

## **PHACS SMARTT PARTICIPANT SUMMARY**

**Title:** Safety of Tenofovir Use During Pregnancy: Associations with Low Birth Weight and Early Growth in HIV-Exposed Uninfected Infants

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**Study Description:** Tenofovir (Viread, or TDF) is a medicine used by many adults with HIV infection. TDF is also used more and more by pregnant women, so that their babies won't get HIV or to treat their own HIV. Because so many pregnant women with HIV are beginning to use TDF, we want to make sure it is safe for their babies. Studies in animals show TDF may affect how babies grow. We conducted this study to see if growth differed between babies whose mothers took TDF and those whose mothers did not.

**Study Population:** We used data from babies who joined the SMARTT study through February 2010. We looked at how much 1855 babies weighed when they were born. Our study focused on babies born at low weight (less than 2.5kg, or about 5 ½ lbs). We also looked at body size for 470 babies when they were one year old.

**Results:** Overall, 20% of mothers in our study used TDF when pregnant. 15% used TDF in 2003 compared to 38% in 2009. The percent of babies with low birth weight did not differ between mothers who used TDF and mothers who did not (21 vs. 20%). Even after we took into account other factors, like mother's cigarette smoking, there was no difference in low birth weight. However, at age 1, babies whose mothers used TDF when pregnant were more likely to be shorter and to weigh less. Babies whose mothers used TDF early in pregnancy were also more likely to have small head size at one year of age.

**Conclusions:** Over time, we found that more and more mothers of SMARTT babies used TDF when pregnant. There was no relationship between TDF and low birth weight. However, babies whose mothers took TDF while pregnant tended to be smaller on average when they were one year old. More studies are needed to look at this possible effect of TDF on growth in the first year.

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