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Research article

The Tingathe programme: a pilot intervention using community health workers to create a continuum of care in the prevention of mother to child transmission of HIV (PMTCT) cascade of services in Malawi

Maria H Kim*[§,1], Saeed Ahmed*[1], W Chris Buck[2], Geoffrey A Preidis[1], Mina C Hosseinipour[3,4], Avni Bhalakia[2], Debora Nanthuru[2], Peter N Kazembe[2], Frank Chimbwandira[5], Thomas P Giordano[6], Elizabeth Y Chiao[6], Gordon E Schutze[1] and Mark W Kline[1]

[§]**Corresponding author:** Maria H Kim, Baylor College of Medicine International Pediatric AIDS Initiative at Texas Children's Hospital, Baylor College of Medicine, Houston, TX, USA. Tel: 832-822-1038. (mhkim@bcm.edu)
*These authors contributed equally to this work.

Abstract

Introduction: Loss to follow-up is a major challenge in the prevention of mother to child transmission of HIV (PMTCT) programme in Malawi with reported loss to follow-up of greater than 70%. *Tingathe*-PMTCT is a pilot intervention that utilizes dedicated community health workers (CHWs) to create a complete continuum of care within the PMTCT cascade, improving service utilization and retention of mothers and infants. We describe the impact of the intervention on longitudinal care starting with diagnosis of the mother at antenatal care (ANC) through final diagnosis of the infant.

Methods: PMTCT service utilization, programme retention and outcomes were evaluated for pregnant women living with HIV and their exposed infants enrolled in the *Tingathe*-PMTCT programme between March 2009 and March 2011. Multivariate logistic regression was done to evaluate maternal factors associated with failure to complete the cascade.

Results: Over 24 months, 1688 pregnant women living with HIV were enrolled. Median maternal age was 27 years (IQR, 23.8 to 30.8); 333 (19.7%) were already on ART. Among the remaining women, 1328/1355 (98%) received a CD4 test, with 1243/1328 (93.6%) receiving results. Of the 499 eligible for ART, 363 (72.8%) were successfully initiated. Prior to, delivery there were 93 (5.7%) maternal/foetal deaths, 137 (8.1%) women transferred/moved, 51 (3.0%) were lost and 58 (3.4%) refused ongoing PMTCT services. Of the 1318 live births to date, 1264 (95.9%) of the mothers and 1285 (97.5%) of the infants received ARV prophylaxis; 1064 (80.7%) infants were tested for HIV by PCR and started on cotrimoxazole. Median age at PCR was 1.7 months (IQR, 1.5 to 2.5). Overall transmission at first PCR was 43/1047 (4.1%). Of the 43 infants with positive PCR results, 36 (83.7%) were enrolled in ART clinic and 33 (76.7%) were initiated on ART.

Conclusions: Case management and support by dedicated CHWs can create a continuum of longitudinal care in the PMTCT cascade and result in improved outcomes.

Keywords: prevention of mother to child transmission (PMTCT); early infant diagnosis (EID); paediatric HIV; HIV; task shifting; community engagement; community health workers; retention; loss to follow up.

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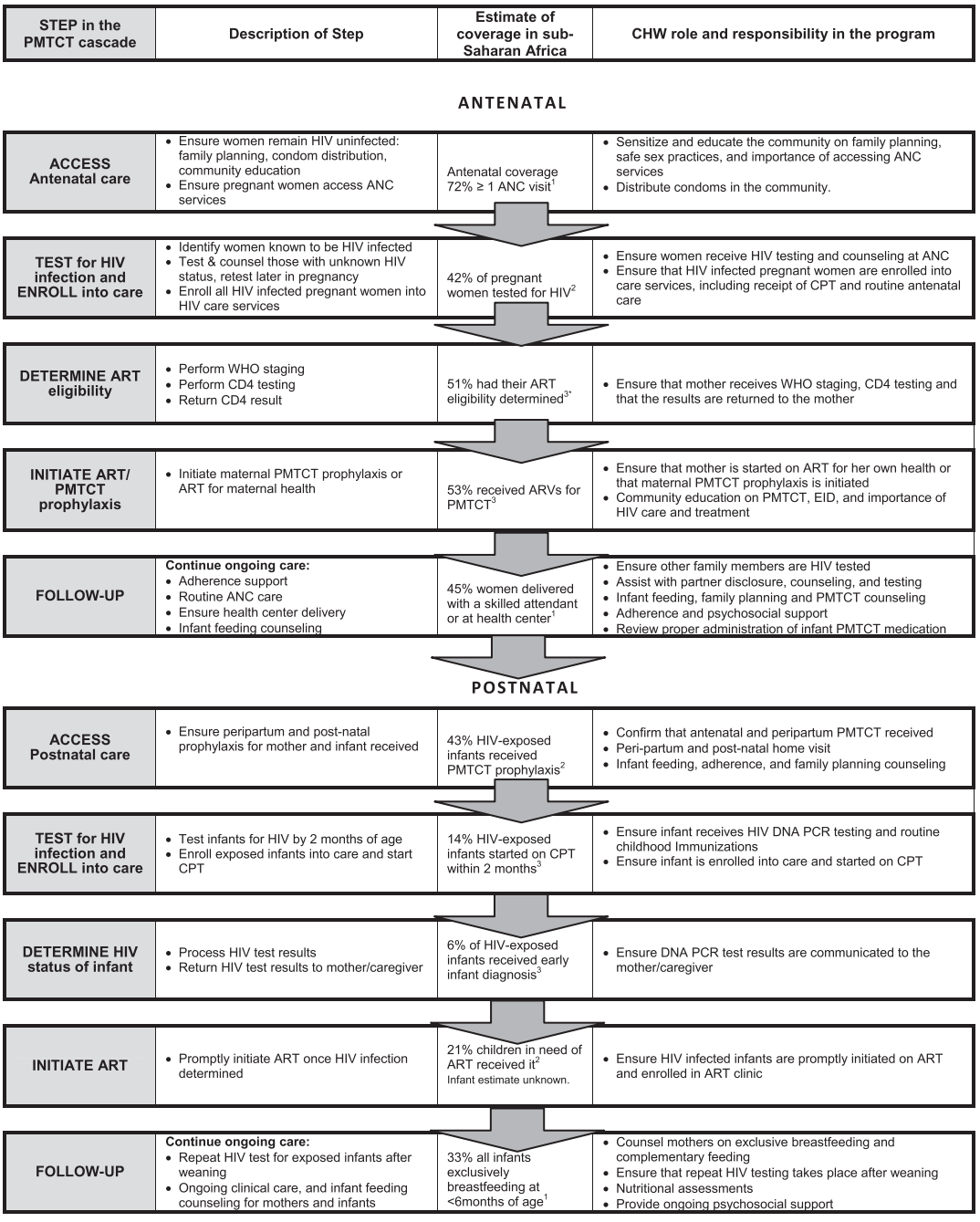
Introduction

