Seasonal H1N1 Influenza in Pregnancy

A Resource Guide for Obstetrician-Gynecologists
H1N1 Influenza in Pregnancy
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Dear Woman’s Health Care Provider,

The H1N1 Influenza infection is a new influenza viral strain that was first detected in the United States in the spring of 2009. Six percent of all H1N1-related deaths investigated by the Centers for Disease Control and Prevention to date have occurred in pregnant women and pregnancy itself, particularly in the third trimester, incurs a heightened risk for contracting H1N1 by causing severe respiratory illness and the potential to pass the infection to the fetus. Pregnant women with confirmed or probable H1N1 infection have a four-fold increase in hospitalization rates compared to the general population with H1N1 infection.

It is quite possible for an individual to experience both seasonal influenza and H1N1 influenza infection simultaneously or in tandem with serious results. As an obstetrician-gynecologist and primary care provider, your attention to this new viral strain is imperative. As the regular influenza season begins and this new virus affects more and more of your patients, proper guidance on how to manage complex cases will be necessary. This resource guide, *Seasonal and H1N1 Influenza in Pregnancy*, will assist you in addressing patient concerns while understanding the appropriate treatment recommendations set forth by The American College of Obstetricians and Gynecologists and leading governmental public health agencies.

Updates to this guide will be made available to you on The American College of Obstetricians and Gynecologists, District II website at [www.acogny.org](http://www.acogny.org). If you require further assistance with any of the information contained within this guide, please contact ACOG District II at (518) 436-3461 or info@ny.acog.org.

Sincerely,

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*A PHYSICIAN’S CALL TO ACTION*
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This resource guide is designed to provide you with updated information on both seasonal influenza and H1N1 influenza infection in pregnancy. This information is continually evolving and The American College of Obstetricians and Gynecologists, District II will routinely provide its members with updated guidance throughout the influenza season, particularly on H1N1 infection control and vaccination practices. Contained within this guide you will find information on:

- How to recognize symptoms of influenza infection;
- How to manage and care for your pregnant patient with a suspected infection;
- How to counsel patients on minimizing transmission of influenza;
- How to prepare your workplace for a potential infection and manage staff accordingly; and,
- How to code for routine care and administration of H1N1 influenza infection.

Recognition of a potentially fatal influenza infection is a patient and provider’s first line of defense. While we cannot predict how many pregnant patients the new H1N1 influenza strain will affect, we can prepare ourselves as providers on how to manage the patient that presents to us with symptoms. It is our hope that through the education that this resource guide provides, more pregnant women will become immunized during one of the most critical influenza seasons we have seen to date, reversing a national trend of previously low immunization rates in the pregnant population.

*Seasonal and H1N1 Influenza in Pregnancy* also provides information on issues of extreme importance to your pregnant patients such as:
- Breastfeeding and what to do if they become ill;
- Influenza vaccine and its ingredients; and,
- Vaccines currently recommended.

As a provider, you will find essential information on how to receive the H1N1 influenza vaccine from various government agencies and how to provide the vaccine to your patients if you wish to do so. This information varies depending on your location.

This resource guide has been compiled using comprehensive information available from numerous government agencies, journal articles, and guidance from leading medical organizations to date.
H1N1 INFLUENZA INFECTION IN PREGNANCY

The varying influenza viruses that circulate every year infect up to 20% or more of the population. H1N1 influenza virus is a new viral strain that was first detected in the United States in the spring of 2009. This virus was originally referred to as “swine flu” because laboratory testing demonstrated that many of the genes in this new virus were very similar to influenza viruses that normally occur in pigs (swine) in North America. However, further study has shown that this new virus is very different from what normally circulates in North American pigs. It is a “quadruple reassortant” virus, with two genes from flu viruses that normally circulate in pigs in Europe and Asia, bird (avian) genes, and human genes. Pregnant women with confirmed or probable H1N1 infection have a four-fold increase in hospitalization rates compared to the general population with H1N1 infection.

It is expected that cases of H1N1 influenza will rapidly multiply in the United States, particularly during the fall months. Pregnant women (particularly those in the third trimester and/or those with underlying medical conditions) and infants are at very high risk for influenza related complications. A recent report noted that one-third of pregnant women with confirmed cases of pandemic H1N1 influenza infection were hospitalized (mostly with severe respiratory distress) and deaths of otherwise healthy pregnant women are continuously reported. Additionally, it is quite possible for an individual to experience both seasonal influenza and H1N1 influenza simultaneously or in tandem with serious results.

It is prudent and advisable for obstetrical care providers and the institutions where obstetrical care is given to develop strategies to assist their patient populations by:

- Reducing transmission of the virus;
- Efficiently evaluating and providing diagnosis for suspected infection;
- Prescribing effective antiviral prophylaxis or treatment when indicated; and
- Managing severe illness as needed.

The Scary Truth: Pregnancy and H1N1 Infection

A recent CDC study found that pregnant women are about four times more likely to be hospitalized as a result of an H1N1 infection. Unfortunately, statistics show that only 15% of pregnant women in the United States receive the trivalent inactivated influenza vaccine (TIV).

From April 15 to May 18, 2009, 34 confirmed or probable cases of pandemic H1N1 influenza infection in pregnant women were reported to the Centers for Disease Control and Prevention from 13 states. Eleven women, or 32%, were admitted to the hospital. The estimated rate of admission for pandemic H1N1 influenza virus infection in pregnant women during the first month of the outbreak was higher than it was in the general population (0.32 per 100,000 pregnant women versus 0.076
per 100,000 of the population at risk). Between April 15 and June 16, 2009, six deaths in pregnant women were reported to the CDC; all were in women who had developed pneumonia and subsequent acute respiratory distress syndrome requiring mechanical ventilation. That all six deaths reported during the present outbreak were in relatively healthy pregnant women is noteworthy.

Of the 266 H1N1 deaths investigated by the CDC to date, 6% were among pregnant women – a startling statistic considering that only 1% of the general population is pregnant. As of Sept 1, 2009 there have been 595 deaths reported in the United States across the general population. Influenza-related hospitalization of healthy pregnant women occurs at the rate of 1-2 per 1,000 or 0.1%.

These data lend support to the present recommendation to promptly treat pregnant women with H1N1 influenza virus infection with anti-influenza drugs.

The Scary Truth: Infants and Influenza-related Illness

Infants infected with an influenza-related illness are to be taken seriously. Across the United States, 40-150 children die each year from illness associated with influenza; a high proportion of these children are in the 0-6 month age range. In fact, nearly 10% of infants less than six months of age have serious illness with laboratory-proven influenza infection. Influenza immunization of pregnant women reduced febrile influenza-like illness by more than 30% in both mothers and young infants.

Pregnancy and Seasonal Influenza

There are two types of flu vaccine. Pregnant women should receive the “flu shot” - an inactivated vaccine (containing fragments of killed influenza virus) that is given with a needle, usually in the arm. **The flu shot is approved for use in pregnant women.**

The other type of flu vaccine, nasal-spray flu vaccine (sometimes called LAIV), is not currently approved for use in pregnant women. This vaccine is made with live, weakened flu viruses that do not cause the flu. **LAIV (FluMist®) is approved for use in healthy individuals 2-49 years of age who are not pregnant.** Family and household members and other close contacts of pregnant women (including healthcare personnel) who are 2 through 49 years old, healthy and not pregnant may receive live nasal spray vaccine.

Pregnancy and H1N1 Infection

A pregnant woman who contracts any type of flu is at risk for serious complications and hospitalization. In comparison to the general population, a greater proportion of pregnant women infected with the 2009 H1N1 influenza virus have been hospitalized. In addition, severe illness and death has occurred in pregnant women. Six percent of confirmed fatal 2009 H1N1 flu cases have presented in pregnant women while only about 1% of the general population is pregnant.
Maternal influenza virus infection and accompanying hyperthermia place fetuses at risk for complications such as birth defects and pre-term birth. The Centers for Disease Control and Prevention (CDC) recommends that pregnant women with confirmed, probable, or suspected H1N1 influenza virus infection should receive antiviral treatment for five days. Oseltamivir is the preferred treatment for pregnant women, and the drug regimen should be initiated within 48 hours of symptom onset, if possible. Pregnant women who are in close contact with a person with confirmed, probable, or suspected H1N1 influenza infection should receive a 10-day course of chemoprophylaxis with zanamivir or oseltamivir. For further guidance, please refer to the Prevention and Prophylaxis of Seasonal and H1N1 Influenza section in this resource guide.
SEASONAL AND H1N1 INFLUENZA VIRUS: THE VACCINES

Inactivated influenza vaccine has been used in pregnant women since the 1960s in both the United States and Canada; however, currently, only 15% of pregnant women receive the vaccine. A randomized, controlled trial has shown that influenza immunization of pregnant women reduced influenza-like illness by more than 30% in both the mothers and the infants and reduced laboratory-proven influenza infections in 0- to 6-month-old infants by 63%.

A cost-effectiveness analysis of influenza immunization in pregnant, American women suggests that, compared with supportive treatment of influenza illnesses in pregnancy, the use of influenza vaccine reduces costs overall, resulting in an estimated savings of approximately $50 per immunized woman. The cost savings from prevention of infant influenza hospitalization are likely to be even greater.

