

# Use of nutritional and water hygiene packages for diarrhoeal prevention among HIV-exposed infants in Lilongwe, Malawi: an evaluation of a pilot prevention of mother-to-child transmission post-natal care service

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## Summary

**OBJECTIVE** To evaluate a pilot prevention of mother-to-child transmission post-natal programme in Lilongwe, Malawi, through observed retention and infant diarrhoeal rates.

**METHODS** Free fortified porridge and water hygiene packages were offered to mothers to encourage frequent post-natal visits and to reduce diarrhoeal rates in infants on replacement feeding. Participant retention and infant health outcome were assessed.

**RESULTS** Of 474 patients enrolled, 357 (75.3%) completed 3-month follow-up visits. Ninety-nine percent of women reported hygiene package use, and only 17.7% (95% CI 13.8–22.0%) of the infants had diarrhoea at least once over the 3-month period. Being 12 months or younger, confirmed HIV positive, access to tap water, and having a mother with diarrhoea were all associated with increased risk of infant diarrhoea.

**CONCLUSION** The majority of participants adhered to their scheduled visits and retention was favourable, possibly because of the introduction of hygiene and nutrition incentives. The infant diarrhoeal rate was low, suggesting benefits of regular medical care with hygiene package usage and reliable replacement feeding options. Continuation and expansion of the programme would allow further studies and improve the post-natal care of HIV-exposed infants in Malawi and in other resource-constrained countries.

**keywords** post-natal care, HIV, Malawi, infantile diarrhoea, hygiene

## Introduction

Worldwide, an estimated 2 million children under the age of 15 are infected with HIV, mostly through maternal-to-child transmission (UNAIDS). In 2004, at least 9.8% of pregnant Malawian women were HIV-infected; mortality for Malawian children under age of five is estimated to be 13.3% (National Statistical Office 2005). Prevention of mother-to-child transmission (PMTCT) is a critical strategy that employs antiretroviral agents before, during, and after delivery to protect the neonate from HIV (Abrams *et al.* 2007; Moses *et al.* 2008). Most PMTCT programmes utilize administration of single-dose nevirapine to both mothers and infants (Abrams *et al.* 2007), follow-up HIV

testing of exposed infants, and more recently dietary counselling based on HIV infant feeding guidelines.

Continued monitoring of HIV-exposed infants after delivery is challenging because of high rates of lost to follow-up. In routine care settings, nearly 50% of infants miss their first post-natal visit at 2 weeks (Sherman *et al.* 2004; Jones *et al.* 2005). Increasing participant retention is critical to the prevention of vertical HIV transmission through breastfeeding and the provision of medical care to mothers and infants. While early breastfeeding cessation lowers the risk of vertical HIV transmission, the weaned infants are more susceptible to gastrointestinal and respiratory illnesses without the immunological benefits of breast milk, especially in the first 6 months of life (WHO

Collaborative Study Team on the Role of Breastfeeding on the Prevention of Infant Mortality 2000, Homsy *et al.* 2010). Cost and contaminated water supplies limit the use of powdered formula, leading to infant diarrhoea and malnutrition, increasing infant mortality.

At the time of the pilot study, WHO recommended breastfeeding for the HIV-exposed infants in the first 6 months followed by rapid weaning between the 6th and 7th months, provided that the replacement diet is acceptable, feasible, affordable, sustainable and safe (World Health Organization 2003). Recent publications from Malawi and Uganda indicate that higher mortality and morbidity is associated with early weaning at 6 months compared to breastfeeding into the second year of life (Onyango-Makumbi *et al.* 2010; Kafulafula *et al.* 2010), suggesting that safe weaning at 6 months is difficult to achieve even under PMTCT care settings. In November, 2009, WHO revised its recommendations for breastfeeding of HIV-exposed infants to 12 months of age provided that either mother or infant is receiving antiretroviral drugs (World Health Organization 2009).

