

History of heart defect	1	<0.5%	-	-	2	1%	-	-	-	-
Mother died	1	<0.5%	1	1%	-	%	-	-	-	-
Missed more than 7 days triple antiretroviral therapy	-	-	-	-	32	9%	27	9%	3	5%
Unwilling to participate	-	-	-	-	29	8%	45	15%	13	21%
Social/other circumstances	-	-	-	-	15	4%	12	4%	-	-
Serious illness/hospitalization	-	-	-	-	9	2%	2	1%	2	3%
Receipt TB treatment within 30 days	-	-	-	-	2	1%	3	1%	2	3%
More than 42 days after infant	-	-	-	-	1	<0.5%	-	-	-	-

confirmed HIV+										
More than 42 days after last breastfeeding	-	-	-	-	-	-	43	15%	-	-
History of WHO stage IV disease	-	-	-	-	-	-	2	1%	-	-
Prohibited medications prior to enrollment	-	-	-	-	-	-	1	<0.5%	-	-
Both Mother and Infant reasons	690	61%	38	32%	-	-	-	-	-	-
Other reason not enrolled	300	27%	26	22%	182	49%	94	32%	19	31%
Missed time line (excluding no test result)	185	16%	3	3%		%	-	-	-	-

Test result not available	85	8%	5	4%	5	1%	4	1%	3	5%
Subject did not return	55	5%	2	2%	33	9%	23	8%	8	13%
Lab values out of range	39	4%	2	2%	10	3%	-	-	4	7%
Not enrolled and no reason given	14	1%	-	-	-	-	-	-	-	-
Not willing, gave reason	12	1%	-	-	-	-	-	-	-	-
Infant reasons	222	20%	11	9%	-	-	-	-	-	-
Infant not alive	102	9%	1	1%	-	-	-	-	-	-
Birth weight <2 kg	76	7%		%	-	-	-	-	-	-
Positive HIV test result	32	3%	10	8%	-	-	-	-	-	-
Life threatening illness	12	1%		%	-	-	-	-	-	-

Supplemental Table 2: Brief outline of the primary results of the PROMISE study

	Results
Antepartum Component	<ul style="list-style-type: none"> • The rate of transmission was significantly lower with antiretroviral therapy than with zidovudine alone • The rate of maternal moderate, severe, or life-threatening adverse events was significantly higher with zidovudine-based antiretroviral therapy than with zidovudine alone • The rate of moderate, severe, or life-threatening abnormal blood chemical values was higher with tenofovir-based antiretroviral therapy than with zidovudine alone • A birth weight of less than 2500 g was more frequent with zidovudine-based antiretroviral therapy than with zidovudine alone and was more frequent with tenofovir-based antiretroviral therapy than with zidovudine alone • Preterm delivery before 37 weeks was more frequent with zidovudine-based antiretroviral therapy than with zidovudine alone • Tenofovir-based antiretroviral therapy was associated with higher rates of very preterm delivery before 34 weeks and early infant death than zidovudine-based antiretroviral therapy • The rate of HIV-free survival through day 14 was highest among infants whose mothers received zidovudine-based antiretroviral therapy

Postpartum Component	Both prolonged infant antiretroviral prophylaxis (infant nevirapine) and maternal antiretroviral therapy strategies were safe and associated with very low breastfeeding HIV-1 transmission and high infant HIV-1-free survival at 24 months
Maternal Health Component	<ul style="list-style-type: none"> • After a median follow-up of 1.6 years, progression to AIDS-defining illness or death was rare and there was no significant difference between arms • HIV disease progression (WHO Stage 2/3 events) was reduced with continued antiretroviral therapy • Moderate, severe, or life-threatening adverse events were rare in both arms

Footnote to Supplemental Table 2

The PROMISE study provided evidence in support of continuing triple antiretroviral therapy for all HIV-infected women pregnant women for life (Option B+) recommended by WHO during the 2013 WHO Programming update. Important advantages of triple antiretroviral therapy for life include further simplification of regimen and service delivery and harmonization with antiretroviral therapy programs, protection against mother-to-child transmission in future pregnancies, a continuing prevention benefit against sexual transmission to serodiscordant partners and avoiding stopping and starting of antiretroviral drugs.

For additional results of the PROMISE study refer to

<https://impaactnetwork.org/news/promiseresults.html>