From the CDC website, posted 10/7/09
http://www.cdc.gov/h1n1flu/vaccination/vaccine_keyfacts.htm

Key Facts About 2009 H1N1 Flu Vaccine

A flu vaccine is the single best way to protect against influenza illness. This season, there is a seasonal flu vaccine to protect against seasonal flu viruses and a 2009 H1N1 vaccine to protect against the 2009 H1N1 influenza virus (sometimes called "swine flu").

This page contains information about the 2009 H1N1 flu vaccine.

There are two kinds of 2009 H1N1 vaccines being produced:

- **A 2009 H1N1 "flu shot"** — an inactivated vaccine (containing killed virus) that is given with a needle, usually in the arm. The indications for who can get the 2009 H1N1 flu shot are the same as for seasonal flu shots. 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 same manufacturers who produce seasonal flu shots are producing 2009 H1N1 flu shots for use in the United States this season. The 2009 H1N1 flu shot is being made in the same way that the seasonal flu shot is made.

- **The 2009 H1N1 nasal spray flu vaccine** — a vaccine made with live, weakened viruses that do not cause the flu (sometimes called LAIV for "live attenuated influenza vaccine"). The indications for who can get the 2009 H1N1 nasal spray vaccine are the same as for seasonal nasal spray vaccine. LAIV is approved for use in healthy* people 2 years to 49 years of age who are not pregnant. The nasal spray vaccine for use in the United States is being made by MedImmune, the same company that makes the seasonal nasal spray vaccine called "FluMist®." The 2009 H1N1 nasal spray vaccine is being made in the same way as the seasonal nasal spray vaccine.

About 2 weeks after vaccination, antibodies that provide protection against 2009 H1N1 influenza virus infection will develop in the body.

The 2009 H1N1 vaccine will not protect against seasonal influenza viruses.

When to Get Vaccinated
Vaccination against 2009 H1N1 should begin as soon as vaccine is available and continue throughout the influenza season, into December, January, and beyond. This is because the timing and duration of flu activity can vary. Flu seasons can last as late as April or May. By early October 2009, extensive 2009 H1N1 flu activity was being reported in the United States. It's possible that there may be waves of 2009 H1N1 activity during the 2009-2010 flu season that hit communities more than once over the course of the season. While 2009 H1N1 viruses are likely to be the most common cause of influenza this season, CDC still expects that seasonal influenza viruses will circulate and

continues to recommend that people get a seasonal flu vaccine to protect against seasonal flu viruses. The ACIP has issued separate recommendations on who should get the 2009-10 seasonal vaccine

Vaccine Supply
The U.S. government has purchased 250 million doses of 2009 H1N1 vaccine, so anyone who wants to get the vaccine will have the opportunity to do so. Vaccine will be made available as quickly as possible as it rolls off the production lines, so initially, the vaccine will be available in limited quantities.

Who Should Get Vaccinated
CDC's Advisory Committee on Immunization Practices (ACIP), a panel made up of medical and public health experts, met July 29, 2009, to make recommendations on who should receive the 2009 H1N1 vaccine when it becomes available. While the federal government has purchased enough vaccine so that anyone who wants to get vaccinated can, ACIP's statement on the "Use of Influenza A (H1N1) 2009 Monovalent Vaccine" recommends that vaccination efforts should focus first on people in five target groups who are at higher risk for 2009 H1N1 influenza or 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 younger than 6 months (who are too young to be vaccinated). These five target groups make up an estimated 159 million people in the United States.

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

- pregnant women,
- people who live with or provide care for infants younger than 6 months (e.g., parents, siblings, and day care providers),
- health care and emergency medical services personnel,
- people 6 months through 24 years of age, and,
- people 25 years through 64 years of age who have certain medical conditions that put them at higher risk for influenza-related complications.

No shortage of 2009 H1N1 vaccine is expected, but vaccine availability and demand can be unpredictable and initially the vaccine may be available in limited quantities. Because the amount of vaccine available at first will be small, the ACIP also made recommendations regarding which people within the groups listed above should be prioritized if the vaccine is initially available in extremely limited quantities. For more information see the ACIP recommendations on the Use of Influenza A (H1N1) 2009 Monovalent Vaccine at http://www.cdc.gov/mmwr/preview/mmwrhtml/rr58e0821a1.htm

Once the demand for vaccine for the target groups has been met at the local level, ACIP recommends that programs and providers begin vaccinating everyone from the ages of 25

through 64 years. Current studies indicate that the risk for infection among persons 65 and older is less than the risk for younger age groups. However, once vaccine demand among younger age groups has been met, ACIP recommends that programs and providers should offer vaccination to people 65 or older.

