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## 2009 H1N1 Influenza Vaccine and Pregnant Women: Information for Healthcare Providers

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### Introduction

The purpose of this document is to provide information for healthcare providers on 2009 H1N1 influenza vaccination and pregnant women. Additional information about the 2009 H1N1 vaccine can be found at <http://www.cdc.gov/h1n1flu/vaccination/> (<http://www.cdc.gov/h1n1flu/vaccination/>).

### Background

Some pregnant women who have been infected with the 2009 H1N1 virus have had severe illness. Overall, pregnant women have had higher rates of hospitalization than the general population. About 6% of confirmed H1N1 2009 influenza deaths in the US have been in pregnant women, while only about 1% of the general population is pregnant at any given time. One recent large case control study found that the seasonal flu shot (inactivated flu vaccine) given to pregnant women reduced flu illness in their infants under 6 months of age by 63%\*. This study confirms that seasonal flu vaccination of pregnant women can benefit both mothers and infants. The Advisory Committee on Immunization Practices (ACIP) designated pregnant women as one of the initial target groups to receive the 2009 H1N1 vaccine as soon as it is available. Clinical trials evaluating the vaccine in pregnant women are underway by the National Institute of Allergy and Infectious Diseases (NIAID). Additional information about these trials can be found at <http://www3.niaid.nih.gov/news/QA/H1N1pregnanttrials.htm> (<http://www3.niaid.nih.gov/news/QA/H1N1pregnanttrials.htm>).

### ***What supply and distribution information is available to providers for the 2009 H1N1 flu vaccine?***

Visit [http://www.cdc.gov/h1n1flu/vaccination/clinicians\\_qa.htm](http://www.cdc.gov/h1n1flu/vaccination/clinicians_qa.htm) ([http://www.cdc.gov/h1n1flu/vaccination/clinicians\\_qa.htm#SupplyDistribution](http://www.cdc.gov/h1n1flu/vaccination/clinicians_qa.htm#SupplyDistribution)) for supply and distribution information, including flow of vaccine from manufacturers to providers, how to become a provider, and how to obtain vaccine.

### ***How should healthcare providers organize their clinics for vaccination?***

One of the most important actions providers of obstetrical care can take is to strongly recommend to their patients that they receive vaccine. Provider recommendation has repeatedly been shown to be a key predictor of acceptance of influenza vaccination.

Providers who care for pregnant women are in an ideal position to provide vaccine given the frequency of visits during pregnancy. There are many ways that clinics and offices can support vaccination of their pregnant patients. Some suggestions include vaccinating patients at the time of their prenatal visit or offering separate vaccination days or clinics when all well pregnant patients can receive vaccine. This should be done in conjunction with administering seasonal flu vaccine. Offering vaccine during regular clinic visits should occur even in practices with separate vaccination days or clinics, in order to reach pregnant women who may not take advantage of those opportunities.

Practices that do not choose to stock and provide vaccine should identify locations for referral of patients for vaccination.

Options for referral include:

- Partnering with other offices in the geographic region and designate one site for vaccination
- Partnering with local hospitals or birthing centers where patients deliver
- Providing information to patients about local vaccination clinics

### ***How many vaccine doses will a pregnant woman need to get?***

The U.S. Food and Drug Administration (FDA) has approved the use of one dose of vaccine for full protection for persons 10 years and older. Therefore, a pregnant woman is recommended to get one dose of the 2009 H1N1 vaccine.

### ***If a pregnant woman delivers her baby before receiving her seasonal flu shot or her 2009 H1N1 flu shot, should she still receive them?***

Yes. In addition to protecting her from infection, the vaccine may also help protect her young infant. Flu vaccines are recommended only for infants 6 months or older. It is recommended that everyone who lives with or provides care for an infant less than 6 months old receive both the seasonal flu vaccine and the 2009 H1N1 flu vaccine.

## ***Can a woman who is breastfeeding receive the 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.

## ***Is the 2009 H1N1 flu vaccine safe for pregnant women?***

Flu vaccines have not been shown to cause harm to a pregnant woman or her baby. The seasonal flu shot has been recommended for pregnant women for many years. The 2009 H1N1 flu vaccine will be made using the same processes as the seasonal flu vaccine. Studies that test the 2009 H1N1 flu vaccine in pregnant women began in September. More information is available at <http://www3.niaid.nih.gov/news/QA/vteuH1N1qa.htm> (<http://www3.niaid.nih.gov/news/QA/vteuH1N1qa.htm>).

