



2009 H1N1 Flu

Question: How safe is the 2009 H1N1 flu vaccine for pregnant women?

October 2009

Brief Answer

Leading public health organizations and medical groups agree that the benefits of the 2009 H1N1 flu vaccine outweigh the risks. Immunization is the most effective method of preventing infection and has been shown to reduce influenza complications. This year, otherwise healthy pregnant women have gotten very sick from the 2009 H1N1 flu.

Pregnant women are not at greater risk of getting the flu, but they are more likely to suffer serious complications from the illness. Women in their second and third trimesters in particular have been at increased risk. Some women have been hospitalized, a few have even died. Reports show that 6.1% of patients hospitalized for 2009 H1N1 flu complications are pregnant women. Approximately 6% of confirmed deaths related to 2009 H1N1 have been pregnant women, yet only 1% of the overall population is pregnant. Others have had a miscarriage or preterm birth as a result of a 2009 H1N1 flu-related illness. For these reasons, pregnant women are among those considered “high risk” and are strongly advised to get the vaccine.

The 2009 H1N1 flu vaccine has just become available, so the full effects of the vaccine have not yet been observed. However, the 2009 H1N1 flu vaccine has been developed using the same process and in the same facilities that make the annual seasonal flu vaccines. Millions of pregnant women have gotten seasonal flu shots over the years, and studies have revealed that flu shots have not been shown to cause harm to pregnant women or their babies. The U.S. Food and Drug Administration (FDA) has approved the use of the one-shot 2009 H1N1 vaccine for full protection for people 10 years and older, including pregnant women. The Centers on Disease Control and Prevention (CDC) report that the 2009 H1N1 flu vaccine is safe and effective.

Note: Experts are carefully monitoring the 2009 H1N1 situation and continually provide updated news and recommendations. For the most current information, talk to your doctor or visit one of the sites recommended on page 8.

What the Experts Are Saying About 2009 H1N1 Flu

#1: Pregnant women are at increased risk for severe complications and death from the 2009 H1N1 flu virus (formerly known as “swine flu”)

Pregnant women do not have a higher risk of catching 2009 H1N1 flu than anyone else, but they are more likely to suffer serious complications from the virus. Complications include adult respiratory distress syndrome, bacterial pneumonia, kidney failure, pulmonary embolus (when a lung artery is blocked, often by a blood clot) and maternal death. Furthermore, the 2009 H1N1 flu is different than the seasonal flu that circulates every year because the people suffering the most serious and potentially deadly complications are younger. Many pregnant women are between 25 and 49 years of age, and over 40% of deaths caused by 2009 H1N1 have been in this group. In comparison, approximately 90% of deaths from the seasonal flu are among people 65 years of age and older.

The CDC does not have an exact count of 2009 H1N1-related deaths and hospitalizations, but existing reports suggest the infection has caused more than 600 deaths and more than 9,000 hospitalizations since the virus was first identified in April 2009. Pregnant women have been particularly susceptible to the flu, and CDC officials say they are aware of 28 deaths of pregnant women.

Dr. Anne Schuchat, director of the National Center for Immunization and Respiratory Diseases at the CDC, explains why pregnant women are at greater risk for getting the flu and suffering serious complications: A woman's immune system changes during pregnancy to prevent an immune reaction against the fetus and “the risk of infections can be greater [as a result]....The other reason is mechanical. As the womb gets larger, with the baby growing, there can be pressing on the airways and a restrictive lung disease. So it's harder to take a deep breath, and it's harder to fight off a lung infection, especially in the later stages of pregnancy.”

