

# Compliance with infant formula feeding by HIV-positive women one week after delivery in Khayelitsha, South Africa

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When mixed feeding occurs a few days following delivery, the risk of HIV transmission is likely high. The study aim was to assess infant feeding practices, one week following delivery of HIV-positive mothers who intended to formula feed their infants. A consecutive sample of 95 HIV-positive mother-infant pairs was recruited soon after delivery from a midwife obstetric unit in Khayelitsha. Face-to-face interviews were conducted one week after delivery at the clinic to determine the actual infant feeding practices. Sixty-four HIV-positive mother-infant pairs completed the study. The response rate was 67%. The median interview day was day 8. Sixty-two mothers (97%) (95% CI: 95% to 99%) exclusively formula fed their infants. Fifty (78%) (95% CI: 73% to 83%) mothers gave their infants formula milk only. Two mothers breast-fed their babies. Twelve (19%) gave their babies other fluids or food. Eleven gave water, glucose water or gripe water and one gave cereal or porridge. Breast engorgement occurred in 51 (80%) mothers. Only five (8%) mothers had received advice about breast engorgement from the facility health providers. Compliance with formula feeding of HIV-positive mothers one week following delivery is at an acceptable level. Levels of breast engorgement and lack of counselling on breast engorgement were high. Advice about non-pharmacological methods of managing breast engorgement must be given to women choosing to formula feed their babies. Mothers must be informed about the dangers of mixed feeding during the first week after delivery.

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## Introduction

“The HIV pandemic remains the most serious of infectious disease challenges to public health”.<sup>1</sup> Sub-Saharan Africa carries the largest burden of HIV/AIDS disease, with more than two-thirds of the HIV-infected global population and more than 72% of AIDS deaths in 2008.<sup>2</sup> Of public health concern is that one in seven of HIV infections and approximately one in six AIDS-associated deaths have been described in children under the age of 15 years.<sup>3</sup> In 2007, approximately 5.7 million HIV-infected people were living in South Africa.<sup>2</sup> An HIV prevalence of 29.4% among pregnant women between the ages of 20-24 years attending antenatal care at public health clinics in South Africa was reported in 2007.<sup>4</sup>

Immunological and nutritional advantages of exclusive breastfeeding in HIV-uninfected populations are known.<sup>5</sup> Uncertainty remains on overall net benefit of breastfeeding HIV-infected children without antiretroviral (ARV) treatment. Vertical transmission of HIV through breastfeeding has introduced a dilemma among policy makers and health practitioners especially in areas where HIV prevalence is high and where breastfeeding is the most culturally acceptable infant-feeding method.<sup>6</sup> It is estimated that 23% to 42% of

mother-to-child transmission (MTCT) of HIV occurs over two years of breastfeeding with no intervention.<sup>7</sup> MTCT of HIV is responsible for over 300,000 HIV infections annually in children in sub-Saharan Africa.<sup>8</sup> HIV-positive children in resource-limited settings have poor health outcomes, high risk of infections, frequent hospital visits and premature death.<sup>9</sup>

The 2010 World Health Organization (WHO) guideline on HIV and infant feeding recommends that decisions on appropriate infant feeding options for specific populations should be made at national or sub-national level by health authorities.<sup>10</sup> HIV-infected mothers should be counselled to make informed decisions. Recommended feeding options are breastfeeding with ARV interventions during the entire breastfeeding period, or replacement feeding. Replacement feeding should be used only when it is acceptable, feasible, affordable, sustainable, and safe.