A randomized, controlled prospective study in Bangladesh showed that immunizing pregnant women not only benefits the women but also their young infants aged less than six months. Influenza immunization of pregnant women reduced febrile influenza-like illness by more than 30%. This study substantively expands the concept raised two decades ago that natural maternal influenza antibodies passed to the infant before birth or via breast milk could offer young infants protection against serious illness from influenza.

Surveys suggest that few pregnant women, even those with co-morbidities, receive influenza vaccine. Several reasons have been forwarded, including the lack of availability of influenza vaccine in obstetric practices, inadequate reimbursement, unawareness that healthy pregnant women are at increased risk of hospitalization in influenza season, and ongoing concerns about vaccine safety for the mother and her fetus. In a recent study, less than half of obstetrician-gynecologists screen patients for vaccination status and few provide the full complement of vaccines appropriate for pregnant women.

The Advisory Committee on Immunization Practices (ACIP) and ACOG recommend trivalent inactivated vaccine (TIV) for all pregnant women in every trimester for the prevention of seasonal influenza and related complications. The vaccine should also be administered to all eligible and interested patients when it becomes available each flu season. While vaccination benefits pregnant women, some studies have shown the passive transfer of anti-influenza antibodies from vaccinated mothers to neonates as well. Live attenuated influenza vaccine (LAIV) is contraindicated for use in pregnant women, as it is a live virus vaccine.

If you have not already done so, immediately order your seasonal flu vaccine from an Influenza Vaccine Availability Tracking System (IVATS) distributor. IVATS was developed to enable healthcare providers to find influenza vaccine to purchase, especially during the critical vaccination period.
Providers interested in ordering additional vaccine should be encouraged to use the supplies that they have now and continue to look for additional flu vaccine for purchase in the coming weeks. IVATS can assist providers in this capacity. Further information on IVATS can be found at:

http://www.preventinfluenza.org/ivats/

The H1N1 Vaccine

The same four manufacturers who produce and market seasonal influenza vaccine are also producing the H1N1 influenza vaccine. This vaccine is expected to:

- Be formulated just like seasonal influenza vaccine but with a change in the influenza strain that is included;
- Be exclusive to the H1N1 influenza strain;
- Be a licensed vaccine;
- Be available in both the injectable form (approved for use in pregnant women) and the nasal spray (not licensed for pregnant women);
- Be provided at no cost by the federal government;
- Be able to be given in the inactivated form at the same time as inactivated seasonal influenza vaccine; and,
- Be safe and effective.

In general, influenza vaccines have not been shown to cause harm to a pregnant woman or her baby. The seasonal flu shot (injection) has been given to millions of pregnant women and is recommended for pregnant women in any trimester. The 2009 H1N1 influenza vaccine is manufactured using the same processes and facilities that are used to make seasonal influenza vaccines.

For more information on vaccination, please refer to Prevention and Prophylaxis of Seasonal and H1N1 Influenza in this resource guide.
PREVENTION AND PROPHYLAXIS OF SEASONAL AND H1N1 INFLUENZA

Development of the H1N1 influenza vaccine is currently underway. However, seasonal flu vaccine is available now for administration to patients, including pregnant women. The American College of Obstetricians and Gynecologists urges providers to make provisions for all pregnant women to receive both the H1N1 and seasonal flu vaccine and strongly encourage ALL pregnant women to be immunized for both. This may require a provider’s counseling on the safety of immunization during pregnancy.

Reducing Transmission of Influenza Infection

Because the H1N1 virus can survive on surfaces anywhere from two to eight hours (possibly up to 3 days in lab testing), it is especially important to communicate these important precautionary measures to patients. Suggestions to patients for minimizing transmission include:

- Washing hands frequently with soap and warm water, particularly after having contact with respiratory secretions and contaminated objects/materials. Wash with soap and water any items that have come in contact with infants’ mouths and limit the sharing of toys. Alcohol-based hand cleaners are also good to use.
- Covering your nose and mouth with a tissue when coughing or sneezing, or sneeze into your sleeve. Dispose of the tissue in the trash after use.
- Avoiding touching your eyes, nose, or mouth.
- Staying at home if illness is suspected, unless seeking medical care.
- Minimizing contact with those who might be ill with influenza.
- Having a plan to care for sick family members.
- Reducing unnecessary social contact.
- Avoiding crowded settings as much as possible.

Medical conditions that confer a higher risk for influenza-related complications include disorders of the following kind:

- Chronic pulmonary (including asthma)
- Cardiovascular (except hypertension)
- Renal
- Hepatic
- Cognitive
- Neurologic/neuromuscular
- Hematologic
- Metabolic (including diabetes mellitus) and immunosuppression (including immunosuppression caused by medications or by human immunodeficiency virus)
Vaccination Against H1N1 Influenza

The U.S. Food and Drug Administration (FDA) has approved four vaccines for use against the 2009 H1N1 influenza virus. These vaccines are manufactured by CSL Limited, MedImmune LLC, Novartis Vaccines and Diagnostics Limited, and Sanofi Pasteur Inc. All four firms manufacture the H1N1 vaccines using the same processes. The vaccines induce a robust immune response in most healthy adults eight to 10 days after a single dose, as occurs with the seasonal influenza vaccine.

While it is not expected that there will be a shortage of H1N1 vaccine, influenza vaccine availability and demand can be unpredictable and there is some possibility that initially, the vaccine will be available in limited quantities. ACIP recommends that the following five target groups receive the H1N1 vaccine:

- Pregnant women
- Household contacts and caregivers for children younger than 6 months
- Healthcare and emergency medical services personnel
- All people from 6 months through 24 years
- Persons aged 25 through 64 years who have health conditions associated with higher risk of medical complications from influenza.

Once the demand for vaccine for the targeted groups has been met at the local level, programs and providers should also begin vaccinating everyone from the ages of 25 through 64 years. Current studies indicate that the risk for infection among persons age 65 or older is less than the risk for younger age groups. However, once vaccine demand among younger age groups has been met, programs and providers should offer vaccination to people 65 or older.

Priority should be given to persons in the subset of the five target groups only if initial vaccine availability is not sufficient to meet demand for all persons in the five target groups. As vaccine availability increases, vaccination programs should be expanded to include all members of the initial target groups. Vaccination of other adult populations is recommended as vaccine availability increases.

Subset of Target Groups during Limited Vaccine Availability

- Pregnant women;
- Persons who live with or provide care for infants aged <6 months (e.g. parents, siblings, and daycare providers);
- Health care and emergency medical services personnel who have direct contact with patients or infectious material;
- Children aged 6 months to 4 years; and,
- Children and adolescents aged 5 to 18 years who have medical conditions that put them at higher risk for influenza-related complications.
For further information on target groups and to learn more about ACIP’s rationale behind its recommendations, visit the ACIP website at:

http://www.cdc.gov/vaccines/recs/provisional/default.htm

**NOTE:** These target groups vary from those groups that are recommended for the seasonal influenza vaccine. For information on recommendations for seasonal influenza vaccine, review *Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices, 2009*, at:

http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5808a1.htm

**Potential Side Effects of H1N1 Vaccination**

The side effects from the H1N1 influenza vaccine are expected to be similar to those of seasonal flu vaccine. The most common side effects following vaccination are expected to be mild and include:

- Soreness, redness, tenderness or swelling at the injection site
- Headache
- Muscle aches
- Fever
- Nausea
- Fainting

If these problems occur, they usually begin soon after the injection and may last as long as 1-2 days. Like any medicine, vaccines can cause severe allergic reactions. However, life-threatening allergic reactions to vaccines are very rare.

In 1976, an earlier type of swine flu vaccine was associated with cases of a severe paralytic illness called Guillain-Barre Syndrome (GBS) at a rate of approximately 1 case of GBS per 100,000 persons vaccinated. Studies completed since 1976 have demonstrated a small risk of GBS in persons who receive the seasonal influenza vaccine. This risk is estimated to be no more than 1 case of GBS per 1 million persons vaccinated.

GBS has a number of different causes and GBS can occur in a person who has never received an influenza vaccine. **It is important to communicate to patients that the potential benefits of vaccines to prevent serious illness, hospitalization, and death substantially outweigh the risk for vaccine-associated GBS.**

Studies will be conducted by the Centers for Disease Control and Prevention (CDC) and vaccine manufacturers to monitor for GBS and any unusual adverse events. New York State will also carefully monitor reports of GBS. The Vaccine Adverse Events Recording System (VAERS) will be used to accept reports of adverse events after vaccination. The New York State Department of Health (NYSDOH) will receive reports from the CDC on any adverse events that occur in New York State on a regular basis. If an adverse event is suspected, it should be reported directly to VAERS by calling 1-800-822-7967 or by visiting:

http://www.vaers.hhs.gov
Anyone who has a severe (life-threatening) allergy to eggs or to any other substance in the vaccine should not receive the H1N1 influenza vaccine.

Thimerosal as a Vaccine Preservative

Public concern over the vaccine preservative thimerosal and its link to autism still linger. It is anticipated that enough thimerosal-free vaccine in pre-loaded syringes will be available for young children and pregnant women. **There is no evidence that thimerosal is harmful to a pregnant woman or a fetus.** However, as with the seasonal influenza vaccine, the H1N1 vaccine will also be produced with and without thimerosal. **The CDC recommends that pregnant women may receive influenza vaccine with or without thimerosal.** See New York State law below.