To address some of the difficulties associated with weaning, we developed a pilot programme that includes distribution of fortified porridge (VitaMeal) and hygiene packages that contain water treatment and storage devices in two antenatal clinics in Lilongwe. Such incentives increase clinic visits compared to routine service (Sherman *et al.* 2004), which may encourage more frequent follow-ups and promote safe replacement feeding of HIV-exposed infants. Point-of-use water treatment and hygiene education can lower risks of diarrhoea in children and in infants during the pre-weaning and post-weaning period (Arnold & Colford 2007; Harris *et al.* 2009), and offering free fortified porridge may avoid risks of food-borne pathogens and inadequate nutrition that are associated with typical replacement feeding in developing countries (Motarjemi *et al.* 1993). This report evaluates participant retention and infant health outcome in the post-natal programme after distribution of incentives.

## Materials and methods

### PMTCT programme and setting description

The Malawi PMTCT programme has been described previously (Moses *et al.* 2008). Briefly, the programme offers antenatal care and counselling along with DNA PCR testing for the exposed infants at 6 weeks, 6 months and 18 months at Bwaila Hospital and several Lilongwe area health centres. Single-dose nevirapine is given to mothers at onset of labour and to infants within 72 h of

birth. Mothers with CD4 lymphocyte counts of <500 cells/ $\mu$ l receive cotrimoxazole (CPT), and all HIV-exposed infants receive CPT from 6 weeks to 18 months unless they are weaned and confirmed HIV negative. Following the Malawi national guidelines, women are recommended to wean infants from breastfeeding at 6 months if feasible, including infants who are confirmed HIV positive.

### Population and post-partum programme

Any HIV-positive woman attending area 18 or area 25 health centres in Lilongwe, Malawi, with a child approximately 6 months of age or older is invited to participate in the post-partum programme, which includes hygiene packages and VitaMeal nutritional distribution. This includes women who visited Lilongwe PMTCT services during the pre-natal period as well as any mothers with infants who are not previously cared by PMTCT. Participating households receive 4 kg of VitaMeal and a hygiene package that includes water disinfectant, filtering cloth, soap and a bucket with lid and spout. VitaMeal is a vitamin-fortified porridge supplied by Feed The Children.

Two water disinfectant products are distributed depending on the water source(s). Water disinfectant, a dilute hypochlorite solution, is provided by Population Services International (2008) for clear drinking water sources such as tap and boreholes. PuR<sup>®</sup> Purifier of Water is a combination ferric sulphate coagulant and calcium hypochlorite disinfectant provided by Proctor & Gamble, distributed to those with unprotected drinking water sources such as open wells and rivers. The closed bucket with spout and soap are for post-treatment water and food handling contamination. The participants are educated on post-natal care and good hygiene practices through water disinfectant usage. Women and their infants were scheduled for one follow-up visit per month where they receive additional hygiene and VitaMeal supplies.

### Design

This is a prospective, observational study of the women and infants who were enrolled in the pilot post-natal programme between October 2008 and March 2009. One follow-up visit is scheduled every month after enrolment, preliminary data at the 3-month visit is examined. Data collection continued until 1st July 2009, to allow for at least 3 months of enrolment from all participants who started their visits before April, 2009. Women who enrolled within 90 days prior to July 1st were excluded from the analysis.

### Data collection and analysis

Baseline demographics and health status data are collected at the initial visit for enrolment into the programme. The initial visit for this study is defined as the first postpartum visit at which the infant–mother pair received incentive products, and the mother is encouraged to begin rapid weaning if the infant is not already on replacement feeding. At each monthly follow-up visit after receiving Vitameal and hygiene packages, data is collected to evaluate the general health status of mother and infant. Mothers are asked to report their weaning status and any episodes of diarrhoeal-related illnesses in both the mothers and infants over the previous month. They also report on the usage of water treatment and hygiene products. The infant's weight and length is measured at the enrolment visit as well as at each follow-up visits. No infant mortality data are collected as only returning participants are followed in the study.

All data are first recorded by clinic staff in a log book and then transcribed into a Microsoft Access database. Data is transformed and analysed using Stata9.1 (Stata Corps, College Station, TX, USA) and baseline demographics are summarized by median values and frequencies. Acute malnutrition of the child is estimated by a WHO weight-for-length Z score of 2SD below the median (WHO Multicentre Growth Reference Study Group 2006). The WHO defines severe acute malnutrition as below  $-3Z$  of the median weight-for-length standards (World Health Organization, United Nations Children's Fund 2009). The 3-month retention rate of participants, water disinfectant usage and participant health outcomes are assessed. Retention is examined by the percentage of participants who remain in PMTCT for care at 3 months as well as by how well the mothers adhered to their scheduled monthly follow-ups. The primary outcome of interest is the 3-month infant diarrhoeal incidence based on monthly report by the mothers. As some participants returned before or after

their scheduled monthly visits, the visit that is closest and within 21 days of the 3-month mark is used.