In 2011, UNAIDS announced a call to eliminate new paediatric HIV infections among children by 2015 [1]. Effective medical interventions for prevention of mother to child transmission of HIV (PMTCT) have been known since the late 1990s, and in developed countries, almost no new paediatric HIV infections occur [2,3]. Globally, though, an estimated 370,000 children acquired HIV in 2009, the vast majority through vertical transmission [1]. This disparity in outcomes has not been due to a lack of effective medications or tools. The World Health Organization (WHO) PMTCT guidelines detail simple and effective interventions that make transmission rates of less than 5% feasible, even among breastfeeding populations [4]. Rather, persistent poor outcomes in developing countries are the result of mothers living with HIV and exposed infants not receiving the full array of available services [5–8].

Figure 1 provides details on the full PMTCT cascade and current utilization rates in sub-Saharan Africa. National guidelines and programs in high burden countries, including Malawi, often subdivide aspects of this cascade into separate PMTCT (vertical transmission), antiretroviral therapy (ART), early infant diagnosis (EID) and paediatric HIV programs, frequently with different providers and service locations for



[1] UNICEF: *The State of the World's Children*. New York, 2011.
[2] WHO: *Towards universal access: scaling up priority HIV/AIDS interventions in the health sector: progress report*. Geneva, 2010.
[3] UNICEF: *Children and AIDS Fifth Stocktaking Report, 2010*. New York, 2010.
* Data available only for low/middle income countries, not available for sub-Saharan Africa
Abbreviations: CHW (community health worker), ANC (antenatal care), ARVs (anti-retrovirals), ART (antiretroviral therapy), PMTCT (prevention of mother-to-child transmission), EID (early infant diagnosis), sdNVP (single dose nevirapine), CPT (co-trimoxazole prophylaxis)

Figure 1. The PMTCT cascade of services: steps, estimates of coverage in sub-Saharan Africa and CHW responsibilities in the programme.

each component. Resulting poor utilization of available services, lack of coordination between providers and high rates of loss to follow-up have led to persistent high infection rates in exposed children [1,8,9]. It has been shown that, even with highly efficacious combination antiretroviral interventions, only marginal reductions in childhood HIV infections can be achieved without improved retention of pregnant mothers and infants within the PMTCT cascade of services [10]. Human resource shortages in high burden countries further compound programme inefficiencies and limit the ability of the healthcare system to make improvements. If the goal of eliminating new paediatric infections is to be reached, interventions to improve health systems performance and to address human resource needs are required. Task shifting with the use of community health workers (CHWs) has been suggested as one strategy to

(a)

Components of the PMTCT cascade available at programme intervention sites:

- HIV testing of all antenatal clinic attendees via provider initiated opt-out testing
- CD4 testing for all newly identified HIV-infected pregnant women. Women already on anti-retroviral therapy (ART) generally do not receive a new CD4
- Transport of CD4 samples to the Central Hospital laboratory for processing, as well as transport of results back to the facility
- WHO staging at initial HIV diagnosis
- Provision of PMTCT prophylaxis for ART ineligible women
- DNA PCR testing by national early infant diagnosis program starting at 6 weeks of age and repeat six weeks after breast feeding cessation
- Co-trimoxazole preventative therapy (CPT) for pregnant women and HIV-exposed infants
- Supplementary food for pregnant/lactating mothers and treatment for malnutrition for children with acute malnutrition
- Monthly follow-up of exposed infants at HIV clinic until weaning
- Paediatric and adult HIV and ART treatment

(b)

Curriculum of Community Health Worker Training

1. Basics of HIV/AIDS
2. PMTCT: what are the steps and how to promote utilization of services
3. Caring for the exposed infant: importance of early infant diagnosis and cotrimoxazole prophylaxis
4. Diagnosing HIV infection
5. Nutrition: exclusive breast feeding, complementary feeding, and malnutrition screening
6. Children with HIV: identification, care and treatment
7. Anti-retroviral therapy and adherence counseling
8. Reducing stigma and discrimination
9. Counseling and community mobilization and education skills
10. Conducting the patient home visit

Figure 2. (a) Components of the PMTCT cascade available at programme intervention sites. (b) Curriculum of community health worker training.

