

Recommended Instructions for the Use of this Prenatal Tdap/Influenza Immunization Declination Form

The [Advisory Committee on Immunization Practices \(ACIP\)](#) recommends Tdap immunization at the earliest opportunity between 27-36 weeks gestation of every pregnancy (irrespective of Tdap history) and influenza immunization for all women who are, or will be, pregnant (regardless of trimester) during flu season. Studies show that your recommendation and offer of these immunizations positively impact your patients' decision to get vaccinated.¹ Despite a strong provider recommendation and offer, some patients will nonetheless decline to be immunized; this prenatal immunization declination template form was developed to help you reinforce the seriousness of your recommendation as well as the risks and potential consequences of not getting immunized during pregnancy. You are welcome to modify this tool to reflect the particular circumstances of a patient or medical practice. Please note that while this tool may help lower your risk of liability should your unimmunized patients or their infants develop influenza or pertussis, it does not ensure absolute protection from liability and should not substitute for legal advice from a qualified attorney.

See below for recommended instructions for use of this template form:

1. Make a strong recommendation and offer of flu and Tdap immunization during pregnancy. Use a statement rather than a question: "Now that you're in the third trimester, it's time to get a whooping cough vaccine to protect your baby." Visit CDC's Pregnancy and Immunization site for more information about making a strong recommendation: <http://bit.do/pregnancyandvaccination>. If you do not administer the immunizations on-site, please make a strong referral:
 - a. See CDC's piece on [Making a Strong Referral for Pregnant Women](#) for key steps and messaging.
 - b. Order FREE copies of the [pre-filled immunization RX-pad \(IMM-1143\)](#) from your local health department (<http://bit.do/immunization>).
 - c. Ask your office manager to contact health plans' member services (for each patient who needs an off-site referral) with the patient to identify specific locations where the patient can access the immunization.
 - a. For patients enrolled in Medi-Cal Managed Care, the member services number is located on the back of their Medi-Cal Benefits Identification Card.
 - b. For patients enrolled in Medi-Cal Fee-For-Service, call 1-800-541-5555 (or if calling from a cell phone with a non-California area code, call 916-636-1980).
2. Provide patients with the federally-mandated [Vaccine Information Statement](#) (VIS) for each immunization at each immunization visit.
3. Address patient concerns regarding recommended immunizations, and reassure them of the safety and benefits of the immunizations for both mom and baby.
4. Provide hesitant patients with the informational handout on the first page. You can also order [FREE patient educational materials](#) from your local health department (find the number at: <http://bit.do/immunization>).
5. If patient wishes to decline immunization, place a check mark next to the recommended and declined immunization(s) on a copy of the *Refusal to be Vaccinated* template form. Ask that they review and sign the *Refusal to be Vaccinated* template form. Stress that they can change their mind and accept immunization in the future.
6. Keep the template form in the patient's medical record, along with documentation of your discussion with the patient about the risks associated with not getting immunized.
7. Continue to encourage the patient to get immunized at subsequent visits. This template form is available for download on the California Academy of Family Physicians website at www.familydocs.org.

¹ Ding, Helen, et al. "Influenza vaccination coverage among pregnant women—United States, 2013–14 influenza season." *MMWR Morb Mortal Wkly Rep* 63.37 (2014): 816-21.

What shots are recommended during pregnancy?

- ✓ Flu shot as soon as possible and
- ✓ Tdap shot (immunization that protects against whooping cough, tetanus, and diphtheria) at the earliest opportunity between 27 and 36 weeks gestation of every pregnancy

Why should I get immunized during pregnancy?

- Your ability to fight off germs decreases when you are pregnant, making it easier to catch flu or whooping cough.
- Flu can lead to serious complications such as high fever, pneumonia, and even death for you and your baby.² Flu can also lead to pre-term birth, low birth weight, and stillbirth.³
- For babies, catching whooping cough can lead to trouble breathing (turning blue or gasping for air), pneumonia, hospitalization, and death.⁴
- Getting flu and whooping cough (Tdap) shots while you are pregnant can help protect you and your baby against these serious diseases. **The protection you get from these shots passes to your baby during pregnancy. This will help protect your baby until she/he is old enough to get immunized.**⁵

How safe are these immunizations during pregnancy?

