Influenza Immunization During Pregnancy



The American College of Obstetricians and Gynecologists WOMEN'S HEALTH CARE PHYSICIANS



November 1, 2015

Dear Colleague:

Influenza (flu) season is here and the time is now for all individuals 6 months and older to be vaccinated, including pregnant women. **Pregnant women are at an increased risk of serious illness and hospitalization from complications of influenza and thus should receive an inactivated influenza vaccine during any trimester.** The American College of Obstetricians and Gynecologists (ACOG) recommends that all individuals 6 months and older receive a flu shot every year. As the trusted health care providers of women, we are in a critical position to recommend and offer influenza vaccines to our patients.

Study after study demonstrates that our recommendation is the most effective way to increase influenza immunization rates among adults and, in particular, pregnant women. I urge you to strongly recommend the flu shot to all of your pregnant and nonpregnant patients throughout the flu season until May 2016. If your patient does not accept your recommendation initially, continue to offer her the flu shot on subsequent office visits. If your practice does not administer the flu shot in your office, have a referral plan and be sure to follow up with your patients for documentation of their vaccines. It is important to remember that live, attenuated influenza vaccine is contraindicated for pregnant women. See ACOG's Committee Opinion on Influenza Vaccination During Pregnancy in this tool kit or on ACOG's Immunization for Women web site at www.immunizationforwomen.org for specific details.

This tool kit includes materials to help you and your staff communicate with pregnant women about the importance of receiving a flu shot. If your patient has questions about receiving the flu shot, please give her a copy of the Frequently Asked Questions for Pregnant Women Concerning Influenza (Flu) Vaccination and Frequently Asked Questions for Patients Concerning Vaccine Safety tear pads. If a pregnant patient calls describing influenza-like illness, use the laminated Assessment and Treatment Algorithm to determine the best course of action. Health care provider FAQs are also included for you and your staff.

Set an example for your patients by getting yourself and all of your office staff vaccinated. Educate your practice team about the importance of flu vaccination during pregnancy. For up-to-date information on influenza, please encourage your staff and patients to visit ACOG's immunization web site, Immunization for Women, www.immunizationforwomen.org.

We hope the enclosed materials are helpful to you, your practice team, and your patients. If you have additional questions or would like additional materials, please contact us at 202-863-2489.

Sincerely,

Christopher M. Zahn, MD Vice President, Practice Activities

Saura Belgios

Laura E. Riley Chair, ACOG Immunization Expert Work Group

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The American College of Obstetricians and Gynecologists WOMEN'S HEALTH CARE PHYSICIANS

ACOG COMMITTEE OPINION

Number 732 • April 2018

(Replaces Committee Opinion Number 608, September 2014)

Committee on Obstetric Practice

This Committee Opinion was developed by the American College of Obstetricians and Gynecologists' Immunization and Emerging Infections Expert Work Group and the Committee on Obstetric Practice in collaboration with Neil S. Silverman, MD, and Richard Beigi, MD.

Influenza Vaccination During Pregnancy

ABSTRACT: Influenza vaccination is an essential element of prepregnancy, prenatal, and postpartum care because influenza can result in serious illness, including a higher chance of progressing to pneumonia, when it occurs during the antepartum or postpartum period. In addition to hospitalization, pregnant women with influenza are at increased risk of intensive care unit admission and adverse perinatal and neonatal outcomes. The Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices and the American College of Obstetricians and Gynecologists recommend that all adults receive an annual influenza vaccine and that women who are or will be pregnant during influenza season receive an inactivated influenza vaccine as soon as it is available. In the United States, the influenza season typically occurs from October to May. Ideally, an influenza vaccination should be given before the end of October, but vaccination throughout the influenza season is encouraged to ensure protection during the period of circulation. Any of the licensed, recommended, age-appropriate, inactivated influenza vaccines can be given safely during any trimester. Therefore, it is critically important that obstetrician-gynecologists and other obstetric care providers recommend and advocate for the influenza vaccine. Obstetrician-gynecologists are encouraged to stock and administer the influenza vaccine to their pregnant patients in their offices, and should get the influenza vaccine themselves every season. If the influenza vaccine cannot be offered in a practice, obstetrician-gynecologists and obstetric care providers should refer patients to another health care provider, pharmacy, or community vaccination center. This updated Committee Opinion includes more recent data on the safety and efficacy of influenza vaccination during pregnancy and recommendations for treatment and postexposure chemoprophylaxis.

Recommendations

The American College of Obstetricians and Gynecologists (ACOG) makes the following recommendations:

- The Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices and ACOG recommend that all adults receive an annual influenza vaccine and that women who are or will be pregnant during influenza (flu) season receive an inactivated influenza vaccine as soon as it is available. Any of the licensed, recommended, age-appropriate, inactivated influenza vaccines can be given safely during any trimester.
- Maternal influenza immunization is an essential component of prenatal care for women and their newborns. Obstetrician-gynecologists and other health care providers should counsel pregnant women about the safety and benefits of influenza

immunization for themselves and their fetuses and advocate for the benefits of passive immunity from maternal immunization for their newborns.

- Obstetrician-gynecologists are encouraged to stock and administer the influenza vaccine to their pregnant patients in their offices, and should get the influenza vaccine themselves every season.
- If the influenza vaccine cannot be offered in a practice, obstetrician-gynecologists and obstetric care providers should refer patients to another health care provider, pharmacy, or community vaccination center.
- Obstetrician-gynecologists should strongly encourage their office staff to be vaccinated against influenza every season.
- Individuals with a history of egg allergy who have experienced only hives after exposure to egg can

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receive any licensed and recommended influenza vaccine that is otherwise appropriate for their age and health status.

