

**Prevention of mother-to-child HIV transmission at primary health care level in Moshi urban Tanzania: uptake challenges and transmission rate**

Running head: Challenges of implementing PMTCT program at PHC level in Tanzania

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## **Abstract**

**Background:** Tanzania has extended prevention of mother-to-child HIV transmission (PMTCT) services to primary health care clinics (PHC). Information on challenges and rates of MTCTC of HIV at this level is limited. The study aimed to describe the uptake of PMTCT interventions and MTCT rates at 18 months post delivery.

**Methods:** Pregnant women, in their 3<sup>rd</sup> trimester (N=2654), attending 2 primary health facilities in Moshi were recruited. They were interviewed, tested and women-infant pairs were followed-up for 18 months post-delivery, at which point the exposed children were tested for HIV.

**Results:** Of the 2654 women, 99% accepted testing, 93% returned for their HIV-test results and 7% (184) were HIV-positive. Of the 184 HIV-positive women, 93% (171/184) came for test-results, 71% (130/184) took NVP in labor and 59% (103/175) infants received NVP prophylaxis. HIV-testing at 18 months was conducted for 68% of the exposed infants. The rate of MTCT of HIV was 15.8%.

**Conclusion:** Nearly 40% of infants do not receive ARV prophylaxis and there is high rate of loss to follow-up after delivery, which needs urgent improvements. The high transmission rate support testing of exposed-children earlier due to high number of deaths among children < 18 months and missed opportunity to offer early ART care.

*Key words:* PMTCT; nevirapine; ARV prophylaxis, MTCT of HIV; challenges; Tanzania

## INTRODUCTION

Mother-to-child transmission (MTCT) of HIV remains a major public health problem in sub-Saharan Africa (SSA). Of the estimated 330,000 children infected with HIV worldwide in 2011, more than 90% occurred in SSA (UNAIDS, 2012). Most of the pediatric HIV infection (> 90%) is due to transmission from infected mothers during pregnancy, labor and delivery or through breast feeding. Pediatric HIV substantially increase childhood mortality rates, responsible for up to 40% of under-five deaths in the worst affected areas (Newell *et al*, 2004; UNAIDS, 2011).

Without interventions an estimated MTCT transmission rates were 15%–25% in Europe and USA, and 25%–40% among breastfeeding populations in resource-limited countries (DeCock *et al*, 2000). Substantial reductions to < 2% in MTCT of HIV has been achieved in the developed countries by using potent antiretroviral drugs (ARV), caesarian section and avoidance of breastfeeding (Mofenson, 2010; Mepham *et al*, 2010). In resource limited settings, the use of shorter and simpler prophylactic ARV regimens has been shown to reduce antepartum and peripartum MTCT of HIV rates to 5-15% depending on the duration of prophylaxis and whether breastfeeding occurs (Jackson *et al*, 2003; Lallema *et al*, 2004; Shapiro *et al*, 2006; Tonwe-Gold *et al*, 2007; WHO, 2010). Antiretroviral treatment of the mother or infant during breastfeeding and exclusive breastfeeding for 4-6 months, has the potential to reduce the risk of HIV transmission further to 1-5% (Kilewo *et al*, 2008; Chasela *et al*, 2009; Becquet *et al*, 2009; de Vincenzi *et al*, 2011; Coovadia *et al*, 2012; ). Given the success of these interventions, prevention of MTCT of HIV is a priority in high prevalence, limited resource settings.

Tanzania, with HIV prevalence of 6.9% among pregnant women, is among the 22 SSA countries with the highest estimated numbers of pregnant women living with HIV (UNAIDS, 2011). The national PMTCT programme was introduced in 2004, and by the end of 2011, 91% of the health facilities with reproductive and child health (RCH) services were offering PMTCT service (MOHSW, 2012). The interventions include integration of HIV counseling and testing

(VCT) into routine antenatal care. Those diagnosed as HIV positive are given maternal ARV prophylaxis or treatment depending on the immune status, exposed infants are given ARV and cotrimoxazole prophylaxis, and women extensively counseled on infant feeding (MOHSW, 2007 & 2012). In 2004 -2009, HIV-exposed children were followed-up monthly and tested at 18 months of age (MOHSW, 2007). Since 2009 early infant diagnosis (EID) has been introduced and children are checked at 6 weeks postpartum by PCR and antibody test is repeated when breastfeeding has stopped (MOHSW, 2012). While systematic data is collected on proportion of pregnant women who have ever tested for HIV or used ARV, information on infant ARV, cotrimoxazole prophylaxis and MTCT rates is limited in Tanzania. Further, with the scale-up to PHC level, information on program challenges at this level is needed to help the providers in planning for effective delivery of PMTCT interventions.