It is important to emphasize to patients that, after multiple scientific studies and an extensive review by the Institute of Medicine, there is no evidence that thimerosal causes harm to patients. The known risk of disease from lack of vaccination far outweighs the risk of harm, if any, from thimerosal.

Safety and Adverse Events

Influenza vaccines have not been shown to harm a pregnant woman or her baby. The seasonal flu shot is proven as safe and is already recommended for pregnant women. Available data indicate that seasonal influenza vaccine does not cause fetal harm when administered to a pregnant woman or effect reproductive capacity. A recent international review of data on the safety of TIV concluded that no evidence exists to suggest harm to the fetus.

The 2009 H1N1 vaccine will be made using the same processes and facilities that are used to make seasonal influenza vaccines. Licensure of vaccines against H1N1 influenza virus will be based on the same standards used for seasonal influenza vaccines, as is routinely done when strains are changed in the seasonal vaccine. Additional safety studies, over and beyond what is done for seasonal influenza vaccine, are being performed on the H1N1 vaccine to reassure the public and providers that it is safe.

Effective July 1, 2008, New York State Public Health Law (PHL) §2112 prohibits the administration of vaccines containing more than trace amounts of thimerosal to children less than 3 years of age and women who know they are pregnant, with certain exceptions. This law requires that the Commissioner of Health make a yearly determination as to whether there exists an adequate supply of influenza vaccine that contains not more than 1.25 micrograms of mercury per 0.50 milliliter dose for women who know they are pregnant. The Commissioner of Health has determined
that, as of August 15, 2009, there appears to be an adequate supply of such influenza vaccine for vaccination of pregnant women. In addition, there also appears to be an adequate supply of influenza vaccine that contains not more than 0.625 micrograms of mercury per 0.25 milliliter dose for vaccination of children less than 3 years of age. Therefore, providers are required to purchase seasonal influenza vaccine that complies with PHL §2112 for pregnant women and children under three years of age only. In the event of late failure of vaccine production, it may be necessary for the Commissioner to modify this determination.

Providers are expected to seek out vaccine that complies with PHL §2112. However, in those instances when providers have in good faith sought out influenza vaccine that complies with PHL §2112 but such vaccine cannot be obtained, vaccination of children under 3 years old and pregnant women is still recommended because the substantial risk of complications or death from influenza disease in these groups outweighs the unproven risk of vaccination with thimerosal-containing vaccine.

Please be advised that further guidance will be released in regard to thimerosal and the H1N1 vaccine once it is available to the public.

**Obtaining H1N1 Influenza Vaccination**

The CDC will be distributing the H1N1 influenza vaccine to each state. NYSDOH will manage vaccine distribution outside of the five boroughs of New York City, with assistance from a variety of sources. Many providers and pharmacists will be receiving the H1N1 vaccine directly through the CDC’s central distributor, McKesson Specialties. Some providers and pharmacists may receive vaccine from their local health department or from NYSDOH.

**In New York State (outside of New York City):**

If you are a provider located outside of the five boroughs of New York City and want to provide the vaccine to your patients, you can contact NYSDOH’s Bureau of Immunization at:

https://hcsteamwork1.health.state.ny.us/pub/top.html

You may also use this site to set-up a Health Commerce System (HCS) account, also referred to as the Health Provider Network or HPN, or pre-register to receive the vaccine.

**NOTE:** This is the same account that physicians use to order prescription pads and update their Physician Profile; all physicians should have an account.

The information you provide during pre-registration will assist in allocating H1N1 vaccine throughout the state, taking into consideration the targeted population...
groups to receive the H1N1 vaccine. This pre-registration process is designed for you to express interest only and does not obligate you to receive/administer vaccine nor does it guarantee you will receive vaccine if supplies are limited.

Once your pre-registration is received and the remaining details of the vaccination campaign have been finalized, you will be contacted by the vaccine program to sign the federal Provider Agreement and instructed how to order vaccine.

In order to receive the H1N1 vaccine, providers must sign a federally-mandated Provider Agreement agreeing to appropriately store and handle the vaccine, to administer the vaccine according to the recommendations of the CDC’s Advisory Committee on Immunization Practices, and to report vaccine usage. The federal government requires that providers of vaccine report at a minimum, vaccine doses administered by age group on a weekly basis. NYSDOH has set up a mechanism for this reporting.

The vaccine will be distributed with a kit which will contain needles, syringes, sharps containers and alcohol swabs and will be provided free of charge; however, providers may bill for vaccine administration.

In New York City (five boroughs):

The Citywide Immunization Registry (CIR) is a centralized repository of immunization records for individuals vaccinated in New York City. These records are available to authorized persons, families, health care providers, health plans, and schools. CIR information is kept confidential and is disclosed solely for public health purposes. The CIR’s mission is to help ensure that NYC residents receive all recommended immunizations to protect them from vaccine preventable diseases. The CIR contains nearly 3.7 million records and 42 million immunizations.

In order to be eligible to receive the H1N1 vaccine in New York City, providers must register with the Citywide Immunization Registry (CIR). Most health care practices that care for adult patients are not currently registered with the CIR and will need to register, sign a provider agreement, and report H1N1 vaccine doses administered to patients to the CIR. Providers who treat only inpatients or whose clinic practice is solely hospital-based and operated will not need to register independently as both vaccine ordering and reporting will be conducted by the facility. The New York City Department of Health and Mental Hygiene (NYCDOHMH) will provide technical assistance to providers interested in registering with CIR. To register your practice, or to receive more information about the CIR, call (212) 676-2323 or visit:

Liability Concerns

The PREP Act authorizes the Secretary of the Department of Health and Human Services to issue a declaration that provides immunity from tort liability (except for willful misconduct) for claims of loss caused, arising out of, relating to, or resulting from administration or use of countermeasures to diseases, threats and conditions determined by the Secretary to constitute a present, or credible risk of a future public health emergency to entities and individuals involved in the development, manufacture, testing, distribution, administration, and use of such countermeasures. A PREP Act declaration is specifically for the purpose of providing immunity from tort liability, and is different from, and not dependent on, other emergency declarations. The PREP Act also authorizes an emergency fund in the United States Treasury to provide compensation for injuries directly caused by administration or use of a countermeasure covered by the Secretary’s declaration. While no funds have been appropriated for this purpose, if funds are appropriated, compensation may then be available for medical benefits, lost wages and death benefits to individuals for specified injuries.

In addition, an Emergency Use Authorization (EUA) may also be issued by the Food and Drug Administration (FDA) to allow either the use of an unapproved medical product or an unapproved use of an approved medical product during certain types of emergencies with specified agents.

For more information on the PREP Act, visit the Department of Health and Human Services’ website at:

http://www.hhs.gov/disasters/emergency/manmadedisasters/bioterrorism/medication-vaccine-qa.html

For more information on emergency use authorization, visit The Centers for Disease Control and Prevention website at:

http://www.cdc.gov/h1n1flu/eua/

Patient Referrals

Many resources are available for providers and their patients to help answer questions about vaccination, particularly against the H1N1 virus.

New York State Department of Health H1N1 hotline for the public, including for health care personnel with questions about influenza vaccination requirements:

1-800-808-1987

Depending on severity, hospitalization may be a life-saving measure and should not be delayed.
TREATING PATIENTS WITH H1N1 INFLUENZA INFECTION

While many pregnant women will go on to have a typical course of uncomplicated influenza after presenting with symptoms of infection, for some pregnant women illness might progress rapidly and might be complicated by secondary bacterial infections, including pneumonia. Knowing how to treat patients is the first step.

Symptoms of H1N1 Influenza Infection

The period of communicability of H1N1 influenza infection ranges from one day prior to the onset of symptoms to seven days following. Symptoms of H1N1 influenza illness are similar to seasonal influenza and may include:

- Fever
- Cough
- Sore throat
- Body aches
- Headaches
- Chills and fatigue
- Diarrhea
- Vomiting

Ideally, pregnant women who have suspected H1N1 infection should be tested for influenza. However, treatment should not be delayed pending results of testing and treatment should not be withheld in the absence of testing. This is because antiviral treatment is most effective when started as early as possible after the onset of symptoms (i.e. within the first two days). Testing is not available in many instances and, when available, results of H1N1 testing often take several days.

Actions that should be taken to reduce delays in treatment initiation include:

- Ensuring rapid access to telephone consultation and clinical evaluation for these patients as well as patients who report severe illness.
- Considering empiric treatment of patients at higher risk for influenza complications based on telephone contact if hospitalization is not indicated and if this will substantially reduce delay before treatment is initiated.
- Providing selected patients at higher risk for influenza-related complications (e.g., patients with neuromuscular disease) with prescriptions that can be filled at the onset of symptoms after telephone consultation with the provider.

