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Evaluating the impact of community health worker integration into prevention of mother-to-child transmission of HIV services in Tanzania

July 2017

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Summary

Community health workers are key frontline health paraprofessionals who have the potential to enhance the World Health Organization's Option B+ strategy to eliminate mother-to-child transmission of HIV. By extending the reach of health services into communities facing a shortage of skilled health workers, community health workers may enhance retention in prevention of mother-to-child transmission (PMTCT) services, including HIV care and adherence to antiretroviral therapy.

To test this hypothesis, we evaluated the *Mama na Mtoto Pamoja* (Mother and Child Together) intervention that integrated community health workers into PMTCT services in the Shinyanga region, Tanzania. We randomized 32 health facilities offering PMTCT services within size strata to the intervention (n = 15) or comparison standard (n = 17) of care groups.

Amref Health Africa implemented the intervention, using four integrated approaches:

1. Formally linking community health workers to health facilities via weekly meetings with health facility staff;
2. Community health worker-led antiretroviral therapy adherence counseling for pregnant and postpartum women with HIV;
3. Community health worker tracing of HIV-positive pregnant and postpartum women who had been lost to healthcare follow-up; and
4. Distribution of action birth cards, an interactive birth planning tool.

Intervention effectiveness was determined with a difference-in-differences strategy based on clinical and pharmacy data from HIV-infected postpartum women at baseline (births in 2014) and endline (births from April to October 2015). There were three primary outcomes:

1. Timing of pregnant women's antiretroviral therapy initiation as measured by week of gestation;
2. Women's retention in care between 60 and 120 days postpartum; and
3. Women's antiretroviral therapy adherence 90 days postpartum, measured using the medication possession ratio (MPR) with a standard 95 per cent cut-off for good adherence (MPR ≥ 95%).

We hypothesized that the women receiving the intervention would initiate antiretroviral therapy earlier in their pregnancy, be more likely to remain in care postpartum and be more adherent to antiretroviral therapy. Secondary outcomes measured maternal and child health indicators, including receipt of antenatal care, postnatal care, giving birth in a health facility and early infant HIV diagnosis.

The intervention was implemented for 11 months between May 2015 and April 2016, during which 466 meetings took place between community health workers and health staff and 2,440 action birth cards were distributed. Characteristics of intervention and comparison facilities were similar at baseline. Medical record data were reviewed for 1,152 and 678 mother–infant pairs at baseline and endline, respectively.

In control sites, there were significant improvements over time in the timing of antiretroviral therapy initiation, retention in care and MPR. Among women with evidence of prior HIV care, the intervention was associated with a non-significant 5 percentage-

point improvement in retention in care at 90 days postpartum (95% CI: –5.9, 15.9, p = 0.36) and an 11.3 percentage-point increase (95% CI: –0.7, 23.3, p = 0.06) in MPR equal to or greater than 95% at 90 days postpartum.

Once adjusted for baseline imbalance, however, the effect of the intervention on MPR of at least 95 per cent was attenuated (9.5, CI: 2.9, 22.0, p = 0.13). There was no significant change in the timing of antiretroviral therapy initiation (2.5-week difference, p = 0.22) or in the secondary outcomes. Qualitative data suggests that community health workers uniquely supported HIV-infected women by encouraging and organizing clinic visits, which may have contributed to the women having fewer days of medication non-possession.

In conclusion, temporal changes in the control group coincide with the scale-up of Option B+, suggesting a potential relationship between this programmatic shift and overall improvements in the uptake of PMTCT services.

The treatment group experienced increases in adherence among postpartum women in care compared with the control group, though this increase was not statistically significant once adjusted for baseline imbalances. However, further evaluation of this approach may still be warranted. Qualitative data suggests that community health workers play a key role in encouraging and supporting women to attend reproductive and child health clinics.

The study faced several challenges that have hindered results, including limited oversight of community health worker visit content, low literacy levels among community health workers, and diminished statistical power due to low sample size. Future iterations that address these issues may further elucidate potential programmatic effects.

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Abbreviations and acronyms

ABC	Action birth card
ANC	Antenatal care
ART	Antiretroviral therapy
ARV	Antiretroviral
CHW	Community health worker
CI	Confidence interval
CTC	Care and treatment center (for HIV care)
CTC2	Care and treatment center patient record form (kept at clinic)
DiD	Difference-in-differences
Diff	Difference between treatment and control groups
EID	Early infant diagnosis
EMTCT	Elimination of mother-to-child transmission of HIV
HCW	Healthcare worker
HEI	HIV-exposed infant
MNCH	Maternal, newborn and child health
MPR	Medication possession ratio
MTCT	Mother-to-child transmission (of HIV)
OPHID	Organisation for Public Health Interventions and Development in Zimbabwe
PMTCT	Prevention of mother-to-child transmission (of HIV)
RCH	Reproductive and child health
SE	Standard error
UNAIDS	Joint United Nations Programme on HIV/AIDS
WHO	World Health Organization

1. Introduction

This report highlights findings from the impact evaluation of the *Mama na Mtoto Pamoja* (Mother and Child Together) intervention. This intervention aimed to increase the uptake of prevention of mother-to-child transmission of HIV (PMTCT) services among women living with HIV infection in Shinyanga, Tanzania. The intervention provided community health workers (CHWs) with the training to support HIV-positive pregnant and postpartum women to receive both maternal and HIV-specific clinic care services.