Replacement feeding eliminates postnatal MTCT of HIV.<sup>11</sup> While in well resourced settings replacement feeding has eliminated postnatal transmission of HIV, “unfortunately, most at-risk infants are in the developing world”.<sup>12</sup> Estimates are that 1.5 million child deaths per year are associated with avoidance of breastfeeding, when formula feeds are prepared

with unsafe water.<sup>13</sup> These risks are known to vary among individuals and are largely preventable.<sup>14</sup>

The South African prevention of mother-to-child transmission (PMTCT) programme adapted the 2010 WHO guideline on HIV and infant feeding. Women are counselled to choose either exclusive breastfeeding with ARV treatment (daily nevirapine or maternal highly active antiretroviral therapy [HAART]) during the breastfeeding period or exclusive formula feeding with free infant formula provided for up to six months.<sup>15</sup> “Compliance with formula feeding is not assured by subsidies or free supplies”.<sup>16</sup> Exclusive breastfeeding and exclusive formula feeding have been reported to be rare practices in most African communities.<sup>17</sup> Mothers formula feeding in African communities are often stigmatised; this has diluted the effect size of the intervention in such communities.<sup>18</sup>

Earlier observations suggest the highest risk of postnatal transmission of HIV through breast milk to be during the first months of life especially soon after delivery.<sup>19</sup> “Breast milk viral load is an important determinant of postnatal HIV transmission”.<sup>20</sup> Breast engorgement that occurs a few days after delivery in association with onset of lactation is associated with an increase in breast milk viral load.<sup>21</sup> Resuming breastfeeding after a period of cessation may substantially increase HIV transmission risk among HIV-exposed infants. Two dangerous periods for transmission will be:

- When a mother who decides to formula feed develops engorged breasts day 3 to 5 postpartum and puts the baby on the breasts and starts mixed feeding. Social pressures at home make women even more vulnerable during this time.
- When a mother decides to wean the baby and put the baby back on breastfeeding, a period of mixed feeding will follow.

When mixed feeding occurs during these periods the risk of HIV transmission is likely to be high. No information is provided in the national and Western Cape provincial PMTCT guidelines regarding suppression of lactation during any of the two high risk periods mentioned. Presently natural methods are used to manage engorged breasts that include mild compression, expressing and discarding breast milk.

This study aims to assess infant feeding practices of HIV-positive mothers who intended to exclusively formula feed their infants, one week following delivery. The assumption was made that those mothers who complied with exclusive formula feeding by day seven postpartum, were unlikely to resort to mixed feeding later.

## Methods

A cross-sectional study was conducted to assess infant feeding practices of HIV-positive women one week following delivery at Michael Maphongwana Midwife Obstetric Unit in Khayelitsha. HIV-positive mother-infant pairs were consecutively recruited

soon after delivery from 11 May 2010 to 25 August 2010. On recruitment, research counsellors and the principal investigator had no knowledge on exposure variables of study participants. Study purposes and processes were explained during the consent process. Enrolled participants intended to exclusively formula feed their infants. Written informed consent was obtained on recruitment. Socio-demographic information and intended infant feeding option were recorded before discharge. Follow-up interviews to assess actual feeding practices were scheduled one week after delivery for the mothers enrolled in the study. Participants were reminded of the study appointment a day before through an SMS. Mother-infant pairs who failed to turn-up for the follow-up interview were contacted telephonically to reschedule the appointment. Participants were reimbursed with R50.00 for transport costs.

HIV counselling, HIV testing and infant feeding counselling were provided through established provider-initiated counselling and testing services offered to all pregnant women attending antenatal care at public health clinics according to the Western Cape provincial PMTCT guideline. Formula feeds were initiated soon after delivery. Mothers received two tins of infant formula for the first week free of charge and were to obtain subsequent formula supplies from their local clinics as part of routine services.

HIV-positive mothers at least 14 years of age, who intended to exclusively formula feed their infants, were to receive free supplies of infant formula from the PMTCT programme and had consented to participate, were eligible to participate in the study. Exclusion criteria included mothers who were HIV-negative, HIV-positive women who were to exclusively breast feed their infants, age of less than 14 years and those who declined to provide written informed consent.

Study variables were defined as follows:

- Disclosure of HIV status was defined as disclosure of the mother’s HIV status to anyone in the household.
- Infant feeding counselling as: whether the mother had received infant feeding counselling from the facility counsellors during the antenatal period or soon after delivery or not.
- Breast engorgement as: breasts that were over-full with milk and increased tissue fluid and as a result milk flow is inhibited and painful.