- In the case of allergic symptoms more serious than hives, the vaccine should be administered in an inpatient or outpatient medical setting (including, but not necessarily limited to hospitals, clinics, health departments, and physician offices).
- Patients with flu-like illness should be treated with antiviral medications presumptively regardless of vaccination status. Health care providers should not rely on test results to initiate treatment and should treat patients presumptively based on clinical evaluation.
- Because of the high potential for morbidity, the CDC and ACOG recommend that postexposure antiviral chemoprophylaxis (75 mg of oseltamivir once daily for 10 days) be considered for pregnant women and women who are up to 2 weeks postpartum (including pregnancy loss) who have had close contact with someone likely to have been infected with influenza. If oseltamivir is unavailable, zanamiver can be substituted, two inhalations once daily for 10 days.

Introduction

Published data continue to demonstrate the need for influenza vaccination during pregnancy as well as the importance of recommending and providing vaccination in the office (1-4). During the 2016–2017 influenza season, 53.6% of women reported receiving the influenza vaccine before or during pregnancy (5). Although these numbers reflect significant progress, much room remains for improvement to meet the U.S. Health and Human Services' Healthy People 2020 goal of vaccinating 80% of pregnant women against influenza (6). The American College of Obstetricians and Gynecologists' Immunization and Emerging Infections Expert Work Group and the Committee on Obstetric Practice recommend that all women who are pregnant during influenza season receive an inactivated influenza vaccine in accordance with recommendations from the CDC's Advisory Committee on Immunization Practices (5). This updated Committee Opinion includes more recent data on the safety and efficacy of influenza vaccination during pregnancy and recommendations for treatment and postexposure chemoprophylaxis.

Background

Influenza vaccination is an essential element of prepregnancy, prenatal, and postpartum care because influenza can result in serious illness, including a higher chance of progressing to pneumonia, when it occurs during the antepartum or postpartum period. For example, a retrospective cohort study in Nova Scotia found that women hospitalized for respiratory illness during pregnancy (especially during the third trimester) were more likely to have an increased number of medical visits or an increased length of stay when compared with the number of visits the year before their pregnancy (7). In this study, the association between pregnancy status and hospital admission was particularly striking for women with comorbidities (7). However, it is important to note that many studies, including the aforementioned study, were not able to confirm the influenza diagnosis with laboratory results, and more studies using confirmatory laboratory results are needed in pregnant women. In addition to hospitalization, pregnant women with influenza are at an increased risk of intensive care unit admission and adverse perinatal and neonatal outcomes (8-10). Finally, morbidity and mortality among pregnant women increases during influenza pandemics, including the 2009 H1N1 influenza pandemic (10–18). Taken together, these data emphasize the importance of influenza vaccination as a vital intervention that all obstetrician-gynecologists and other obstetric care providers should recommend and administer.

In the United States, the influenza season typically occurs from October to May. The CDC's Advisory Committee on Immunization Practices and ACOG recommend that all adults receive an annual influenza vaccine and that women who are or will be pregnant during influenza season receive an inactivated influenza vaccine as soon as it is available. Ideally, an influenza vaccination should be given by the end of October, but vaccination throughout the influenza season is encouraged to ensure protection during the period of circulation. The inactivated influenza vaccine can be given to all pregnant women during any trimester (5). Because influenza vaccines are recommended annually for all adults, pregnant women should be vaccinated even if they received an influenza vaccine during a previous pregnancy. Vaccination in the postpartum period is an alternative only when vaccination during pregnancy cannot be completed.

Safety

Numerous studies, including clinical trials and observational studies, and data from safety reporting systems have demonstrated consistently the safety of influenza vaccination during pregnancy (19-23). To date, only one small retrospective case-control study has suggested a possible association between receipt of an influenza vaccine containing A/H1N1pdm early in the first trimester and spontaneous abortion in women who also received an influenza vaccine containing A/H1N1pdm in the previous influenza season (24). This association has not been observed during other seasons or other versions of the influenza vaccine. Because of the lack of evidence of biological plausibility, several notable flaws in this study, and the preponderance of other data showing no association, the recommendation for influenza vaccine given in any trimester has not changed (24, 25). Although some researchers have raised concerns that thimerosal, a mercury-containing preservative used in multidose vials of the influenza vaccine, may be unsafe, there is no

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scientific evidence that thimerosal-containing vaccines cause health or developmental problems in children born to women who received vaccines with thimerosal during pregnancy (26–28). Therefore, although thimerosal-free formulations of the influenza vaccine are available, the CDC's Advisory Committee on Immunization Practices does not indicate a preference for thimerosal-containing or thimerosal-free vaccines for any group, including pregnant women (19).

Individuals with a history of egg allergy who have experienced only hives after exposure to egg can receive any licensed and recommended influenza vaccine that is otherwise appropriate for their age and health status. A recent study found the rate of anaphylaxis after all vaccines to be 1.31 per one million vaccine doses given (29). Individuals who report having had reactions to egg involving symptoms other than hives (such as angioedema, respiratory distress, lightheadedness, or recurrent emesis) or those who have required epinephrine or another emergency medical intervention, also may receive any licensed and recommended influenza vaccine. However, in the case of allergic symptoms more serious than hives, the vaccine should be administered in an inpatient or outpatient medical setting (including, but not necessarily limited to hospitals, clinics, health departments, and physician offices).

Vaccine administration should be supervised by a health care provider who is able to recognize and manage severe allergic conditions. A previous severe allergic reaction to influenza vaccine, not to eggs, regardless of the component suspected of being responsible for the reaction, is the only current contraindication to future receipt of the influenza vaccine (5).

Currently, pregnant women should receive any licensed, recommended, age-appropriate, inactivated influenza vaccine during any trimester (5). If the timing of the tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis (Tdap) vaccine and the influenza vaccine align, it is safe and effective to administer both vaccines during the same visit. It is also safe for breastfeeding women to receive the influenza vaccine if they did not receive it during pregnancy.

Efficacy and Benefits

The efficacy of seasonal influenza vaccination in pregnant women is similar to its efficacy among the general adult population (30). Although the effectiveness of the influenza vaccine can be lower than that of other adult vaccines, vaccination still offers significant protection against influenza. It can mitigate the severity of the effect of influenza when infection does occur and is the primary preventive intervention for pregnant women. A study during the 2012–2013 influenza season demonstrated that pregnant women who were vaccinated had significantly fewer hospitalizations than those who were not (31).