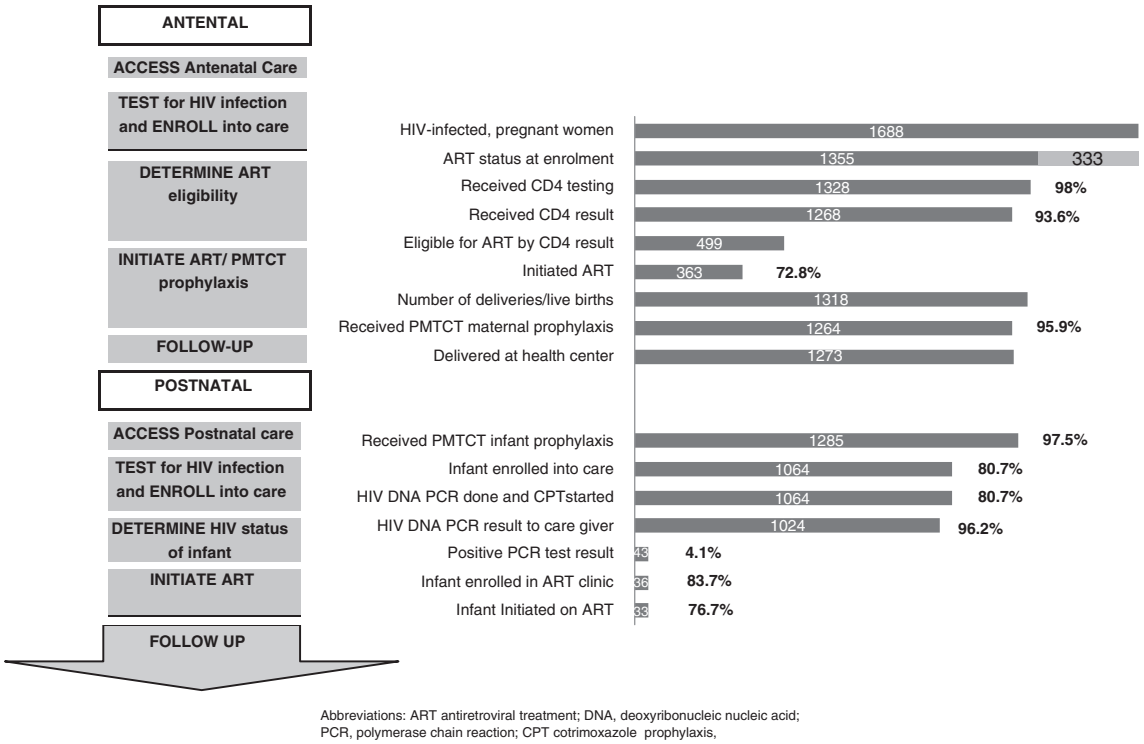
address these challenges within resource-limited settings [11–15].

In March 2009, Baylor College of Medicine Children's Foundation Malawi, in collaboration with the Malawi Ministry of Health (MOH), initiated a pilot community-based intervention in Lilongwe that uses lay CHWs as a bridge linking the government PMTCT, EID and paediatric HIV programs. Called *Tingathe*-PMTCT (meaning ''yes we can'' in the local Chichewa language), the intervention was designed to create a new paradigm in PMTCT service delivery and end the compartmentalization of services into distinct PMTCT, EID and paediatric HIV subunits [9]. *Tingathe* CHWs ensured longitudinal care throughout the full PMTCT cascade, starting with diagnosis of the mother at antenatal care (ANC) and ending with final diagnosis and treatment of the infant. This paper provides details on the pilot intervention as well as a current snapshot of our patient cohort. Impact on patient retention, utilization of services and outcomes was evaluated.

Methods

Intervention setting and patient population

The *Tingathe*-PMTCT pilot programme took place in Area 25 and Kawale, two large peri-urban communities in Lilongwe. The estimated population is 310,000 people, with 15,000



Abbreviations: ART antiretroviral treatment; DNA, deoxyribonucleic nucleic acid; PCR, polymerase chain reaction; CPT cotrimoxazole prophylaxis,

Figure 3. Steps of PMTCT cascade completed by mother-infant pairs in programme intervention.

deliveries/year, 2000 HIV-exposed infants delivered/year and 12% adult HIV prevalence [16]. Over 96% of pregnant women attend at least one antenatal visit [17] and 99% of ANC attendees are tested for HIV [18,19].

Routine PMTCT services available at intervention sites

All PMTCT clinical care was provided in accordance with MOH and WHO guidelines [20,21]. Figure 2a details all components of the PMTCT cascade available at the intervention sites. HIV testing, counselling and consent were conducted via opt-out testing per MOH guidelines.

At the start of our programme, ART eligibility was defined as WHO Stage 3 or 4 or CD4 $\leq$250 cells/mm^3 [21]. ART eligibility changed in August 2010 to CD4 $\leq$350 cells/mm^3 for pregnant or lactating women living with HIV.

For women who did not qualify for ART, single dose nevirapine for the mother and infant and a bottle of zidovudine (AZT) syrup for the infant was dispensed at the first ANC visit. AZT was dispensed beginning at 28 weeks, and mothers returned for monthly refills. A 1-week supply of AZT/lamivudine (3TC) tail was distributed during labour and delivery [21].

