Ask the Experts: Questions Received by the Immunization Service Desk

“Our pregnant patients are concerned about getting the flu shot because of a new study that states the vaccine might cause miscarriages. What should I share with our patients about this study and their risk?”

For over thirteen years the CDC has been recommending that pregnant women be vaccinated at some point in their pregnancy with the influenza vaccine. The recommendation is based on concerns for influenza related complications that could lead to significant illness or hospitalizations to the Mom and/or baby after birth.

A new study1 funded by the CDC and published in the journal Vaccine by JG Donahue and colleagues is raising questions in the lay media about the safety of the influenza vaccine in pregnant women. The study was a case controlled study that compared women who had miscarried to those who did not to determine if there was a possible relationship to miscarriage and being vaccinated with the influenza vaccine. The study looked at data from the 2010-2011 and 2011-2012 influenza seasons. The trivalent inactive influenza vaccines during these seasons contained the H1N1pdm09 strain to provide protection from “swine flu” that had reached pandemic levels in the 2009 year, an A-H3N2 strain and B strain.

Study results found that the odds for women vaccinated early in pregnancy with the flu vaccine had increased odds of miscarriage [aOR 2.0 (95% CI, 1.1-3.6)]. Additional analysis found that women vaccinated in the prior season with the H1N1 pdm09 flu vaccine had an increased odds of miscarriage in the 28 days after vaccination [aOR 7.7 (95% CI, 2.2-27.3)].

The study finds an association but is not an 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 vaccines. The study was not designed to determine a biological cause for the miscarriage events. Follow-up studies are being conducted by the CDC to evaluate the risk for miscarriage with repeated influenza vaccinations during the 2012-2013, 2013-2014, and 2014-2015 influenza seasons.

What the pharmacist should know:

- ACIP continues to recommendations for influenza vaccination in pregnancy.
- Complications from influenza infection can be of greater harm to the pregnant woman than influenza vaccination.
- Data regarding odds or risk for miscarriage with the vaccines currently in use today is unknown; therefore it is not known if would see the same results with the vaccines we are using today.
- Like all medications, vaccines come with a risk for adverse events. Concerned patients should discuss her healthcare provider vaccine risk and benefit.
- Continue to encourage pregnant women to be vaccinated with influenza vaccines.