Influenza vaccination during pregnancy also can benefit the newborns of women who received the vaccine. Four large-scale, randomized controlled trials and numerous observational studies have demonstrated neonatal protection from maternal influenza vaccination (32-35). Studies also have demonstrated a reduction in hospitalization related to influenza infection among infants born to women who received the vaccine during pregnancy (36, 37). Therefore, because the influenza vaccine is not effective in infants younger than 6 months, passive immunization of fetuses through transplacentally transmitted antibodies is currently the best prevention strategy for newborns (32). Thus, maternal influenza immunization is an essential component of prenatal care for women and their newborns. Obstetriciangynecologists and other health care providers should counsel pregnant women about the benefits of influenza immunization for themselves and their fetuses and advocate for the benefits of passive immunity from maternal immunization for their newborns.

Treatment and Postexposure Chemoprophylaxis in Pregnant Women

Pregnant women are at high risk of serious complications of influenza infection such as intensive care unit admission, preterm delivery, and maternal death. Patients with flu-like illness should be treated with antiviral medications presumptively regardless of vaccination status. Treatment with oseltamivir (75 mg twice daily for 5 days) is preferred; however, if oseltamivir is unavailable, zanamivir (two inhalations [10 mg] twice daily for 5 days) may be substituted. Health care providers should not rely on test results to initiate treatment and should treat patients presumptively based on clinical evaluation (38).

Because of the high potential for morbidity, the CDC and ACOG recommend that postexposure antiviral chemoprophylaxis (75 mg of oseltamivir once daily for 10 days) be considered for pregnant women and women who are up to 2 weeks postpartum (including pregnancy loss) who have had close contact with someone likely to have been infected with influenza. If oseltamivir is unavailable, zanamivir can be substituted, two inhalations once daily for 10 days. All women who are pregnant or are in the first 2 weeks postpartum should be counseled to call for evaluation immediately if the early signs and symptoms of influenza infection (eg, a fever greater than 100°F coupled with shortness of breath, syncope, or chest pain) develop (38). For more information about treatment and dosage see ACOG and the Society for Maternal–Fetal Medicine's Seasonal Influenza Assessment and Treatment of Pregnant Women with Influenza-like Illness algorithm at www.acog.org/More-Info/FluVaccine.

The Obstetrician–Gynecologist's Role

Discussion with patients regarding the effects of influenza and the potential benefits of vaccination during pregnancy is particularly important because a lack of knowledge about the benefits of the influenza vaccine has

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been shown to be a barrier to vaccine acceptance (39-41). Educational tools with simple chart prompts increase the frequency of discussion between physicians and pregnant women regarding influenza vaccination (42). Moreover, studies consistently suggest that when recommendations for influenza vaccination during pregnancy come directly from a woman's obstetrician-gynecologist or other obstetric care provider and the vaccine is available in the physician's office, the odds of vaccine acceptance and receipt are 5-fold to 50-fold higher (1, 2). Therefore, it is critically important that all obstetrician-gynecologists and other obstetric care providers recommend and advocate for the influenza vaccine. Obstetrician-gynecologists are encouraged to stock and administer the influenza vaccine to their pregnant patients in their offices, and should get the influenza vaccine themselves every season. Depending on the size of a practice and services provided, there may not be the means to stock and offer the influenza vaccine in the office. If the influenza vaccine cannot be offered in a practice, obstetrician-gynecologists and obstetric care providers should refer patients to another health care provider, pharmacy, or community vaccination center.

If a patient receives the influenza vaccine outside of the obstetrician–gynecologist's office, it is important for the site that provided the vaccination to provide proper vaccine documentation if the site does not work directly with a centralized vaccine registration program, so that the patient's immunization record can be updated appropriately. These combined efforts send a powerful message to pregnant women that vaccination is very important for their protection and for their newborns.

Conclusion

Pregnant women are particularly vulnerable to influenza infection and its resulting morbidities; therefore, influenza vaccination is an integral element of prepregnancy, prenatal, and postpartum care. It is imperative that obstetrician-gynecologists, other health care providers, health care organizations, and public health officials continue efforts to improve the rate of influenza vaccination among pregnant women. Doing so will benefit women and their newborns.

For More Information

The American College of Obstetricians and Gynecologists has identified additional resources on topics related to this document that may be helpful for obstetrician– gynecologists, other health care providers, and patients. You may view these resources at: www.acog.org/More-Info/FluVaccine.

These resources are for information only and are not meant to be comprehensive. Referral to these resources does not imply the American College of Obstetricians and Gynecologists' endorsement of the organization, the organization's website, or the content of the resource. The resources may change without notice.

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Frequently Asked Questions Concerning Seasonal Influenza for Obstetrician–Gynecologists

Should pregnant women be immunized against seasonal influenza?

Yes. Influenza vaccination is an essential element of prenatal care because influenza can lead to serious illness, including a higher chance of developing pneumonia, when it occurs either in the antepartum or postpartum period. The Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices and the American College of Obstetricians and Gynecologists recommend that all adults receive an annual influenza vaccine and that all women who are or will be pregnant during influenza season receive any licensed, recommended, age-appropriate, inactivated influenza vaccine during any trimester, as soon as it is available. Multiple studies indicate that during pregnancy, women are at increased risk of serious medical complications from influenza. In addition, because the influenza vaccine is not effective in infants younger than six months, passive immunization of fetuses through transplacentally transmitted antibodies is currently the best prevention strategy for newborns. Vaccination in the postpartum period is an alternative only when vaccination during pregnancy cannot be completed. It is safe for breastfeeding women to receive the flu vaccine.

Is it safe for pregnant women to be immunized against seasonal influenza?

