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).

Questions? Call 866.626.6847 | Text 855.999.3525 | Email or Chat at MotherToBaby.org.

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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).

Media Contact: Lori Wolfe, 940-565-3892, lwolfe@unt.edu. Interviews in Spanish can also be arranged.

Questions? Call 866.626.6847 | Text 855.999.3525 | Email or Chat at MotherToBaby.org.

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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.

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