During the intervention period, the national infant feeding guidelines recommended exclusive breastfeeding until 6 months of age followed by gradual weaning [22,23]. Universal ART initiation for HIV-infected infants younger than 1 year of age was the standard of care.

Preintervention data

We used three sources for preintervention data. The first was a published report of maternal and infant utilization of PMTCT, EID and paediatric HIV services at five sites (including our two intervention sites) within Lilongwe between 2004 and 2008 [19]. This source contained preintervention comparison data for PMTCT prophylaxis, infant PCRs and ART initiation for HIV-infected infants. For information not included in this report, we used the 2004 Malawi Demographic and Health Survey, which provided national statistics for numbers of women accessing ANC, location of delivery and infant feeding choice after birth [17]. Finally, ANC CD4 log records documented CD4 test dates and whether or not results were returned to pregnant women. Consistent records were not kept at A25. At Kawale, records were available from March to October 2008.

Details of the pilot intervention

Intervention overview

The main focus of this programme was CHW-based patient case management in both the health facility and community (Figure 1). The intervention began at ANC when pregnant women identified as living with HIV were assigned a dedicated CHW and voluntarily enrolled into the programme. CHWs ensured that mother-infant pairs received all necessary PMTCT services. They followed their clients at their homes and at health centres, from initial diagnosis up until confirmation of definitive HIV-uninfected status after cessation of breastfeeding or successful ART initiation for HIV-infected infants. Receipt of PMTCT was recorded only upon confirmation with the mother after delivery to verify that medication had actually been ingested, not just dispensed [7]. Women living with HIV who were identified at labour and delivery

or after the birth of the infant were also followed up and provided services but were not included in this cohort.

CHW selection, training and roles

Criterion for CHW selection included living within the community, completion of primary schooling and ability to read and write in English and Chichewa, ability to ride a bicycle and HIV-infected or affected. Both men and women were recruited. Due to the large volume of applicants, we first conducted group interviews, inviting those who performed well in these for individual interviews. Once selected, CHWs earned a stipend for work-related transportation and food (2.50 USD/day).

A specialized 2-week training, followed by a 2-week on-site orientation, was developed (Figure 2b). Trainees were monitored closely by supervisors and were only allowed to conduct unsupervised patient visits after competency had been verified. CHWs also received half-day quarterly refresher trainings by Baylor paediatricians.

To help free up clinical staff for essential clinical care, specific tasks were shifted to CHWs, including patient registration, nutritional assessments, infant feeding counselling, pill counting and distribution of nutritional supplements. All CHWs were responsible for both health centre-based tasks (40% time) and community work (60% time). CHWs generally followed up to a maximum of 50 mother-infant pairs at one time.

Community sensitization/education

Prior to the programme intervention, consultative meetings were conducted with community leaders. CHWs conducted daily education sessions in the health centres and held ongoing sensitization meetings in the community. The main focus of education was promoting the utilization of PMTCT, EID and paediatric HIV treatment services.

Monitoring, evaluating and supervising CHW activities

An individual patient mastercard was used to facilitate patient case management, and a patient register was used to monitor CHW activities. The mother-infant mastercard was opened on programme entry, updated after every visit and key data entered into registers weekly. Information from registers was entered into a Microsoft Access database bimonthly. CHWs were supervised weekly by site supervisors and monthly by the programme coordinator. Supervisors also conducted unscheduled visits with patients to ensure that they were satisfied with the services being provided. CHWs received bi-annual performance evaluations.

Programme exit/patient outcomes

Mother-infant pairs exited the programme if they reached one of the following outcomes: (1) maternal death; (2) miscarriage, stillbirth; (3) infant death; (4) transferred/moved outside the catchment area; (5) lost (patient tracing attempted but patient could not be found); (6) despite counselling, patient refused to return for clinical care; (7) infant infected and successfully enrolled into care and started on ART; and (8) infant definitively not infected (weaned and repeat PCR negative).

Statistical analysis

Data from pregnant women and exposed infants enrolled in the *Tingathe*-PMTCT programme between March 2009 and March 2011 were analysed. The closing date for follow-up was October 31, 2011. Data were de-identified prior to analysis. Aggregate data were reported as mean with standard deviation or median with interquartile range (IQR) based on normality. For the multivariate logistic regression, all outcomes preventing completion of the PMTCT cascade were grouped together including miscarriage/foetal demise, maternal/infant death, transferred/moved, lost and refused ongoing care. To identify factors that predicted non-completion, unadjusted and adjusted odds ratios and 95% confidence intervals were obtained using binary and multivariate logistic regression, respectively. All covariates, irrespective of the significance of the binary model, were entered into the multivariate model by forward stepwise selection, with entry testing based on the significance of the score statistic and removal testing based on the likelihood-ratio statistic with conditional parameter estimates. Only covariates with a significant score statistic ($p < 0.05$) were retained in the final model. Analyses were performed using IBM SPSS Statistics (version 19; SPSS, Inc., Chicago, IL, USA). The Malawi National Health Sciences Research Committee and the Baylor College of Medicine institutional review board granted ethics approval.

Results

Maternal characteristics at enrolment

Records from 1688 pregnant women living with HIV were analysed (Table 1). The majority, 92.9%, enrolled during their second or third trimesters and 76.3% were newly diagnosed with HIV. At enrolment, 19.7% were on ART.

Service utilization of antenatal components of the PMTCT cascade

CHWs tracked service utilization by each mother-infant pair through the PMTCT cascade (Table 2, Figure 3). Of those mothers not on ART at enrolment, 98% had a CD4 drawn, and 93.6% of these mothers received these results. This compares to 22.5% who received results before the intervention.