Complications from Lack of Treatment

There is insufficient information to date about clinical complications of H1N1 viral infection. Among persons infected with previous variants of swine influenza viruses, clinical syndromes have ranged from mild respiratory illness, to lower respiratory tract illness, dehydration, or pneumonia. Deaths caused by previous variants of swine influenza viruses have occasionally occurred. Although data on the spectrum of illness
is not yet available for H1N1, providers should expect complications to be similar to seasonal influenza:

- Exacerbation of underlying chronic medical conditions
- Upper respiratory tract disease (sinusitis, otitis media, croup)
- Lower respiratory tract disease (pneumonia, bronchiolitis, status asthmaticus)
- Cardiac (myocarditis, pericarditis)
- Musculoskeletal (myositis, rhabdomyolysis)
- Neurologic (acute and post-infectious encephalopathy, encephalitis, febrile seizures, status epilepticus)
- Toxic shock syndrome
- Secondary bacterial pneumonia with or without sepsis

**Treatment of H1N1 Infection in Pregnancy**

Keeping pregnant women free of H1N1 influenza as well as seasonal influenza is preferred and non-pharmacologic measures should be encouraged. Parents and caretakers should also be instructed on how to protect their infants and household members from the spread of germs that cause respiratory illnesses such as influenza. ACOG strongly urges providers to educate and inform their patients. The following is recommended:

- Instruct all pregnant women to report the symptoms of influenza or close exposure to persons with influenza to you immediately.
- Instruct in the use of antipyretics.
- Treat flu exposure with a prophylactic course of oseltamivir (75 mg. once daily for 10 days). Treat those with flu-like symptoms with a therapeutic course of oseltamivir (75 mg twice daily for 5 days). Limited data suggest that oseltamivir is not a major human teratogen and that it is currently effective for both prevention of H1N1 influenza and the reduction of flu severity if started within 48 hours of the initial symptoms.
- If H1N1 is prevalent in your community, consider all pregnant women with flu-like symptoms as having H1N1. The Centers for Disease Control and Prevention (CDC) advises that you do not need to confirm influenza to initiate treatment.

As a provider, you will determine if your patients need antiviral drugs such as Tamiflu® (oseltamivir) or Relenza® (zanamivir). These medications work best when started within two days of symptom onset, but they may also be prescribed to very sick or high risk individuals after this time frame. Recommended duration of treatment is five days. Both Tamiflu® and Relenza® may be used to prevent H1N1 influenza and are taken for ten days.

The Centers for Disease Control and Prevention has made the following additional treatment recommendations for H1N1 influenza illness:
• Treatment with oseltamivir or zanamivir is recommended for all persons with suspected or confirmed influenza requiring hospitalization.
• Persons who are not at higher risk for complications or do not have severe influenza requiring hospitalization generally do not require antiviral medications for treatment or prophylaxis. However, any suspected influenza patient presenting with warning symptoms (e.g., dyspnea) or signs (e.g., tachypnea, unexplained oxygen desaturation) for lower respiratory tract illness should promptly receive empiric antiviral therapy.
• Clinical judgment is an important factor in antiviral treatment decisions for all patients presenting for medical care who have illnesses consistent with influenza.
• Treatment should not wait for laboratory confirmation of influenza because laboratory testing can delay treatment and because a negative rapid test for influenza does not rule out influenza. The sensitivity of rapid tests can range from 10% to 70%.

NOTE: The H1N1 influenza infection is resistant to the adamantane antiviral medications, amantadine (Symmetrel®) and rimantadine (Flumadine®). Oseltamivir and zanamivir treatment and chemoprophylaxis regimens recommended for pregnant women are the same as those recommended for adults who have seasonal influenza. Pregnancy should not be considered a contraindication to oseltamivir or zanamivir use.

Although a few adverse effects have been reported in pregnant women who took these medications, no relation between the use of these medications and those adverse events has been established.

Chemoprophylaxis Recommendations

Post exposure antiviral chemoprophylaxis can be considered for pregnant women who are close contacts of persons with suspected or laboratory-confirmed H1N1 influenza. The drug of choice for prophylaxis is probably zanamivir because of its limited systemic absorption. However, respiratory complications that may be associated with zanamivir because of its inhaled route of administration need to be considered, especially in women at risk for respiratory problems. For these women, oseltamivir is a reasonable alternative. Recommended duration of chemoprophylaxis is for 10 days after the last known exposure to H1N1 influenza. In situations where multiple exposures are likely to occur, such as within families, the total length of chemoprophylaxis for a pregnant woman may depend on clinical considerations. Close monitoring for influenza like illness in exposed pregnant women is recommended.
Fever Treatment

One of the more well-studied adverse effects of influenza is its associated hyperthermia. Studies have shown that maternal hyperthermia during the first trimester doubles the risk of neural tube defects and may be associated with other birth defects and adverse outcomes. Limited data suggest that the risk for birth defects associated with fever might be mitigated by antipyretic medications and/or multivitamins that contain folic acid. Maternal fever during labor has been shown to be a risk factor for adverse neonatal and developmental outcomes, including neonatal seizures, encephalopathy, cerebral palsy, and neonatal death. Even though distinguishing the effects of the cause of fever from the hyperthermia itself is difficult, fever in pregnant women should be treated because of the risk that hyperthermia appears to pose to the fetus. Acetaminophen appears to be the best option for treatment of fever during pregnancy. It is important for patients to be proactive in their treatment and to address any fever right away.

Pregnant Women With Confirmed, Probable, or Suspected H1N1 Illness

In general, guidance for the control of H1N1 influenza infection in obstetric settings is consistent with that in other healthcare settings but also includes special considerations for prevention of infection in the newborn. Infants are known to be at higher risk of severe illness from seasonal influenza virus infections. Based on this experience, infants are also considered to be at higher risk for severe illness from H1N1 infection. Because very little is known about prevention of H1N1 flu infection in infants, the CDC has made the following recommendations which are intended to minimize the potential for exposure to H1N1 influenza when an ill pregnant woman delivers her baby.

- Initiate appropriate antiviral treatment as soon as possible.
- Isolate the ill mother from healthy pregnant women as mentioned above.
- Place a surgical mask on the ill mother during labor and delivery, if tolerable, in order to decrease exposure of the newborn, healthcare personnel, and other labor and delivery patients to potentially infectious respiratory secretions.
- Place the ill mother in isolation after delivery. The mother who has influenza-like-illness at delivery should consider avoiding close contact with her infant until the following conditions have been met:
  - she has received antiviral medications for 48 hours,
  - her fever has fully resolved, and
  - she can control coughs and secretions.
Meeting these conditions may reduce, but not eliminate, the risk of transmitting influenza to the baby.

- Before these conditions are met, the newborn should be cared for in a separate room by another person who is well, and the mother should be encouraged and assisted to express her milk. **Breast milk is not thought to be a potential source of influenza virus infections.**

- As soon as all conditions are met, the mother should be encouraged to:
  - wear a facemask
  - change to a clean gown or clothing
  - adhere to strict hand hygiene and cough etiquette when in contact with her infant
  - begin breastfeeding (or if not able to breastfeed, bottle feeding)

She should continue these protective measures, both in the hospital setting and at home, for at least seven days after the onset of influenza symptoms. If symptoms last more than seven days, she should discuss the symptoms with her doctor. Protective measures might need to be continued until she is symptom-free for 24 hours. Individuals who are once again well seven days after becoming sick are thought to be at low risk for transmitting the virus to others.

### Testing for Influenza-like Illness

Providers should test persons for the H1N1 virus if they have an acute febrile respiratory illness or sepsis-like syndrome. Certain groups may have atypical presentations including infants, elderly and persons with compromised immune systems. Priority for testing includes persons who:

- Require hospitalization; or
- Are at high-risk for severe disease.

To test for H1N1 influenza virus, providers should collect the following:

- Upper respiratory specimens, such as a nasopharyngeal swab or aspirate;
- Nasal swab plus a throat swab or nasal wash; or
- Tracheal aspirate.

There is no test that can determine whether a person previously had 2009 H1N1 influenza. Patients for whom influenza vaccine is recommended should receive the 2009 H1N1 vaccine, even if they had an influenza-like illness previously, unless they can be certain they had 2009 H1N1 influenza based on laboratory testing that can specifically detect the H1N1 virus. There is no harm in vaccination if a patient had 2009 H1N1 influenza in the past.

According to the CDC, testing for 2009 H1N1 influenza infection with real-time reverse transcriptase-polymerase chain reaction (rRT-PCR) should be prioritized for persons with suspected or confirmed influenza requiring hospitalization and based on guidelines from local and state health departments.
Newborns of Ill Mothers

Because the risk for transmission of H1N1 influenza from mother to fetus is unknown, the newborn should be considered to be potentially infected if delivery occurs during the two days before through seven days after illness onset in the mother. Infection control procedures developed for H1N1 influenza should be used for the newborn throughout the hospital stay. The newborn should be closely monitored for signs and symptoms of influenza. If signs or symptoms develop, testing should be performed, infection control measures should be continued, and treatment with anti-influenza medications should be considered. Oseltamivir is approved for prevention of influenza in patients one year of age and older; however, an emergency use authorization (EUA) has been issued for oseltamivir for influenza treatment and prevention in patients less than one year of age.

Chemoprophylaxis of infants less than three months of age is not typically recommended, as there are very limited data available on the safety and effectiveness of chemoprophylaxis for infants less than three months. However, in situations which are judged to be critical, chemoprophylaxis with oseltamivir can be considered.