Yes. Numerous studies, including clinical trials and observational studies, and data from safety reporting systems have consistently demonstrated the safety of influenza vaccination during pregnancy. In fact, data show that newborns of women who received the flu vaccine while pregnant have much lower rates of influenza than newborns whose mothers were not vaccinated during pregnancy. To date, only one small retrospective case–control study has suggested a possible association between receipt of an influenza vaccine containing A/H1N1pdm early in the first trimester and spontaneous abortion in women who also received an influenza vaccine containing A/H1N1pdm in the previous influenza season (1). This has not been observed in other seasons. Pregnant women should be counseled that because of the lack of evidence of biological plausibility, several notable flaws in this study, and the preponderance of other data showing no association of influenza vaccine is made the same way each year with the only difference being the use of different strains of influenza virus.

When should pregnant women be immunized?

All women who are or will be pregnant during influenza season should receive an inactivated influenza vaccine as soon as it is available. Ideally, an influenza vaccination should be given by the end of October, but vaccination at any time during the influenza season is encouraged to ensure protection during the period of circulation. The inactivated influenza vaccine can be given to all women during any trimester. Because flu vaccines are recommended annually for all adults, pregnant women should be vaccinated even if they received a flu vaccine during a previous pregnancy.

Which influenza vaccine should pregnant women receive?

Pregnant women should receive any licensed, recommended, age-appropriate inactivated influenza vaccine, given as an intramuscular injection in the deltoid muscle. The Centers for Disease Control and Preventions' Advisory Committee on Immunization Practices and the American College of Obstetricians and Gynecologists do not preferentially recommend a specific formulation of the influenza vaccine.

Can a person with an egg allergy receive an influenza vaccine?

Egg allergy, including hives, is no longer a contraindication to receipt of the influenza vaccine. Individuals, including pregnant women, who have experienced only hives after exposure to egg should receive any licensed, recommended, age-appropriate, influenza vaccine. Individuals who reported symptoms other than hives (eg, angioedema, respiratory distress, lightheadedness, or recurrent emesis) or who required epinephrine or another emergency medical intervention, also may receive any licensed and recommended influenza vaccine that is otherwise appropriate. However, their vaccine should be administered in an inpatient or outpatient medical setting and under the supervision of health care providers who are able to recognize and manage severe allergic conditions. A previous severe allergic reaction to influenza vaccine, regardless of the component suspected of causing the reaction, is a contraindication to future receipt of the vaccine.



The American College of Obstetricians and Gynecologists WOMEN'S HEALTH CARE PHYSICIANS



(continued)

Is it safe for pregnant women to receive an influenza vaccine that contains mercury (thimerosal)?

Yes. Although some individuals have raised concerns that thimerosal, a mercury-containing preservative used in multidose vials of the influenza vaccine, may be unsafe, there is no scientific evidence that thimerosal-containing vaccines cause health or developmental problems in children born to women who received vaccines with thimerosal during pregnancy. Therefore, although thimerosal-free formulations of the influenza vaccine are available, the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices does not indicate a preference for thimerosal-containing or thimerosal-free vaccines for any group, including pregnant women.

Can I administer the tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis vaccine and the flu vaccine during the same visit?

Yes. You can give the tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis (Tdap) vaccine and the flu vaccine in the same visit. Receiving these vaccinations at the same time is safe and effective.

How should I treat a pregnant patient with suspected influenza illness?

Pregnant women are at high risk of serious complications of influenza (flu) infection such as intensive care unit admission, preterm delivery, and maternal death. Patients with flu-like illness should be treated with antiviral medications presumptively regardless of vaccination status. Treatment with oseltamivir (75 mg twice daily for 5 days) is preferred, however if oseltamivir is unavailable zanamivir (two inhalations [10 mg] twice daily for 5 days) may be substituted. Health care providers should not rely on test results to initiate treatment; and should treat presumptively based on clinical evaluation. See the American College of Obstetricians and Gynecologists and Society for Maternal–Fetal Medicine's "Influenza Season Assessment and Treatment for Pregnant Women with Influenza-Like Illness" algorithm for more information.

Should we provide antiviral chemoprophylaxis to pregnant women exposed to influenza?

Yes. Because of the high potential for morbidity, the Centers for Disease Control and Prevention and the American College of Obstetricians and Gynecologists recommend that postexposure antiviral chemoprophylaxis (75 mg of oseltamivir once daily for 10 days) be considered for pregnant women and women who are up to 2 weeks postpartum (which includes pregnancy loss) who have had close contact with someone likely to have been infected with influenza. If oseltamivir is unavailable, zanamivir can be substituted, two inhalations once daily for 10 days. All women who are pregnant or in the first 2 weeks postpartum should be counseled to immediately call for evaluation if the early signs and symptoms of influenza infection (eg, a fever greater than 100.0°F coupled with shortness of breath, syncope, or chest pain) develop.

Resources

For more information on antiviral chemoprophylaxis in pregnant and postpartum women, see the Centers for Disease Control and Prevention's website at www.cdc.gov/flu/professionals/antivirals/avrec_ob.htm.

For more information on seasonal flu vaccine safety and pregnant women, see the Centers for Disease Control and Prevention's website at www.cdc.gov/flu/protect/vaccine/qa_vacpregnant.htm.

For physician and patient resources, see the American College of Obstetrician and Gynecologists' Immunization for Women website at www.immunizationforwomen.org.

Reference

1. Donahue JG, Kieke BA, King JP, DeStefano F, Mascola MA, Irving SA, et al. Association of spontaneous abortion with receipt of inactivated influenza vaccine containing H1N1pdm09 in 2010–11 and 2011–12. Vaccine 2017;35:5314–22.

This information is designed as an educational resource to aid practitioners in assessing their patients' needs, and use of this information is voluntary. This information should not be considered as inclusive of all proper treatments or methods of care or as a statement of the standard of care. It is not intended to substitute for the independent professional judgment of the treating clinician. Variations in practice may be warranted when, in the reasonable judgment of the treating clinician, such course of action is indicated by the condition of the patient, limitations of available resources, or advances in knowledge or technology. The American College of Obstetricians and Gynecologists reviews its publications regularly; however, its publications may not reflect the most recent evidence. Any updates to this document can be found on www.acog.org or by calling the ACOG Resource Center.