What the Experts Are Saying About 2009 H1N1 Flu (Continued)

#2: Doctors and pregnant women should take flu-like symptoms seriously and immediately begin treatment

The CDC recommends that doctors initiate treatment within 48 hours after a pregnant woman first notices flu-like symptoms (*may* include fever, cough, sore throat, runny or stuffy nose, body aches, headache, and/or chills). Do NOT stay at home and treat yourself with rest, fluids, Tylenol and chicken soup, as you may do if you have the seasonal flu. The 2009 H1N1 illness rapidly progresses in pregnant women, so it is critical that you call your doctor immediately if you start having flu-like symptoms. Doctors are advised not to wait for flu test results before treating pregnant women because the illness can rapidly get worse before the results are ready. Also, the results are between 10% and 70% accurate, so many cases are missed.

Treatment with anti-viral medications oseltamivir (Tamiflu®) or zanamivir (Relenza®) for five days is recommended for pregnant women and can be taken during any pregnancy trimester. Although it is best to get treatment within the first 48 hours, treatment at any time is beneficial. Your doctor will determine if he or she thinks you have 2009 H1N1 flu and if and how you should be treated. No clinical studies have been conducted to assess the safety of these two anti-viral medications, but experts recommend the treatment because available information about the benefits of the drugs outweigh the risks the flu may pose.

The 2009 H1N1 flu virus is a new strain of virus. It is very different from the seasonal flu that circulates on a yearly basis. Most people have gotten the seasonal flu at one point and have developed antibodies so they have some immunity to that illness. Although the seasonal flu mutates slightly every year, many people's bodies have built up some ability to fight off this virus. Conversely, most people have little or no immunity to 2009 H1N1 flu. Therefore, the 2009 H1N1 influenza spreads quickly from one person to the next, and the complications—including hospitalization and death—are more serious than those associated with the seasonal flu.

#3: Doctors and pregnant patients should be talking about 2009 H1N1 flu

Ask your doctor about the flu and how to recognize flu-like symptoms. Discuss warning signs and what to do if you think you have the 2009 H1N1 flu. Find out what number you should call and what else you should do to ensure you get immediate care. Ask how to keep yourself healthy and protected if others around you have the flu. Discuss when and where you can get the 2009 H1N1 vaccine and any questions or concerns you have about the virus or the vaccine.

#4: Pregnant women should get both the seasonal flu virus and the 2009 H1N1 flu vaccines

The CDC and the American College of Obstetricians and Gynecologists (ACOG), among other public health and medical organizations, recommend the two vaccines for women this year. The vaccines are not interchangeable, so you must receive both for protection against both the seasonal flu and 2009 H1N1.

Many pregnant women are reluctant to get any vaccine or take any medication that they do not need or that may have adverse effects on them or their fetus during pregnancy. Some obstetricians are also reluctant to vaccinate or treat women with anti-viral medications because the effects of some vaccines on pregnant women and fetuses have not been studied thoroughly. However, the 2009 H1N1 virus is new. People do not have antibodies against this strain of influenza. Pregnant women have disproportionately high complications, including hospitalization and death, from 2009 H1N1. For these reasons, public health experts strongly recommend that pregnant women get vaccinated.

What the Experts Are Saying About 2009 H1N1 Flu (Continued)

#5: *Pregnant women should not get the nasal spray vaccine*

The live-attenuated intranasal vaccine (LAIV) is made from a weakened version of the 2009 H1N1 virus. This version of the vaccine, which is used in the nasal spray, has been approved for healthy people ages two through 49 who are not pregnant and who do not have long-term health problems (e.g., asthma, heart conditions, lung problems, kidney diseases or metabolic problems). People with health problems and weakened immune systems, including pregnant women, are not approved for the LAIV and should get the shot, which is made from the dead, inactive virus. The first 2009 H1N1 vaccines that are available are the LAIV version. The shot with and without mercury (thimerosal) becomes available in mid-October.

