

1048. Pregnancy Registry for Varicella-Zoster Virus-Containing Vaccines: 18-Year Summary of Pregnancy Outcomes

English Willis, MD¹; Ann Marko, BSN, RN¹; Mona Marin, MD²; Sonja Rasmussen, MD³; Stephanie R. Bialek, MD, MPH²; Ann Redfield, MSN, RN¹; Maureen Mcgee, BSN, RN¹; Adrian Dana, MD¹; ¹Clinical Safety and Risk Management, Merck Research Laboratories, Merck and Co., Inc., North Wales, PA; ²Division of Viral Diseases, Centers for Disease Control and Prevention, Atlanta, GA; ³Influenza Division, Centers for Disease Control and Prevention, Atlanta, GA

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Background. VARIVAX[®], ProQuad[®] and ZOSTAVAX[®] contain live attenuated varicella zoster virus (VZV) and are contraindicated during pregnancy. Merck and Co., Inc. and the Centers for Disease Control and Prevention collaboratively established a pregnancy registry for VZV-containing vaccines to monitor congenital varicella syndrome (CVS) and other birth defects in offspring of women inadvertently exposed to these vaccines during pregnancy. A summary of 18 years of registry data is presented.

Methods. Health-care providers from the United States, Puerto Rico, and Canada voluntarily report administration of VZV-containing vaccines to women within 3 months before or during pregnancy. Follow-up is conducted to obtain pregnancy outcomes. Reports are classified by timing of registry notification (before vs after

pregnancy outcome is known), VZV serostatus at vaccination, and timing of exposure in relation to gestational age. The theoretical risk for CVS is defined as "high" if vaccination occurred during the 1st or 2nd trimester. Prospective reports (received before the outcome of pregnancy was known) are used for rate calculations. Metropolitan Atlanta Congenital Defects Program methodology is used to define birth defects and calculate rates.

Results. From March 17, 1995 through March 16, 2013, 893 prospective reports with outcomes available for analysis were received. Most exposures (n = 886) were to VARIVAX. No features consistent with CVS were identified among all 810 live births in the registry or among those of varicella-susceptible women exposed during the high risk period (n= 95, rate = 0%, 95% confidence interval [CI] 0.0, 3.8). Major birth defects were reported in 18 offspring of women with pregnancy outcomes ≥ 20 weeks gestation resulting in a birth prevalence of 2.1 per 100 liveborn infants (95% CI 1.2, 3.4), similar to the prevalence in the general population. No specific pattern or clustering by type of defect was identified.

Conclusion. We observed no cases of CVS and no increased prevalence for other birth defects after exposure to VZV-containing vaccines during pregnancy. However, the number of exposures is insufficient to exclude a very low risk of CVS in varicella-susceptible women exposed during the high risk period. VZV-containing vaccines remain contraindicated for pregnant women.

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