Breastfeeding: A Message for Your Patients

Influenza can be very serious in young babies. Babies who are breastfed do not get as sick and are sick less often from the flu, than do babies who are not breastfed. Breastfeeding protects babies. Breast milk passes on antibodies from the mother to a baby. Antibodies help fight off infection.

A mother’s milk is made to fight diseases in her baby. This is really important in young babies when their immune system is still growing. **Breastfeed early and often; do not stop breastfeeding if you are ill.** Limit formula feeds if you can. This will help protect your baby from infection. Be careful not to cough or sneeze in the baby’s face, wash your hands often with soap and water. Your doctor might ask you to wear a mask to keep from spreading this new virus to your baby. If you are too sick to breastfeed, pump and have someone give the expressed milk to your baby.

Mothers who are breastfeeding can continue to nurse their babies while being treated for the flu.

If possible, only adults who are not sick should care for infants. Sick women who are able to express their milk for bottle feedings by a healthy family member should be encouraged to do so. **Antiviral medication treatment or prophylaxis is not a contraindication for breastfeeding.** Careful adherence to hand hygiene and cough etiquette is critical. Women with influenza like illness are recommended to use face masks when proving infant care and feedings.
Additional Therapy

Additional therapy such as antibacterial agents, should be used at the provider’s discretion given the patient’s clinical presentation. For hospitalized patients with severe community-acquired pneumonia (CAP) requiring intensive care unit admission, methicillin-resistant staphylococcus aureus (MRSA) infection should be suspected and treated empirically in addition to other causes of CAP if they have necrotizing or cavitary infiltrates or empyema.
It is critical to assure that medical offices and other medical facilities can manage an increased demand for services in the midst of an influenza outbreak. Begin coordination with key medical, clinical facilities and public health departments in your community to learn about how they will manage patients during a pandemic. Medical offices, emergency rooms, urgent care centers and hospitals in communities with outbreaks will likely have difficulty managing a large influx of patients; a coordinated community response is important to manage surge and assure optimal patient care.

Staff Preparation and Policies

**Business Continuity & Absenteeism:**
- Identify office/clinic’s essential functions.
- Train/Cross-train enough staff for essential functions.
- Order supplies and make alternate plans for supply ordering.
- Plan for staff absenteeism due to illness in personnel or their family members.
- Create a non-punitive policy for sick or symptomatic employees and their family members that:
  - Requires staff with febrile respiratory illness to remain home until they are no longer infectious (afebrile for 24 hours after discontinuing antipyretic medications).
  - Sending staff home if they become ill at work.

**Health Care Personnel Mandatory Influenza Immunization (only for those personnel who are hospital-based)**
- All New York State health care facility personnel are required to receive annual influenza vaccinations (per August 2009 emergency regulation).
- The requirement includes immunization against H1N1 as well as seasonal influenza.
- Vaccinations must be completed by November 30th of each year.
- Personnel who must be vaccinated include all those affiliated with the employer, paid or unpaid, who have direct contact with patients or whose activities are such that they pose a risk of transmission of influenza to patients or to those who provide direct care to patients.
- The purpose of this regulation is to protect the health and safety of vulnerable patients and reduce transmission of influenza.

More details of the regulation are available at:

http://www.nyhealth.gov/nysdoh/phforum/nycrr10.htm
The CDC recommends the following for medical offices/clinics with employed pregnant health care personnel:

- Whenever feasible, limit exposure to situations of influenza exposure.
- If pregnant personnel have direct patient contact with confirmed, probable, or suspected H1N1 influenza cases, consider reassignment to lower-risk activities.
- If reassignment is not possible, pregnant women should avoid participating in procedures that may generate increased small-particle aerosols of respiratory secretions in patients with known or suspected influenza.

For more information, follow CDC guidance at:

http://www.cdc.gov/h1n1flu/pregnancy

Vaccination Planning

- Educate and train staff on immunization practices.
- Encourage all patients to receive both the seasonal influenza and the H1N1 immunizations.
- Designate staff responsible for the vaccine plan, inventory logs, adequate refrigerator and thermometers, temperature monitoring and logs, and a plan in the event of a refrigerator failure.
- Assure that one prescribing medical professional in practice has registered with the New York State Department of Health or the New York City Department of Health and Mental Hygiene to express interest in receiving H1N1 vaccine. See the section entitled, Prevention and Prophylaxis of Seasonal and H1N1 Influenza for more details.

Symptomatic Patient Care

Surge Capacity and Triage

- Assure a system is in place to cope with additional surge during H1N1 and/or seasonal influenza outbreaks.
- Develop systems for patient triage that may include alternate methods of communication (telephone, e-mail, etc.).
- Consider plans to manage patient care at the height of influenza activity, including the following possibilities:
  - Using your telephone system to deliver messages to incoming callers about when to seek medical care at your facility, when to seek emergency care, and where to go for information about caring for a person with flu at home.
  - Determine how to provide after hours care/consultation.
  - Extending your hours of operation for telephone triage.
  - Limiting office visits to those that are medically necessary.
  - Temporarily canceling non-essential medical visits (e.g., annual physical examination).
  - Designating separate blocks of time for non-influenza and influenza-related patient care.
Infection Control in the Office/Clinic

- Screen patients for signs and symptoms of febrile respiratory illness at entry to the facility.
  - Consider using language appropriate signage to direct patients and those accompanying them to notify reception personnel if they have symptoms of influenza.
- If feasible, use separate waiting and exam rooms for possible H1N1 flu patients.
  - In small waiting rooms, emphasize use of masks, prompt placement in exam room, scheduling at end of day.
- Ensuring adequate mask supplies, distributing masks to symptomatic patients who are able to wear them (adult and pediatric sizes should be available), providing facial tissues and receptacles for their disposal, and hand hygiene materials in waiting areas and examination rooms.
- Educate and communicate respiratory hygiene/cough etiquette with staff and patients.
- Require healthcare personnel to use Standard and Droplet Precautions (i.e., mask for close contact) with symptomatic patients.

For more information, visit:

www.cdc.gov/flu/professionals/infectioncontrol/resphygiene.htm
CODING AND REIMBURSEMENT

Cost of Vaccine and Supplies

The H1N1 influenza vaccine itself and supplies to administer it, will be provided without charge by the federal government.

Vaccine Reimbursement and Codes

In September 2009, the ACOG Workgroup on Immunization mailed to you the Immunization Coding Guide for Obstetricians and Gynecologists. It addresses reimbursement for vaccinations, coding for vaccinations, coding examples and other coding resources.

It is expected that the cost of vaccine administration will be covered by most private health insurance plans as well as Medicaid and Medicare. Medicare will pay for influenza vaccines that are rendered earlier than usual and will pay for multiple vaccinations (i.e., a seasonal and H1N1 influenza vaccination). However, if either vaccine is provided free to a health care provider, Medicare will only pay for the vaccine’s administration, not for the vaccine itself.

For those who do not have health insurance or whose insurance will not cover the administration fee, the fee may be charged to the patient, unless the provider waives it. The administration fee cannot exceed the regional Medicare vaccine administration fee. Those who cannot afford to pay the administrative fee may be directed to local health departments.

H1N1 Codes

Effective September 1, 2009, the Centers for Medicaid and Medicare Services (CMS) has created new procedure codes for H1N1 influenza vaccination:

**H1N1 vaccine: 90663 or G9142** *(Influenza A [H1N1] vaccine, any route of administration)* describes the vaccine. Since there will be no cost to providers, G9142 will have a $0 price assigned. The vaccine code may or may not be billed to Medicaid at the provider’s discretion.

**Administration of the vaccine: 90465 – 90474 or G9141** *(Influenza A [H1N1] immunization administration, including physician counseling of the patient/family)* describes the administration of the vaccine.

**Diagnosis codes: V04.81 (influenza) or 488.1 (Influenza due to identified novel H1N1 influenza virus).** New codes are reported only if the personal history or family circumstance affected treatment at the time of the visit, or if the patient was receiving counseling concerning only those issues.