Integrating antiretroviral therapy (ART) services and maternal, newborn and child health services (MNCH) is essential for PMTCT and has been demonstrated to improve ART coverage among HIV-infected pregnant and postpartum women (Suthar et al. 2014; Stone-Jiminez et al. 2011; WHO 2010). Despite the proven effectiveness of delivering MNCH and other health services at the community level (Lewin et al. 2010; Wouters et al. 2012), there is a paucity of evidence on the effect of integrating MNCH and PMTCT services using CHWs.

CHWs are integral members of the health system who have received training to promote health and/or to carry out some healthcare services, but who are not healthcare professionals (Lewin et al. 2010; Mwai et al. 2013). It is well known that CHWs can enhance the reach, coverage and quality of HIV services delivered to the general population (Mwai et al. 2013). However, specific evidence for leveraging this essential cadre to link community-based MNCH services with the PMTCT service cascade is small and primarily focused on infant outcomes (Kim et al. 2012; le Roux et al. 2013; Suthar et al. 2014; Tomlinson et al. 2014).

PMTCT services are an integrated chain of maternal and child services intended to interrupt HIV transmission from mother to infant; such services include antenatal care (ANC), HIV testing and ART for HIV-infected pregnant women. Integration of community-based MNCH services with PMTCT is especially critical because Tanzania is scaling up Option B+, a PMTCT strategy whereby HIV-infected pregnant and breastfeeding women start lifelong ART immediately after diagnosis.

Given the significant risk of women stopping regular clinic visits after ART initiation, coupled with the high workload of healthcare workers, there is a strong argument for integrating community-based MNCH activities with PMTCT services using CHWs. This is especially the case for ART adherence counseling and tracing pregnant women who drop out of the HIV care system.

To address this gap, we implemented and evaluated a pilot program in Shinyanga region, Tanzania to integrate MNCH and PMTCT services using CHWs. The intervention aimed to integrate community-based MNCH services with HIV prevention, treatment and care – bridging the gap between community and health facility, and enhancing the potential benefits of Option B+.

This report focuses on the evaluation, which has assessed whether this approach: (1) resulted in earlier initiation of ART; (2) increased the proportion of HIV-infected pregnant women who are retained in care; and (3) increased ART adherence. This evaluation will help to illuminate both the impact and feasibility of the intervention, which in turn will highlight the potential role that CHWs can play in eliminating mother-to-child

transmission of HIV (EMTCT) in Tanzania. Results will be disseminated to local and regional authorities, community organizations and donors, informing them whether this strategy may improve outcomes in the HIV care continuum.

2. Background

2.1 Context

2.1.1 Prevention of mother-to-child transmission of HIV in Tanzania

Globally, the number of children born with HIV declined 35 per cent from 2009–2012, a reduction partly attributable to antiretroviral (ARV) prophylaxis preventing 670,000 children from acquiring HIV infection in low- and middle-income countries (UNAIDS 2013). However, despite this substantial achievement in PMTCT, there are still significant challenges facing the global effort to achieve the Joint United Nations Programme on HIV/AIDS (UNAIDS) target of the elimination of new HIV infections among children by reducing new infections to less than 40,000 by 2018 and 20,000 by 2020 (UNAIDS 2016).

To prevent transmission to their infants, HIV-positive pregnant women need to receive a series of services, including ANC, HIV testing, disease staging and ART or ARV prophylaxis. In addition, HIV-exposed infants should receive ARV prophylaxis, be tested for HIV infection, be exclusively breastfed for the first six months of life and receive cotrimoxazole prophylaxis to prevent opportunistic infections (WHO 2010).

These services have been shown to reduce the risk of MTCT to less than 5% in breastfeeding populations (and less than 2% in non-breastfeeding populations) in Sub-Saharan Africa. However, 49 per cent of HIV-infected pregnant women drop out of HIV care between ANC registration and delivering their baby, and miss some or all of the essential PMTCT services (the 'PMTCT cascade') (Paintsil and Andiman 2009; Sibanda et al. 2013; WHO 2010). Consequently, only 57–70% of pregnant women living with HIV receive ART or ARV prophylaxis, a key step in the cascade (UNAIDS 2013).