#6: *Maternal vaccination and breastfeeding can help protect infants*

Infants under six months old are not eligible for the 2009 H1N1 vaccine. Breastfeeding mothers can safely get the 2009 H1N1 flu vaccine; preventing maternal infection helps provide secondary protection to the baby. In addition, some studies show that the transfer of vaccination-related antibodies in breast milk further reduces the infant's chances of getting sick. Infants who are breastfeeding are less vulnerable to infection and hospitalization for severe respiratory illness than infants who receive formula. Researchers have found that it is rare that the flu virus passes from a mother to a baby via breast milk, so women are encouraged to get the vaccine and continue breastfeeding even if they get the flu (taking proper precautions). Although studies have not specifically looked the effects of breastfeeding on infants and the 2009 H1N1 flu, these assumptions are based on seasonal flu studies.

Concerns about the Vaccine

Does the vaccine contain mercury and, if so, does that lead to autism or other disorders?

It is true that some vaccines contain thimerosal, a mercury preservative added to some multi-dose vials of vaccines. Thimerosal prevents bacteria from growing in multi-dose vaccine vials and keeps the vaccine from becoming contaminated before the second dose is administered. Contaminated vaccines can lead to serious illness or death. The CDC, FDA and National Institutes of Health (NIH) have all reviewed medical studies on the effects of thimerosal and found that it is safe to be used in vaccines. There is no evidence that thimerosal is harmful to pregnant women or a fetus.

In response to some women's concern about a 2009 H1N1 vaccine containing mercury, vaccine producers have developed a mercury-free (without thimerosal), single-dose vaccine. The CDC recommends that women get flu shots either with or without thimerosal. The live-attenuated intranasal version of the vaccine (LAIV), which is administered as a nose spray, does not contain thimerosal but is not approved for pregnant women. For more information, please see the CDC's "General Questions and Answers on Thimerosal" site: http://www.cdc.gov/h1n1flu/vaccination/thimerosal_qa.htm.

Does the 2009 H1N1 flu vaccine contain squaline?

Squalene is an adjuvant. Adjuvants are sometimes added to vaccines to boost the immune system's response. The 2009 H1N1 vaccine currently offered in the United States does not contain adjuvants. Dr. Anne Schuchat of the CDC explains: "We [the United States] have bought adjuvant to have on the shelf. It's really an emergency provision or a contingency plan. If this virus mutates and becomes much, much different and more severe, we might need to add adjuvants in order to have an immune response that's effective. But for the time being, we really aren't expecting to use them. We're...using vaccines that are produced exactly the same as the seasonal influenza vaccines are, and they don't have adjuvants here in the United States."

Concerns about the Vaccine (Continued)

Was the 2009 H1N1 flu vaccine rushed onto the market?

Flu vaccines—both the annual seasonal flu vaccine and the 2009 H1N1 flu vaccine—take five to six months to develop. The 2009 H1N1 flu vaccine was developed using the same process that is used to make the annual seasonal flu vaccine. In fact, the new 2009 H1N1 vaccine underwent more testing for effectiveness and safety than the seasonal flu, which has not undergone clinical trials in recent years because it has been proven safe and effective. The 2009 H1N1 flu vaccine trials indicate that the vaccine provides a good immune response to the new H1N1 flu virus and resulted in no significant, adverse effects.

Can I get either the nasal spray vaccine or the injection if I am pregnant?

Pregnant women are not approved for the nasal spray vaccine (the live-attenuated intranasal vaccine (LAIV)). This vaccine is made from weakened versions of the virus, and the effects on higher-risk groups, including pregnant women, are not known. Therefore, public health officials and doctors recommend that pregnant women only get the injection, which is made from the inactivated, dead virus. However, your family, friends and those around you who are healthy can get the nasal spray without putting you at higher risk of getting the virus. If you have just delivered and/or are breastfeeding, either vaccination method is safe and you can choose which you prefer. The nasal spray vaccine has been determined as safe for healthy people ages two to 49 who are not pregnant.

Can I get the seasonal flu vaccine and the 2009 H1N1 vaccine together?

The two vaccines do not react with each other, so you can safely get both on the same day. Be aware that you may not be able to get the vaccine in the same physical locations at the same time. Check with your doctor, employer, local clinic or drugstore about where and when you can get the vaccinations. The 2009 H1N1 vaccine just became available and initial supply may exceed demand. However, pregnant women are found to be disproportionately affected by the 2009 H1N1 flu and therefore are a top-priority group advised to get the vaccine.

