

Assessing the Teratogenic Potential of Antiretroviral Drugs: Data from the Antiretroviral Pregnancy Registry (APR)

P.M. GARCIA*¹, D.H. WATTS², H.E. FOX³, R. SAMELSON⁴, E. RODRIGUEZ⁵, C. SCHWAMLEIN⁶, and J. ELDER⁷ for the APR. ¹Northwestern Univ. Med. Sch., Chicago, IL., ²NIH /NICHHD, Bethesda, MD., ³Johns Hopkins Med., Baltimore, MD., ⁴Albany Med. Coll., Albany, NY., ⁵FDA, Bethesda, MD., ⁶Abbott Labs., Chicago, IL. and ⁷PharmaResearch Corp., Wilmington, NC.

Objective: To detect any increased rate or pattern of birth defects from exposure to antiretroviral drugs used in pregnancy.

Methods: A registry was established in 1989 of pregnancies exposed to antiretroviral agents prospectively reported by health care providers. Timing of exposure and dosage is obtained. Immediate newborn outcome data are solicited at the time of delivery. Birth defects risks are compared with data from the CDC's population-based birth defects surveillance system.

Results: As of July 1999, 916 evaluable, prospective cases have been reported. The prevalence of birth defects among **first** trimester exposures is 2.0/100 live births (7 defects / 343 LB, 95%CI = 0.9%, 4.3%) for **any** antiretroviral drug. The greatest number of first trimester exposures has been reported for zidovudine monotherapy, and there was one defect among these 111 live births (0.9%, 95% CI 0%, 5.6%). This prevalence does not significantly differ from those diagnosed within the first day of life by the CDC surveillance program (2.17%, 95% CI 2.10%, 2.23%). No consistent or unique pattern of defects was seen.

Conclusion: To date, registry data demonstrate no increase in the prevalence of birth defects among first trimester zidovudine monotherapy exposures, although the power to detect such an increase is limited. Accumulated cases of exposures to other antiretroviral agents are, as yet, insufficient to make reliable assessments of fetal risk. Prospective reports of antiretroviral exposures are critically important to determine their teratogenic potential and can be made by calling (800) 258-4263.

Presented at the 7th Conference on Retroviruses and Opportunistic Infections, January 2000.