Since information on H1N1 Influenza is continually evolving, be sure to contact the insurance companies with whom you conduct business to ensure accurate coding practices.
CITATIONS AND RESOURCES

The American College of Obstetricians and Gynecologists. Information on Influenza from ACOG President Gerald F. Joseph, Jr., MD, FACOG. http://www.acog.org/departments/dept_notice.cfm?recno=30&bulletin=4902#iii


-- 2009 H1N1 Vaccine Recommendations. http://www.cdc.gov/h1n1flu/vaccination/acip.htm

-- 2009 H1N1 Influenza Vaccine and Pregnant Women. http://www.cdc.gov/h1n1flu/vaccination/

-- Clinical Data Collection Forms and Templates for Collection of Information on Patients Infected with Novel Influenza A (H1N1). http://www.cdc.gov/h1n1flu/clinicians/clinician_forms_templates.htm


-- H1N1 Flu (Swine Flu): Resources for Pregnant Women. http://www.cdc.gov/h1n1flu/pregnancy


-- Interim Biosafety Guidance for All Individuals Handling Clinical Specimens or Isolates Containing 2009 H1N1 Influenza A Virus (Novel H1N1), Including Vaccine Strains. http://www.cdc.gov/h1n1flu/guidelines_labworkers.htm


-- Interim Guidance for Infection Control for Care of Patients with Confirmed or Suspected Novel Influenza A (H1N1) Virus Infection in a Healthcare Setting. http://www.cdc.gov/h1n1flu/guidelines_infection_control.htm

-- Interim Guidance for Novel H1N1 Flu (Swine Flu): Taking Care of a Sick Person in Your Home. http://www.cdc.gov/h1n1flu/guidance_homecare.htm#c

-- Interim Guidance on Case Definitions to be Used for Investigations of Novel Influenza A (H1N1) Cases. http://www.cdc.gov/h1n1flu/casedef.htm

-- Interim Guidance on Specimen Collection, Processing, and Testing for Patients with Suspected Novel Influenza A (H1N1) Virus Infection. http://www.cdc.gov/h1n1flu/specimencollection.htm

-- Novel H1N1 Flu (Swine Flu) and Feeding Your Baby: What Parents Should Know. http://www.cdc.gov/h1n1flu/infantfeeding.htm


-- Pregnant Women and Novel Influenza A (H1N1) Virus: Considerations for Clinicians. http://www.cdc.gov/h1n1flu/clinician_pregnant.htm


-- Updated Interim Recommendations for the Use of Antiviral Medications in the Treatment and Prevention of Influenza for the 2009-2010 Season. http://www.cdc.gov/h1n1flu/recommendations.htm#C


United States Food and Drug Administration. FDA Approves Vaccines for 2009 H1N1 Influenza Virus; Approval Provides Important Tool to Fight Pandemic. http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm182399.htm

OBG Management. That time of the year: Turn back the clock, watch H1N1 flu return, and adopt a new ICD-9 code set. Vol 21, No. 9, Sept. 2009.
Articles of Note


### Additional Governmental Resources

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<td><strong>New York State Department of Health</strong></td>
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<td><em>For H1N1 Guidance</em></td>
<td><a href="http://www.nyhealth.gov/diseases/communicable/influenza/h1n1/">www.nyhealth.gov/diseases/communicable/influenza/h1n1/</a></td>
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<tr>
<td><em>For Clinical Guidance for Assessment, Testing, and Treatment of H1N1Influenza in Children</em></td>
<td><a href="http://www.health.state.ny.us/diseases/communicable/influenza/h1n1/clinical_guidance_for_children.htm">www.health.state.ny.us/diseases/communicable/influenza/h1n1/clinical_guidance_for_children.htm</a></td>
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<td><strong>New York City Department of Health and Mental Hygiene</strong></td>
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<td><em>For regular updates on H1N1</em></td>
<td><a href="http://www.nyc.gov/health/nycmed">www.nyc.gov/health/nycmed</a></td>
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<tr>
<td><strong>Centers for Disease Control and Prevention</strong></td>
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<td><em>For global alert and response, guidance, and FAQs</em></td>
<td><a href="http://www.who.int/en/">www.who.int/en/</a></td>
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<td><strong>U.S. Department of Health and Human Services</strong></td>
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<td><a href="http://www.flu.gov">www.flu.gov</a></td>
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<td><strong>U.S. Food and Drug Administration: Use of Influenza Medicines and Diagnostic Testing Information</strong></td>
<td><a href="http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm150305.htm">www.fda.gov/NewsEvents/PublicHealthFocus/ucm150305.htm</a></td>
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<td><strong>New York State Office of Homeland Security</strong></td>
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<td><a href="http://www.security.state.ny.us/preparedness/index.html">www.security.state.ny.us/preparedness/index.html</a></td>
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<td><strong>New York State Department of Insurance: Information on Vaccine Insurance Requirements</strong></td>
<td><a href="http://www.ins.state.ny.us/health/ih_hreqimmun.htm">www.ins.state.ny.us/health/ih_hreqimmun.htm</a></td>
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### Clinical Information and Literature Reviews

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<td><strong>American Academy of Pediatrics</strong></td>
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<td><strong>American Medical Association</strong></td>
<td><a href="http://www.ama-assn.org/ama/pub/physician-resources/medical-science/infectiousdiseases/topics-interest/novel-influenza-a-h1n1.html">www.ama-assn.org/ama/pub/physician-resources/medical-science/infectiousdiseases/topics-interest/novel-influenza-a-h1n1.html</a></td>
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<tr>
<td><strong>Center for Infectious Disease Research &amp; Policy Academic Health Center -- University of Minnesota</strong></td>
<td><a href="http://www.cidrap.umn.edu/">www.cidrap.umn.edu/</a></td>
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<tr>
<td><strong>New England Journal of Medicine</strong></td>
<td>h1n1.nejm.org/?emp=marcom</td>
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Pages 33-40 may be copied and distributed to your patients
FIGHT THE FLU

Preventing H1N1 (Swine Flu)

What is H1N1 influenza?

H1N1 influenza (formerly called “swine flu”) is caused by a virus that infects the nose, throat and lungs. It can cause fever and a cough or sore throat that can last a week or longer. It can also cause headaches, body aches, chills and tiredness. Some people also suffer from vomiting and diarrhea.

How does H1N1 affect pregnant women?

Healthy, pregnant women have been severely impacted by the 2009 H1N1 influenza virus. Pregnant women are four times as likely to be hospitalized for the 2009 H1N1 influenza virus.

Who should receive the new H1N1 vaccine?

- Pregnant women
- People 6 months to 24 years of age
- People living with or caring for children younger than 5 – especially infants younger than 6 months. (Babies this age can get the flu, but are too young for a flu shot.)
- Health care and emergency medical services workers
- People 25 to 64 years of age with long-term health problems and those caring for them

Will my seasonal flu vaccination protect me against H1N1 influenza?

No. Seasonal flu vaccine will not work against H1N1 flu. To protect against both kinds of flu, you will need two different vaccinations: one for seasonal flu, and one for H1N1.

How does the H1N1 flu spread?

Infected people can spread the virus when they cough or sneeze into the air. People can get infected by breathing in droplets released when the infected person coughs or sneezes, or by touching something with flu viruses on it, then touching their mouth or nose. Infected people may be able to infect others from one day before getting sick to five to seven days after – or even longer for some people.

H1N1 Hotline:
1-800-808-1987
New York City residents
Call 311

The American College of Obstetricians and Gynecologists
District II
Visit us at www.acogny.org
The American College of Obstetricians and Gynecologists
District II
Visit us at www.acogny.org

Information adapted from: New York City Department of Health and Mental Hygiene, Centers for Disease Control and Prevention, New York State Department of Health, American College of Obstetricians and Gynecologists

**FIGHT THE FLU**

**Preventing Seasonal Flu**

The best way to avoid seasonal flu is to get vaccinated – but good health habits can help stop the spread of germs. There are also seasonal flu medications that can be used to treat and prevent flu. Here are some more ways to protect yourself and others:

- **Avoid close contact**
  Avoid close contact with people who are ill. If you are sick, keep your distance from others to protect them from the flu.

- **If you are sick, stay home**
  If you can, stay home from work, school and errands when you are ill. This will help prevent others from getting sick.

- **Cover it!**
  Cover your mouth and nose with a tissue when sneezing or coughing. You may prevent others from getting the flu.

- **Wash up**
  Washing your hands regularly will help protect you from germs. When soap and water are not available, try alcohol-based disposable hand wipes or gel sanitizers.

- **Avoid touching your eyes, nose or mouth**
  Germs are often spread when a person touches something that is contaminated with germs and then touches his or her eyes, nose, or mouth.

- **Also...**
  Get lots of sleep, be physically active, manage stress, drink plenty of fluids, and eat nutritious food.
2009 H1N1 influenza vaccine

WHAT YOU NEED TO KNOW

1 What is 2009 H1N1 influenza?

2009 H1N1 influenza (which was earlier called Swine Flu) is a type of flu caused by a new strain of influenza virus. Because it has spread to many countries, it has been declared a pandemic influenza strain.

Like other flu viruses, 2009 H1N1 spreads from person to person through coughing, sneezing, nasal secretions, and sometimes through handling objects contaminated with the virus.

Signs of 2009 H1N1 can include:

- Fatigue
- Fever
- Sore Throat
- Muscle Aches
- Chills
- Coughing
- Sneezing
Some people also have diarrhea and vomiting.

Most people recover within a week. But some people get pneumonia or other serious illnesses. Some people have to be hospitalized and some die.

2 How is 2009 H1N1 different from regular (seasonal) flu?

Seasonal flu viruses change from year to year, but they are closely related to each other.

People who have had prior flu infections usually have some immunity to seasonal flu viruses.

The 2009 H1N1 flu virus is a new virus strain. It is very different from seasonal flu viruses.

Most people have little or no immunity to 2009 H1N1 flu.

3 2009 H1N1 influenza vaccine

Vaccines are being made to protect against 2009 H1N1 influenza.

- These vaccines are produced just like seasonal flu vaccines.
- They are expected to be as effective as seasonal flu vaccines.

- They will not prevent “influenza-like” illnesses caused by other viruses.
- They will not prevent seasonal flu. You should also get seasonal influenza vaccine, if recommended.

Inactivated (killed) vaccine is injected into the muscle, like the annual flu shot. This statement describes the inactivated vaccine.

A live, intranasal vaccine is also available. It is described in a separate statement.