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Influenza (Flu) Vaccination During Pregnancy

I am pregnant. Should I get the influenza vaccine (flu shot)?

Yes. Getting a flu shot is the best way to protect you and your baby from serious illness from the flu. Pregnant women and their fetuses have a higher risk of serious complications from the flu. The flu shot given during pregnancy protects women and their newborns. You need a flu shot each year because the flu viruses targeted by the vaccine can change from year to year. The flu shot has been safely given to millions of pregnant women for many years.

How does my flu shot protect my newborn?

When you get a flu shot, your body makes antibodies that also pass to your fetus. This means your baby has protection against the flu after birth. This is important because infants less than 6 months of age are too young to get the flu shot.

Why is it important for pregnant women to get the flu shot?

The flu is a mild-to-severe illness that can cause fever, body aches, sore throat, cough, and fatigue. Pregnant women who get the flu can become much sicker than women who get the flu when they are not pregnant. Pregnant women who get the flu have a higher chance of the flu turning into pneumonia than women who are not pregnant. Pneumonia is a serious infection in the lungs that usually requires treatment in the hospital. Pregnant women who get the flu often need more medical visits and frequently need to be admitted to the hospital for observation and treatment.

During which trimester is it safe to get a flu shot?

The flu shot can be safely given during any trimester. Pregnant women can get the flu shot at any point during the flu season (typically October through May). Pregnant women should get the shot as soon as possible when it becomes available. If you are pregnant, talk with your obstetrician-gynecologist (ob-gyn) about getting the flu shot.

Will the flu shot give me the flu?

No. You cannot get the flu from getting the flu shot.

I got the flu even though I had a flu shot. What happened?

The flu shot does not protect against all strains of the flu virus. Experts do their best to determine the virus strains that are most likely to cause illness the following season. Sometimes additional strains end up causing illness. Also, after your flu shot, it takes about 2 weeks for your body to develop antibodies, which are what protects you from the flu. So, if you are exposed to the flu during the time immediately after your flu shot, you can still get the flu. That is why it is important to get the flu shot before flu season becomes very active. The flu shot does not protect against the common cold or other respiratory viruses. During the flu season, you can still get a respiratory illness that is not the flu, even though you got a flu shot.

What are the side effects of the flu shot?

Some people can develop low-grade fevers, headaches, and muscle aches 1 to 2 days after a flu shot. These side effects are temporary. The risk of minor side effects outweighs the risks of the flu, which is a serious illness that can make you or your baby seriously ill for much longer.

Is there any reason I should not get the flu shot?

There are very few reasons that a pregnant woman should not get a flu shot. A history of egg allergy, including hives, is not a reason to avoid the flu shot. But, if you have had a severe allergic reaction after a previous flu shot, you should not get another flu shot. Talk with your ob-gyn about any reactions you may have had with past flu shots.

Are preservatives in flu vaccines safe for my baby?

Yes. Thimerosal is a mercury-containing preservative used in very small amounts in some flu shots. There is no scientific evidence that thimerosal causes health or developmental problems for pregnant women or children born to women who received thimerosal-containing shots during pregnancy. Thimerosal-free types of the flu shot also are available. Pregnant women can get the flu shot with or without the preservative.

What else can I do to keep my baby healthy and free of the flu?

Getting your flu shot while you are pregnant is the best step in protecting yourself and your baby against the flu. Data show that babies born to women who got the flu shot while pregnant have much lower rates of flu compared with babies whose mothers did not get the shot. Breastfeeding your baby and making sure family members and caregivers get the flu shot also will protect your baby.

I am breastfeeding my baby. Is it safe for me to get the flu shot?

Yes. It is safe for breastfeeding women to get the flu shot if they did not get the shot during pregnancy. The antibodies your body makes after the flu shot can be passed to your baby through breast milk. This reduces your baby's chance of getting sick with the flu.

Is it safe to get a flu shot at my local pharmacy?

Yes. Flu shots are available at most major pharmacies. You can find a location for a flu shot at <u>www.vaccinefinder.org</u>. Be sure to let your ob-gyn know when you have gotten the flu shot so that your medical record can be updated. The pharmacy also should provide you with documentation of your flu shot.

Can I get the Tdap and flu shots at the same time?

Yes. You can get the tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis (Tdap) shot and the flu shot in the same visit. Receiving these shots at the same time is safe and effective.

Resources

ACOG FAQ: The Flu Vaccine and Pregnancy www.acog.org/womens-health/faqs/the-flu-vaccine-and-pregnancy

Centers for Disease Control and Prevention (CDC) www.cdc.gov/flu/protect/vaccine/pregnant.htm

Immunization

www.acog.org/topics/immunization

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Frequently Asked Questions

Vaccine Safety During Pregnancy



How do vaccines work?

Vaccines train the immune system to attack specific viruses and bacteria. This makes vaccination an important part of preventing infections during pregnancy. Pregnant women and women who are thinking about getting pregnant need certain vaccines. At different points during their lives, babies, children, teens, adults, and seniors all need certain vaccines, too.

How are vaccines made?

Most vaccines are made with inactivated (killed) versions of a pathogen (a virus or bacteria that causes disease). Some vaccines are made with parts of the pathogen or with a killed toxin made by the pathogen. None of these things can cause the disease itself when given as a vaccine. Most vaccines also contain some other ingredients, including

- · water or other fluids
- · preservatives and stabilizers
- · chemicals added to inactivate the virus or bacteria
- substances that help create a stronger immune response to the vaccine
- small amounts of the material that was used to grow the virus or bacteria

The amounts of these ingredients are very small. All of them are tested extensively to make sure they are safe. You can learn more about these ingredients at the website of the Centers for Disease Control (CDC), <u>www.cdc.gov/vaccinesafety</u>. Also, for information on the vaccine for coronavirus (COVID-19), see the question "How do the coronavirus (COVID-19) vaccines work?".

How are vaccines approved?