Based on CD4 count, 36.8% of mothers met criteria for ART eligibility. Of these, 72.8% were successfully initiated on ART.

Of the 1318 live births, 87.3% received the most ideal combination of either full combination prophylaxis (47.3%) or ART (40%). Prior to the intervention, only 8.8% of mothers received ART.

Prior to delivery, there were 5.7% maternal/foetal deaths/still births, 8.1% transferred/moved. 3.0% lost and 3.4% refused ongoing PMTCT services. There were 1.8% women still recorded as pregnant as of the closing date for data analysis.

Service utilization of postnatal components of the PMTCT cascade

Of the 1318 live births, 97.5% received infant PMTCT, and 90.5% received the correct single dose nevirapine plus AZT tail (see Table 2 and Figure 3).

Table 1. Characteristics of mothers at programme enrolment

	Total (n = 1688)
Median maternal age, years (IQR)	27.0 (23.8 to 30.8)
Trimester of pregnancy, n (%)	
First (0 to 13 weeks)	107 (6.3)
Second (14 to 26)	1025 (60.7)
Third (27 to 40)	543 (32.2)
Unknown-missing	13 (0.8)
HIV status at enrolment, n (%)	
Already known to be HIV-infected	400 (23.7)
Newly diagnosed as HIV-infected	1288 (76.3)
ART eligibility by CD4 count[a], n (%)	
On ART	333 (19.7)
ART eligible	499 (29.6)
Does not meet ART criterion	777 (46)
ART eligibility was not determined	79 (4.7)
WHO stage at programme registration, n (%)	
Stage 1/2	30 (1.7)
Stage 3	11 (0.7)
Stage 4	8 (0.5)
Not done	1639 (97.1)
CD4 cells/mm^3 for women not on ART[b]	1355
<200, n (%)	204 (15.1)
200 to 349, n (%)	336 (24.8)
350 to 499, n (%)	353 (26.0)
≥ 500, n (%)	375 (27.7)
CD4 taken but unknown result[c]	60 (4.4)
CD4 not taken	27 (2.0)
Partner disclosure status, n (%)[d]	
Partner involved and disclosed	423 (25.1)
Partner involved but not disclosed	1158 (68.6)
Partner not involved	106 (6.3)
Missing data	1 (<0.0)

[a]Definition of ART eligibility changed in August 2010 from CD4 ≤ 250 cells/mm^3 to CD4 ≤ 350 cells/mm^3 for HIV-infected pregnant women; [b]CD4 routinely performed only on women not already on ART at registration; [c]the majority of these were CD4 samples that were clotted or otherwise could not be processed by the laboratory facility; [d]partner disclosed defined as partner having knowledge of maternal HIV status. Partner non-involved defined as a partner who is dead or is otherwise separated from the mother.
Abbreviations: IQR, interquartile range; ART, antiretroviral therapy.

DNA PCR testing was performed on 80.7% of the infants. Of the remaining infants, 3.2% were still awaiting their first PCR, and 16.1% exited the programme (as a result of being lost, died, transferred, moved and refused ongoing care) before first PCR. The median age at first PCR was 1.7 months (IQR, 1.5 to 2.5). The overall MTCT transmission rate was 4.1%.

Of the 43 infants found to be HIV-infected, 76.7% were started on ART, with median age at initiation of 4.9 months (IQR, 4.0 to 6.0). This is in contrast to the preintervention period where 34.4% on infected infants were started on ART at a median age of 9.1 months (IQR, 5.4 to 13.8).

Outcomes and continued follow up

Overall, of the initial 1688 women, 1% of mothers died, 4.9% of pregnancies terminated in miscarriages and stillbirths and 3.7% infants died. Furthermore, 16.8% mother-infant pairs moved out of the catchment area, 5.0% were lost, 10.8% refused ongoing care and 16.5% exited the programme after receiving a definitive HIV-negative diagnosis. Of those 182 mothers who refused care, 31.8% refused care during pregnancy, 45.6% refused after delivery but before first PCR and 22.5% refused after the first PCR. There are 672 mother-infant pairs still active in the programme, including 31 mothers who are still pregnant and 641 exposed infants still being breastfed.

Maternal characteristics at programme enrolment associated with failure to complete PMTCT cascade

In bivariate analysis, maternal age of at least 20 years, along with being ART-eligible but not on ART, were associated with failure to complete the PMTCT cascade, whereas enrolment later in pregnancy and having a partner who was not involved (partner dead or separated from mother) were associated with a higher rate of successful completion of the cascade (Table 3). On multivariate analyses, two variables predicted failure to complete the PMTCT cascade, namely, being ART-eligible but not receiving therapy (odds ratio (OR), 1.69; 95% confidence interval (CI), 1.18 to 2.42) and having a partner who was involved but not disclosed to (unaware of the maternal HIV status; OR, 1.54; 95% CI, 1.06 to 2.23). On the other hand, the strongest predictors of successful completion of the PMTCT cascade were enrolment in the third trimester (OR, 0.37; 95% CI, 0.24 to 0.58), having newly diagnosed HIV infection (OR, 0.50; 95% CI, 0.33 to 0.75) and having a partner who was not involved (OR, 0.43; 95% CI, 0.24 to 0.78).

Discussion

Ensuring a continuum of care between services in the PMTCT cascade is essential if the goal of ending new paediatric HIV infection is to be reached. Our results demonstrate that coordinated, longitudinal care of mother-infant pairs is possible in high-burden, resource-limited countries like Malawi. In this intervention, dedicated CHWs functioning as case coordinators created a bridge between disparate clinical services and improved retention and service utilization at virtually every step within the PMTCT cascade.

