Reassuring Findings for Mothers Who Have Influenza Vaccine While Pregnant

Researchers from the UC San Diego School of Medicine and Boston University, in collaboration with the American Academy of Allergy Asthma and Immunology (AAAAI), have found evidence of the H1N1 influenza vaccine's safety during pregnancy. The national study, which was launched shortly after the H1N1 influenza outbreak of 2009, is summarized in two companion papers published online on September 19 in the journal, *Vaccine*.

"The overall results of the study were quite reassuring about the safety of the flu vaccine formulations that contained the pandemic H1N1 strain," said Christina Chambers, PhD, MPH, Director of the non-profit Organization of Teratology Information Specialists (OTIS) Research Center and lead investigator of UC San Diego's team. "We believe our study's results can help women and their doctors become better informed about the benefits and risks of flu vaccination during pregnancy."

Despite federal health authorities' recommendations that all pregnant women be vaccinated for influenza, it is estimated that less than 50 percent of women follow this advice, largely because they are concerned about the effects flu vaccines might have on the developing baby.

Since it was anticipated that the 2009 H1N1 influenza season would be severe, a national study was launched by the Vaccines and Medications in Pregnancy Surveillance System (VAMPSS), a collaboration between UC San Diego School of Medicine and Boston University and coordinated by AAAAI to gather data on the safety of this vaccine during pregnancy.

The team from UC San Diego followed 1,032 pregnant women across the United States and Canada who either chose to receive an influenza vaccine or were not vaccinated during one of the three seasons from 2009-2012. Women were recruited through MotherToBaby, a service of OTIS.

Chamber's team found that women vaccinated during pregnancy were no more likely to experience miscarriage, have a baby born with a birth defect or have a baby born smaller than normal compared with those who did not receive a vaccination. Although vaccinated women were more likely to have their babies before term, on average these infants were delivered three days earlier than those born to unvaccinated women.

The VAMPSS team from Boston University's Slone Epidemiology Center interviewed 4,191 mothers from four regional centers in the United States, who had either delivered a baby with one of 41 specific birth defects or delivered a normal infant. They compared the use of influenza vaccine in the two groups during the 2009-2011 seasons. The team also compared the risk of preterm delivery in vaccinated versus unvaccinated women. Overall, no significant evidence of an increased risk of any specific birth defects was noted. While the team did observe a slight increase in preterm delivery rates among pregnant women who received the H1N1 vaccine specifically during the 2009-2010 season, vaccinated women overall only delivered an average of two days earlier compared to the unvaccinated group. For those vaccinated during 2010-2011, the situation was reversed, and vaccinated women were less likely to deliver a preterm baby.
"We found no meaningful evidence of an increase in risk for many specific major birth defects if a woman received the flu shot early in pregnancy," said Carol Louik, ScD, lead investigator of the Boston University team. "A concern about the risk of specific birth defects was a critical question that has not been considered very much until now, and our data are reassuring."

The studies were funded by the U.S. Department of Health and Human Services Biomedical Advanced Research and Development Authority.

Additional contributors to the paper authored by UC San Diego included Diana Johnson, Ronghui Xu, Yunjun Luo, Allen A. Mitchell, Michael Schatz, Kenneth L. Jones and the OTIS Collaborative Research Group.

The VAMPSS system was established in 2010 under the umbrella of AAAAI, a professional practice group with a strong interest in prenatal exposures that might affect their asthma, allergy and immunology patients. VAMPSS fills a critical gap in evaluating the safety of vaccines and medications in pregnancy since most cannot be tested in pregnant women using clinical trials. To learn more about VAMPSS, please visit PregnancyStudies.org.

"Risks and Safety of Pandemic H1N1 Influenza Vaccine in Pregnancy: Birth Defects, Spontaneous Abortion, Preterm Delivery, and Small for Gestational Age Infants".
Doi: 10.1016/j.vaccine.2013.08.097 (pp. 5058-5064).

"Risks and Safety of Pandemic H1N1 Influenza Vaccine in Pregnancy: Exposure Prevalence, Preterm Delivery, and Specific Birth Defects".
Doi: 10.1016/j.vaccine.2013.08.096 (pp. 5065-5072).

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Tdap Vaccine During Pregnancy Provides Some Protection To Newborns.

DENTON, TX – As Texas state health officials issue an alert urging the public, including pregnant women, to receive the Tdap vaccine, MotherToBaby North TX, a free counseling service for expectant mothers at the University of North Texas, begins fielding questions from those concerned the vaccine could impact pregnancy.
The health alert comes after officials declare pertussis, otherwise known as "whooping cough," cases in Texas have reached epidemic levels on track to be the highest in 50 years. At least two infant deaths associated with the outbreak have been reported.

"Infants are the most at risk when it comes to pertussis," said Lori Wolfe, MS, CGC, MotherToBaby North TX program director. "However, receiving the vaccine during pregnancy could offer some protection to newborns too young to get the vaccine themselves," she added. Infants don't begin the Tdap vaccination series until two months of age.

In general, vaccines that cannot give a person the disease, like Tdap, are not considered contraindicated for pregnancy, according to Wolfe. Tdap is a combination vaccine against pertussis, diphtheria, and tetanus. The Texas Department of State Health Services recommends pregnant women get a dose of pertussis vaccine during every

pregnancy, preferably between 27 and 36 weeks of pregnancy.