The ACIP has issued separate recommendations on who should get the 2009-10 seasonal vaccine.

Who Should Not Be Vaccinated
There are some people who should not get any flu vaccine without first consulting a physician. These include:

- People who have a severe allergy to chicken eggs.
- People who have had a severe reaction to an influenza vaccination.
- People who developed Guillain-Barré syndrome (GBS) within 6 weeks of getting an influenza vaccine previously. (For information, see General Questions and Answers on Guillain-Barré syndrome (GBS).
- Children younger than 6 months of age (influenza vaccine is not approved for this age group), and
- People who have a moderate-to-severe illness with a fever (they should wait until they recover to get vaccinated.)

Vaccine Effectiveness
The ability of a flu vaccine to protect a person depends on the age and health status of the person getting the vaccine, and the similarity or "match" between the viruses or virus in the vaccine and those in circulation. CDC analyzes circulating inflIuenza viruses on an ongoing basis to determine how closely matched they are to vaccine viruses and publishes the information weekly in FluView. In addition, every year CDC monitors vaccine effectiveness. For more information about flu vaccine effectiveness, see How Well Does the Seasonal Vaccine Work?

Vaccine Side Effects (What to Expect)
The same side effects typically associated with the seasonal flu shot and the seasonal nasal spray vaccine are expected with the 2009 H1N1 flu shot and 2009 H1N1 nasal spray vaccine.

These are:

The flu shot: The viruses in the flu shot are killed (inactivated), so you cannot get the flu from a flu shot. Some minor side effects that could occur are:

- Soreness, redness, or swelling where the shot was given
- Fever (low grade)
- Aches

If these problems occur, they begin soon after the shot, are usually mild, and usually last 1 to 2 days. Almost all people who receive influenza vaccine have no serious problems from it. However, on rare occasions, flu vaccination can cause serious problems, such as severe allergic reactions.

The nasal spray: The viruses in the nasal-spray vaccine are weakened and do not cause severe symptoms often associated with influenza illness. (In clinical studies, transmission of vaccine viruses to close contacts has occurred only rarely.)
In children, side effects from LAIV can include:

- runny nose
- wheezing
- headache
- vomiting
- muscle aches
- fever

In adults, side effects from LAIV can include

- runny nose
- headache
- sore throat
- cough

For more information about vaccine side effects and safety see General Questions and Answers on 2009 H1N1 Influenza Vaccine Safety.

More Information

- 2009 H1N1 Flu Shot: Vaccine Information Statement (VIS)
- 2009 H1N1 Nasal Spray: Vaccine Information Statement (VIS)
- Seasonal Flu Shot: Vaccination Information Statement (VIS)
- Seasonal Nasal Spray: Vaccination Information Statement (VIS)

Questions & Answers: 2009 H1N1 Nasal Spray Vaccine

October 7, 2009, 6:30 PM ET

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

What is the nasal spray flu vaccine?

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

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

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

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

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

Can health care providers get the live attenuated influenza vaccine?

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

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

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

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

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

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

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

Are there any contraindications to giving breastfeeding mothers the 2009 H1N1 vaccine?

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

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

The nasal-spray flu vaccine can be given to people with minor illnesses (e.g., diarrhea or mild upper respiratory tract infection with or without fever). However, if nasal congestion

is present that might limit delivery of the vaccine to the nasal lining, then delaying of vaccination until the nasal congestion is reduced should be considered.

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

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

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

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

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

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

How effective is the nasal-spray seasonal flu vaccine?

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

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

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

How many doses of nasal spray vaccine are needed?

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

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

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

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

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

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

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

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

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

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

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

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

How is the nasal-spray flu vaccine stored?

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

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

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

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

Personal protective equipment (gloves and masks) are not needed when administering the nasal spray vaccine, including the 2009 H1N1 nasal spray vaccine.

Does the nasal spray flu vaccine contain thimerosal?

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

Can the nasal spray flu vaccine give you the flu?

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

Who makes the nasal spray vaccine?

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

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

More Information About Flu Vaccine

- 2009 H1N1 Nasal Spray: Vaccine Information Statement (VIS)
- Seasonal Nasal Spray: Vaccination Information Statement (VIS)
- 2009 H1N1 Flu Shot: Vaccine Information Statement (VIS)
- Seasonal Flu Shot: Vaccination Information Statement (VIS)

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

Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices (ACIP), 2009.
http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5808a1.htm

Influenza Vaccination of Health-Care Personnel: Recommendations of the Healthcare Infection Control Practices Advisory Committee (HICPAC) and the Advisory Committee on Immunization Practices (ACIP).
http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5502a1.htm