## ***Does the 2009 H1N1 flu vaccine have preservative in it?***

Multi-dose vials of flu vaccine contain the preservative thimerosal to prevent bacterial growth. There is no evidence that thimerosal is harmful to a pregnant woman or a fetus. However, because some women are concerned about exposure to preservatives during pregnancy, manufacturers are producing preservative-free seasonal flu vaccine and 2009 H1N1 flu vaccine in single dose syringes. CDC recommends that pregnant women receive flu vaccine with or without thimerosal.

## ***Does the 2009 H1N1 flu vaccine have an adjuvant or squalene in it?***

Adjuvants are agents that are sometimes added to a vaccine to increase its effectiveness. There are no adjuvants (such as squalene) in either the 2009 H1N1 or seasonal flu vaccines used in the United States.

## ***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 Advisory Committee on Immunization Practices also recommends that 2009 H1N1 flu vaccine be given to all pregnant women at any time during pregnancy.

## ***Will the seasonal flu vaccine also protect against the 2009 H1N1 flu?***

The seasonal flu vaccine is not expected to protect against the 2009 H1N1 flu. Similarly, the 2009 H1N1 flu vaccine will not protect against seasonal flu.

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

Seasonal flu and 2009 H1N1 vaccines may be administered on the same day but given at different sites (e.g. one shot in the left arm and the other shot in the right arm). However, the seasonal vaccine is available now in numerous areas and the 2009 H1N1 influenza vaccine won't be available until mid-October. So, pregnant women are encouraged to get their seasonal flu vaccine as soon as it is available in their community. The usual seasonal influenza viruses are still expected to cause illness this fall and winter.

## ***Can pregnant women receive the nasal spray vaccine?***

The nasal spray vaccine is not licensed for use in pregnant women. Pregnant women should not receive nasal spray vaccine for either seasonal flu or 2009 H1N1 flu. After delivery, women can receive the nasal spray vaccine, even if they are breastfeeding.

## ***What are the possible side effects of the 2009 H1N1 flu vaccine?***

Pregnant women are not known to have an increased risk of side effects from the flu vaccine. The side effects from 2009 H1N1 flu vaccine are expected to be similar to those from seasonal flu vaccines. The most common side effects following vaccination are expected to be mild, such as soreness, redness, tenderness or swelling where the shot was given. Some people might experience headache, muscle aches, fever, fatigue, and nausea. If these problems occur, they usually begin soon after the shot is given and may last as long as 1-2 days. Fainting may occur shortly after receiving any injection and has uncommonly been reported after the flu shot. Like any medicines, vaccines can cause serious problems like severe allergic reactions. However life-threatening allergic reactions to vaccines are very rare.

Anyone who has a severe (life-threatening) allergy to eggs or to any other substance in the vaccine should not get the vaccine, regardless of whether they are pregnant. Providers should ask patients whether they have any severe allergies or if they have ever had a severe allergic reaction following flu vaccination.

## ***Is the 2009 H1N1 flu vaccine expected to be associated with Guillain-Barre Syndrome (GBS)?***

During the 1976 Swine Flu vaccination program in the U.S., using a vaccine virus very different than the 2009 H1N1 virus, the 1976 vaccine was associated with cases of a severe paralytic illness called Guillain-Barre Syndrome (GBS). Approximately 1 additional case of GBS per 100,000 persons vaccinated occurred with the 1976 swine flu vaccine. Most studies done on seasonal flu vaccines after the 1976 vaccine showed no

increased risk of GBS. However, two studies did demonstrate a small risk of approximately 1 additional case of GBS per 1 million persons vaccinated.

GBS occurs at a rate of 10--20 cases per 1 million adults per year, regardless of vaccination. Substantial evidence exists that multiple infectious illnesses, most notably *Campylobacter jejuni* gastrointestinal infections and upper respiratory tract infections, including respiratory illness caused by influenza, are associated with GBS.

In general, seasonal flu vaccine has not been found to increase the risk for GBS. If a risk exists it is low (i.e., approximately one additional case per 1 million persons vaccinated). The potential benefits of flu vaccination in preventing serious illness, hospitalization, and death substantially outweigh this estimate of risk for flu vaccine-associated GBS. Persons who have previously had GBS should not receive influenza vaccine.

## ***What can providers do if there is a clinical adverse event following vaccine administration?***

The Vaccine Adverse Event Reporting System (VAERS) is a US vaccine safety surveillance system, co-managed by CDC and FDA.

Clinically significant adverse events that follow vaccination should be reported to VAERS. Reports may be filed securely online at <http://vaers.hhs.gov/>, by mail, or by fax. Report forms are available online or can be obtained by calling 1-800-822-7967 to request reporting forms or other assistance.

\* Zaman K, Roy E, Arifeen S, et al. Effectiveness of maternal influenza immunization in mothers and infants. NEJM 2008;359:1555-64

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