Some inactivated H1N1 vaccine contains a preservative called thimerosal. While some people have suggested that thimerosal may be related to developmental problems in children, that theory has not been supported by research.

Thimerosal-free vaccine is also available.

4 Who should get 2009 H1N1 influenza vaccine and when?

WHO

Groups recommended to receive 2009 H1N1 vaccine first are:

- Pregnant women
- People who live with or care for infants younger than 6 months of age
- Health care and emergency personnel
- Anyone from 6 months through 24 years of age
- Anyone from 25 through 64 with certain chronic medical conditions or a weakened immune system

These groups should also be vaccinated:

- Healthy 25-64 year olds
- Adults 65 and older

WHEN

Get vaccinated as soon as the vaccine is available.

Recommendations may change if we learn that other groups of people are at particularly high risk.

Some people may need two doses of vaccine.
5 Some people should not get the vaccine or should wait

You should not get 2009 H1N1 flu vaccine if you have a 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.

Also tell them if you have ever had:
• a life-threatening allergic reaction after a dose of seasonal flu vaccine,
• Guillain Barré 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.

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.

Pregnancy or breastfeeding are not reasons to avoid getting 2009 H1N1 flu vaccine.

2009 H1N1 vaccine may be given at the same time as other vaccines, including seasonal influenza vaccine.

6 What are the risks from 2009 H1N1 influenza vaccine?

A vaccine, like any medicine, could cause a serious problem, such as a severe allergic reaction. But the risk of any vaccine causing serious harm, or death, is extremely small.

The virus in inactivated 2009 H1N1 vaccine has been killed, so you cannot get influenza from the vaccine.

The risks from 2009 H1N1 vaccine are expected to be similar to those from seasonal flu vaccine:

Mild problems:
• 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.

Severe problems:
• Life-threatening allergic reactions to vaccines are very rare. If they do occur, it is usually within a few minutes to a few hours after the shot.
• In 1976, an earlier type of swine flu vaccine was associated with cases of Guillain-Barré Syndrome (GBS). Since then, flu vaccines have not been clearly linked to GBS.

7 What if there is a severe reaction?

What should I look for?
Any unusual condition, such as a high fever or behavior changes. Signs of a severe allergic reaction can include difficulty breathing, hoarseness or wheezing, hives, paleness, weakness, a fast heart beat or dizziness.

What should I do?
• Call a doctor, or get the person to a doctor right away.
• Tell the doctor what happened, the date and time it happened, and when the vaccination was given.
• Ask your provider to report the reaction by filing a Vaccine Adverse Event Reporting System (VAERS) form. Or you can file this report through the VAERS website at www.vaers.hhs.gov, or by calling 1-800-822-7967.

VAERS does not provide medical advice.

8 Vaccine injury compensation

The Federal government is providing this vaccine for receipt on a voluntary basis. However, state law or employers may require vaccination for certain persons.

If you or your child has a reaction to the vaccine, your ability to sue is limited by law.

However, a federal program has been created to help pay for the medical care and other specific expenses of certain persons who have a serious reaction to this vaccine. For more information about this program, call 1-888-275-4772 or visit the program’s website at: www.hrsa.gov/countermeasurescomp/default.htm.

9 How can I learn more?

• Ask your provider. They can give you the vaccine package insert or suggest other sources of information.
• Call your local or state health department.
• Contact the Centers for Disease Control and Prevention (CDC):
  - Call 1-800-232-4636 (1-800-CDC-INFO) or
  - Visit CDC’s website at www.cdc.gov/h1n1flu or www.cdc.gov/flu
• Visit the web at www.flu.gov

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Disease Control and Prevention

Vaccine Information Statement (Pre-Licensure)
2009 H1N1 Influenza Vaccine 8/26/09
LIVE, INTRANASAL INFLUENZA VACCINE

WHAT YOU NEED TO KNOW

Many Vaccine Information Statements are available in Spanish and other languages. See www.immunize.org/vis.

1 Why get vaccinated?

Influenza (“flu”) is a contagious disease.

It is caused by the influenza virus, which can be spread by coughing, sneezing, or nasal secretions.

Other illnesses can have the same symptoms and are often mistaken for influenza. But only an illness caused by the influenza virus is really influenza.

Anyone can get influenza, but rates of infection are highest among children. For most people, it lasts only a few days. It can cause:

- fever
- sore throat
- chills
- muscle aches
- cough
- headache
- fatigue

Some people, such as infants, elderly, and those with certain health conditions, can get much sicker. Flu can cause high fever and pneumonia, and make existing medical conditions worse. It can cause diarrhea and seizures in children. On average, 226,000 people are hospitalized every year because of influenza and 36,000 die—mostly elderly. Influenza vaccine can prevent influenza.

2 Live, attenuated influenza vaccine - LAIV (nasal spray)

There are two types of seasonal influenza vaccine:

1. Live, attenuated influenza vaccine (LAIV) contains live but attenuated (weakened) influenza virus. It is sprayed into the nostrils.
2. Inactivated influenza vaccine, sometimes called the “flu shot,” is given by injection. Inactivated influenza vaccine is described in a separate Vaccine Information Statement.

Influenza viruses are always changing. Because of this, influenza vaccines are updated every year, and an annual vaccination is recommended.

Each year scientists try to match the viruses in the vaccine to those most likely to cause flu that year. When there is a close match the vaccine protects most people from serious influenza-related illness. But even when there is not a close match, the vaccine provides some protection. Influenza vaccine will not prevent “influenza-like” illnesses caused by other viruses.

It takes up to 2 weeks for protection to develop after the vaccination. Protection lasts up to a year.

LAIV does not contain thimerosal or other preservatives.

3 Who can get LAIV?

LAIV is approved for people from 2 through 49 years of age, who are not pregnant and do not have certain health conditions (see #4, below). Influenza vaccination is recommended for people who can spread influenza to others at high risk, such as:

- Household contacts and out-of-home caregivers of children up to 5 years of age, and people 50 and older.
- Physicians and nurses, and family members or anyone else in close contact with people at risk of serious influenza.

Health care providers may also recommend a yearly influenza vaccination for:

- People who provide essential community services.
- People living in dormitories, correctional facilities, or under other crowded conditions, to prevent outbreaks.

Influenza vaccine is also recommended for anyone who wants to reduce the likelihood of becoming ill with influenza or spreading influenza to others.

4 Some people should not get LAIV

LAIV is not licensed for everyone. The following people should get the inactivated vaccine (flu shot) instead:

- Adults 50 years of age and older or children between 6 months and 2 years of age. (Children younger than 6 months should not get either influenza vaccine.)
- Children younger than 5 with asthma or one or more episodes of wheezing within the past year.
- People who have long-term health problems with:
  - heart disease
  - kidney or liver disease
  - lung disease
  - metabolic disease, such as diabetes
  - asthma
  - anemia, and other blood disorders
- Anyone with certain muscle or nerve disorders (such as seizure disorders or cerebral palsy) that can lead to breathing or swallowing problems.
- Anyone with a weakened immune system.
- Children or adolescents on long-term aspirin treatment.
- Pregnant women.

Tell your doctor if you ever had Guillain-Barré syndrome (a severe paralytic illness also called GBS). You may be able to get the vaccine, but your doctor should help you make the decision.
The flu shot is preferred for people (including health-care workers, and family members) in close contact with anyone who has a severely weakened immune system (requiring care in a protected environment, such as a bone marrow transplant unit). People in close contact with those whose immune systems are less severely weakened (including those with HIV) may get LAIV.

Anyone with a nasal condition serious enough to make breathing difficult, such as a very stuffy nose, should get the flu shot instead.

Some people should talk with a doctor before getting either influenza vaccine:

- Anyone who has ever had a serious allergic reaction to eggs or another vaccine component, or to a previous dose of influenza vaccine. Tell your doctor if you have any severe allergies.
- People who are moderately or severely ill should usually wait until they recover before getting flu vaccine. If you are ill, talk to your doctor or nurse about whether to reschedule the vaccination. People with a mild illness can usually get the vaccine.

5 When should I get influenza vaccine?

You can get the vaccine as soon as it is available, usually in the fall, and for as long as illness is occurring in your community. Influenza can occur any time from November through May, but it most often peaks in January or February. Getting vaccinated in December, or even later, will still be beneficial in most years.

Most people need one dose of influenza vaccine each year. Children younger than 9 years of age getting influenza vaccine for the first time — or who got influenza vaccine for the first time last season but got only one dose — should get 2 doses, at least 4 weeks apart, to be protected.

Influenza vaccine may be given at the same time as other vaccines.

6 What are the risks from LAIV?

A vaccine, like any medicine, could possibly cause serious problems, such as severe allergic reactions. The risk of a vaccine causing serious harm, or death, is extremely small.

Live influenza vaccine viruses rarely spread from person to person. Even if they do, they are not likely to cause illness. LAIV is made from weakened virus and does not cause influenza. The vaccine can cause mild symptoms in people who get it (see below).

