “Name.” Carefully read **everything** there. This is where it explains who is eligible to be vaccinated at that clinic. Please note that there may be age restrictions.

Who do I call with a question about the "Flu Finder"?

Call the NJDHSS Office of Public Health Infrastructure at 609-986-0363.

Why doesn't “Flu Finder” show all of the flu clinics in the state?

The “Find A Flu Shot” locator lists only public clinics sponsored by public health agencies. It does not list private providers or retail outlets that are offering vaccine. Influenza vaccine is being delivered in staggered shipments. As soon as we receive a vaccine shipment, it is distributed to providers and local health departments, who then add clinics to the “Find A Flu Shot” locator. We recognize that there is a demand for the vaccine and anticipate greater availability of the influenza vaccine over the next few days/weeks.

Do private practices have to accept new patients who just want H1N1 vaccine?

No.

Will I be able to get a vaccination at my local pharmacy?

Check with your local pharmacy to see if the vaccine is available.

Can a local health department restrict vaccine so that they provide it only the residents of the communities that they serve?

Individuals in priority groups for vaccination can go to any public health clinic to receive the vaccine, regardless of where they live in NJ. After we are certain that all priority groups in NJ who want the vaccine have received it, it will be available to the general public. At that time, public health clinics may give preference to their residents.

Do I have to wait around for 15 minutes after I receive an H1N1 vaccine?

Although both fainting and allergic reactions are rare, it is recommended that people stay for observation for 15 minutes after they receive any vaccine. This is a recommendation;

however, you and your health care provider can determine what is best for you when you receive a vaccine.

H1N1 VACCINE COST/INSURANCE

Is the 2009 H1N1 influenza vaccine be free?

Private health care providers may charge patients if they are uninsured. The administration fee cannot exceed the regional Medicare vaccine administration fee. For more information, go to the Centers for Medicare and Medicaid Services web site at www.cms.hhs.gov and see the state reimbursement rates for Medicare and Medicaid. There will be no administration fee for vaccination in public-health organized large scale vaccination clinics.

If I go to my private doctor's office for the vaccine or to a local public health flu clinic, will I be charged if I have insurance? Will I have to pay a co-pay? What if I don't have insurance?

The administrative cost of providing the vaccine will be covered by Medicare and most, if not all, health insurers, including Medicaid, that insure New Jersey residents. Insurers are covering this cost the way they cover other vaccines, so whatever co-pay you typically have for a vaccine-related doctor's visit will apply here. However, people also have the option to use retail pharmacies (Walgreens, CVS, etc.) that may or may not charge the patient an administrative fee, and public flu clinics where an administrative fee will not be charged.

H1N1 VACCINE PRIORITY GROUPS

How is the priority group "healthcare and emergency medical services personnel" defined?

Healthcare personnel are defined as all persons who are licensed or certified to provide direct patient care. It also includes students or trainees of the same. This includes healthcare providers working in the following settings: acute care hospitals, nursing homes, skilled nursing facilities, physician's offices (providers licensed by a health-related board), urgent care centers, outpatient clinics, and home healthcare agencies.

Who can be vaccinated first with the 2009 H1N1 influenza vaccine that comes to New Jersey? (Please note that the first doses of 2009 H1N1 vaccine that arrived in NJ were the nasal mist which is not recommended for all individuals within the priority groups.)

- **Pregnant women** because they are at higher risk of complications and can potentially provide protection to infants who cannot be vaccinated;
- **Household contacts and caregivers for children younger than 6 months of age** because younger infants are at higher risk of influenza-related complications and cannot be vaccinated. Vaccination of those in close contact with infants

younger than 6 months old might help protect infants by “cocooning” them from the virus;

- **Healthcare and emergency medical services personnel** because infections among healthcare workers have been reported and this can be a potential source of infection for vulnerable patients. Also, increased absenteeism in this population could reduce healthcare system capacity;
- **All people from 6 months through 24 years of age:**
 - **Children from 6 months through 18 years of age** because cases of 2009 H1N1 influenza have been seen in children who are in close contact with each other in school and day care settings, which increases the likelihood of disease spread, and
 - **Young adults 19 through 24 years of age** because many cases of 2009 H1N1 influenza have been seen in these healthy young adults and they often live, work, and study in close proximity, and they are a frequently mobile population; and,
- **Persons aged 25 through 64 years who have health conditions associated with higher risk of medical complications from influenza.**

I’m a senior citizen (over 65). Should I get a 2009 H1N1 flu shot?