This operational research was carried out from mid 2002 to 2006 at two primary health care clinics in Moshi urban district, northern Tanzania with the aim of evaluating the uptake and adherence to cascade of PMTCT interventions as well as to determine the rate of MTCT of HIV at 18 months when single dose nevirapine was the main ARV prophylaxis used.

## **METHODS**

### **Study subjects and procedures**

This prospective cohort study was conducted in two government primary health care clinics that provide antenatal, delivery and postnatal care in Moshi urban district, Kilimanjaro region in Northern Tanzania. These 2 community clinics, Majengo and Pasua, were selected because they attend the largest volume of clients and represent the largest geographical area, giving the best possible random selection among women of reproductive age.

The methods have been described in detail elsewhere (Msuya et al, 2006). Briefly, all pregnant women attending the clinics for routine care, were in their 3<sup>rd</sup> trimester and residing in

Moshi urban, were informed about the study and were invited to participate in the study between June 2002 to March 2004. Women willing to participate ~99% (2654/2664) gave written informed consent. The women received individual pretest HIV counseling which was conducted by trained research nurses, followed by interview, clinical examination and biological sample collection. The counseling and interviews were conducted in Kiswahili, the national language, which is spoken by every Tanzanian. The women were assigned numeric identifiers and all the questionnaires, follow-up forms, appointment cards and laboratory samples were labeled using numbers to maintain confidentiality.

### **Follow up**

The women were asked to return for their HIV/STI results in one week. Post- test counseling was done individually with each woman, where possible by the same nurse who conducted the pre-test counseling. At post-test counseling all HIV positive women were given a 200-mg nevirapine tablet, with instruction to take the medication at the onset of labor. They were instructed to bring the infants for administration of Nevirapine syrup within 3 days after delivery. Limitations regarding nevirapine prophylaxis were discussed. Benefits of exclusive breast feeding were discussed in detail. The women were invited to come at any time before delivery for further consultation.

Follow-up was scheduled at delivery, at 1 month, and at 3, 6, 9, 12, 15, 18 and 24 months after delivery. Two research nurses visited the labor ward at the district and tertiary hospitals daily to record delivery information for the clients and to administer NVP syrup to infants of HIV-positive women and/or NVP to women in labor who hadn't received it. This was necessary because some women (~32%) had indicated earlier that they would prefer to deliver at the district or referral hospital. At the time of implementing this study, there was no PMTCT program at the district hospital, it started in late 2004. There was however a PMTCT program at the referral

hospital, and in order to receive care women needed to identify themselves and inform the midwives about their status when admitted for delivery.

Routine monthly pediatric care for growth monitoring and immunization, according to the national guidelines was conducted as usual. During follow-up at the study specified times, the research nurses collected information on neonatal and delivery details, infant feeding patterns, infection episodes and cotrimoxazole use. Complete physical examination was conducted including recording of weight and height. Cotrimoxazole prophylaxis was offered free of charge from the age of 6 weeks until the child was tested for HIV. Once a month, a pediatrician from the referral hospital conducted a clinic for children born to HIV-positive women at the local PHC clinics. The pediatrician was responsible for monitoring the children especially in terms of neurodevelopmental and adjusting the cotrimoxazole dosage according the child's age. HIV testing of the children was done at 18 months of age using rapid tests. Children found to be HIV-infected were immediately referred to the pediatric clinic at the referral hospital. Community follow-up for children who didn't turn up at scheduled visits was conducted by the research nurses on every second Saturday for the duration of the project (June 2002 – June 2006).

At enrollment the study was unable to test the women for CD4 cell count. The WHO clinical HIV disease staging was used to assess the women and cotrimoxazole prophylaxis offered according to guidelines. Highly active antiretroviral treatment (HAART) became available at the district hospital through the national program only from October 2004, and women were referred from that period onwards (MOHSW, 2005). All the women were encouraged to inform their partners and bring them for free counseling and testing.