The 1976 swine flu vaccine has been associated with Guillain-Barre Syndrome (GBS). Will the 2009 H1N1 vaccine cause the same effects?

Official studies report that one in 100,000 people vaccinated for swine flu in 1976 developed Guillain-Barre Syndrome, a severe paralytic illness. Experts do not anticipate the same outcome for the 2009 H1N1 flu vaccine. The 2009 H1N1 flu vaccine has been developed the same way as the seasonal flu vaccine. GBS occurs at a rate of 10-20 cases per million people on an annual basis—regardless of vaccination—and has been associated with some gastrointestinal and upper respiratory tract infections. Based on studies on the risk of people developing GBS after getting the seasonal flu vaccine, experts anticipate a small risk of one additional case of GBS per one million people vaccinated. If you have had GBS in the past, you should tell your doctor before getting the flu shot.

What are possible side effects of the vaccine?

The H1N1 flu vaccine just became available, so no large studies have been done on the side effects of the vaccine. However, the side effects are expected to be similar to those of the seasonal flu vaccine. The site around the injection location may be sore, tender and red. You may have a headache, muscle aches, fever, nausea or tiredness. These side effects may last one to two days. Some people faint when they get shots; if you have fainted in the past after getting a shot, let the healthcare worker giving you the shot know beforehand.

In rare cases, people have serious allergic reactions to the seasonal flu vaccine, especially if they are allergic to eggs. If you have had a life-threatening reaction to eggs or another substance in the vaccine, you should not get the shot, even if you are pregnant. Let your doctor know BEFORE you get the shot if you have any severe allergies. Your doctor will help you decide if the vaccine is safe for you. Allergic reactions to the seasonal flu vaccine are rare, and it is expected that the same will be true for the 2009 H1N1 vaccine. Reactions usually occur immediately or within the first few hours after receiving the vaccine, and signs include difficulty breathing, hoarseness or wheezing, hives, paleness, weakness, a fast heart beat or dizziness. Call your doctor immediately if you think you are having a reaction to the vaccine.

Symptoms of H1N1 Flu

If you or a family member shows signs of coming down with a flu-like illness, pay attention to the symptoms and call your doctor immediately. A cold and the seasonal flu have similar symptoms, although flu symptoms are usually more severe; the seasonal flu and H1N1 also have similar symptoms, but H1N1 symptoms may be more severe. The chart below will help you compare symptoms. However, people experience flu symptoms differently, and your doctor will determine what type of illness you have and how you should be treated. **Do not wait to call your physician if you have flu-like symptoms.**

The chart below presents symptoms for the common cold, the seasonal flu and 2009 H1N1:

Illness	Common Cold	Seasonal Flu	2009 H1N1 Flu
Cause	Cold virus	Influenza B virus	H1N1 (type of Influenza A) virus
Common Symptoms	Cold symptoms often include: <ul style="list-style-type: none"> • Low-grade fever • Coughing • Sore throat • Runny or stuffy nose • Headache • General discomfort 	All types of flu can cause: <ul style="list-style-type: none"> • Fever (usually over 101°F) • Coughing • Sore throat • Runny or stuffy nose • Headaches • Body aches • Chills • Fatigue and weakness 	Same as seasonal flu, but may be more severe: <ul style="list-style-type: none"> • Fever (usually over 101°F) • Coughing • Sore throat • Runny or stuffy nose • Headaches • Body aches • Chills • Fatigue and weakness
Occasional Symptoms		Some people with the flu have stomach-related issues, including: <ul style="list-style-type: none"> • Nausea • Vomiting • Diarrhea 	Many people with H1N1 also experienced: <ul style="list-style-type: none"> • Vomiting • Diarrhea