Key areas of improvement for mothers included receiving CD4 counts, being started appropriately on ART if eligible and receiving proper combination prophylaxis if not eligible for ART. Prior to our intervention, over 90% of women only received single dose nevirapine, reflecting the slow adoption of the 2006 WHO recommendations [20,21]. In our cohort, the majority of mother-infant pairs received the recommended regimen of either combination prophylaxis or ART, resulting in a significant reduction in HIV transmission at first PCR. Enrolment of exposed infants into care, measurement and receipt of DNA PCR results and, finally, initiation of ART for infected infants also improved dramatically.

Our results show marked improvement in retention compared, not only to preintervention data from Malawi

Table 2. Steps of the PMTCT cascade completed by mother-infant pairs: preintervention data and programme intervention results

STEP in PMTCT Cascade	Description	Preintervention data	Programme intervention result
ANTENATAL			
ACCESS Antenatal Care	**Pregnant women accessing antenatal care**	96.4% [Ref. 17][a]	NA
TEST for HIV infection and ENROLL into care	**Number of women tested for HIV**	99% [Ref. 19][b]	NA
	HIV-infected pregnant women, n		1688
DETERMINE ART eligibility	**ART status, n/N (%)**		
	on ART	Unknown	333/1688 (19.7)
	Not on ART	Unknown	1355/1688 (80.3)
	Needed CD4 testing		1355
	Mom received CD4 testing, n/N (%)	91.3%[b,c]	1328/1355 (98)
	CD4 results returned to health centre from laboratory, n/N (%)	Unknown	1268/1328 (95.5)
	Mom received CD4 results, n/N (%)	22.5%[b,c]	1243/1328 (93.6)
INITIATE ART/PMTCT prophylaxis	**ART eligible by CD4 count, n/N (%)[d]**		499/1688 (29.6)
	Started on ART, n/N (%)	Unknown	363/499 (72.8)
	Number of live births to date, n		1318
	Mom received PMTCT prophylaxis or ART n/N (%)		1264/1318 (95.9)
	Nevirapine only	90.6% [Ref. 19][b] (meds distributed at ANC only)	39/1318 (2.9)
	Nevirapine and AZT only	Not applicable[e]	75/1318 (5.7)
	Full combination prophylaxis (sdNVP, AZT and Combivir)	Not applicable[e]	624/1318 (47.3)
	Antiretroviral therapy for mothers health	8.8% [Ref. 19][b]	526/1318 (40.0)
	None	0.1%	53/1318 (4.0)
	Unknown/missing data	Not applicable	1/1318 (0.1)
FOLLOW UP	**Place of delivery, n/N (%)**		
	Hospital/health centre	57.2% [Ref. 17][a]	1273/1318 (96.6)
	Home	29.4% [Ref. 17][a]	36/1318 (2.7)
	Traditional birth attendant	12.1% [Ref. 17][a]	2/1318 (0.2)
	Other/unknown/missing data	1.2% [Ref. 17][a]	7/1318 (0.5)
POSTNATAL			
ACCESS Postnatal Care	**Infant received PMTCT prophylaxis, n/N (%)**		1285/1318 (97.5)
	Nevirapine only	47.2% [Ref. 19][b]	89/1318 (6.8)
	Neviparine and zidovudine	Not applicable[e]	1193/1318 (90.5)
	AZT syrup only	Not applicable[e]	3/1318 (0.2)
	None	Not applicable	22/1318 (1.7)
	Unknown/missing data	52.8% [Ref. 19][b]	11/1318 (0.8)
	Infant feeding choice after birth, n/N (%)		
	Exclusive breastfeeding	75.2% [Ref. 17][a]	1249/1318 (94.8)
	Replacement feeding	1.6% [Ref. 17][a]	20/1318 (1.5)
	Mixed feeding	23.3% [Ref. 17][a]	2/1318 (0.2)
	Unknown/missing data		47/1318 (3.5)
TEST for HIV infection and ENROLL into care	**Infant received PCR test and CPT, n/N (%)[f]**	53.6% [Ref. 19][b]	1064/1318 (80.7)
	Number (%) tested at $\leq$2months of age	Unknown	680/1064 (63.9)
	Number (%) tested at $\leq$3months of age	Unknown	904/1064 (85)
	Median infant age at first HIV DNA PCR, months (IQR)	3 (0.5 to 8.6) [Ref. 19][b]	1.7 (1.5 to 2.5)

Table 2 (*Continued*)

STEP in PMTCT Cascade	Description	Preintervention data	Programme intervention result
DETERMINE HIV status of infant	First DNA PCR test result returned from lab	53.6% [Ref. 19][b]	1047/1064 (98.2)
	First DNA PCR test results given to the caregiver	Unknown	1024/1064 (96.2)
	Median time from first DNA PCR test to results given to caregiver, days (IQR)	Unknown	47.5 (29.0 to 63.0)
	First DNA PCR result negative	86.2%	1004/1047 (95.9)
	First DNA PCR result positive	13.8% [Ref. 19][b]	43/1047 (4.1)
INITIATE ART	Enrolled in ART clinic	29.5% [Ref. 19][b]	36/43 (83.7)
	Infected children started on ART	34.4% [Ref. 19][b]	33/43 (76.7)
	Median age at ART initiation months (IQR)	9.1 (5.4 to 13.8) [Ref. 19][b]	4.9 (4.0 to 6.0)
FOLLOW UP	**Mother-infant pairs still being followed in programme intervention**		672