- Millions of pregnant women have safely received flu and whooping cough immunizations.
- Multiple studies have shown that the shots do not affect the growth or development of your baby.^{6,7,8,8}
- Flu shots given to pregnant women are made from killed viruses, so it is impossible to get flu from the flu vaccine.⁹
- Similarly, Tdap shots do not contain any live bacteria and can't give you whooping cough.¹⁰ Also, it is safe to receive Tdap even if you have had a tetanus booster in the recent past.

How common are flu and whooping cough?

- During the last six flu seasons in California, there were at least 103 infants under six months of age and 39 pregnant women admitted to the ICU due to flu; ten infants and four pregnant women also died due to flu.¹¹
- In 2014, over 11,000 people were diagnosed with whooping cough in California, and 3 babies died.¹²

For more information, see www.cdc.gov/vaccines/pregnancy



Dylan's Story

Before Dylan was born, I was sick and had a bad cough. I coughed so hard that it caused contractions to start early. Dylan was born a healthy, beautiful baby. But I continued to cough, and it was hard to keep Dylan awake during feedings – the only sign of pertussis he ever had.

Two weeks later, my son Dylan died of pertussis that he caught from me. He was 17 days old. It is possible to prevent babies like Dylan from catching pertussis. Now I urge parents to vaccinate their children, and adults, especially pregnant women, to get a Tdap booster. I don't want to see any family suffer the way mine has.

—Mariah Bianchi

For more personal stories, go to shotbyspot.org

² Rasmussen S, et al. Am J Obstet Gynecol. 2012; 207(3Suppl): S3-8.

³ Creanga AA, et al. Obstet Gynecol. 2010; 115(4): 717-26.

⁴ Lloyd KL. J Midwifery Womens Health. 2013; 58(3): 288-96.

⁵ Maertens K, et al. Vaccine. 2014; 32: 1786-1792.

⁶ Munoz FM, et al. JAMA. 2014; 311(17): 1760-1769.

⁷ Nordin JD, et al. J Pediatr. 2014; in press.

⁸ Naleway AL, et al. Vaccine. 2014; 32: 3122-3127.

⁸ Donegan K. et al. BMJ. Published online 11 July 2014.

<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4094143/>.

⁹ CDC. 2014, May. www.cdc.gov/flu/about/ga/misconceptions.htm.

¹⁰ Munoz FM. Pediatr Ann. 2013; 42(8): 153-8.

¹¹ California Department of Public Health, Immunization Branch, unpublished data.

¹² California Department of Public Health. 2014, May.

<http://www.cdph.ca.gov/HealthInfo/discond/Pages/Pertussis.aspx>

Refusal to be Vaccinated Form

Patient's name: _____ Patient's medical record number: _____

Recommended vaccine	Declined
<input type="checkbox"/> Inactivated influenza vaccine	<input type="checkbox"/>
<input type="checkbox"/> Tetanus, diphtheria, and acellular pertussis (Tdap) vaccine	<input type="checkbox"/>

I received a copy of and had a chance to read each Vaccine Information Statement from the Centers for Disease Control and Prevention. This handout has information that explains the vaccine(s) and the disease(s) it prevents for each of the recommended vaccine(s) checked above.

I have had the chance to discuss the recommendation and my refusal with my doctor or nurse. My doctor or nurse has answered all of my questions about the recommended vaccine(s). A list of reasons for vaccinating, possible health consequences of non-vaccination, and possible side effects of each vaccine is available at http://bit.do/vis_cdc.

I understand the following:

- The purpose of and the need for the recommended vaccine(s).
- The risks and benefits of the recommended vaccine(s).

If I do **not** receive the vaccine(s), the consequences include an increased risk of:

- Getting the disease that the vaccine is designed to prevent.
- My newborn baby becoming very ill with the disease that the vaccine is designed to prevent. (During early life, babies rely on their mothers' prenatal immunizations for protection.)

My doctor, the California Academy of Family Physicians, the American College of Obstetrics and Gynecology, and the Centers for Disease Control and Prevention all strongly recommend that the vaccine(s) be given according to recommendations. Yet I have decided at this time to decline or defer the vaccine(s) recommended for me by checking the appropriate box under the column titled "Declined." I know that failure to follow the recommendations about vaccination may endanger my health or the life of my child.

I know that I may talk again with my doctor or nurse about these vaccines at any time and that I may change my mind and accept vaccination in the future. I acknowledge that I have read this entire document and fully understand it. I have had the opportunity to discuss my decision not to receive recommended vaccine(s) and still decline the vaccine(s).

Patient name (print): _____

Patient signature: _____ Date: _____

Witness name (print): _____

Witness signature: _____ Date: _____