Other Warning Signs of 2009 H1N1 Flu

If someone in your family has the flu, you should immediately contact your healthcare provider. Infants and children may have a fever or act lethargic when they have the flu, but they may not have a cough or other respiratory problems. Call your doctor if your child has flu symptoms or any of the following conditions:

- Fast breathing or trouble breathing
- Bluish or gray-colored skin
- Severe or persistent vomiting
- Not drinking enough fluids
- Not urinating or no tears when crying
- Not wanting to wake up or interact
- Being very irritable and not wanting to be held
- Flu-like symptoms that improve but then return with fever and worse cough

Where to Get the Vaccine

Public health officials recommend **two different** flu vaccines this fall: the seasonal flu vaccine and the 2009 H1N1 vaccine. The seasonal flu protects only against this year’s seasonal flu (a strain of influenza B). The 2009 H1N1 vaccine protects only against 2009 H1N1 flu (a strain of influenza A). They are not interchangeable, and you need both to be protected against both flu viruses. If the vaccines closely matches the flu strains that are circulating this season, the shot is 70%–90% effective at keeping you from catching the virus. Even if you do catch the flu, your symptoms will be less severe. Several locations offer vaccinations, including the following:

- Local health departments
- Healthcare provider offices
- Schools
- Pharmacies
- Some workplaces

Find a location near you using Flu.gov’s Flu Shot Locator:

<http://www.flu.gov/individualfamily/vaccination/locator.html>

Staying Healthy

Doctors and public health experts recommend that pregnant women get the 2009 H1N1 vaccine. However, there are several other ways for you to keep yourself healthy:

- **Stay informed**—Visit Flu.gov or the CDC’s Web site for up-to-the-minute updates about 2009 H1N1. Read up about H1N1, read the paper or watch the news and talk to your doctor if you have any questions or concerns.
- **Follow public health advice**—Experts only discovered the 2009 H1N1 influenza virus in humans in April 2009, but this has become a top public health concern. Public health organizations have outlined ways to minimize the impact of 2009 H1N1 flu. Follow advice regarding school closures, avoiding crowds and other “social distancing” measures (isolating and wearing a face mask if you must be in contact with others when you are sick, forgoing a hug or kiss on the cheek in greeting if you have the flu, etc.).

- **Understand how influenza spreads**—H1N1 spreads primarily person-to-person. You can take steps to minimize your risk of getting the virus:
 - Cover your mouth and nose with a tissue (or the crook of your elbow if you do not have a tissue) when you cough or sneeze. Throw away used tissues immediately after you use them.
 - Wash your hands often with hot water and soap. Alcohol-based hand sanitizer is an effective alternative if you can’t wash your hands.
 - Avoid touching your eyes, nose and mouth with your hands. You can spread or contract the virus this way.
 - Stay home if you are sick. Limit your contact with others and avoid passing on your illness to your coworkers or classmates. Plus, you can focus your energy on resting and getting better.
 - Call your doctor immediately if you have flu-like symptoms
- **Get plenty of rest, eat well and hydrate**—Keep your immune system in top shape by getting enough sleep, eating a well-balanced diet and drinking plenty of fluids.
- **Protect your infant**—After you have given birth, do what you can to protect your baby from 2009 H1N1 influenza. Although the risk for 2009 H1N1 flu transmission through breast milk is not known, studies show that the seasonal flu influenza infection rarely passes from mother to baby through breast milk. Therefore, experts expect that mothers are not likely to pass 2009 H1N1 on to their babies in this manner. Mothers and family members who are sick with 2009 H1N1 should wear a facemask if they have to be near the baby, and those who are sick should try to stay away from the baby until completely better. If a woman is sick, experts recommend that she bottle breast milk so someone else can feed the baby until she is better. If this is not possible, she should wear a facemask while feeding and be diligent about washing her hands frequently and following coughing etiquette. Experts also think that babies who are breastfeeding are less vulnerable to infection and hospitalization for respiratory illness than infants who receive formula.