Univariate and multivariate risk ratios (RR) of relevant exposures for infant diarrhoea are determined by binary regression analysis. Only variables with  $P < 0.1$  in the univariate calculations are included in the multivariate analysis. Variables that have independent associations with infant health outcome are reported by adjusted risk ratios, 95% confidence intervals and  $P$  values. As a complete case analysis, all missing data for any variable are automatically excluded in regression calculations; imputation is not used.

### Ethics and consent

Institutional Review Board (IRB) approvals were obtained from Malawi and UNC-CH IRB before the start of the study. All participants verbally consented to data collection at the enrolment visit of the study.

### Results

Between October 2008 and March 2009, 474 women were enrolled at area 18 and area 25 health clinics (Table 1). All enrolled women tested HIV positive through PMTCT, and 34 of 474 (7.2%) of the infants were confirmed HIV positive. At the initial post-natal visit where hygiene packages were distributed, the median age of the infants was 11.7 months, ranging from 2.4 to 24 months. About half of the infants (219/474, 46.2%) were over 12 months old. Their median length was 69 cm and the median weight was 8.2 kg. Among the 34 HIV-positive infants of the pool of 474 infants, 30 of 34 (88.2%) of them received CPT, the percentage is similar to that of HIV-positive women who were dispensed CPT (88.0%). Overall, 251 of 474 (53.0%) exposed infants received CPT.

As of 1st July 2009, a total of 2370 visits were recorded for 474 participants enrolled during the first 6 months (October, 2008–March, 2009) of the pilot programme.

**Table 1** Baseline data of mothers and infants enrolled in area 18 and area 25 postnatal program, Lilongwe, Malawi, 2008–2009

	Yes (%)	No (%)	Unknown (%)
Infant replacement-fed	413/474 (87.2)	54/474 (11.4)	7/474 (1.5)
Infant malnutrition	27/474 (5.7)	424/474 (89.5)	23/474 (4.9)
Infant HIV-positive	34/474 (7.2)	358/474 (75.5)	82/474 (17.3)
Infant CPT dispensed	251/474 (53.0)	216/474 (45.6)	7/474 (1.5)
Mother CPT dispensed	417/474 (88.0)	56/474 (11.8)	1/474 (0.2)
Mother on ART	195/474 (41.1)	278/474 (58.7)	1/474 (0.2)
Tap water	386/474 (81.4)	86/474 (18.1)	2/474 (0.4)
Disinfectant received	474/474 (100)	0	0
VitaMeal received	266/474 (56.1)	196/474 (41.4)	12/474 (2.5)

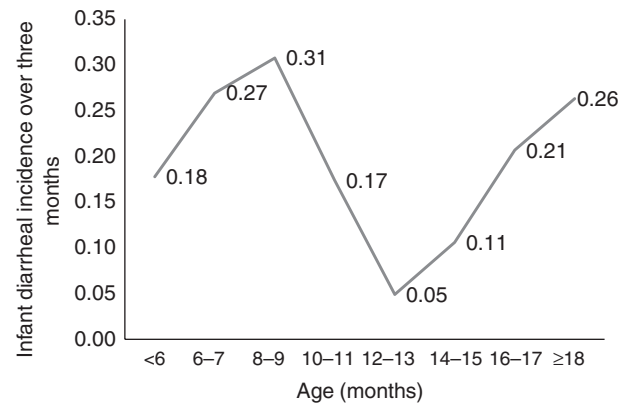
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The total number of consecutive visits ranged from 1 to 8 visits (median three visits). All of the women enrolled had the opportunity to complete four visits, one enrolment visit and three follow-up visits. During the 3 months after enrolment, 49 of 474 women (10.3%) completed only one follow-up visit, 92 (19.4%) completed two follow-up visits, and 301 (63.5%) completed three or more. Thirty-two of the 474 women (6.8%) did not return for any follow-up visits. At the end of the 3 months, 357 (75.3%) participants remained in follow-up.