It seems that older adults are having fewer complications from 2009 H1N1 influenza than from seasonal flu. So, for seniors, it is more important to get a seasonal flu vaccine. Seniors may also want to talk to their health care providers about getting a pneumonia vaccine.

Why are people 65 and older prioritized for antiviral treatment if they get sick with the flu, but they are not in one of the early groups prioritized to get 2009 H1N1 vaccine?

People 65 and older are the least likely to be infected with 2009 H1N1 flu, but, if they become infected, they are more likely than people in some other groups to develop serious complications from their illness. That is why people 65 years and older are prioritized for treatment with antiviral drugs this season if they do become sick.

I am not in a priority group. Will I get turned away at the clinic? When do I get vaccinated?

The H1N1 vaccine is currently available in limited amounts. So yes, you will likely be turned away from clinics that are, at this time, focusing on the target priority groups. After individuals in the priority groups in NJ who want the vaccine have received it, the vaccine will then be available to others. There is expected to be enough vaccine available to vaccinate everyone who wants it. Shipments of the vaccine continue to arrive each day; please be patient and continue to check availability on <http://nj.gov/health/>.

Where can I get a seasonal flu shot?

You can call your local health department or health care provider to check on the availability on season flu vaccine. Retail outlets in your area may also be offering seasonal flu vaccine. The Department does have a list of flu clinics. Go to: <http://nj.gov/health/flu/findflushot.shtml> to see this list.

I tried to get a seasonal flu shot and there are no more clinics in my town or county.

We understand that people may be concerned that there is a limited amount of seasonal flu vaccine available at physicians' offices and public health clinics. We have been advised that there may be manufacturing delays or distribution center issues that are beyond the control of public health. This seems to be a national problem and is affecting some areas in New Jersey. It is our understanding that there is seasonal flu vaccine available in our area at other sites such as pharmacies and chain stores such as Walmart, ShopRite, etc. Those individuals who want to get flu shots should contact their health care provider, area pharmacies and local retail stores that are providing flu shots. When you call, be sure to tell them the exact age of the person in need of vaccine. Some pharmacies and retail stores are not providing immunizations for individuals under certain ages.

If H1N1 is the predominant flu virus that is circulating, why do I need a seasonal flu shot?

Seasonal flu viruses will also be circulating. The H1N1 flu vaccine does not protect you from them. Only the seasonal flu vaccine will do that.

PNEUMONIA VACCINATION

In the news, I hear that some people with H1N1 flu are getting pneumonia and are getting really sick and even dying. Would vaccination against pneumonia prevent this?

The best protection against pneumonia related to the flu is to be vaccinated against the flu. On its own, the flu virus can cause pneumonia, an inflammatory disease of the lungs. Vaccination against the flu will help prevent this flu complication.

The flu virus also can damage the lungs, making you more susceptible to bacterial infections that cause pneumonia. One of the bacteria that cause pneumonia is *Streptococcus pneumoniae*. There are many strains of pneumococcal bacteria; the pneumococcal vaccine provides protection against infection with the most common of these strains. Check with your doctor to see if you might be a candidate for the pneumococcal vaccine.

Other bacteria, such as MRSA (Methicillin-resistant *Staphylococcus aureus*, can also cause pneumonia after the flu. There is no vaccine for this bacterial infection or for a number of other bacterial infections that can cause pneumonia. The best way to avoid pneumonia after the flu is to avoid the flu altogether, and flu vaccination helps to protect against the flu.

How often should people be vaccinated against pneumonia?

Pneumococcal conjugate vaccine (PCV) is routinely given to infants and toddlers to protect them when they are at greatest risk for serious diseases caused by pneumococcal bacteria. Older children and adults with certain chronic illnesses may get a different vaccine called pneumococcal polysaccharide vaccine (PPV). In addition, the PPV is recommended for healthy adults 65 years and older. A second dose of PPV is recommended for people 65 years and older who got their first dose when they were younger than 65 and it has been 5 or more years since the first dose.

ADDITIONAL H1N1 INFORMATION/RESOURCES

Where can I learn more?

The CDC website will be providing daily updates regarding the status of this flu investigation in the US. They also have information posted such as questions and answers regarding Novel Influenza A (H1N1).

The web address is: www.cdc.gov/h1n1flu/.

For NJ information, go to: <http://www.nj.gov/health/flu/h1n1/>

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