### **Laboratory testing**

Within 6 hours of collection, blood was centrifuged on site, and serum tested for HIV by using two rapid tests, Determine HIV-1/2 test (Abbott Laboratories) and Capillus HIV1 /HIV 2 (Trinity Biotech, Ireland). HIV was diagnosed when both test results were positive. In case of

discordance between the two tests (in < 1% of the samples), a third test, the ELISA test, Virinostika HIV Uni-form II (Organon Teknika, Boxtel, Netherlands) was used. Testing of the children's blood at 18 months was also done using the same rapid tests described above.

### **Statistical analysis**

Descriptive statistics were used to summarize the data. Loss to follow-up was defined as failure to attend the clinic at least once and there is absolute no information on mother-infant pairs from post-test to the 18<sup>th</sup> month post delivery. The denominator for calculation of uptake of PMTCT interventions which is given as a proportion is based on the total number of HIV-positive women (184). Data were analyzed using SPSS for windows, version 17.0 software (SPSS, Chicago, IL, USA).

### **Ethical clearance**

Ethical clearance for the study was given by the Tanzanian Ministry of Health and by the Norwegian Ethical Committee.

## **RESULTS**

The acceptance of HIV-counseling and testing was high (99%; 2654/2664). Of the 2654 participating women, seven percent (184) were HIV- positive. Table 1 shows baseline characteristics of the 184 HIV-positive women. Their median age was 26 years (interquartile range [IQR] 22-29 yrs) and median gestation age at enrollment was 30 weeks (IQR 28-32 wks). Median hemoglobin level was 10.6 g/dL (IQR 9.3-12.0 g/dL) and the majority of women (77% [132]) were classified as WHO clinical stage 1. Eighteen percent (34) of the partners of HIV-positive women came for HIV counseling and testing.

A total of 171 HIV-positive women (93%), returned for the HIV-post test results. One hundred and thirty (71%) took the NVP in labor, and most took it within 48 hours before delivery, Table 2. One hundred and three (59%) of the live born infants received NVP syrup and

~91% received it within 72 hours after delivery. Reasons for failure of infants to take NVP are shown in table 2. The most common reason (37 [45.6%]) was that the mothers failed to bring the infants to the study clinic for ARV administration as agreed. Place of delivery had a major influence on failure of infant ARV uptake because the majority of those who failed to bring the infants delivered at the district/referral hospital and not at the study clinics, i.e. 25/37 (68%) delivered at the district hospital, 5/37 (13%) at the referral hospital, 2/37 (5%) at home and 3 (8%) at the study clinics.

Cotrimoxazole prophylaxis was given at least once to 74 (45%) of the exposed infants. The median age at commencing the prophylaxis was 4.5 months (IQR 3.0-6.3 months). Only 42% of those who received cotrimoxazole initiated it at  $\leq 3$  months of age. Few collected the prophylaxis regularly i.e. at the monthly pediatric visits (21), the rest, their pattern of collecting the prophylaxis was erratic.

Figure 1 and Table 3 shows postnatal follow-up and the proportion of HIV exposed infants tested at 18 months. Loss to follow up was 10% by the time of delivery, 35% at the 3<sup>rd</sup> month post delivery, and 50% at the 12<sup>th</sup> month post delivery. Due to community follow up however, the proportion of HIV-exposed children who were tested at 18 months or later increased to 68% (107). Most common reasons for failure to test the 77 HIV-exposed children at 18 months were; child death < 18 months (27 [35%]), loss to follow-up (19 [25%]), and 14 (18%) who were simply lost without any trace, Table 4.

Sixty eight percent (107/157) exposed children were tested at 18 months, Figure 1. Out of 107, 17 were positive giving the mother-to-child transmission rate of 15.8% at 18 months post-delivery.

Finally we looked at adherence of some selected PMTCT interventions using only those who knew their status (171) as the denominator. The proportion of maternal uptake of NVP



during labor was 76%, 64% of the infants received NVP, and 74% of exposed infants were tested at 18-months, see Figure 2.

## DISCUSSION

Adherence to cascade of PMTCT intervention and provider initiated counseling into routine antenatal care, has the potential of saving infants lives by averting HIV transmission, and thus facilitating attainment of the MDG 4. However, the results of this operational research show that there are several implementation bottlenecks in the program which need to be addressed to get the full benefit of the program. Of special concern was low uptake of NVP especially for infants, low cotrimoxazole utilization and progressive loss to follow-up of mother-infant pairs. The main question to address is how to improve uptake and adherence at each step of the cascade of PMTCT services in this setting.