Vaccines are subject to strict safety standards. In the United states, vaccines are approved by the U.S. Food and Drug Administration (FDA) only after thorough research. Testing starts with animals and small groups of human volunteers. Later, vaccines are tested in large clinical trials with thousands of volunteers. If a clinical trial shows that a vaccine is safe and effective, there are a few other safety reviews. Then vaccine experts meet to review the testing results.

What happens after a vaccine is licensed?

Once a vaccine is licensed by the FDA, a committee called the Advisory Committee on Immunization Practices (ACIP) recommends how best to use it to control disease. This recommendation goes to the CDC.

How does getting vaccinated during pregnancy protect my baby?

Vaccines cause the body to create antibodies. Antibodies are proteins that that can identify bacteria and viruses and stop them from entering cells and making a person sick. After a pregnant woman gets a vaccine and her body creates antibodies, some of those antibodies pass to the fetus. This means the fetus will have the antibodies to protect against disease after birth. Antibodies are a safe, normal reaction to a vaccine. They protect your baby until he or she can be vaccinated during the first few months of life.

How do I know which vaccines I need?

The ACIP recommends that all pregnant women receive vaccines for the flu and pertussis (whooping cough) during each pregnancy. Other vaccines are recommended for adults based on their risk of getting a particular disease. Talk with your obstetrician–gynecologist (ob-gyn) about the vaccines that you have had in the past. Your ob-gyn may recommend vaccines based on your medical history and occupation.

Which vaccines can be given during pregnancy?

It is safe to get shots for the flu, whooping cough, hepatitis, pneumonia, and meningitis during pregnancy. All pregnant women should get the flu and whooping cough shots. Talk with your ob-gyn about whether you need other vaccines. For information on the vaccine for coronavirus (COVID-19), see the question "How do the coronavirus (COVID-19) vaccines work?".

Are there vaccines that should not be given during pregnancy?

Certain vaccines should not be given to pregnant women because they contain live, attenuated viruses. "Attenuated" means that the virus has been weakened so that it cannot cause disease in a healthy person. The vaccines that women should not get during pregnancy include

- live, attenuated flu vaccine given as a nasal spray (but the flu shot is safe)
- · measles-mumps-rubella (MMR) vaccine
- chickenpox vaccine

Also, the vaccine for human papillomavirus (HPV) is not a live, attenuated vaccine but it still should not be given during pregnancy.

Are vaccines safe for me and my baby?

Yes, vaccines are safe for both of you. In fact, vaccination is one of the most important things that you can do to protect your health and your baby's health. Keep in mind that vaccines have been safely given to millions of pregnant women for more than 50 years.

Is there mercury in vaccines?

Yes, there is a tiny amount of mercury (also called thimerosal) in some vaccines. It's important to understand what thimerosal is and why it may be added. Some vaccines come in single-dose vials. This means just one person gets a vaccine from a vial. Other vaccines come in multidose vials. This means the vial has enough vaccine for more than one person. Vials with more than one dose need to be kept pure. This is where thimerosal comes in. It helps prevent germs from growing in a vial that has multiple doses.

Is it safe to get a vaccine with thimerosal?

Yes, it is safe to get a vaccine that has thimerosal. It is not harmful for pregnant women or fetuses. Thimerosal naturally leaves the body after a vaccine. Thimerosal is safe and has been used in vaccines since the 1930s. For information about thimerosal and vaccine safety, visit this page from the CDC: www.cdc.gov/vaccinesafety/concerns/thimerosal/faqs.html.

Are there side effects from getting a vaccine?

Some people have no side effects from getting a vaccine. Other people have mild side effects, such as a sore arm or a low fever, that go away within a day or two. Severe side effects and reactions are rare. The CDC monitors reactions for all vaccines given in the United States. When you get a vaccine, you should get an information sheet that lists the possible side effects associated with that vaccine. If you have ever had a reaction to a vaccine, or if you have concerns about side effects, talk with your ob-gyn.

How do the coronavirus (COVID-19) vaccines work?

Currently there are two types of COVID-19 vaccines. The first are called mRNA vaccines. The surface of COVID-19 cells contains a spike protein. In the body this protein attaches to and infects healthy cells. The mRNA vaccines work by telling your body to fight the spike protein so it cannot bind to healthy cells. There is no live or inactive (killed) virus in the mRNA vaccines.

The second type is called an adenovirus vector vaccine. It contains inactive adenoviruses, which are similar to common cold viruses. These inactive viruses have been changed to be like parts of the virus that cause COVID-19. When your body starts to react against the inactive adenovirus, it also learns to protect against the similar parts of the COVID-19 virus. There is no live virus in adenovirus vector vaccines.

These vaccines cannot give you COVID-19. The vaccines do not affect your genes or DNA. There is no evidence that the COVID-19 vaccines cause infertility or have an impact on pregnancy.

Are the COVID-19 vaccines safe for pregnant women?

The tests done before the first COVID-19 vaccines were approved for emergency use did not include pregnant women. But based on how the vaccines were made and the science behind how the vaccines work in the body, experts believe they should be safe in pregnancy.

The CDC and some of the COVID-19 vaccine makers are now testing with pregnant women. And thousands of pregnant women have already chosen to receive COVID-19 vaccines. Some of them have enrolled in the CDC's vaccination tracking program at www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html. Data from this program do not show any safety concerns.

Should I talk with my ob-gyn before getting a COVID-19 vaccine?

If you are pregnant and want to know more about the vaccines, you can talk with your ob-gyn. This conversation is not required to get a vaccine, though it may be helpful. You can discuss your risk of getting COVID-19 and your risk of severe illness if you get sick. A vaccine may protect you from severe illness, which could help both you and your fetus. You can find up-to-date information from the CDC at www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/pregnancy.html.

Where can I find more information about vaccines for me and my family?

You can find accurate, trusted information about vaccines at the resources listed below.

