UC San Diego Researchers Help Create New System to Improve Safe Use of Medicines and Vaccines by Pregnant Women

March 2, 2010

Kim Edwards

Tracking the effects of drugs on pregnant women has long been a difficult and nearly impossible task for researchers, until now. Researchers in the Department of Pediatrics at University of California, San Diego School of Medicine along with Boston University and The American Academy of Allergy, Asthma & Immunology (AAAAI) have created a new system to provide information to pregnant women and their doctors about using medications and vaccines safely in pregnancy.

The Vaccines and Medications in Pregnancy Surveillance System (VAMPSS) will collect data from women who are pregnant or have recently completed their pregnancies in order to provide information on issues that could be of concern to women and their babies.

"Many women are reluctant to use any medications or receive vaccines during pregnancy out of fear about possible harms to their unborn child," explained principal investigator, Christina D. Chambers, PhD, MPH, associate professor of Pediatrics and Family and Preventive Medicine at UCSD School of Medicine. "But many medical conditions, such as asthma and influenza, particularly if left untreated, can harm both the mother and her baby. So it is important to capture the experiences from women who use medications or vaccines during their pregnancy."

VAMPSS takes advantage of two different, well-established surveillance systems. Both have proven records in determining the safety to the mother and her offspring of the wide range of prescription drugs, over the counter drugs, herbal products and vaccines.

"The combined efforts of UC San Diego and our colleagues at Boston University give us a top-down, bottom-up view of this perplexing situation. Together, we create a much more powerful way to systematically evaluate risk and/or demonstrate the safety of a medication or vaccine in pregnancy," said Chambers.

A major strength of the VAMPSS system is that it obtains comprehensive information on various medicine and vaccine exposures from women who are pregnant or who have recently delivered, including those exposures that are unlikely to be included in the woman's medical record. Mothers are asked about all medicines taken, regardless of whether they were prescribed, purchased over-the-counter, on the internet or borrowed from others.

Women are also asked about all vaccines they may have received, including those given in non-traditional settings such as health fairs or at the supermarket. The research by OTIS and SEC relies on women and their doctors to participate in this new system in order to improve their pregnancies and those of other women.

The initial focus of VAMPSS will be on the respiratory health of pregnant women, including asthma medications, seasonal and H1N1 influenza vaccines, and antiviral medications used to prevent and treat influenza. Although there is no evidence to suggest that influenza vaccines pose any harm to pregnant women or their offspring, the newer and more comprehensive data provided by VAMPSS will improve understanding of the safety of these and other medicines and vaccines that are taken in pregnancy.

Using complementary approaches, VAMPSS evaluates risk or safety of pregnancy exposures with respect to spontaneous abortions, preeclampsia, fetal deaths, preterm births, intrauterine growth restriction, total major congenital malformations and specific major malformations. In addition, the case-control component of VAMPSS provides exposure prevalence data drawn from a population-based sample.

Along with UCSD researchers and coordination by the AAAAI, the VAMPSS team includes researchers from the Organization of Teratology Information Specialists (OTIS), and the Slone Epidemiology Center (SEC) at Boston University. The federal agencies that cooperated to make this initiative possible include: the Agency for Health Care Research and Quality (AHRQ); the U.S. Office of Biomedical Advanced Research and Development Authority (BARDA); the Centers for Disease Control and Prevention (CDC); the Food and Drug Administration (FDA); and the National Institutes of Health (NIH).

Women are encouraged to enroll in the study so they and their infants can be followed through pregnancy and the post-partum period. Pregnant women who have taken asthma medications and/or have received the seasonal influenza vaccine, the H1N1 vaccine or any antiviral medications to prevent or treat the flu can contact OTIS at (877) 311-8972 for more information.

Media Contact: Kim Edwards 619-543-6163 kedwards@ucsd.edu