Pertussis has not been established to cause pregnancy problems, although it is not well studied, says Wolfe. “What’s important to point out, however, is that severe disease does have a potential concern for pregnancy. Pertussis tends to be less severe in adults than children, but can still result in adult hospitalization,” she noted.

Some symptoms of whooping cough include runny nose and coughing, which can worsen to rapid fits of coughing that create a high-pitched whooping sound.

Wolfe points out that each pregnancy is different. She recommends women consult with their doctor before receiving the vaccine as well as receive an individualized risk assessment from an expert resource, like *MotherToBaby*. All Texans can be connected with an expert to receive free information regarding the risks associated with vaccines, medications and other exposures during pregnancy and breastfeeding through the toll-free counseling service (866) 626-6847 or online at MotherToBabyNorthTX.org.

MotherToBaby North TX is a one-stop-shop for evidence-based free counseling available to women, health care providers, and the general public. It is a service of the international non-profit Organization of Teratology Information Specialists (OTIS). OTIS and its information service, *MotherToBaby*, are suggested resources by many agencies including the Centers for Disease Control and Prevention (CDC).

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SKILLMAN, New Jersey – More than 200,000 bottles of concentrated MOTRIN® Infants’ Drops Original Berry Flavor 1/2 fl oz are being pulled off store and pharmacy shelves this week over fears they may contain plastic particles, according to the medicine’s manufacturer, McNeil Consumer Healthcare Division of McNEIL-PPC, Inc.

In a press release issued by the New Jersey-based division of Johnson & Johnson, the company says tiny plastic

particles approximately the size of a poppy seed were discovered in at least three lots, or shipments, of the product, including lot #DCB3T01, DDB4R01 and DDB4S01. So far, no illnesses or injuries have been reported as the result of consuming a contaminated dose.

The product's manufacturer recommends that all consumers stop using the medication and call the company for a refund at 1-877-414-7709. For more information, as well as a picture of the affected product, please visit the manufacturer's website by clicking here.

Reassuring Findings for Mothers Who Have Influenza Vaccine While Pregnant

Many women have questions about changing their diet and lifestyle in order to have a healthy baby. Often, the question "is it safe to drink during pregnancy or while breastfeeding?" comes up. For years, it has been recommended that women do not consume alcohol during pregnancy. However, some recent reports suggest occasional drinking is not harmful to a pregnancy. This information can be confusing and may leave you with more questions than answers.

Below are some of the common myths and facts about the use of alcohol during pregnancy and breastfeeding:

Myth – Drinking before finding out you are pregnant is safe.

Fact– Even though you may not realize you are pregnant, the baby is still growing and developing. Drinking at any time in pregnancy, even early on, might have some effects on the baby. It depends on several factors, including how much alcohol you were drinking, how often you drink, and if you continue to drink during pregnancy. It is always recommended for a pregnant woman to stop using alcohol, no matter how far along in her pregnancy she is. The baby will benefit by no longer being exposed to alcohol.

Myth – It's safe to drink a small amount of alcohol later in pregnancy.

Fact – There are different opinions about this, which can be confusing. Babies grow and develop throughout the entire pregnancy. Right now, there is not enough known about how alcohol can possibly affect a baby at different times

during pregnancy to be able to say that any time is safe for drinking alcohol. And, while drinking more alcohol puts the baby at greater risk for problems related to fetal alcohol syndrome, drinking less alcohol does not mean there is no risk. Because there is no amount of alcohol that has been proven to be safe in pregnancy, it is recommended that women do not drink at any time in their pregnancy.

Myth – Certain kinds of alcohol are safe to drink during pregnancy.

Fact – The same amount of alcohol is found in a standard serving of beer, wine, or hard liquor. A standard serving is considered to be 12 ounces of beer, 4-5 ounces of wine, or 1.5 ounces of hard liquor. Because there is no amount of alcohol that has been proven to be safe in pregnancy, it is recommended that women do not drink any alcoholic beverages at any time in their pregnancy.

Myth – Drinking alcohol will help increase milk production.

Fact – It used to be believed that beer raised levels of prolactin, a hormone in the body that plays a role in making breast milk. However, it is now known that alcohol lowers the release of another hormone called oxytocin. Lower oxytocin levels can affect the amount of milk that is released from the breast, meaning a baby may actually get less milk.

Myth – "Pumping and dumping" will get the alcohol out of breast milk.

Fact – Even if you dump milk after drinking, alcohol still remains in your blood for a period of time, depending how much you had to drink. Alcohol in the blood can still be passed into your milk. The only way to get rid of alcohol from your system is to wait for your body to break it down and get rid of it. It takes about 2 to 2.5 hours for each standard drink to clear from breast milk. For each additional drink, a woman must wait another 2-2.5 hours per drink. Pumping and dumping, drinking water, taking caffeine, or exercising, do not help your body get rid of the alcohol faster.

There are many factors that can play a role in how alcohol can possibly affect a developing baby. Differences in genetics and metabolism of alcohol by both the mother and the developing baby may result in a wide range of risk. The risk may be different even in the same mother in different pregnancies. The good news is you can avoid the possible effects of alcohol on a developing baby by choosing not to drink during pregnancy or breastfeeding.

If you are concerned about your drinking or think you cannot stop, talk to your healthcare provider for more information on treatment and counseling for alcohol dependency.

Click here to read more about alcohol's effects during pregnancy and breastfeeding in our fact sheet.

By: Chris Colón, MS, LCGC.