2.1.2 PMTCT and Option B+ in Tanzania

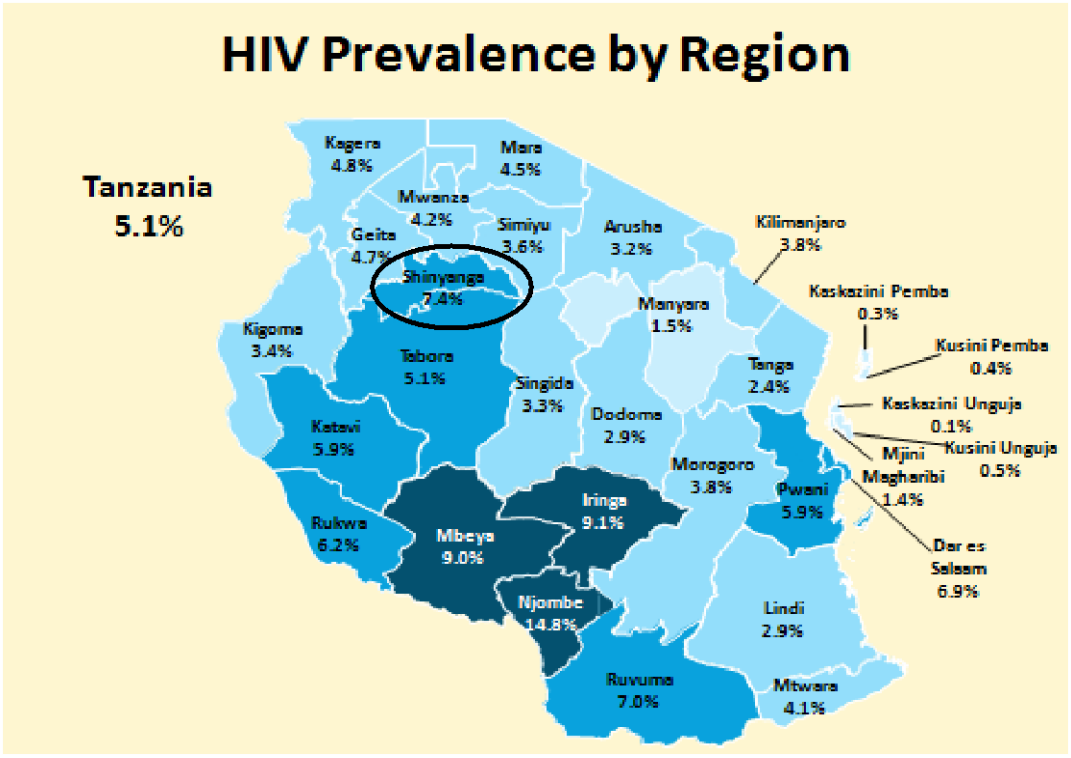
Increasing retention in the PMTCT cascade is particularly critical in high-burden, priority countries like Tanzania (Figure 1), where 6.2 per cent of women aged 15–49 are HIV positive (National Bureau of Statistics 2013) and nearly one quarter of pregnant women living with HIV do not receive ART for themselves or ART for PMTCT (UNAIDS 2013).

Our study took place in Shinyanga, one of Tanzania's 30 regions in the northern lake zone and an area where we have an existing programmatic and research experience. In Shinyanga, HIV prevalence is 7.4% (8.1% among women). In Tanzania, achievements in PMTCT could have important impacts on the national epidemic, as one in five new HIV infections are due to MTCT – an estimated 36,225 infections per year (Ministry of Health and Social Welfare 2013).

Option B+ is the PMTCT strategy recommended by the World Health Organization (WHO), whereby HIV-infected pregnant women receive ART throughout their lives regardless of clinical stage (WHO 2012). In September 2013, Tanzania began rolling out Option B+ to all 6,270 reproductive and child health (RCH) facilities. By simplifying service delivery and drug regimens, and reducing the steps that mothers need to

negotiate (such as CD4 testing), Option B+ is expected to improve retention in the PMTCT cascade (Centers for Disease Control and Prevention 2013).

Figure 1: HIV prevalence by region, Tanzania 2010



Source: Tanzania 2011–2012 HIV/AIDS and malaria indicator survey: key findings

However, the postulated benefits of Option B+ are predicated on mothers remaining on lifelong ART, starting at the time of HIV diagnosis. Thus, a critical unresolved issue is how best to ensure that women who learn their HIV status during pregnancy initiate and adhere to ART, and are retained in care and treatment after delivery.

Relevant operating environment

Under Option B+, ANC, postnatal care, and HIV treatment and care are now provided in the majority of Tanzania's 6,270 RCH clinics (Pangaea Global AIDS Foundation and Clinton Health Access Initiative 2013). This integrated 'one-stop' strategy eliminates the need to refer pregnant and breastfeeding women to separate clinics to access ART services. Instead, HIV-infected pregnant women and their infants are followed in RCH clinics from diagnosis (often in ANC) through delivery and until the baby's final HIV serostatus is confirmed at 18 months of age, or until the mother has stopped breastfeeding her baby.

Under this approach, women who test positive for HIV infection during ANC at any RCH clinic receive a CD4 test, adherence counseling and ART in the RCH clinic, instead of in the general HIV care and treatment center (CTC). RCH nurses specially trained in HIV care conduct the majority of these activities, including prescribing ART. After 18 months, the mother–infant pair are transferred to the main CTC, although many women prefer to continue receiving services through RCH due to feeling stigmatized at the CTC (Pangaea Global AIDS Foundation and Clinton Health Access Initiative 2013).

