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Anti-HIV drug use during pregnancy does not affect infant size, birth weight

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Infants born to women who used the anti-HIV drug tenofovir as part of an anti-HIV drug regimen during pregnancy do not weigh less at birth and are not of shorter length than infants born to women who used anti-HIV drug regimens that do not include tenofovir during pregnancy, according to findings from a National Institutes of Health network study. However, at 1 year of age, children born to the tenofovir-treated mothers were slightly shorter and had slightly smaller head circumference—about 1 centimeter each, on average—than were infants whose mothers did not take tenofovir.

The study authors described the findings as reassuring, noting that the study did not identify any serious safety concerns during pregnancy for tenofovir. In combination with other anti-HIV drugs, tenofovir is the first line of treatment for adults with HIV. The researchers called for additional studies to follow the children as they grow and develop, to identify any potential long term effects of the treatment.

The study was undertaken because earlier studies had shown laboratory animals exposed to tenofovir in the womb were smaller at birth than were their unexposed peers.

Because of its safety and effectiveness, many women who have HIV take the drug for their health, often before they become pregnant. Similarly, because the drug is so effective for adult use and because there have been no problems reported in human infants related to their mother's use of tenofovir, many physicians will prescribe it for pregnant

women, both to safeguard the women's health and to prevent the virus from being passed on to their infants. However, before the current research, the drug had not been specifically studied for its potential effects on infants whose mothers took it during pregnancy.

"Physicians treating pregnant women for HIV face a dilemma: do they continue treating a pregnant woman with a drug that is highly effective for adults but which has not been studied for its effects on infants, or do they switch the woman to another therapy, which may not be as effective and well-tolerated?" said first author George K. Siberry, M.D., of the Pediatric, Adolescent and Maternal AIDS Branch of the NIH's Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), the NIH institute that conducted the study. "Our findings indicate that tenofovir does not affect the growth of the fetus."

Over the seven years of the study, the number of participants being treated with tenofovir increased sharply, the study authors noted. In 2003, 14 percent of mothers in the study had been prescribed the drug, compared with 43 percent in 2010.

"The priority has been to treat mothers and prevent an infant's infection," said co-author Paige L. Williams, Ph.D., of the Harvard School of Public Health, Boston. "However, it's important to monitor the effects of these drugs on the infant."

The research was conducted as part of the Pediatric HIV/AIDS Cohort Study (PHACS), which is supported by the NICHD, the National Institute of Allergy and Infectious Diseases, the National Institute on Drug Abuse, the National Institute of Mental Health, the National Institute on Deafness and other Communication Disorders, the National Heart, Lung, and Blood Institute, the National Institute of Neurological Disorders and Stroke, and the National Institute on Alcohol Abuse and Alcoholism.

Dr. Siberry and Dr. Williams collaborated with colleagues at the State University of New York Downstate, Brooklyn; University of Miami School of Medicine; Indiana University School of Medicine, Indianapolis; Harvard; and the NICHD.

Their findings appear online in the journal *AIDS*.

The study included 2,000 U.S. infants born to HIV-positive mothers between 2003 and 2010. The researchers collected data for the infants' size relative to their gestational age (time they had spent in the womb), their birth weight, length at birth, and the circumference of their head. The researchers recorded similar measurements when the child was 1 year old.

They found that mothers taking tenofovir in combination with other anti-HIV medications and mothers on anti-HIV drug combinations that did not include tenofovir gave birth to infants who were smaller, on average, than infants born to HIV-negative mothers. However, they did not find significant differences between infants from the two groups of HIV-positive mothers.

The tenofovir-exposed infant's smaller average size and head circumference at one year of age suggests tenofovir could have a delayed effect on growth. Further research on this and other classes of anti-HIV drugs is ongoing in the PHACS.

"Overall, this study produced reassuring information regarding the use of tenofovir," said Dr. Siberry. "Although further research is needed, on balance, our findings favor the use of tenofovir in pregnancy to ensure good outcomes in the mother and prevent transmission of HIV to the infant."

More information: