

PHACS SMARTT Protocol  
Participant Summary

**Title:** Safety of Perinatal Exposure to Antiretroviral Medications: Developmental Outcomes in Infants

**Authors:** Patricia A. Sirois, PhD, Yanling Huo, MS, Paige L. Williams, PhD, Kathleen Malee, PhD, Patricia A. Garvie, PhD, Betsy Kammerer, PhD, Kenneth Rich, MD, Russell B. Van Dyke, MD, and Molly L. Nozyce, PhD, for the Pediatric HIV/AIDS Cohort Study (PHACS)

**Study Description:** Many children are born to mothers who have HIV, but the children do not get the virus. This is because the mothers can take medicine before the babies are born, and the babies can take medicine in their first weeks of life. This study checked on the safety of HIV medicines on the babies' development. The babies took a test when they were about one year old. The test measured how well they were doing in five areas: problem-solving, language, movement, social and emotional health, and everyday behavior. We looked at the test scores for babies whose mothers took HIV medicines while they were pregnant and for babies whose mothers did not take those medicines.

**Study Population:** By May 2010, there were 374 babies who took the test and had information about the HIV medicines their mothers had taken. Almost half the babies were boys, 79% were black, and 16% were Hispanic. Almost 25% were born prematurely, and 8% were small at birth. Most of the babies were exposed to more than one kind of HIV medicine before they were born.

**Results:** For the most part, the babies were right where they should be for their age. We did not find large differences in test scores for babies whose mothers took certain kinds of HIV medicines compared to babies whose mothers did not. A few individual medicines were connected to lower scores on some parts of the test, and a few were connected to higher scores. Some things about the mother or baby were also connected to lower or higher scores on some parts of the test.

**Conclusions:** In this study, most babies whose mothers took HIV medicines to keep them from getting the virus did not have lower scores on a test of infant development. The results suggest that HIV medicines taken during pregnancy are not harmful for a baby's development. It will be important to make sure that new medicines that come out are safe. Also, the meaning of small differences in the babies' test scores may become clearer as the babies get older. We also need to take into account other things, like prematurity and birth weight, when we think about the effects of early exposure to HIV medicines.

**Support:** This study was supported by NICHD with co-funding from NHLBI, NIAID, NIDA, NIMH, and NIDCD.