2.1.3 Health sector challenges and opportunities for mobilizing CHWs

Challenges around retaining women in the PMTCT cascade must be viewed in light of the broader health system. Sub-Saharan Africa has only 3 per cent of the global health workforce and faces a persistent shortage of physicians, nurses and other health professionals (Anyangwe and Mtonga 2007; WHO 2006). The Tanzanian health sector is facing a workforce crisis (Kwesigabo et al. 2012). It has one of the lowest physician-to-patient ratios in the world (1:125,000), and is among the 10 countries with the lowest density of nurses and midwives (WHO Global Health Observatory 2014).

In this context, it is unclear whether the full benefits of Option B+ can be realized. Although Option B+ has been lauded for its streamlined approach (Business Leadership Council, UNICEF and Clinton Health Access Initiative 2012; Fasawe et al. 2013), early data from Tanzania is worrisome.

Our analysis of the initial cohort of Option B+ women in Shinyanga revealed that more than 36 per cent of HIV-infected pregnant women who initiated ART dropped out within 100 days, many before delivering their infants (Andersen, Njau and McCoy 2014). Furthermore, 78 per cent of RCH clinics included in a 2013 evaluation cited staff shortages as limiting their ability to manage clients and provide ART-related services, along with space limitations and more training needs (Pangaea Global AIDS Foundation and Clinton Health Access Initiative 2013).

Community health workers (CHWs) present a potential opportunity to alleviate some of the burden of this crisis. There are approximately 12,000 CHWs in Tanzania (UNICEF Health Section and Program Division 2014), including 1,512 CHWs in Shinyanga region who serve 490 villages. This part-time volunteer force receives three weeks of training and tools (mobile phone, bicycle, water, raincoat and reporting registers) to provide referrals to care and sensitize the community on health-related issues. Topics covered include family planning, early ANC booking, health facility delivery, breastfeeding, and water, sanitation and hygiene practices.

CHWs in Shinyanga work 1–3 days per week and receive remuneration for transport costs and completed reports (we supplemented their earnings for the new activities). They each serve approximately 60 households in one community, visiting most households monthly, and are informally linked to a health facility in the area (UNICEF Health Section and Program Division 2014). They have typically completed form 4 (secondary education). Ordinarily, CHWs in Shinyanga do not participate in providing any care for HIV-infected pregnant women, PMTCT, or Option B+. (Home-based care volunteers are a smaller cadre focused exclusively on providing care to bedridden or late-stage HIV-infected clients and are not included in the current study.)

Consequently, there is potential to integrate some PMTCT services with the MNCH services already being delivered by CHWs, including services related to ART provision under Option B+. Indeed, the Tanzanian Ministry of Health and Social Welfare's Health Sector Reform Strategy advocates for health service decentralization in order to address inadequacies in health service delivery. The ministry's 2009–2015 Community-Based Health Care Strategy also promotes empowerment and involvement of communities to improve their own health.

Furthermore, community involvement in delivering community EMTCT and pediatric care and treatment services is a strategic objective of Tanzania's National Strategy for EMTCT (Ministry of Health and Child Welfare 2012). Part of this goal envisages using CHWs to increase PMTCT service uptake, provide ART adherence counseling and trace HIV-infected pregnant women who have fallen out of care (Ministry of Health and Child Welfare 2012).

However, to date, these plans to integrate community-based MNCH and PMTCT services have not been widely implemented or evaluated in Tanzania, aside from some efforts to use CHWs for community-based HIV testing and counseling. Although most communities have CHWs coordinated by council health management teams, as well as fragmented projects supported by development partners, these MNCH services are typically disconnected from the formal healthcare system.

2.2 The intervention

Mama na Mtoto Pamoja (Mother and Child Together) seeks to integrate community-based MNCH and PMTCT services by implementing four interconnected strategies.

2.2.1 Formally linking CHWs to RCH clinics

Although an informal relationship existed between CHWs and a single health facility for referral in relation to MNCH services, there was previously no process for CHWs to review activities with clinic staff, receive mentorship and determine which women have been lost to follow-up. During the intervention period, we assigned each CHW to the in-charge nurse in the RCH clinic for a weekly meeting to discuss their activities, with the objective of overcoming the limitations of the current model.

2.2.2 Action birth card

The action birth card (ABC) (Online Appendix A) is an interactive, integrated health planning tool distributed by CHWs that links community MNCH services to health facility-based PMTCT and HIV treatment and care services. It asks pregnant and breastfeeding women to define and overcome barriers to reproductive health services related to PMTCT and WHO's core health indicators (WHO n.d.). Furthermore, the card facilitates discussion between CHWs and their clients and serves as a user-friendly record of completed services and behaviors (e.g. breastfeeding) for maternal health, PMTCT, HIV treatment, family planning and infant health.

