HEALTH ADVISORY

Public Health
Prevent. Promote. Protect.
REGION IV PUBLIC HEALTH
Clark, Cowlitz, Skamania, Wahkiakum counties and Cowlitz Tribe

TO: Physicians and other Healthcare Providers

Please distribute a copy of this information to each provider in your organization.

Questions regarding this information may be directed to the following Region IV health officers:

Alan Melnick, MD, MPH, CPH
Clark County Public Health, (360) 397-8412
Skamania County Community Health, (509) 427-3850

Jennifer Vines, MD, MPH
Cowlitz County Health & Human Services, (360) 414-5599
Wahkiakum County Health & Human Services, (360) 795-6207

Alert categories:
Health Alert: conveys the highest level of importance; warrants immediate action or attention. **Health Advisory:** provides important information for a specific incident or situation; may not require immediate action. **Health Update:** provides updated information regarding an incident or situation; no immediate action necessary.

HEALTH ADVISORY
Sept. 19, 2017

Recent Study Suggesting a Possible Risk of Miscarriage Related to Flu Vaccination: Information & Guidance for Health Care Providers

Public Health
Prevent. Promote. Protect.
Region IV Public Health
Clark, Cowlitz, Skamania, Wahkiakum counties and Cowlitz Tribe

Summary

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 advisory contains information about influenza and influenza vaccination during pregnancy and provides guidance on how to address concerns that patients may have after hearing or reading media stories about a recent study suggesting an association between influenza vaccination and miscarriage.**

Background

A CDC-funded study, first presented to ACIP at a public meeting in June 2015, found an increased risk of spontaneous abortion (miscarriage) after vaccination among pregnant women vaccinated early in pregnancy with the flu vaccine that included H1N1 (H1N1pdm09) component during both the 2010-11 and 2011-12 flu seasons.

The study, described below was done by reputable sources, but has some limitations related to study design. It indicates a correlation, but was not designed to quantify the risk of miscarriage from flu vaccination; investigate the actual causes of the miscarriages; or to eliminate other potential factors that might have had an influence. This study does not prove that flu vaccine was the cause of the miscarriage.

In addition, this study contradicts earlier studies that have not found a link between flu vaccination and miscarriage. While this study is inconsistent with previous studies, it is being taken seriously and ongoing research is being conducted in response to these findings. Including a study 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 ACIP continue to recommend influenza vaccination for pregnant women during any trimester of their pregnancy because flu poses a well-known danger to pregnant women. As always, health care decisions should be part of an ongoing discussion between providers and patients. 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.

Importance of Influenza in Pregnant Women

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, influenza vaccination is recommended 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.

Study 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 their medical record. Cases had a miscarriage confirmed by medical record review.
    - ➔ 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.
    - ➔ 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.
- 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.
- Study limitations include:
    - ➔ The study examined data from a small number of women in a subgroup who received H1N1-containing vaccines during the 2010-11 and 2011-12 flu seasons. The small numbers in the study could have led to imprecise results.
    - ➔ This 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 in two consecutive years.
    - ➔ 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.

➔ It is not known how many women in the study were aware they were pregnant at the time of vaccination.

Additional flu and pregnancy resources:

For more information and to review earlier studies that support the safety of flu vaccination in pregnant women, visit: https://www.cdc.gov/flu/professionals/vaccination/vaccination-possible-safety-signal.html.

- FAQ about Flu (Influenza) Vaccine and Pregnancy (from WA DOH)
- Pregnancy and Vaccination (from CDC)
- Vaccines & Pregnancy (from the American College of Nurse-Midwives)

Thank you for your partnership.

LHJ	Phone	Fax
Clark County Public Health:	(360) 397-8182	(360) 397-8080
Cowlitz County Health Department:	(360) 414-5599	(360) 425-7531
Skamania County Community Health:	(509) 427-3850	(509) 427-0188
Wahkiakum County Health and Human Services:	(360) 795-6207	(360) 795-6143