



Dear Colleagues:

The IMPAACT network leadership is pleased to report a number of important updates from the Breastfeeding, Formula Feeding and HAART Standard Versions of the PROMISE study. Initiated in 2010, these studies were designed to answer some of the most important global public health questions related to prevention of mother-to-child transmission of HIV (PMTCT) and maternal and infant health.

As of the end of October 2014, 3747 mother-infant pairs had been enrolled in the breastfeeding and formula feeding versions of the PROMISE study in India, Malawi, South Africa, Tanzania, Zambia, and Zimbabwe, and 1633 women had been enrolled in the HAART standard version in Argentina, Botswana, Brazil, China, Haiti, Peru, Thailand, and the United States. All versions of the PROMISE study enroll HIV-infected women with high CD4+ cell counts who do not meet clinical criteria for initiating antiretroviral therapy (ART) for their own health. Any women who meet clinical or immunologic criteria to initiate ART after having enrolled in the study are provided ART regardless of their prior random assignments for the study.

Since their initiation, the PROMISE studies have been overseen by an independent Data and Safety Monitoring Board (DSMB). At the most recent DSMB review, on 4 November 2014, the DSMB determined that data collected in the Antepartum Component of the breastfeeding and formula feeding versions of the study were sufficient to answer the primary study question regarding the efficacy of maternal prophylaxis regimens for PMTCT during pregnancy, intrapartum, and through two weeks postpartum. As such, the DSMB also recommended that the primary outcomes of the Antepartum Component be publicly released. As highlighted in the press release (<http://www.nih.gov/news/health/nov2014/niaid-17.htm>), the overall risk of MTCT among study participants was low, and the triple antiretroviral (ARV) regimens evaluated in the study were superior to the single ARV based regimen for PMTCT. The Antepartum Component also provided insights into the safety of the ARV regimens for mothers and infants, which the study team is continuing to explore.

We would like to take this opportunity to commend and thank the PROMISE study sites, as well as the many thousands of study participants, for their dedication and commitment, without which the achievements of the PROMISE study thus far would not have been possible.

Importantly, the Postpartum and Maternal Health components of the breastfeeding and formula feeding versions of the PROMISE study are continuing, in order to determine the optimal ARV regimen for PMTCT during breastfeeding and to determine whether maternal health is better served by stopping or continuing use of a triple ARV regimen after the period of risk for MTCT. **Follow-up in these components is expected to be completed in April 2017.**

The HAART standard version of the PROMISE study, which will also address the question of whether maternal health is better served by stopping or continuing use of a triple ARV regimen after the period of risk for MTCT, is also continuing. **Accrual into this study will close at the end of November 2014, with follow-up expected to be completed in August 2016.**

We look forward to the continued progress of the PROMISE studies and the important data they will provide in support of the health and wellbeing of women and children worldwide.

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