Infant-feeding practices were defined according to WHO:<sup>22</sup>

- Breastfeeding as: the child had received breast milk direct from the breast with a sucking episode that lasts two minutes or longer or receiving expressed breast milk.
- Exclusive formula feeding meant that the infant was receiving only infant commercial formula and not breastfeeding at all, other fluids and foods not restricted.
- Exclusive breastfeeding was defined as the infant receiving only breast milk and no other liquids including water, with the exception of medicines, vitamin drops or syrups and mineral supplements.

- Mixed feeding was defined as formula feeding while giving breast milk or food-based fluid or solid food at the same time.

Data collection was done by the principal investigator with assistance of two research counsellors. Structured questionnaires were used to measure study demographic, clinical, and outcomes variables. Demographic information was obtained before discharge using a socio-demographic questionnaire. Face-to-face interviews were conducted one week following delivery at the clinic to ascertain study outcomes and other study variables of interest simultaneously. The infant feeding questionnaire was developed using the validated WHO generic questionnaire for MTCT and infant feeding patterns.<sup>22</sup> Clinical records were used to confirm reported HIV status of the mothers and to obtain some selected variables. Infants were classified at follow-up visit as exclusively formula fed, exclusively breast fed or mixed fed using mother's recall history of the actual feeding practices during the first week of infant's life. The study relied on information provided by the mothers to assess self reported infant feeding practices. Questions were included to assess the validity of the self reported infant feeding practices. Specific procedural instructions and structured questionnaires were designed to ensure a uniform and standardised approach to data collection.

A total sample size of 62 HIV-positive mothers-infant pairs was required to estimate the proportion of women who exclusively formula feed one week following delivery. The sample size was determined to achieve a precision of  $\pm 5.5\%$  (95% confidence interval). This was derived from approximately 95% adherence level observed in a cross-sectional survey.

Statistica version 9.0. (StatSoft Inc, 2009) was used for descriptive analysis. All participants with complete data were included in primary analysis. Baseline characteristics were compared between mother-infant pairs who had responded to the follow-up interview and non responders using t-tests for continuous variables or Mann-Witney U test, if the continuous variables were not normally distributed. Comparisons between categorical variables were investigated with contingency tables and likelihood ratio chi-squared tests.

The study was approved by Human Research Ethics committee of Stellenbosch University (Ref N10/02/042). Permission to conduct the study at the research site was obtained from the Western Cape Department of Health (Ref RP52/2010). The study was conducted according to the ethical guidelines and principals of the International Declaration of Helsinki, South African Guidelines for Good Clinical Practice and the Medical Research Council Ethical Guidelines for Research.

## Results

Two hundred and eighty-three mother-infant pairs were examined for eligibility in the study; 95 were confirmed eligible and enrolled. Figure 1 shows flow of participants in the

study. Non eligible and mothers who declined to participate were excluded from the study. Main reasons for non-eligibility were: mothers' HIV-negative status who were exclusively breastfeeding their infants (n=184), and HIV-positive mother who was exclusively breastfeeding (n=1). Reasons for declining to participate were: lack of interest about the study (n=2), mother stayed too far from the research site to return for the follow-up interview (n=1).

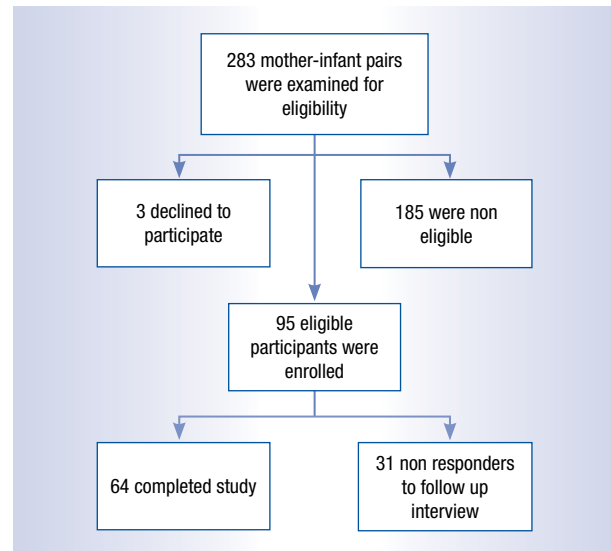


Figure 1: Flow of participants in the study

Table I describes the baseline characteristics of mother-infant pairs enrolled in the study. There were no statistically significant differences in baseline characteristics between mother-infant pairs who responded to the follow-up interview and non responders. All birth outcomes were singletons, with 86 (91%) being normal deliveries and nine (9%) were completed births before arrival at the clinic.