Resources

American College of Obstetricians and Gynecologists www.immunizationforwomen.org www.acog.org/Vaccine-Resources

Centers for Disease Control and Prevention www.cdc.gov/vaccinesafety www.flu.gov

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Society for Maternal · Fetal Medicine

Assessment and Treatment for Pregnant Women With Suspected or Confirmed Influenza

Pregnant women are at high risk of serious complications of influenza (flu) infection such as intensive care unit admission, preterm delivery, and maternal death. Patients with suspected or confirmed influenza should be treated with antiviral medications presumptively regardless of vaccination status. Do not rely on test results to initiate treatment; treat presumptively based on clinical evaluation. The following algorithm is designed to aid practitioners in promptly assessing and treating suspected or confirmed influenza in pregnant women, and can be used for telephone triage.



*Oseltamivir (preferred) (75-mg orally twice daily for 5 days) or Zanamivir (two 5-mg inhalations [10 mg total] twice daily for 5 days). [†]Check with institution to determine requirements for testing. Do not rely on test results to initiate treatment; treat presumptively based on clinical evaluation.

[‡]Treatment within 48 hours of the onset of symptoms is ideal but treatment should not be withheld if the ideal window is missed. Because of the high potential for morbidity and mortality for pregnant and postpartum patients, the CDC advises that postexposure antiviral chemoprophylaxis can be considered for pregnant women and women who are up to 2 weeks postpartum (including after pregnancy loss) who have had close contact with infectious individuals. The chemoprophylaxis recommendation is oseltamivir 75 mg once daily for 7–10 days.

Seasonal influenza vaccination will help reduce incidence of influenza. Check ACOG's Immunization for Women website at www.immunizationforwomen.org for any future updates on this information.

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Please be advised that this guidance may become out-of-date as new information on influenza in pregnant women becomes available from the Centers for Disease Control and Prevention (CDC).

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Influenza (Flu) Vaccine (Inactivated or Recombinant): What you need to know

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

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

1

Why get vaccinated?

Influenza vaccine can prevent influenza (flu).

Flu is a contagious disease that spreads around the United States every year, usually between October and May. Anyone can get the flu, but it is more dangerous for some people. Infants and young children, people 65 years of age and older, pregnant women, and people with certain health conditions or a weakened immune system are at greatest risk of flu complications.

Pneumonia, bronchitis, sinus infections and ear infections are examples of flu-related complications. If you have a medical condition, such as heart disease, cancer or diabetes, flu can make it worse.

Flu can cause fever and chills, sore throat, muscle aches, fatigue, cough, headache, and runny or stuffy nose. Some people may have vomiting and diarrhea, though this is more common in children than adults.

Each year thousands of people in the United States die from flu, and many more are hospitalized. Flu vaccine prevents millions of illnesses and flu-related visits to the doctor each year.

2

Influenza vaccine

CDC recommends everyone 6 months of age and older get vaccinated every flu season. Children 6 months through 8 years of age may need 2 doses during a single flu season. Everyone else needs only 1 dose each flu season.

It takes about 2 weeks for protection to develop after vaccination.

There are many flu viruses, and they are always changing. Each year a new flu vaccine is made to protect against three or four viruses that are likely to cause disease in the upcoming flu season. Even when the vaccine doesn't exactly match these viruses, it may still provide some protection.

Influenza vaccine does not cause flu.

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

Talk with your health care 3 provider

Tell your vaccine provider if the person getting the vaccine:

- Has had an allergic reaction after a previous dose of influenza vaccine, or has any severe, lifethreatening allergies.
- Has ever had Guillain-Barré Syndrome (also called GBS).

In some cases, your health care provider may decide to postpone influenza vaccination to a future visit.

People with minor illnesses, such as a cold, may be vaccinated. People who are moderately or severely ill should usually wait until they recover before getting influenza vaccine.

Your health care provider can give you more information.



U.S. Department of Health and Human Services Centers for Disease Control and Prevention

4 Risks of a vaccine reaction

- Soreness, redness, and swelling where shot is given, fever, muscle aches, and headache can happen after influenza vaccine.
- There may be a very small increased risk of Guillain-Barré Syndrome (GBS) after inactivated influenza vaccine (the flu shot).

Young children who get the flu shot along with pneumococcal vaccine (PCV13), and/or DTaP vaccine at the same time might be slightly more likely to have a seizure caused by fever. Tell your health care provider if a child who is getting flu vaccine has ever had a seizure.

People sometimes faint after medical procedures, including vaccination. Tell your provider if you feel dizzy or have vision changes or ringing in the ears.

As with any medicine, there is a very remote chance of a vaccine causing a severe allergic reaction, other serious injury, or death.

5 What if there is a serious problem?

An allergic reaction could occur after the vaccinated person leaves the clinic. If you see signs of a severe allergic reaction (hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness), call **9-1-1** and get the person to the nearest hospital.

For other signs that concern you, call your health care provider.

Adverse reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your health care provider will usually file this report, or you can do it yourself. Visit the VAERS website at **www.vaers.hhs.gov** or call **1-800-822-7967**. VAERS is only for reporting reactions, and VAERS staff do not give medical advice.

6 The National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program (VICP) is a federal program that was created to compensate people who may have been injured by certain vaccines. Visit the VICP website at www.hrsa.gov/vaccinecompensation or call 1-800-338-2382 to learn about the program and about filing a claim. There is a time limit to file a claim for compensation.

7 How can I learn more?

- Ask your healthcare provider.
- 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 www.cdc.gov/flu

Vaccine Information Statement (Interim) Inactivated Influenza Vaccine



8/15/2019 | 42 U.S.C. § 300aa-26

DECLARACIÓN DE INFORMACIÓN SOBRE LA VACUNA

Vacuna contra la influenza (gripe) (inactivada o recombinante): Lo que necesita saber

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

Muchas de las hojas de información sobre vacunas están disponibles en español y otros idiomas. Consulte www.immunize.org/vis

1

2

¿Por qué es necesario vacunarse?

La **vacuna contra la influenza** puede prevenir la **influenza (gripe)**.