Uptake to testing, once counseled was high (99%); similar to findings from other studies in Zimbabwe (93%), Malawi (96%), Kenya (83-97%) and Zambia (72%), (Manzi *et al*, 2005; Stringer *et al*, 2005; Moses *et al*, 2008). The design of this study however may have contributed to the loss of women who failed to collect test results and affected maternal ARV intake. The women had to collect test-results after a week and we recruited them in the last trimester (28-36 weeks gestation). An opportunity to provide NVP prophylaxis was sometimes missed as some delivered before their appointed time for results. Rapid HIV testing and giving results on the same day alleviate this problem, and has been shown to increase up to 97% the proportion of women who receive HIV-results (Moses *et al*, 2008; Mofenson, 2010). Furthermore, the combination of rapid HIV testing with the “opt-out” approach, has been shown to increase acceptance for HIV-testing, collection of results and the number of mother-infant pairs that receive antiretroviral prophylaxis (Chandisarewa *et al*, 2007; MOHSW, 2012).

Maternal and infant ARV prophylaxis offered at PMTCT program has changed over time in Tanzania; sdNVP was offered to mothers and infants from 2004-2008, then zidovudine (AZT)

from 28 weeks for mothers and sdNVP and AZT for infants from 2009-2011. By 2012, the country adapted the 2010 WHO guideline, and AZT is offered from 14 weeks of gestation, while infants are given NVP prophylaxis throughout the breastfeeding period (UNAIDS, 2011; UNAIDS, 2012, MOHSW, 2012). It was a concern to note that nearly 40% of exposed infants did not receive ARV prophylaxis in this study. The low uptake of infant ARV wasn't only noted in earlier times, but persist to present as the 2010 National AIDS Control Program (NACP) report showed that only 50% of exposed infants received ARV prophylaxis in 2009 (NACP, 2010). Similar low uptake results (24%-55%) have been reported in PMTCT programs elsewhere in Africa (Manzi *et al*, 2005; Stringer *et al*, 2005; Doherty *et al*, 2007). This vital aspect of the PMTCT program needs new strategies to improve adherence as infants are now supposed to take NVP syrup for a whole year during breastfeeding (UNAIDS, 2011; MOHSW, 2012).

The rate of MTCT of HIV observed in this study of (15.8%) in the background of sdNVP prophylaxis is similar to the results observed in Uganda at 18 months of follow-up when comparing NVP to AZT (Jackson *et al*, 2003). The findings of this study can be used as a baseline when comparing the effect of efficacious ARVs in reducing MTCT of HIV in the country compared to earlier times when sdNVP was used (MOHSW, 2012).

At present, PMTCT services are available in approximately 93% of health facilities (MOHSW, 2012). In our study, 51% of the HIV-positive women delivered at the district/referral hospital and not at the study clinics. This pattern underscores the need of introducing or strengthening the ability of maternity/labor wards to identify HIV positive women tested elsewhere and offer ARV care (WHO, 2010; UNAIDS, 2011). There is also a need to have in place a strong system which helps the health providers at RCH clinics to identify HIV exposed children in order to offer timely care. The challenge of human resources needs to be addressed however in order to offer quality PMTCT services (Doherty *et al*, 2005; MOHSW, 2012).

Progressive loss to follow-up of mother-infant pairs from delivery to 18 months featured as a key problem in this study as has been reported elsewhere (Manzi et al, 2005; Moses et al, 2008; O'Donnell et al, 2013). In a study carried out in Lilongwe, Malawi, only 35% of the infected mothers returned for 6 weeks HIV PCR testing for the infants (Moses et al, 2008). In another study in Malawi, 70% of HIV-positive mothers were lost to follow-up at the 1<sup>st</sup> postnatal visit and loss rose to 81% by the 6-month postnatal visit (Manzi et al, 2005). In this study, 35% of mother-infant pairs were lost by the 1-month postnatal visit and 51% by 12 months. Further, 32% of the HIV exposed children were not tested at 18 months, similar to rates of testing reported from South Africa (Doherty *et al*, 2005). The high mobility that is characteristic of urban inhabitants was observed in our cohort and may partly explain the loss to follow up observed. Nearly 4 in 10 of the children who were not tested were documented to have relocated residence; to a rural area or to other regions or the family left no forwarding address. Qualitative research that looks into community and institutional barriers to follow-up after delivery would be helpful for future programming.