Sixty-four mother-infant pairs completed the study and were all included in the analysis. The response rate was 67%. All mothers were interviewed face-to-face at the clinic except for one mother who was interviewed telephonically for the follow-up visit. Median interview day post delivery was day 8 (lower quartile = day 8, upper quartile = day 9). Most of the mothers (62; 97%) (95% confidence interval [CI]: 95% to 99%), exclusively formula fed their infants. The estimated proportion of mothers who gave formula milk only to their babies is 50 (78%) (95% CI: 73% to 83%). Two mothers breast fed their babies. Twelve mothers (19%) gave their babies fluids or food. Eleven gave water, glucose water or gripe water and one mother gave cereal or porridge. Reported actual infant feeding practices were consistent with questions that tested validity of this self reported information. Table II describes the characteristics of the two mothers who breastfed their infants.

Reasons for mixed feeding were cultural practices, poor infant bowel movements and infants perceived as hungry and family pressures. The main reasons for choosing formula

**Table I:** Baseline characteristics of HIV positive mother-infant pairs enrolled in the study

Characteristics	Responders (%) (n = 64)	Non-responders (%) (n = 31)	p – value <sup>a</sup>
Mean maternal age [years (SD)] <sup>b</sup>	27 (5.3)	27 (5)	0.79
Mean birthweight.[grams(SD)] <sup>b</sup>	3,003 (507)	3,123 (392)	0.25
Median CD4 count [median(n)] <sup>c</sup>	333 (54)	373 (27)	0.21
<b>Highest level of education<sup>d</sup></b>			
Primary	1 (1.6)	2 (6.5)	
Grade 8-10/Std 6-8	24 (37.5)	13 (41.9)	0.42
Grade 11-12/Std 9-10	37 (57.8)	16 (51.6)	
Tertiary	2 (3.1)	0 (0.0)	
<b>Parity<sup>d</sup></b>			
< 3	40 (62.5)	15 (48.4)	0.19
≥ 3	24 (37.5)	16 (51.6)	
<b>Marital status<sup>d</sup></b>			
Unmarried	37 (57.8)	18 (58.1)	
Married	21 (32.8)	8 (25.8)	0.56
Unmarried partners	6 (9.4)	5 (16.1)	
<b>Water supply<sup>d</sup></b>			
Shared tap	36 (56.3)	18 (58.1)	
Own tap	28 (43.8)	13 (41.9)	0.87
<b>Employment status<sup>d</sup></b>			
Unemployed	49 (76.6)	21 (67.7)	
Housewife by choice	4 (6.3)	1 (3.2)	0.37
Wage earner	11 (17.2)	9 (29.0)	
<b>Type of fuel used for cooking<sup>d</sup></b>			
Paraffin	10 (15.6)	4 (12.9)	
Gas	5 (7.8)	4 (12.9)	0.71
Electricity	49 (76.0)	23 (74.2)	

<sup>a</sup>Statistical significance was set at  $p < 0.05$ . Actual p-value is reported as the overall value for the complete variable.

<sup>b</sup>t-test was used for comparisons of mean estimates.

<sup>c</sup>Mann-Witney U test was used to compare median estimates.

<sup>d</sup>Likelihood ratio chi-squared test was used to compare categorical variables.

feeding as their feeding choice were: fear of HIV transmission, 37 (58%), as advice from health providers, 23 (36%), and separation from the infant due to work, four (6%). Six mothers experienced difficulties with their feeding choice: infants had

feeding difficulties (3), disapproval of feeding option by family members (2), infant was not passing stool regularly (1). Fifty-eight (91%) mothers had received infant feeding counselling. Only five (8%) mothers had received advice regarding breast engagement from the facility health providers. Breast engagement occurred in 51 (80%) of the mothers and only one of them consulted a private pharmacy. Median number of household members was five. Fifty (84%) of the mothers had disclosed their HIV status to at least one of the household members. Twenty-seven (42%) mothers were receiving HAART while 37 (58%) were not on treatment.