La **gripe** es una enfermedad contagiosa que se propaga por los Estados Unidos cada año, generalmente entre octubre y mayo. Cualquiera puede contraer la gripe, pero es más peligroso para algunas personas. Los bebés y niños pequeños, las personas de 65 años de edad y mayores, las mujeres embarazadas y las personas con ciertos padecimientos de salud o un sistema inmunitario debilitado tienen un mayor riesgo de sufrir complicaciones por la gripe.

La neumonía, la bronquitis, las infecciones sinusales y las infecciones del oído son ejemplos de complicaciones relacionadas con la gripe. Si tiene un padecimiento médico, como una enfermedad del corazón, cáncer o diabetes, la gripe puede empeorarlo.

La gripe puede causar fiebre y escalofríos, dolor de garganta, dolores musculares, fatiga, tos, dolor de cabeza y secreción nasal o congestión nasal. Algunas personas pueden tener vómito y diarrea, aunque esto es más frecuente en niños que en adultos.

Cada año, **miles de personas mueren por influenza en los Estados Unidos**, y muchas más son hospitalizadas. La vacuna contra la gripe previene millones de enfermedades y visitas al médico relacionadas con la gripe cada año.

Vacuna contra la influenza

Los Centros para el control y la prevención de enfermedades (Centers for Disease Control and Prevention, CDC) recomiendan que todas las personas de 6 meses de edad y mayores se vacunen cada temporada contra la gripe. **Niños de 6 meses a 8 años de edad** pueden necesitar 2 dosis durante una sola temporada de gripe. **Todos los demás** necesitan solo 1 dosis cada temporada de gripe.

La protección tarda aproximadamente 2 semanas en desarrollarse después de la vacunación.

Hay muchos virus de la gripe y siempre están cambiando. Cada año se fabrica una nueva vacuna contra la gripe para proteger contra tres o cuatro virus que probablemente causen enfermedades en la próxima temporada de gripe. Incluso cuando la vacuna no coincide exactamente con estos virus, aún puede brindar cierta protección.

La vacuna contra la influenza **no causa gripe**.

La vacuna contra la influenza puede aplicarse al mismo tiempo que otras vacunas.

3

Hable con su proveedor de atención médica

Informe a su proveedor de vacunas si la persona que va a recibir la vacuna:

- Ha tenido una reacción alérgica después de una dosis previa de la vacuna contra la influenza o si ha tenido cualquier alergia grave y potencialmente mortal.
- Alguna vez ha tenido el síndrome de Guillain-Barré (también llamado SGB).

En algunos casos, su proveedor de atención médica podría decidir que se posponga la vacunación contra la influenza para una visita futura.

Se puede vacunar a personas con enfermedades leves, como la gripe. Personas con enfermedades moderadas o graves usualmente deben esperar hasta recuperarse antes de recibir la vacuna contra la influenza.

Su proveedor de atención médica puede proporcionarle más información.



U.S. Department of Health and Human Services Centers for Disease Control and Prevention

Influenza, Inactivated or Recombinant VIS - Spanish (8/15/19)

Riesgos de una reacción a la vacuna

 Puede presentarse dolor, enrojecimiento e hinchazón donde se aplica la inyección, fiebre, dolores musculares y dolor de cabeza después de recibir la vacuna contra la influenza.

4

 Puede haber un aumento muy pequeño del riesgo de contraer el síndrome de Guillain-Barré (SGB) después de recibir la vacuna inactivada contra la influenza (la vacuna contra la gripe).

Los niños pequeños que reciben la vacuna contra la gripe junto con la vacuna antineumocócica (PCV13) y/o la vacuna DTaP al mismo tiempo pueden tener un poco más de probabilidades de tener una convulsión causada por la fiebre. Informe a su proveedor de atención médica si un niño que recibe la vacuna contra la influenza ha tenido convulsiones alguna vez.

En algunos casos, las personas se desmayan después de un procedimiento médico, incluida la vacunación. Informe a su proveedor de atención médica si se siente mareado o si tiene cambios en la visión o zumbido en los oídos.

Al igual que con cualquier medicina, hay probabilidades muy remotas de que una vacuna cause una reacción alérgica grave, otro daño grave o la muerte.

5 ¿Qué debo hacer si hay un problema grave?

Podría ocurrir una reacción alérgica después de que la persona deje la clínica. Si observa signos de una reacción alérgica grave (ronchas, hinchazón de la cara y garganta, dificultad para respirar, latidos rápidos, mareo o debilidad), llame al **9-1-1** y lleve a la persona al hospital más cercano.

Llame al proveedor de atención médica si hay otros signos que le preocupan.

Las reacciones adversas se deben reportar al Sistema de informes de eventos adversos derivados de vacunas (Vaccine Adverse Event Reporting System, VAERS). Es usual que el proveedor de atención médica informe sobre ello, o también puede hacerlo usted mismo. Visite el sitio web de VAERS en **www.vaers.hhs.gov** o llame al **1-800-822-7967**. *El VAERS es solo para informar sobre reacciones y el personal de VAERS no proporciona consejos médicos.*

6 Programa nacional de compensación por lesiones ocasionadas por vacunas

El Programa nacional de compensación por lesiones ocasionadas por vacunas (National Vaccine Injury Compensation Program, VICP) es un programa federal que se creó para compensar a las personas que podrían haber experimentado lesiones ocasionadas por ciertas vacunas. Visite el sitio web de VICP en **www.hrsa.gov/vaccinecompensation** o llame al **1-800-338-2382** para obtener información acerca del programa y de cómo presentar una reclamación. Hay un plazo límite para presentar una reclamación de compensación.

¿Dónde puedo obtener más información?

• Consulte a su proveedor de atención médica.

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- Llame a su departamento de salud local o estatal.
- Comuníquese con los Centros para el Control y la Prevención de Enfermedades (CDC):
 - Llame al 1-800-232-4636 (1-800-CDC-INFO) o
 - Visite el sitio web **www.cdc.gov/flu** de los CDC

Vaccine Information Statement (Interim)

42 U.S.C. § 300aa-26

Inactivated Influenza Vaccine Spanish

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