Summary

- Pregnant women are at increased risk for severe complications and death from the 2009 H1N1 flu virus (formerly known as “swine flu”).
- Doctors and pregnant women should take flu-like symptoms seriously and immediately begin treatment.
- Doctors and pregnant patients should be talking about 2009 H1N1 flu.
- Pregnant women should get both the seasonal flu virus and the 2009 H1N1 flu vaccines.
- Pregnant women should not get the nasal spray vaccine.
- Maternal vaccination and breastfeeding can help protect infants.

For More Information:

The American College of Obstetricians and Gynecologists (ACOG) “2009 H1N1 Influenza Virus and Seasonal Influenza Virus” page:

http://www.acog.org/departments/dept_notice.cfm?recno=20&bulletin=4866

A compilation of important clinician guidance and resources, including information for pregnant women, that is updated regularly.

Flu.gov: www.flu.gov

Information from the U.S. federal government, including The White House, the U.S. Department of Agriculture (USDA), the U.S. Department of Defense, the U.S. Department of Education, the U.S. Department of Health and Human Services (HHS) including the Centers for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH), the U.S. Department of Homeland Security (DHS), the U.S. Department of the Interior (DOI), the U.S. Department of Labor (DOL), the U.S. Department of State (DOS) and the U.S. Environmental Protection Agency (EPA).

The CDC’s 2009 H1N1 Flu Web site: <http://www.cdc.gov/H1N1FLU/>

Includes situation updates, general information about 2009 H1N1, information about vaccination, information for specific groups, clinical and public health guidance, and tips for staying healthy.

The CDC’s H1N1 (Swine Flu) Resources for Pregnant Women: <http://www.cdc.gov/h1n1flu/pregnancy/>

Includes Webcasts, Q&As, and general information about 2009 H1N1 for pregnant women.

World Health Organization’s Pandemic (H1N1) 2009: <http://www.who.int/csr/disease/swineflu/en/>

Includes recent global updates and news; guidance for individuals, communities, and authorities; FAQs; briefing notes; global news about H1N1 in different regions and situation updates.

UpToDate, Inc.: www.uptodate.com (subscription required)

Peer-reviewed medical articles written by doctors. Includes articles about epidemiology, manifestation, and diagnosis of H1N1 influenza, the H1N1 vaccination and treatment.

Additional Articles

Beigi, Richard, “Pandemic Influenza and Pregnancy: A Call for Preparedness Planning,” *American College of Obstetricians and Gynecologists* (May 2007).

Lowes, Robert, “Most Hospitalized H1N1 Patients Have Underlying Conditions,” *Medscape Medical News* (October 13, 2009). (<http://www.medscape.com/viewarticle/710453>)

MacDonald, Noni, Laura Riley, and M. C. Steinhoff, “Influenza Immunization in Pregnancy,” *American College of Obstetricians and Gynecologists* (August 2009).

Phillippe, Mark, “Pandemic Influenza: What Obstetricians Need to Know,” *American College of Obstetricians and Gynecologists* (August 2009).

Saleeby, Erin, et. al, “H1N1 Influenza in Pregnancy: Cause for Concern,” *American College of Obstetricians and Gynecologists* (October 2009).

Thorner, Anna, “Epidemiology, Clinical Manifestations, and Diagnosis of Pandemic H1N1 Influenza (‘Swine Influenza’),” *UpToDate* (Updated October 2009).

Thorner, Anna, “Prevention of Pandemic H1N1 Influenza (‘Swine Influenza’),” *UpToDate* (Updated October 2009).

Thorner, Anna, “Treatment of Pandemic H1N1 Influenza (‘Swine Influenza’),” *UpToDate* (Updated October 2009).

Zachary, Kimon, “Antiviral Drugs for the Treatment of Influenza in Adults,” *UpToDate* (Updated September 2009).

Note:

The public health and medical information and recommendations discussed in this report were accurate at the time of publishing. For the most up-to-date information, please visit one of the recommended sites listed in the “For More Information” section or speak with your doctor.