Under the intervention, CHWs gave pregnant or postpartum women an ABC at their first meeting, discussed the card at subsequent monthly meetings and collected it after the infant was tested for HIV infection (6–8 weeks postpartum). The cards, containing health content relevant to all women, were distributed to both HIV-infected and uninfected women to prevent stigma. The ABC developer, the Organisation for Public Health Interventions and Development (OPHID) in Zimbabwe, was a consultant on this project. Preliminary data from Zimbabwe suggests that ABCs can increase utilization of ANC and health facility delivery (Ministry of Health and Child Care and OPHID 2014).

2.2.3 Tracing of treatment defaulters

Tracing HIV care defaulters is an important strategy to help HIV-positive patients return to care and is part of our impact pathway (Wouters et al. 2012). In meetings with RCH staff, CHWs reviewed health facility registers to identify women who missed scheduled

appointments and those who were lost to follow-up as defined by the Ministry of Health and Child Welfare: non-attendance at three successive scheduled appointments with two unsuccessful follow-up attempts.

CHWs then attempted to contact these women via mobile phone or home visit and re-engage them in care. CHWs also updated the clinic about their progress and coordinated tracing activities with the clinic, as needed. Previously, only RCH clinic staff traced treatment defaulters.

2.2.4 Adherence counseling for HIV-infected women on ART

Adherence counseling can improve medication adherence and retention in care for HIV-positive clients (Chaiyachati et al. 2014). CHWs used the existing adherence counseling manual used by community-based home-based care volunteers for people living with HIV, with additional messaging customized for asymptomatic women (as many recently diagnosed pregnant women are asymptomatic).

Adherence training covered: types of medication; timetables for taking medication; the importance of ART drugs; procedures for transfers; stigma and how to handle it; nutrition; side effects of medication; and health procedures to follow for side effects. Adherence counseling was conducted during CHWs' monthly home visits.

2.2.5 Implementation

We planned and executed a comprehensive training strategy to implement these activities in April 2015. This included training CHWs on: using the ABC; tracing women who are potentially lost to follow-up; adherence counseling; and ethical issues related to confidentiality (see also Section 3.2.5 Quality control and confidentiality).

Because CHWs are typically part-time volunteers who receive remuneration for their travel expenses and completed reports, we provided financial compensation for these new activities, consistent with WHO recommendations that CHWs should receive 'adequate and appropriate incentives, including wages' (UNAIDS and US President's Emergency Fund for AIDS Relief [PEPFAR] 2008). We provided TZS16,000 (approximately USD5) per month for CHWs serving treatment facilities for additional work and travel during the intervention period and TZS8,000 (approximately USD2.5) for CHWs serving control facilities. We believe this both legitimized and emphasized the vital role that CHWs play in linking communities to health facilities.

In addition, we held orientation meetings for health facility staff and the district health management team about the intervention and impact evaluation. Together, these strategies allowed for the integration of community-based MNCH services and PMTCT using CHWs, bridging the gap between the community and health facility.

2.3 Theory of change

In the study, we hypothesized that the new integration of community-based MNCH services with PMTCT using CHWs would increase demand for ART among HIV-infected pregnant and breastfeeding women, and would improve retention in HIV care and adherence to ART. This hypothesis is bolstered by a small but growing body of evidence that such a strategy can be effective and also help to mitigate the health workforce crisis.

In South Africa, mothers in the Philani program who received antenatal and postnatal home visits from CHWs were more likely to administer infant nevirapine at birth, correctly treat infants with zidovudine and practice one feeding method for the first six months of the infant's life (le Roux et al. 2013). Overall, the odds of completing all services in the PMTCT cascade was nearly twice as high in the CHW intervention group compared with standard care (le Roux et al. 2013).

Also in South Africa, the Goodstart study found that CHW visits to pregnant and postpartum women increased exclusive breastfeeding among HIV-infected women. These visits also increased infant weight and length-for-age z-scores, although no differences were found for MTCT or HIV-free survival (Tomlinson et al. 2014). Similar increases in PMTCT service utilization were observed in Malawi's Tingathe PMTCT program, a CHW-based patient case management intervention (Kim et al. 2012).

Although these studies are promising, they have a clear focus on preventing infant infections and improving infant health; none evaluated whether the mother was retained in care after her baby was delivered and whether she adhered to ART. Furthermore, none have been conducted since the implementation of Option B+, which is a new and integrated approach to PMTCT with specific challenges for healthcare delivery.

In the area of HIV and AIDS, some, but not all, studies suggest potential benefits from integrating CHWs with HIV treatment and care. A cluster randomized trial in Uganda found that a community-based peer health worker intervention halved follow-up drop-out rates at 24 months, from 4.4% to 2.1%. The same intervention decreased virologic failure rates at and after 96 weeks into ART (Chang et al. 2010). Positive benefits on retention in HIV care were also reported in quasi-experimental studies of CHW use in Zambia (Torpey et al. 2008), South Africa (Igumbor et al. 2011) and Malawi (Zachariah et al. 2007).