Mild problems:

Some children and adolescents 2-17 years of age have reported mild reactions, including:

- runny nose, nasal congestion or cough
- fever
- headache and muscle aches
- abdominal pain or occasional vomiting or diarrhea

Some adults 18-49 years of age have reported:

- runny nose or nasal congestion
- cough, chills, tiredness/weakness
- sore throat
- headache

Severe problems:

- Life-threatening allergic reactions from vaccines are very rare. If they do occur, it is usually within a few minutes to a few hours after the vaccination.
- If rare reactions occur with any product, they may not be identified until thousands, or millions, of people have used it. Millions of doses of LAIV have been distributed since it was licensed, and no serious problems have been identified. Like all vaccines, LAIV will continue to be monitored for unusual or severe problems.

7 What if there is a severe reaction?

What should I look for?

Any unusual condition, such as a high fever or behavior changes. Signs of a severe allergic reaction can include difficulty breathing, hoarseness or wheezing, hives, paleness, weakness, a fast heart beat or dizziness.

What should I do?

- Call a doctor, or get the person to a doctor right away.
- Tell the doctor what happened, the date and time it happened, and when the vaccination was given.
- Ask your provider to report the reaction by filing a Vaccine Adverse Event Reporting System (VAERS) form. Or you can file this report through the VAERS website at www.vaers.hhs.gov, or by calling 1-800-822-7967.

VAERS does not provide medical advice.

8 The National Vaccine Injury Compensation Program

A federal program exists to help pay for the care of anyone who has a serious reaction to a vaccine.

For more information about the National Vaccine Injury Compensation Program, call 1-800-338-2382, or visit their website at www.hrsa.gov/vaccinecompensation.

9 How can I learn more?

- Ask your provider. They can give you the vaccine package insert or suggest other sources of information.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
  - Call 1-800-232-4636 (1-800-CDC-INFO) or
  - Visit CDC’s website at www.cdc.gov/flu
INACTIVEINFLUENZA VACCINE
WHAT YOU NEED TO KNOW

2009-10

Many Vaccine Information Statements are available in Spanish and other languages. See www.immunize.org/vis.

1 Why get vaccinated?

Influenza (“flu”) is a contagious disease.

It is caused by the influenza virus, which can be spread by coughing, sneezing, or nasal secretions.

Other illnesses can have the same symptoms and are often mistaken for influenza. But only an illness caused by the influenza virus is really influenza.

Anyone can get influenza, but rates of infection are highest among children. For most people, it lasts only a few days. It can cause:
* fever
* sore throat
* chills
* headache
* muscle aches

Some people, such as infants, elderly, and those with certain health conditions, can get much sicker. Flu can cause high fever and pneumonia, and make existing medical conditions worse. It can cause diarrhea and seizures in children. On average, 226,000 people are hospitalized every year because of influenza and 36,000 die – mostly elderly. Influenza vaccine can prevent influenza.

2 Inactivated influenza vaccine

There are two types of seasonal influenza vaccine:

1. Inactivated (killed) vaccine, or the “flu shot” is given by injection into the muscle.
2. Live, attenuated (weakened) influenza vaccine is sprayed into the nostrils. This vaccine is described in a separate Vaccine Information Statement.

Influenza viruses are always changing. Because of this, influenza vaccines are updated every year, and an annual vaccination is recommended.

Each year scientists try to match the viruses in the vaccine to those most likely to cause flu that year. When there is a close match the vaccine protects most people from serious influenza-related illness. But even when there is not a close match, the vaccine provides some protection. Influenza vaccine will not prevent “influenza-like” illnesses caused by other viruses.

It takes up to 2 weeks for protection to develop after the shot. Protection lasts up to a year.

Some inactivated influenza vaccine contains a preservative called thimerosal. Some people have suggested that thimerosal may be related to developmental problems in children. In 2004 the Institute of Medicine reviewed many studies looking into this theory and concluded that there is no evidence of such a relationship. Thimerosal-free influenza vaccine is available.

3 Who should get inactivated influenza vaccine?

Anyone who wants to reduce the likelihood of becoming ill with influenza or spreading influenza to others.

All children 6 months and older and all older adults:
* All children from 6 months through 18 years of age.
* Anyone 50 years of age or older.

Anyone who is at risk of complications from influenza, or more likely to require medical care:
* Women who will be pregnant during influenza season.
* Anyone with long-term health problems with:
  - heart disease
  - kidney disease
  - liver disease
  - lung disease
  - metabolic disease, such as diabetes
  - asthma
  - anemia, and other blood disorders
* Anyone with a weakened immune system due to:
  - HIV/AIDS or other diseases affecting the immune system
  - long-term treatment with drugs such as steroids
  - cancer treatment with x-rays or drugs
* Anyone with certain muscle or nerve disorders (such as seizure disorders or cerebral palsy) that can lead to breathing or swallowing problems.
* Anyone 6 months through 18 years of age on long-term aspirin treatment (they could develop Reye Syndrome if they got influenza).
* Residents of nursing homes and other chronic-care facilities.

Anyone who lives with or cares for people at high risk for influenza-related complications:
* Health care providers.
* Household contacts and caregivers of children from birth up to 5 years of age.
* Household contacts and caregivers of people 50 years and older, or anyone with medical conditions that put them at higher risk for severe complications from influenza.

Health care providers may also recommend a yearly influenza vaccination for:
* People who provide essential community services.
* People living in dormitories, correctional facilities, or under other crowded conditions, to prevent outbreaks.
* People at high risk of influenza complications who travel to the Southern hemisphere between April and September, or to the tropics or in organized tourist groups at any time.
4 When should I get influenza vaccine?

You can get the vaccine as soon as it is available, usually in the fall, and for as long as illness is occurring in your community. Influenza can occur any time from November through May, but it most often peaks in January or February. Getting vaccinated in December, or even later, will still be beneficial in most years.

Most people need one dose of influenza vaccine each year. **Children younger than 9 years of age getting influenza vaccine for the first time** – or who got influenza vaccine for the first time last season but got only one dose – should get 2 doses, at least 4 weeks apart, to be protected.

Influenza vaccine may be given at the same time as other vaccines, including pneumococcal vaccine.

5 Some people should talk with a doctor before getting influenza vaccine

Some people should not get inactivated influenza vaccine or should wait before getting it.

- **Tell your doctor if you have any severe (life-threatening) allergies.** Allergic reactions to influenza vaccine are rare.
- **Influenza vaccine virus is grown in eggs.** People with a severe egg allergy should not get the vaccine.
- **A severe allergy to any vaccine component is also a reason to not get the vaccine.**
- **If you have had a severe reaction after a previous dose of influenza vaccine, tell your doctor.**

- **Tell your doctor if you ever had Guillain-Barré Syndrome (a severe paralytic illness, also called GBS).** You may be able to get the vaccine, but your doctor should help you make the decision.

- **People who are moderately or severely ill should usually wait until they recover before getting flu vaccine.** If you are ill, talk to your doctor or nurse about whether to reschedule the vaccination. People with a mild illness can usually get the vaccine.

6 What are the risks from inactivated influenza vaccine?

A vaccine, like any medicine, could possibly cause serious problems, such as severe allergic reactions. The risk of a vaccine causing serious harm, or death, is extremely small.

Serious problems from influenza vaccine are very rare. The viruses in inactivated influenza vaccine have been killed, so you cannot get influenza from the vaccine.

**Mild problems:**

- soreness, redness, or swelling where the shot was given
- hoarseness; sore, red or itchy eyes; cough
- fever, aches

If these problems occur, they usually begin soon after the shot and last 1-2 days.

Severe problems:

- **Life-threatening allergic reactions from vaccines are very rare.** If they do occur, it is usually within a few minutes to a few hours after the shot.
- **In 1976, a type of influenza (swine flu) vaccine was associated with Guillain-Barré Syndrome (GBS).** Since then, flu vaccines have not been clearly linked to GBS. However, if there is a risk of GBS from current flu vaccines, it would be no more than 1 or 2 cases per million people vaccinated. This is much lower than the risk of severe influenza, which can be prevented by vaccination.

7 What if there is a severe reaction?

**What should I look for?**

Any unusual condition, such as a high fever or behavior changes. Signs of a severe allergic reaction can include difficulty breathing, hoarseness or wheezing, hives, paleness, weakness, a fast heart beat or dizziness.

**What should I do?**

- **Call a doctor, or get the person to a doctor right away.**
- **Tell the doctor what happened, the date and time it happened, and when the vaccination was given.**
- **Ask your provider to report the reaction by filing a Vaccine Adverse Event Reporting System (VAERS) form.** Or you can file this report through the VAERS website at www.vaers.hhs.gov, or by calling 1-800-822-7967.

*VAERS does not provide medical advice.*

8 The National Vaccine Injury Compensation Program

A federal program exists to help pay for the care of anyone who has a serious reaction to a vaccine.

For more information about the National Vaccine Injury Compensation Program, call **1-800-338-2382**, or visit their website at [www.hrsa.gov/vaccinecompensation](http://www.hrsa.gov/vaccinecompensation).

9 How can I learn more?

- **Ask your provider.** They can give you the vaccine package insert or suggest other sources of information.
- **Call your local or state health department.**
- **Contact the Centers for Disease Control and Prevention (CDC):**
  - Call 1-800-232-4636 (1-800-CDC-INFO) or
  - Visit CDC’s website at [www.cdc.gov/flu](http://www.cdc.gov/flu)

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION

Vaccine Information Statement (Interim)
Inactivated Influenza Vaccine (8/11/09) 42 U.S.C. §300aa-26