[a]Malawi countrywide data; [b]preintervention data from intervention sites; [c]data from Kawale site CD4 logbooks, March to October 2008; [d]definition of ART eligibility changed in August 2010 from CD4 $\leq$ 250 cells/mm^3 to CD4 $\leq$ 350 cells/mm^3 for HIV-infected pregnant women; [e]only maternal ART and nevirapine for mother and infant were available during the preintervention period; [f]of the 1318 live births, 212 were discharged from the programme due to death, moving to another location or refusing ongoing care prior to receiving their first PCR; 42 infants are still active in the programme and awaiting their first PCR.
Abbreviations: ART, antiretroviral therapy; sd-NVP, single dose nevirapine; AZT, zidovudine; PCR, polymerase chain reaction; CPT, cotrimoxazole prophylaxis, IQR, interquartile range.

but also to reports from other countries within the region. WHO estimates that in sub-Saharan Africa, only half of women living with HIV receive any PMTCT intervention, 43% of HIV-exposed infants receive ARV prophylaxis and a mere 6% to 15% of HIV-exposed infants receive an HIV test [24,25].

The small percentage of infants receiving HIV testing is an especially important issue [26]. Improving the continuum of care within the PMTCT cascade is not only critical for preventing HIV in exposed infants but also for reducing mortality in those infants who become infected. The CHER study demonstrated that HIV-infected infants suffer from rapid immunologic deterioration, disease progression and high mortality without early ART initiation [27]. By linking mothers to infants, our CHWs were able to significantly improve DNA PCR testing and entry into care and thereby improve the rate of prompt ART initiation in infected infants.

CHW case management improved not only programme implementation but monitoring as well. Several studies have documented that data collected and reported within national PMTCT programmes are often inaccurate and incomplete [28,29]. Some have suggested routine HIV testing of infants at immunization clinics and inpatient facilities as a means for improving PMTCT monitoring [30]. While such testing is important and will provide reliable measures for programme evaluation, the opportunities for effective interventions have largely been missed by the time testing takes place. CHW case management, by contrast, facilitates both service delivery and programme monitoring.

Though our results demonstrate a marked improvement over preintervention data, we have not yet achieved the desired goal of greater than 90% delivery at each step of the cascade for PMTCT to be optimally effective [10]. Reasons for attrition included refusal to continue follow-up, movement from the area and loss to follow up, such that close to a third of the cohort did not complete the programme.

The population we serve is highly mobile, as demonstrated by the 16.8% of patients who moved outside the catchment area. Many mothers within our programme returned to their home villages for additional support. Though our CHWs were often aware of the move and were able to keep in touch with some of their clients, for most, they had no means to document whether or not mothers successfully entered care in their new location. A national medical ID system would assist with this type of tracking [19]. Within the programme, we are developing improved predelivery counselling to identify those mothers planning to return to home villages, exploring strategies with maternal support groups organized by home villages, and cell-phone text messaging to track clients if they move outside our direct service areas.

We are conducting qualitative studies to further evaluate reasons for and possible strategies to mitigate refusal of CHW follow-up. Refusals occur throughout the cascade. Couples counselling and testing with enhanced disclosure support may help reduce refusal during pregnancy. Characterizing and addressing misconceptions about testing results and the likelihood of infection may reduce the number of mothers refusing to get their children tested. Stressing the importance of follow-up testing after weaning may reduce the number of patients who default after a negative first PCR. Malawi's increasing emphasis on family-centred HIV care may also encourage partners to attend clinic together, possibly improving communication and retention in care [31].

Male involvement has been touted as a possible way to engage more women in PMTCT services. Our findings (Table 3)

Table 3. Maternal characteristics at programme enrolment associated with failure to complete PMTCT cascade[a]

	n/N (%) (n = 1688)	OR of failure (95% CI)	*p*-value	AOR of failure (95% CI)[b]	*p*-value
Maternal age, n (%)					
Maternal age < 20	35/110 (31.8)	1.00			
20 +	673/1578 (42.6)	1.59 (1.05 to 2.41)	0.027	–	0.056
Trimester of pregnancy, n (%)					
First	58/107 (54.2)	1.00		1.00	
Second	480/1025 (46.8)	0.74 (0.50 to 1.11)	0.147	0.79 (0.52 to 1.19)	0.260
Third	164/543 (30.2)	0.37 (0.24 to 0.56)	<0.001	0.37 (0.24 to 0.58)	**<0.001**
Missing data	13				
HIV status at enrolment, n (%)					
Already known to be HIV-infected	178/400 (44.5)	1.00		1.00	
Newly diagnosed as HIV-infected	530/1288 (41.1)	0.87 (0.70 to 1.09)	0.236	0.50 (0.33 to 0.75)	**<0.001**
ART eligibility at enrolment, n (%)					
On ART	134/333 (40.2)	1.00		1.00	
Eligible but not on ART	244/499 (48.9)	1.42 (1.07 to 1.88)	0.014	1.69 (1.18 to 2.42)	**0.004**
Not eligible	284/777 (36.6)	0.86 (0.66 to 1.11)	0.245	1.09 (0.77 to 1.54)	0.632
Missing data	79				
Partner disclosure status at enrolment, n (%)[c]					
Partner involved and disclosed	177/423 (41.8)	1.00		1.00	
Partner involved, not disclosed	510/1158 (44.0)	1.09 (0.87 to 1.37)	0.435	1.54 (1.06 to 2.23)	**0.024**
Partner not involved	21/106 (19.8)	0.34 (0.12 to 0.58)	<0.001	0.43 (0.24 to 0.78)	**0.005**
Missing	1				