At the 3-month visit, 355 of 357 women (99.4%) reported using water disinfectant and other hygiene products at home, and VitaMeal was distributed to 345 (96.6%) of the 357 households. By 3 months, 332 of 357 (93.0%) of the infants were on replacement feeding. Infant malnutrition rate was 7.0% (25 of 357 infants), and only 48 of 357 (13.5%) of the children had unknown HIV status.

Infant health status was examined at the 3-month visit. Seventeen of 357 (4.8%, 95% CI 2.8–7.5%) of the infants and 3 (0.8%, 95% CI 0.2–2.4%) of the mothers were reported to have had at least one episode of diarrhoea within the previous month. Infant diarrhoeal rate peaked between 6 and 11 months of age (9 of 119 infants, 7.6%, 95% CI 3.5–13.9%). Overall, diarrhoeal rates were lower than reported in the 2004 Malawi Demographics and Health Survey (Table 2) (National Statistical Office 2005). Over 3 months of enrolment, 63 of 357 (17.7%, 95% CI 13.8–22.0%) of the infants who remained in the study had diarrhoea at least once, 25 of 357 (7.0%, 95% CI 4.6–10.2%) of mothers reported having diarrhoeal illnesses at least once. The diarrhoeal rate was highest in those who were 8 to 9 months old at enrolment (Figure 1).

Variables associated with diarrhoea in the first 3 months were younger age ( $P = 0.009$ ), testing HIV-positive ( $P < 0.001$ ), using tap water ( $P = 0.04$ ) and mothers having diarrhoea ( $P < 0.001$ ) in the univariate analysis (Table 3). Replacement feeding, infant malnutrition, receiving CPT and VitaMeal were not associated with infant diarrhoea. In the multivariate analysis, being



**Figure 1** Age-specific 3-month infant diarrhoeal incidence at Area 18 & Area 25 clinics, Lilongwe, Malawi.

12 months or older ( $P = 0.004$ ) was independently protective, and again, being infected with HIV ( $<0.001$ ), having tap water ( $<0.001$ ), and having mothers in the same household with diarrhoea ( $P < 0.001$ ) were independent risk factors for infants experiencing diarrhoea within 3 months of the initial visit.

## Discussion

Water disinfectant plus hygiene and VitaMeal package distribution for post-natal mothers resulted in positive uptake and retention in clinical care and an apparent decrease in the frequency of diarrhoea among replacement-fed infants. In this pilot programme, greater than 70% of the participants remained in the post-natal programme for at least 3 months. The majority of the participants adhered to their monthly scheduled visits. In 2008, only about 33% of infants who received CPT at 6 weeks returned for follow-up visits to continue CPT treatment at 6 months in the Lilongwe PMTCT programme (Innocent Mofolo/Internal Communication 2009). The pilot programme was successful in encouraging regular clinic attendance among participants; our incentives of free hygiene packages and VitaMeal likely contributed. It is possible that some participants did not complete a visit within 21 days of 3 months but remained in the programme, thus, the true retention rate may be higher. Infant mortality, time and cost of transportation are likely causes for missing visits. A small proportion of participants returned more frequently than scheduled, which could be because of acute illness in either the mother or the child or desire to obtain additional hygiene and VitaMeal packages.

Vitameal distribution was only at 55.1% during the enrolment visit but increased to 96.6% by the 3-month visit. The lower distribution of nutritional packages at enrolment

**Table 2** PMTCT area 18 and area 25 infant diarrhoea rate at third month compared with 2004 Malawi Demographic and Health Surveys (DHS) biweekly rate (National Statistical Office 2005)

Age (months)	PMTCT % Diarrhoea/4 weeks	DHS % Diarrhoea/2 weeks
<6	0 ( $n = 1$ )	9.2 ( $n = 1109$ )
6–11	7.6 ( $n = 119$ )	41.2 ( $n = 1188$ )
12–23	3.5 ( $n = 231$ )	38.9 ( $n = 2194$ )
24–59	0 ( $n = 6$ )	8.3–21.5 ( $n = 5286$ )

PMTCT, prevention of mother-to-child transmission.