In the South African study, ART patients with CHW adherence support had higher treatment pick-up rates (95% versus 67%, $p = 0.02$) and were more likely to have a suppressed viral load after six months of treatment (70% versus 30%, $p < 0.01$) (Igumbor et al. 2011). In addition, a home-based HIV care strategy in Uganda using lay health workers was found to be as effective as a clinic-based strategy on viral suppression after six months of ART (Jaffar et al. 2009). The benefits observed in these studies may be because CHWs can help to demystify HIV, counteract stigma and act as a bridge between the community and the health facility (Mwai et al. 2013).

At the health facility level, integrating facility-based MNCH and PMTCT services is recommended by WHO and the US President's Emergency Plan for AIDS Relief (PEPFAR) (UNAIDS and PEPFAR 2008; Suthar et al. 2014; PEPFAR 2011; WHO 2012). A systematic review found that ART integration into MNCH facilities significantly improves ART uptake (risk ratio 1.37, 95% confidence interval (CI): 1.05, 1.79) (Suthar et al. 2014). However, only one study has evaluated the effect of facility-based integration of MNCH and PMTCT on retention in care (Killam et al. 2010) and none has evaluated ART adherence.

The theory of change for our intervention (Figure 2) builds on this existing literature to form a comprehensive working theory of how integrating PMTCT and MNCH using

CHWs can improve outcomes across the PMTCT cascade. Currently, CHWs in Shinyanga region (and elsewhere in Tanzania) refer pregnant women to ANC in addition to other health promotion activities. Once registered for ANC, pregnant women may or may not complete the services in the PMTCT cascade, including starting and adhering to ART (if HIV-infected), and they may disengage and re-engage in care.

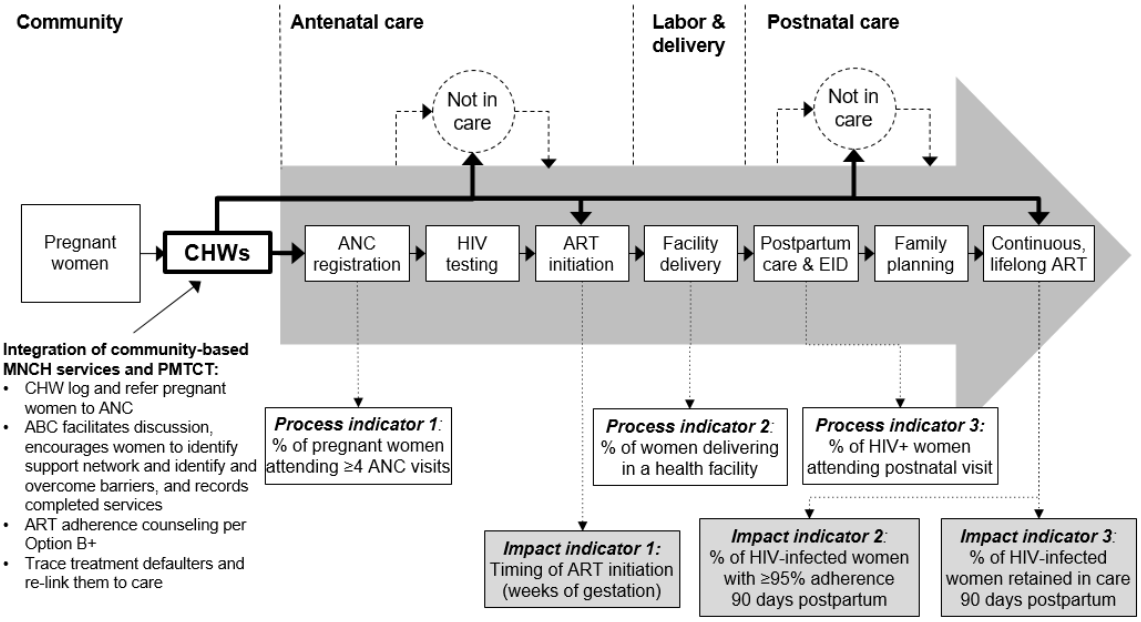
We hypothesized that service integration using CHWs would catalyze HIV-positive pregnant and postpartum women to initiate ART earlier, improve adherence and help these women to stay in HIV care. In addition to these outcomes, we hypothesized that a number of key process indicators would improve across the cascade, including ANC attendance, postnatal visit attendance, HIV-exposed infant (HEI) early diagnosis and delivery of babies in a health facility.

These hypotheses were supported by several assumptions about CHWs and their role. Firstly, our theory of change assumed that CHWs were willing and able to provide accurate and timely information to HIV-positive women about adherence. We also assumed that they were capable of transferring knowledge in a way that minimizes or prevents stigma, as stigma could worsen the demand for PMTCT services. We assumed that health facility staff would be willing and able to work with CHWs to provide mentorship, discuss women in need of tracking and devise strategies for success. Finally, we assumed that this mentorship would result in improved service and counseling provision by CHWs.

If these assumptions held true, we posited that the multi-pronged intervention would effect change across the PMTCT cascade. While the intervention had not previously been evaluated in its entirety, evidence on its component pieces was encouraging (see also Section 2.2 The intervention).

