

## Flu Vaccination & Possible Risk of Miscarriage Information & Guidance for Health Care Providers

*Health care providers of pregnant women play a vital role in advising patients on how to protect themselves and their developing babies against many threats, including influenza (flu). **This fact sheet contains information about influenza and influenza vaccination during pregnancy and provides guidance on how to address concerns that patients may have about influenza vaccination.***

**Background.** Influenza (flu) can be dangerous to pregnant women and their developing babies. A number of studies have shown that flu vaccination can protect pregnant women and their babies from flu. Because pregnant women are at high risk of serious flu complications, they are recommended for influenza vaccination during any trimester of their pregnancy. Millions of flu vaccines have been given for decades, including to pregnant women, with a good safety record. While there is a lot of evidence that flu vaccines can be given safely during pregnancy; these data are limited for the first trimester.

**A potential safety signal associated with flu vaccination of pregnant women.** A CDC-funded study found that women vaccinated early in pregnancy with a flu vaccine containing the pandemic H1N1 (H1N1pdm09) component and who also had been vaccinated the prior season with a H1N1pdm09-containing flu vaccine had an increased risk of spontaneous abortion (miscarriage) in the 28 days after vaccination. While most miscarriages occurred in the first trimester, several occurred during the second trimester. The median gestational age at the time of miscarriage was 7 weeks. This study does not quantify the risk of miscarriage and does not prove that flu vaccine was the cause of the miscarriage. [Earlier studies](#) have not found a link between flu vaccination and miscarriage. There is an ongoing investigation to study this issue further among women who were pregnant and eligible to receive flu vaccine during the 2012-13 through 2014-15 flu seasons. Results are anticipated in late 2018 or 2019.

**CDC Recommendation.** CDC and its Advisory Committee on Immunization Practices (ACIP) are aware of these data, which were first presented to ACIP at a public meeting in [June 2015](#). At this time, CDC and ACIP have not changed the recommendation for influenza vaccination of pregnant women. It is recommended that pregnant women get a flu vaccine during any trimester of their pregnancy because flu poses a danger to pregnant women and a flu vaccine can prevent influenza in pregnant women.

**CDC Guidance.** As always, health care decisions should be part of an ongoing discussion between provider and patient. CDC recommends that any pregnant woman who has questions about vaccines talk to her health care provider. Providers should use their clinical judgement based on various factors including their patient's health status, local influenza activity, and the benefits versus the potential risks from flu vaccination when deciding whether and/or when to immunize their patient against influenza.

**Study Title and Details** Article title: *Association of Spontaneous Abortion with Receipt of Inactivated Influenza Vaccine Containing H1N1pdm09 in 2010-11 and 2011-12.*

- This was a “case-control” study: women who had a miscarriage were compared with a control group of pregnant women who did not.
- Researchers compared 485 women aged 18-44 who miscarried (cases) to 485 pregnant women aged 18-44 who did not miscarry (controls) to determine if the women who had miscarriages were more or less likely to have received the 2010-11 or 2011-12 flu vaccine 1 to 28 days before their date of miscarriage.
  - Cases and controls both had pregnancies confirmed by the medical record. Cases had a miscarriage confirmed by medical record review.
  - Cases were compared with controls from the same age group (less than 30 years or 30 or more years), had nearly the same date of last menstrual period, and were enrolled in the same health care plan.

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- This study used vaccine safety data collected through the Vaccine Safety Datalink (VSD).
  - VSD is a collaboration between CDC's Immunization Safety Office (ISO) and several integrated healthcare organizations across the United States.
  - The VSD uses electronic health information from more than 9 million people, approximately 3% of the US population.
- The health information includes demographic characteristics, vaccinations, and medical outcomes.
- The study has some limitations. These include:
  - The study examined data from a small number of women in a subgroup who received H1N1-containing vaccines in consecutive years. The small numbers in the study could have led to imprecise results.
  - It is possible that women who have an increased risk for miscarriage might also be more likely to have received influenza vaccine. These conditions could have made the women more likely to miscarry.
  - Many miscarriages occur early in pregnancy and may not come to medical attention. The impact on the study findings of miscarriages that were not identified is unknown.
    - Flu vaccinations could have been incompletely recorded because some women could have received flu shots in another setting. The possible impact of unidentified vaccinations is unknown. However, this effect cannot account for the observed association if unidentified vaccinations occurred with similar frequency in cases and controls.
- This study was a case-control study that estimated an odds ratio of vaccination among women who had a miscarriage compared to those who did not. The study did not estimate risk of miscarriage after influenza vaccination. Therefore, the findings cannot be used to estimate the probability of miscarriages for pregnant women who received an H1N1-containing flu vaccinations two years in a row.
- Finally, it is not known how many women in the study were aware they were pregnant at the time of vaccination.

### **Earlier Studies that Support the Safety of Flu vaccination in Pregnant Women**

1. A review of reports to the Vaccine Adverse Reporting System (VAERS (<https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vaers/index.html>) (Moro et al, 2011) found no unusual or unexpected patterns of reporting for pregnancy complications or adverse fetal outcomes among pregnant women and flu shots.
2. A study using VSD (<https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vsd/index.html>) data (Irving et al, 2013) found no increased risk of miscarriage among pregnant women who received flu vaccines in the 2005-06 or 2006-07 flu seasons.
3. A large study using VSD (<https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vsd/index.html>) data (Kharbanda et al, 2013) found no increased risk for adverse obstetric events (like chorioamnionitis, pre-eclampsia, or gestational hypertension) for pregnant women who received the flu vaccine from 2002 to 2009 when compared to pregnant woman who were not vaccinated.
4. A VSD (<https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vsd/index.html>) study (Nordin et al, 2014) compared pregnant women who received the flu shot with an equal number of pregnant women who did not receive the flu shot during the 2004-05 and 2008-09 flu seasons. The study found no differences between the two groups in the rates of premature delivery or small for gestational age infants.

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5. A large August 2017 study using VSD data (<https://www.ncbi.nlm.nih.gov/pubmed/28550954>) found that the babies of women who received the flu shot during their first trimester had no increased risk of having children with major birth defects.