High attrition rate during the postnatal period affects the effectiveness of PMTCT programs in several ways. It compromises the opportunities for ongoing infant feeding counseling and support which is crucial for adherence to the chosen feeding method (Becquet *et al*, 2009). It also hinders early identification of infected infants which is crucial as 30-50% of infected infants dies within the first 2 years of life (Newell *et al*, 2004; UNAIDS, 2011). Many of HIV-infected children will appear at health facilities with advanced disease, thus a poor prognosis (WHO, 2010; UNAIDS, 2011). HIV transmission rate data at 18 months is also biased due to loss of follow-up and the high rate of child death < 18 months. Finally, programs will fail to quantify the number of HIV infections averted in children and overall effectiveness of the PMTCT intervention. These results therefore supports testing of exposed-children early as

currently recommended and introduction of the more efficacious regimens as recommended by the WHO (WHO, 2010; MOHSW, 2012).

In conclusion, the low coverage of some components of PMTCT program, especially infant ARV prophylaxis and poor postnatal follow up, need to be addressed. Institutional and community barriers need to be address. Furthermore, clinics with PMTCT services in place, need to ensure that all pregnant women are offered VCT and rapid HIV testing, are given test results and are provided ARV medication where required.

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## TABLES

**Table 1:** Demographic and obstetric characteristics of 184 HIV-positive women in Moshi urban,

Tanzania

Variable	N	(%)
Age (median, range)	26.00	(16-39 years)
Parity (median, range)	1.00	(0-7)
Married/cohabiting	161	(87.5%)
Secondary education or more	20	(10.8%)
Formally employed	8	(4.3%)
Income > 30 USD /month	18	(9.8%)
History of stillbirth <sup>†</sup>	38	(25.3%)
History of infant death <sup>†</sup>	28	(18.7%)
WHO HIV clinical staging (171)		
Stage 1	132	(77.2%)
Stage 2	34	(19.9%)
Stage 3	5	(2.9%)
Infant feeding method selected at post test (171)		
Exclusive breastfeeding	156	(91.2%)
Exclusive formula feeding	15	(8.8%)
Actual place of delivery (167)		
Study clinics	74	(44.3%)
District hospital	70	(41.9%)
Tertiary hospital	12	(7.2%)
Other hospital/home	11	(6.6%)
Birth weight (kg) (167)		
< 2.5	12	(7.2%)
≥ 2.5	155	(92.8%)
Stillbirths (167)	9	(5.4%)

<sup>†</sup> Minus 34 women whom this was their 1<sup>st</sup> pregnancy



**Table 2:** Maternal and infant nevirapine uptake and reasons for failure to take NVP among 184 HIV-positive women in Moshi urban, Tanzania

Variable	N	Percent
<b>Maternal nevirapine intake</b>		
Maternal nevirapine intake	130/184	70.7%
Time of NVP intake before delivery		
< 2 hours	12	9.2%
2-12 hours	111	85.4%
13-48 hours	6	4.6%
> 48 hours	1	0.8%
Reasons for failure to take maternal NVP (54)		
Tested but didn't come back for test results	13	27.8%
Results at labor ward/few hours after delivery <sup>†</sup>	13	24.1%
Tested, received results but didn't take NVP		
Given the tablet but not sure taken	10	14.8%
Returned the tablet after delivery	6	11.1%
Didn't believe they are positive/faith healing	6	11.1%
Unspecified reasons	6	11.1%
<b>Infant nevirapine intake</b>		
Infant nevirapine intake*	103/175	58.8%
Time of neonatal NVP intake after delivery		
< 12 hours	65	63.1%
13-24 hours	18	17.5%
25-72 hours	11	10.7%
> 72 hours	9	8.7%
Reasons for failure to take neonatal NVP (81)		
Stillbirths or death < 1 hour post-delivery	9	11.1%
Tested but didn't come back for results	13	18.5%
Mother took NVP but didn't bring the neonate	35	40.7%
Returned the tablet but didn't bring the neonate	4	4.9%
Mother lost after posttest counseling	8	10.0%
Didn't believe they are positive/faith healing	6	7.4%
Unspecified reasons	6	7.4%

<sup>†</sup> All the neonates received nevirapine; \* Minus 8 stillbirths and 1 death < 1 hour post-delivery

**Table 3:** Adherence to follow up among 184 HIV-positive women and their infants from testing during pregnancy to 18-months post-delivery in Moshi urban, Tanzania