**Table 3** Association of risk factors with infant diarrhea at 3-month follow-up visit, Lilongwe, Malawi, 2008–2009

	N*	Diarrhea since initial visit	Unadjusted RR (95% CI)	Adjusted RR (95% CI)	P value
Total	357	63 (17.7%) (CI 95% 13.8–22.0%)			
Age ≤ 12 months	189	43 (22.8%)	1	1	
Age > 12 months	168	20 (11.9%)	0.52 (0.32–0.85)	0.55 (0.37–0.83)	0.004
Breast or mixed feeding	37	7 (18.9%)	1		
Replacement feeding	314	54 (17.2%)	0.91 (0.45–1.8)	P > 0.1	
No malnutrition	317	50 (15.8%)	1		
Infant malnutrition	21	4 (19.1%)	1.2 (0.48–3.0)	P > 0.1	
Infant HIV-negative	276	40 (14.5%)	1	1	
Infant HIV-positive	22	9 (40.9%)	2.8 (1.6–5.0)	3.2 (2.2–4.7)	<0.001
No infant CPT	172	25 (14.5%)	1		
Infant CPT dispensed	179	37 (20.7%)	1.4 (0.89–2.3)	P > 0.1	
Well or borehole	63	5 (7.9%)	1	1	
Tap water	292	58 (19.9%)	2.5(1.0–6.0)	2.0 (1.4–3.1)	<0.001
No VitaMeal	133	20 (15.0%)	1		
Vitameal received	213	41 (19.3%)	1.3 (0.79–2.1)	P > 0.1	
Mom healthy	332	49 (14.8%)	1	1	
Mom had diarrhea	25	14 (56.0%)	3.8 (2.5–5.9)	4.9 (3.3–7.2)	<0.001

\*Missing data are not shown in categories where N do not add up to the total number of participants (357).

is probably because of shortage of supplies at programme onset, less familiarity with the programme and more infants were being exclusively breastfed. Infant malnutrition did not seem to decrease during the pilot programme despite supplementation. In Malawi, infant weight gain tends to occur during harvest, after a growth decline in the rainy season from October to April, (Maleta *et al.* 2003), which largely coincides with our programme participation period. In 2004, 6.8–10.7% of Malawian children aged 6–23 months were 2SD below the WHO weight-for-height median measurements (National Statistical Office, 2005). Our supplementation programme may have prevented more severe weight loss during the rainy season.

Water disinfectant usage was 99.4% among returned participants at 3-month visit, whereas in a national household survey, only 12% of Malawian mothers with children under the age of five surveyed used water disinfectant (Stockman *et al.* 2007). The survey examined only one type of water disinfectant option but even when other methods are included, it is found that only 20% of Malawians treat their household water supply (Rosa & Clasen 2010). Our high acceptance rate is likely because of the increased awareness and accessibility through free distribution. It suggests effective hygiene education and potentially improved water sanitation for both the mothers and infants who are at risk of opportunistic infections. However, we cannot account for the 24.7% of participants who are lost to follow-up at 3-months.

At the 3-month follow-up, we compared the monthly diarrhoeal rate for our infants to that of infants under the age of five reported in the Malawi Demographic and Health Surveys/DHS. 4.8% of the returning infants had diarrhoea at least once, which is considerably lower than the rates reported in DHS. However, the methodology varied across these assessments: DHS is a cross-sectional nation-wide survey that reports prevalence of infant diarrhoea 2 weeks prior to time of interview, whereas our data is collected monthly. However, similar trends exist where the rate of diarrhoeal illness peaks between the sixth and eleventh month of age, which is also consistent with other studies (Molbak *et al.* 1997; Kourtis *et al.* 2007). Our participants only come from areas within and nearby Lilongwe, the majority of which already have access to tap water.