Figure 2, adapted from work by Kranzer and Bhardwaj (Kranzer et al. 2012; Bhardwaj et al. 2014), depicts the integration of community-based MNCH services and PMTCT using CHWs, and includes associated process and impact indicators. Boxes in the grey arrow show the steps along the PMTCT cascade for HIV-infected pregnant women, including lifelong ART. The dashed lines and circles show the process of defaulting and re-engaging in care. CHWs promote HIV-specific services through the ABC (bold arrows), adherence counseling and re-engagement in care.

Figure 2: Theory of change



EID = early infant diagnosis.

2.4 Timeframe

The intervention training took place in April 2015 and the intervention was fully implemented by May 2015. The intervention period officially came to a close at the end of March 2016.

The research team was trained on data collection protocols in June 2015 and began collecting data for the baseline cohort (from prior to the intervention) in July 2015. Baseline cohort data collection and data cleaning ended in December 2015 and endline cohort data collection began in January 2016. Endline cohort data collection ended in mid-April 2016 in order to include data from the whole intervention period.

2.5 Primary outcomes of interest

Table 1: Proposed primary outcomes of interest, data sources and definitions

Indicator	Data sources	Definition
1. Impact indicators		
a. Timing of ART initiation	ART register CTC2 cards	Timing of ART initiation, by week of gestation at start date for HIV+ women initiating after becoming pregnant
b. Retention in care at 90 days	ART register CTC2 cards	HIV-infected women retained in care at 60–120 days postpartum, defined as attendance at ≥ 1 scheduled visit between 60 and 120 days postpartum
c. Adherence to ART from 0–90 days postpartum	ARV dispensing register	ART adherence as measured with the MPR, defined as the number of pill days dispensed over the number of days elapsed in the window period. Classified at ≥ 95% adherence (MPR ≥ .95) and ≥ 80% adherence (MPR ≥ .80)
Additional impact indicator: ART initiation after pregnancy (additional outcome indicator)	ART register CTC2 cards	ART initiation, as measured by the number of women in the sample who had any evidence of beginning ART after pregnancy, out of all women without evidence of initiation prior to pregnancy
2. Heterogeneity of impact by intensity of exposure to CHWs	CHW logs	Proposed definition: number of CHW visits to individual women Actual definition: average score of clinic-level variables (see also Section 3.3.1 Evaluation strategy)
3. Process indicators for women in the sample		
a. ANC visits	ANC register	Number of women attending at least 4 ANC visits
b. Health facility delivery	Postnatal and HEI cards	Number of women delivering in a health facility
c. Postnatal visit attendance	Postnatal register	Number of women attending a postnatal visit
d. EID testing	HEI cards	Number of women whose children (from most recent birth) tested for HIV

Note: CTC2 cards = HIV care and treatment center patient record form

2.5.1 Impact indicators

Timing of ART initiation

The timing of ART initiation among HIV-infected pregnant women is defined as the gestational week of treatment initiation and is calculated from data in the ART register and card. We calculated this outcome only among women who have an ARV start date in the clinic records and began ART *after* becoming pregnant (women already on ART at

the start of their pregnancy were excluded). We hypothesized that women in intervention communities would initiate ART earlier in gestation than women in comparison communities.

Retention in HIV care at 60–120 days postpartum
This is defined as whether an HIV-infected pregnant or postpartum woman had evidence of attending at least one HIV primary care visit at 60–120 days postpartum (binary 1/0). In Tanzania, postpartum women on ART are typically scheduled for clinical monitoring for their own health at 7, 28 and 42 days after delivery (1-week, 4-week and 6-week postnatal visits), and then every 30 days thereafter until transfer to the HIV clinic 18 months after delivery.

Thus, we defined a wide window (60–120 days) to capture the various schedules that women may follow during the postpartum period. This definition is similar to the Malawi Option B+ analysis (Tenthani et al. 2014) and is consistent with recommendations about defining and measuring retention in HIV care in the absence of a gold standard (Mugavero et al. 2010). We hypothesized that, from baseline to endline, there would be a greater increase in the proportion of women still accessing care at 60–120 days in the treatment group, compared with the control group.

Adherence to ART during pregnancy and postpartum
We measured adherence with the MPR – the proportion of days when ART was prescribed and an individual is in possession of ART (determined with pharmacy dispensing data) (McMahon et al. 2011). MPR is associated with short-term virologic suppression (Goldman et al. 2008; Hong et al. 2013; McMahon et al. 2011; Messou et al. 2011).

We determined overall MPR and the proportion of women with an MPR of at least 95 per cent at 90 days postpartum (binary 1/0), for ease of comparison with previous studies. We hypothesized that, from baseline to endline, there would be a greater increase in the proportion of women in the treatment group that were 95 per cent adherent or more, compared with the control group.

Additional impact indicator: ART initiation after becoming pregnant
This measure examined the proportion of women in the sample who had any evidence of beginning ART after becoming pregnant, out of all women without evidence of initiation prior to pregnancy. While this indicator was not initially included in our analysis plan, the research team decided to add it to assess whether there is evidence that those in the treatment clinics were more likely to ever initiate ART, given no evidence of prior initiation.