[a]Failure to complete PMTCT cascade defined as maternal death, miscarriage, abortion, infant death, transferred out, moved, lost or refusal of ongoing care prior to the infant's final HIV-negative diagnosis or if found to be HIV-infected-initiatied on ART; [b]all five covariates were tested for entry into the multivariate model, and all covariates except maternal age were retained in the final equation, based on the significance (*p*-value) of the Wald score; [c]partner disclosed defined as partner having knowledge of maternal HIV status. Partner non-involved defined as a partner who has died or is otherwise separated from the mother.
Abbreviations: OR, odds ratio; CI, confidence interval; ART, antiretroviral therapy.

suggest that women without any partner involvement were most likely to complete the cascade, whereas those women with involved but undisclosed partners were least likely. These findings not only reemphasize the importance of partner disclosure but also highlight the potentially obstructive role that partners may play in accessing services, as observed in other studies [32], or the value of women's independence to make their own decisions.

There are several limitations to our study. The first is a lack of directly comparable preintervention data. Our prior referenced study was from the same area and immediately preceded our intervention, retrospectively analysing all available records over a 4-year period [19]. By contrast, the present study only followed up patients enrolled in the *Tingathe* programme, which may have introduced measurement bias and favourably skewed outcomes. On the other hand, the prior study had a much longer follow-up period and also included infant testing data from the inpatient ward at Kamuzu Central Hospital and the attached Baylor Centre of Excellence, which may have inflated the infant follow-up results. Many of these infants likely fell out of the PMTCT cascade, but reentered when ill and were identified on admission at Kamuzu Central Hospital or the Baylor Centre of Excellence. Despite these qualifications, this report provided the most direct preintervention data with which to compare our results. Moving forward, the data presented here provides a good baseline for similarly designed prospective programmatic studies.

Our second limitation was that we did not measure ANC attendance or HIV testing at ANC. As prior studies had already demonstrated both were over 95% [17–19] in our setting, we did not independently assess this. This limits the external validity of our study, as ANC attendance and HIV testing rates are not as robust in many comparable settings.

Third, we noted that some women were lost between HIV testing and referral to our CHWs. To address this issue, HIV testing at ANC was largely shifted to our CHWs, so that registration could be made immediately upon diagnosis. We do not have good data on how many women may have refused services between HIV testing and enrolment into our programme. To address this issue, we have developed an enrolment register that we are now piloting at our sites. This, combined with improved documentation of testing within ANC, will provide us with solid data on this critical service point in the future [31].

Finally, this programme was not implemented as part of a controlled trial, and there were other providers of services at various time points during the intervention. These providers may also have contributed to the overall improved outcomes observed.

Changes being made in the Malawi PMTCT guidelines provide both new opportunities and challenges for effective

service delivery. In 2011, Malawi adopted an approach for PMTCT referred to as Option B+, where pregnant and lactating women living with HIV will automatically be started on ART for life [33]. This welcome approach simplifies the maternal assessment, obviating the need for CD4 measurements. However, the efficacy of this simplified approach will be compromised unless efforts are made to link newly identified women to ART services and to ensure identification, enrolment into care and testing of exposed infants. This is especially true as infant feeding guidelines now recommend breastfeeding for all children, including HIV-exposed infants, through the second year of life [31]. Furthermore, we need to ensure that pregnant women present earlier to care, as a significant portion of women in our study presented late. We also need to prevent women from refusing care and dropping out, for whatever reason. Ensuring continued clinical care and follow-up testing after weaning through this extended period will be a considerable challenge that may be facilitated by CHW case management.

Conclusions

We believe the *Tingathe*-PMTCT programme has defined a new paradigm for PMTCT service delivery. We attempted to break down the compartmentalization and resulting loss to follow-up between PMTCT, EID and paediatric HIV services. We believe that with further refinement, CHWs can help establish a system in which mothers and infants are effectively followed up and linked throughout the full PMTCT cascade. Establishing such systems that ensure continuity of care will be critical if the goal of ending new paediatric infections is to be reached.

Authors' affiliations

[1]Baylor College of Medicine International Pediatric AIDS Initiative at Texas Children's Hospital, Baylor College of Medicine, Houston, TX, USA; [2]Baylor College of Medicine-Abbott Fund Children's Clinical Center of Excellence, Lilongwe, Malawi; [3]UNC Project, Lilongwe, Malawi; [4]University of North Carolina School of Medicine Chapel Hill, NC, USA; [5]Malawi Ministry of Health, Lilongwe, Malawi; [6]Department of Medicine, Baylor College of Medicine, Houston, TX, USA

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

MHK and SA conceived and designed the study, helped analyze the data, interpreted findings and wrote the manuscript. WCB, AB and DN assisted with the study in the field, contributed to data management and reviewed the manuscript. GP revised it critically and participated in statistical analysis and interpretation. MCH, PNK, FC, TPG, EYC, GSC and MWK revised it critically for important intellectual content. All authors have read and approved the final manuscript.

Abbreviations

3TC, lamivudine; ANC, antenatal care; ART, antiretroviral therapy; AZT, zidovudine; CHWs, community health workers; CI, confidence interval; EID, early infant diagnosis; IQR, interquartile range; OR, odds ratio; PMTCT, prevention of mother to child transmission of HIV.

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