## Discussion

The majority of HIV-positive mothers in Cape Town Metropolitan area exclusively formula feed their infants. The level of compliance was high in this study and it is unlikely that such an observation could have occurred by chance. The two mothers who introduced breast milk had not disclosed

**Table II:** Characteristics of two mothers who breast fed their infants

Characteristic	Participants	
	Mother 1	Mother 2
Age	25	21
Marital status	Single	Single
Highest level of education attained	Primary	Grade 11/12
Number of household members	8	6
Received infant feeding counselling	No	Yes
Advised on breast engagement	No	No
Disclosure of HIV status	No	No
Day infant started breastfeeding from date of birth	1	7

their HIV status and one of them did not receive infant feeding counselling. Both mothers reported having experienced breast engorgement.

Hilderbrand et al reported similar findings in Khayelitsha, South Africa, where 95% of the 113 mothers exclusively formula fed their infants in a cross sectional survey of infants with mean age of 12 weeks.<sup>23</sup> Consistent findings among mothers of infants of different age groups may make the assumption, that those mothers who complied with exclusive formula feeding by day 7 postpartum were unlikely to resort to mixed feeding later, considered valid. However, contradicting findings have been reported in other studies. In a prospective cohort study conducted in three national PMTCT sites in South Africa, mothers chose either to breastfeed or formula feed their infants.<sup>24</sup> Mothers were provided with free infant formula. Twenty-nine percent of mothers who chose to formula feed their infants gave breast milk between birth and 36 weeks. Formula supply was reported to be poor. Nduati et al in Kenya reported suboptimal feeding practices; 425 mother-infant pairs were randomised either to breast feed or formula feed their infants and were followed-up for two years. Thirty percent of the mothers in the formula feeding arm introduced breast milk; however, the timing of introduction of breast milk is not mentioned.<sup>25</sup>

Having all mothers receive infant feeding counselling is desirable. Coverage of 91% in a normal practice setting is satisfactory. Most of the women experienced breast engorgement. The finding that almost none of the mothers had received advice regarding what to do when breast engorgement occurs is important. Breast engorgement has been documented to be a significant risk factor for transmission of HIV through breastfeeding. It is uncertain whether this information is made available to mothers during counselling. This has important clinical implications especially in communities where exclusive formula feeding is not the norm. Information on a non-pharmacological method to manage engorged breast can greatly support these mothers. These measures include warm compressions, followed by expressing milk and then cold compressions with mild pressure.

The study has some limitations. The response rate was 67%; this may have weakened the validity of estimates and conclusions drawn from this study. However, during recruitment participants were not aware of study outcomes. Complying or failure to comply with exclusive formula feeding was unlikely influenced by being included in the index study. Given that baseline characteristics were comparable between responders and non responders, we may conclude that the non responders most likely resemble the responders. However, the 33% loss to follow-up is a concern, that this may have biased estimates and conclusions drawn from the study.

The study sample may not be representative of the target population. However, because of the nature of the study population, a random sample was not feasible. Inferences of

study findings may be limited to populations with baseline characteristics that are similar to the study sample. The strengths of the study are that: i) a structured questionnaire that was developed using a validated instrument was used to ensure uniform and standardised approach in data collection; and ii) selection bias was unlikely as the principal investigator and research counsellors were not aware of participant's exposure status on recruitment.

## Conclusion

We are confident that compliance with formula feeding of HIV-positive mothers one week following delivery is at an acceptable level. Levels of breast engorgement and lack of counselling on breast engorgement were high. Advice about non-pharmacological methods of preventing and managing breast engorgement must be given to all women choosing to formula feed their babies. Mothers must be informed about the dangers of mixed feeding when breast engorgement develops during the first week after delivery.

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