It is not surprising then that our infant diarrhoeal rate, even at 4 weeks, was much lower than the DHS reported diarrhoeal rate over 2 weeks in every age group. However, our diarrhoeal rate is still low compared with a preliminary analysis from another recent PMTCT study, where the participant population was similar but households were not offered hygiene education and free water treatment packages, and the diarrhoeal rates varied by month from 21.4 to 47.9% for infants under 1 year old (Kourtis *et al.* 2007). The Malawi Multiple Indicator Cluster Survey 2006 reports that the diarrhoeal rate for children under five in Lilongwe is 26% over 2 weeks, and in the urban setting, it is 22% (Malawi National Statistical Office, United Nations

Children's Fund 2008). The lower rate of illness in our post-natal programme could be partly attributed to better hygiene awareness, high compliance of water disinfectant use and availability of nutritional supplements. Point-of-use water treatment and hygiene education are associated with lowered diarrhoeal rates in HIV-exposed infants before and after weaning, but improved water quality alone is not sufficient to reduce diarrhoea during the weaning period (Harris *et al.* 2009). Incentives that likely encouraged timely follow-ups also allow for better medical treatment and care of the infants when needed.

As expected, younger age and HIV infection are independently associated with 3-month cumulative infant diarrhoeal incidence in both the univariate and multivariate analyses. These results support the new WHO guidelines for prolonging breastfeeding to until 12 months of age (World Health Organization 2009). Infants younger than 12-months and infants with HIV have compromised immune systems and would be expected to be more at risk for bacterial and parasitic infections. Having a mother with diarrhoea is also an independent risk factor for infant having diarrhoea, likely because of shared environmental contamination or person-to-person transmission.

We did not find an association between infant diarrhoea and malnutrition or replacement feeding. Previous studies have found infant malnutrition to be associated with infant diarrhoea (Lima & Guerrant 1992; Mach *et al.* 2009), and lack of breastfeeding increases risk of childhood diarrhoea (WHO Collaborative Study Team on the Role of Breastfeeding on the Prevention of Infant Mortality 2000, Homsy *et al.* 2010). Our subset of sample was too small for proper analysis. Water sanitation and hygiene practice influence rates of diarrhoea as well (Lima & Guerrant 1992; Arnold & Colford 2007; Harris *et al.* 2009), but we were not able to apply water disinfectant usage as an independent variable in our analyses because of high compliance rate.

To our surprise, access to tap water is associated with diarrhoea. Tap water in theory should be less contaminated than wells or boreholes, but one explanation may be that those without tap water access are using filtration products more frequently, and those with tap water are less likely to use filtration every time if they feel that the city tap is sufficient. Our data does not measure frequency of usage in households. Also, different brands of water filtration packets were distributed based on tap water access. For example, the hypochlorite given to tap water users does not inactivate diarrhoea-causing protozoan cysts, whereas the PuR solution does. It is also conceivable that participants used other water sources such as rivers, streams or springs on occasion without reporting the usages.

Limitations in the study include the use of observational and self-reported data. Recall of diarrhoeal illness is

optimal within 24–72 h (Ramakrishnan *et al.* 1999), but our data relied on monthly recall and do not take into account the frequency of diarrhoea within each month. Usage of water disinfectant and VitaMeal intake are monitored through self-report only, so the extent of usage and consumption may vary largely by household. We did not collect infant mortality data, which would provide a more accurate picture of infant health outcome. Our results likely underestimate the actual infant diarrhoeal rates, which could be higher in those who were lost-to-follow up. In an expansion of the programme, infant mortality should be tracked as a part of the study. Seasonal changes are not accounted for in our study, which impacts diarrhoeal rates (Kourtis *et al.* 2007). Women were enrolled at different times between October and March, and follow-up visits span into July, these months encompass both the dry and wet seasons, introducing more variability.

Our pilot study shows a favourable retention of PMTCT participants at the post-natal visits in area 18 and area 25 clinics of Lilongwe. The distribution of free water disinfectant and VitaMeal packages are well-received and should be continued. There is an observed reduction of reported infant diarrhoeal rates in our participants compared to that in historical controls. The combination of VitaMeal, which ensures adequate infant nutrition during replacement feeding, and the hygiene packet make replacement feeding feasible and likely contributed to positive infant health outcome and better sanitation for the entire household. The results are promising, but further studies with non-historical controls are needed to validate our preliminary observations. The continuous post-natal care of HIV-positive mothers and their infants is essential in reducing vertical transmissions and preventing progression of disease. We hope to conduct further studies by extending this model of post-natal care to more rural districts where safe water and reliable replacement feeding options are less accessible.

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