

# 'Reassuring' findings released in national study of influenza vaccine safety in pregnancy

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Researchers from Boston University's Slone Epidemiology Center and UC San Diego, in collaboration with the American Academy of Allergy Asthma and Immunology (AAAAI), have found 'reassuring' evidence of the H1N1 influenza vaccine's safety during pregnancy. The national study, which was launched shortly after the pandemic H1N1 influenza outbreak of 2009 and funded by the U.S. Department of Health and Human Services Biomedical Advanced Research and Development Authority (BARDA), will be summarized in two companion papers published online this month in the journal, *Vaccine*.

Despite [federal health authorities'](#) recommendations that all pregnant [women](#) be vaccinated for influenza in order to avoid serious complications of flu infection, it is estimated that fewer than 50 percent of women follow this advice, largely because they were concerned about the effects flu vaccines might have on the developing baby. Since it was anticipated that the 2009 pandemic H1N1 [influenza outbreak](#) could be particularly severe, it was important to gather data on the safety of this vaccine in pregnancy. Therefore, a national study was launched by the Vaccines and Medications in Pregnancy Surveillance System (VAMPSS), a collaboration between investigative teams at Boston University and UC San Diego, and coordinated by the American Academy of Allergy, Asthma and Immunology.

One investigative team, from Boston University, interviewed 4,191

mothers from four regional centers in the U.S. who had either delivered a baby with one of 41 specific [birth defects](#) or delivered an infant without defects. They compared the use of influenza vaccine in the two groups during the 2009 - 2011 seasons. In their analysis of birth defects, Dr. Carol Louik, ScD, lead investigator of the BU team, stated "We found no evidence of an increase in risk for the most commonly-occurring specific major birth defects, which were the focus of the study, if a woman received the [flu shot](#) in pregnancy. Concerns 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 team also compared the risk of preterm delivery in vaccinated versus unvaccinated women. 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 the 2010 - 2011 season, the situation was reversed, and vaccinated women were less likely to deliver a preterm baby.

The other VAMPSS research team from UC San Diego followed 1,032 [pregnant women](#) across the U.S. 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 the non-profit Organization of Teratology Information Specialists (OTIS) that provides counseling to the public about pregnancy and breastfeeding exposures. Researchers 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. In addition, those who were vaccinated delivered infants three days earlier than unvaccinated women.

"The overall results of the study were quite reassuring about the safety of the [flu vaccine](#) formulations that contained the pandemic H1N1 strain given in these three seasons," said Christina Chambers, PhD, 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 vaccination during [pregnancy](#)."

**More information:** "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)

Provided by Boston University Medical Center

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