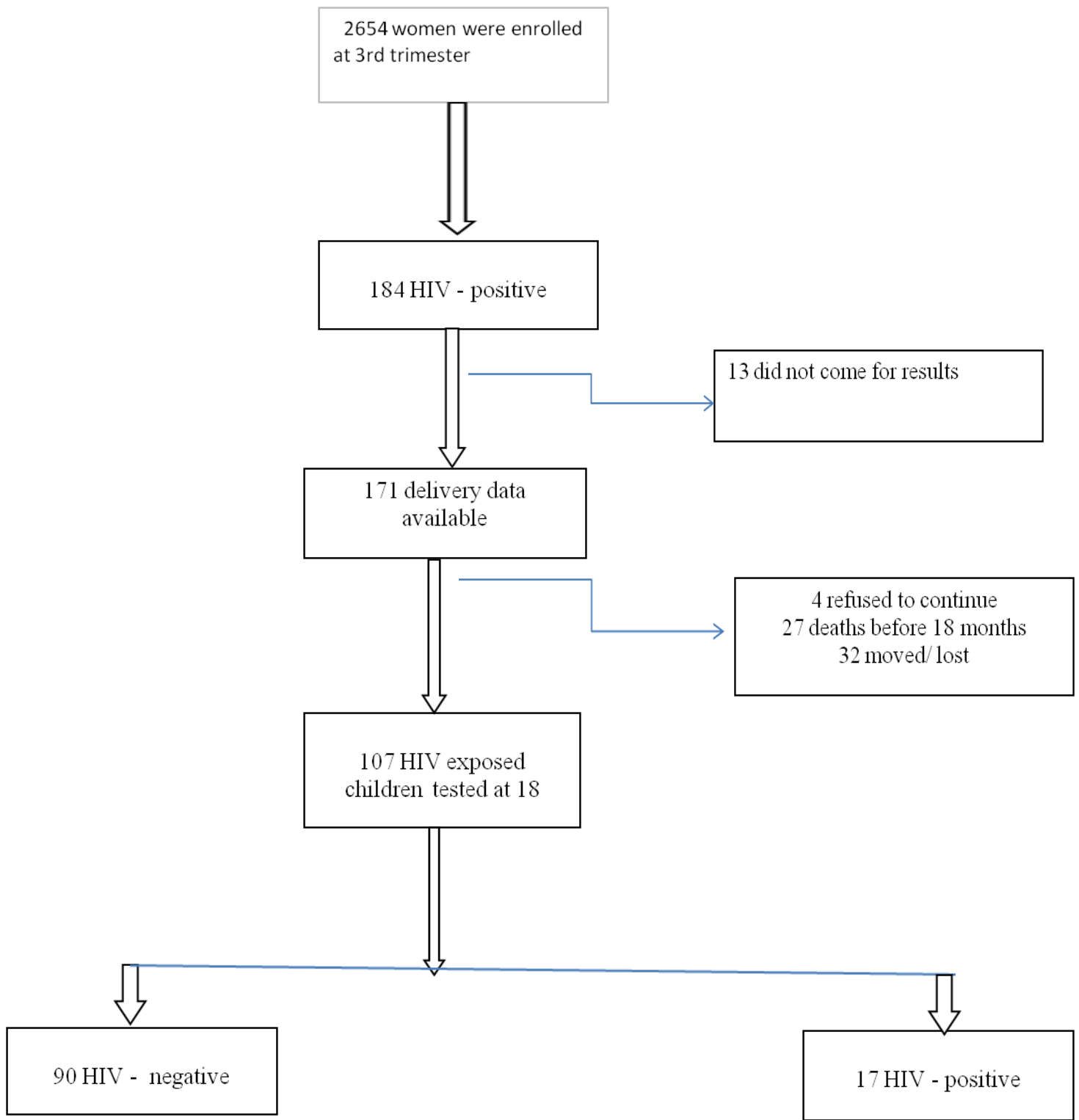
<b>Time</b>	<b>n</b>	<b>N</b>	<b>%</b>
Tested HIV positive	184		
Returned for post test counseling and results	171	184	92.9%
Delivery form filled	167	184	90.7%
Post natal visits			
Attended at 1-month (- 10 deaths after delivery & < 1 month)	113	174	64.9%
Attended at 3-months (- 8 deaths > 1 month < 3 months)	108	166	65.1%
Attended at 6-months (- 3 deaths > 3 months < 6 months)	88	163	54.0%
Attended at 9-months (- 4 deaths > 6 months < 9 months)	92	159	57.9%
Attended at 12-months (- 1 death > 9 month < 12 month)	77	158	48.7%
<u>Exposed children tested at 18 or more months (- 27 deaths &lt; 18 month)</u>	<u>107</u>	<u>157</u>	<u>68.1%</u>

