

Title: Birth outcomes and HIV-free survival with Option B+ in Lesotho: Results from an observational prospective cohort study

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Background: Combination antiretroviral therapy (cART) reduces mother-to-child transmission of HIV and improves maternal health. Since introduction of option B+, there are scant data on birth outcomes of HIV-exposed compared to unexposed infants. We assessed birth outcomes and six-week HIV free survival among HIV-exposed infants (HEI) and HIV-unexposed infants (HUI).

Methods: 941 HIV-negative and 653 HIV-positive pregnant women were enrolled in an observational cohort to evaluate effectiveness of universal maternal cART (Option B+) rolled out within routine programs in 13 health facilities in Lesotho. Birth outcomes included infant birth weight (IBW), maturity, congenital anomalies, and mortality. Infant HIV birth testing by DNA PCR within two weeks of birth was introduced at study sites alongside routine six-week testing. Data were analysed to determine birth outcomes, HIV transmission, and HIV-free survival rates at six weeks.

Results: HIV-positive women were older, 28.7 vs. 24.4 years ($p < 0.001$) and presented for antenatal care earlier at 23 weeks vs. 25.3 weeks gestation ($p < 0.001$). Mean IBWs were similar: 3.0 kgs for HEIs vs 3.1 kgs for HUI. HEI were more likely to be premature, 8.3% vs. 4.0% ($p = 0.001$). Neither Age (median age: 26 vs 25) nor parity (median: 1 vs 1) was associated with prematurity. No differences in stillbirths or congenital anomalies were noted. Six infants were HIV-infected by six weeks: cumulative HIV transmission was 0.9% (N=4) at birth (95%CI: 0.25%-2.36%) and 1.03% (N=6) (95%CI: 0.38%-2.23%) by six weeks. Infant mortality was 4.4% and 4.3% for HUI and HEI respectively ($p = 0.93$). The estimated six-week HIV free survival was 91.5% [95%CI: 89.1% - 93.6%] for HEI. Survival for HUI was 94.1% [95% CI: 92.4% - 95.6%]. Excluding stillbirths, six-week HIV free survival for HEI was 95.2% [95% CI: 93.2% - 96.8%] compared to survival rate of 97.5% [95% CI: 96.2% - 98.4%] among HUI ($p = 0.02$).

Conclusions: A low HIV transmission rate by six weeks was found among mother-infant pairs enrolled in a universal cART prevention of mother-to-child transmission program, though there were higher rates of prematurity; six-week survival among HIV-exposed infants was comparable to HIV-unexposed infants. It will be important to explore if this trend continues at 12 months and 24 months.