- Subtraction or minus sign

**Table 4:** Reasons for failure to test at 18 or more months among HIV- exposed children in Moshi urban, Tanzania

<u>Variable</u>	<u>N</u>	<u>Percent</u>
Tested at 18 months or more	107	
Reasons for failure to test (77)		
Mother didn't return for results	13	16.9
Stillbirths	9	11.7
Died > 1 month < 18 months after delivery	18	23.4
Refused to continue with study	4	5.2
Moved out of district	14	18.1
Lost to follow up	19	24.7

Figure 1: Flow chart of follow up for HIV-positive women and their children in Moshi urban district, Tanzania



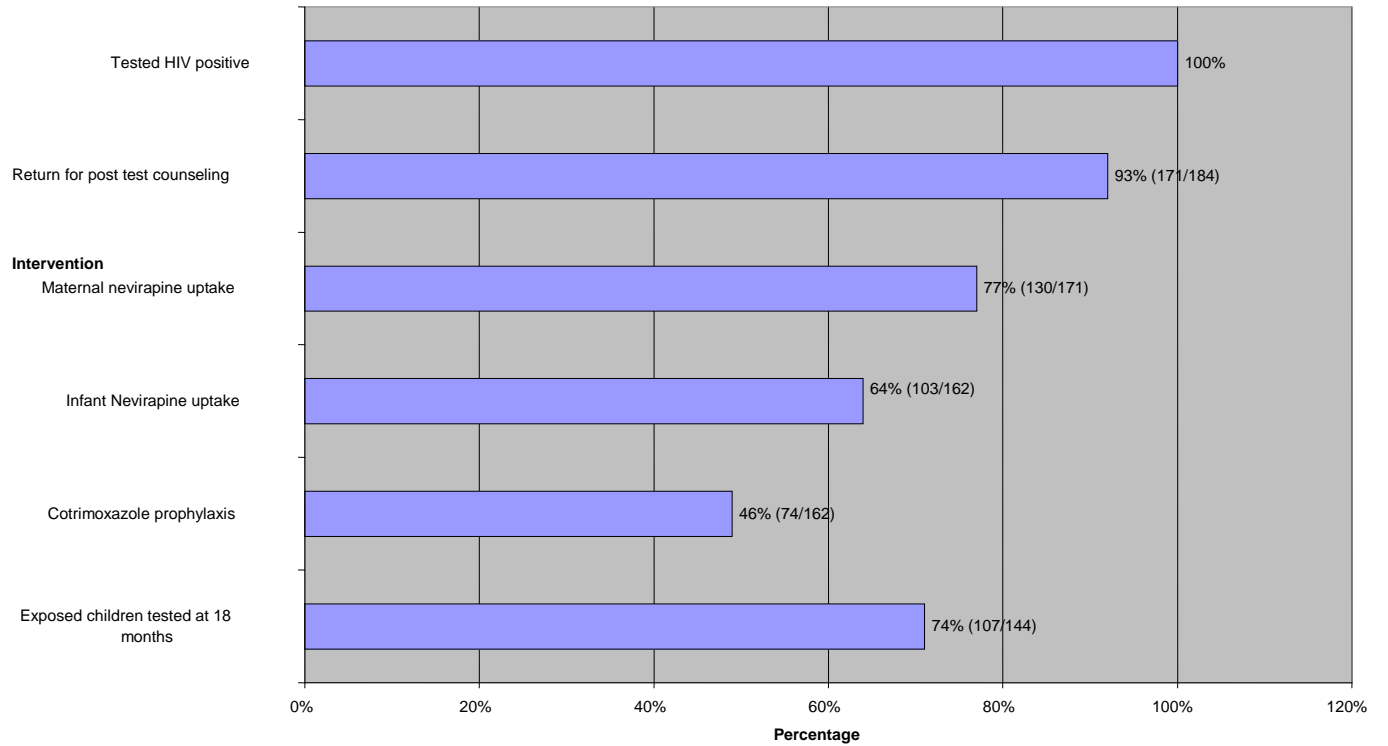


Figure 2: Proportion of HIV-positive women and their children who came for results and received some selected PMTCT interventions in Moshi urban district, Tanzania