2.5.2 Process indicators
In addition to the impact outcomes, we identified process outcomes to ensure that we assessed potential spillover benefits on other maternal health outcomes. Thus, we also collected data on the following process outcomes to assess acceptability and feasibility:

1. ANC visits – the proportion of pregnant women attending the WHO-recommended four or more ANC visits (WHO 2002);
2. Health facility delivery – the proportion of pregnant women who deliver in a health facility;

3. Postpartum visit – the proportion of HIV-infected women who attend the six-week postpartum visit; and
4. HEI testing – the proportion of HIV-exposed infants being tested for HIV in the postpartum period.

2.6 Implementation

Intervention was smoothly implemented in both the treatment and the control sites throughout the study duration. While a number of issues partially impeded the implementation of the intervention, our team addressed them in a timely fashion.

Although it is important to have various stakeholders in the community, including NGOs, to facilitate the accessibility and use of health services, this can also bring challenges. In the case of the present study, most of the CHWs work with multiple NGOs that give different incentives. Some NGOs pay more than we did, so it was a challenge for some CHWs to prioritize our intervention activities. A series of meetings with CHWs as part of supportive supervision helped to rectify this, though prioritization among competing projects continued to be an issue throughout the study.

In addition, various local projects made different demands on the CHWs' time, so it became difficult to find a convenient time to meet with all the CHWs from one site at once. Some NGOs conducted CHW training lasting 21 days during our intervention period. Most of our CHWs attended some training, and therefore missed regularly scheduled visits with pregnant women. Some CHWs were not comfortable with paperwork, especially filling out the logs. As a result, not all logs (used to track the number of CHW visits and topics discussed) were completed as anticipated.

Lastly, we noticed that CHWs from the control arm were not motivated, as they did not receive training, received less compensation and were visited less frequently. For these reasons, they did not feel part of the study.

2.6.1 Intervention monitoring

During the project period, the field supervisor periodically monitored both intervention and control sites. At these visits, he noted the degree to which the intervention was being implemented by tracking various components (described below). For instance, at the beginning of the intervention period we witnessed significant heterogeneity in CHWs' understanding of the CHW log form (used to track the number of visits CHWs implemented and the topics discussed) across sites. Many of these forms were found to be incomplete (Table 2).

This prompted the team to conduct additional training with CHWs at all sites during subsequent monitoring visits. The field coordinator noted marked improvements in form completeness in subsequent visits; most sites had significantly more complete forms during the second and third monitoring. However, even with these focused efforts by an experienced field team, completion rates were poor overall, suggesting that CHWs were not able or willing to keep detailed records. This may be due to their level of compensation, their low levels of education or insufficient motivation.

Though the field coordinator visited all 32 study facilities, recorded activities in a site monitoring form and supported CHWs as often as possible, he was the only field staff

member funded to monitor the intervention, and so the frequency of monitoring visits was constrained by logistics. The unexpectedly poor quality of these logs precludes an individual-level analysis of effect heterogeneity. Instead, we were forced to conduct a site-level analysis of heterogeneity (see also Section 3.2.6 Challenges).

Table 2: Cumulative numbers from field coordinator site visits: CHW log completion[a]

Treatment status of site	Number of visits to sites	Number of CHW visit logs		
		Complete	Missing	Incomplete
Treatment	47	585	107	1,213
Control	51	241	84	2,031
Total	98	826	191	3,244

[a] Data from site monitoring form

At the treatment sites, we also monitored the frequency of meetings between CHWs and the health staff, the topics discussed at each meeting and the number of ABC cards distributed. A total of 466 meetings were conducted between healthcare workers and CHWs during the intervention period.

The field coordinator conducted 47 monitoring visits of the facilities. At nearly all of these visits, he noted evidence of meetings between the health staff and CHWs, as intended in the intervention plan. If there was no evidence of a meeting, it was generally because healthcare staff were away at a training course. Of the topics reported during monitoring visits, the ABC was discussed most frequently, followed by ANC and adherence counseling. All topics were discussed with a high frequency.

Distribution of the ABC was a notable success; CHWs distributed more than 2,440 ABCs across the treatment catchment areas. This was 1,440 more than the 1,000 ABCs we had initially planned to distribute. ABCs were in high demand at all the clinics, and the CHWs constantly gave positive feedback about the utility of the cards during visits with women. At the intervention sites, 407 women were reported to have defaulted from care. Of those women, 336 (82.6%) were traced and 133 returned to care.

Table 3: Cumulative monitoring data from intervention site visits

Number of monitoring visits by field coordinator	Topics reported to be discussed at CHW or HCW meetings, count (%)					Number of CHW or HCW meetings	Number of ABCs distributed	Tracing defaulters		
	ABC	ANC	AD	RH	TD			Number of defaulters	Number traced	Number returned to care
47	42 (89%)	40 (85%)	39 (83%)	37 (79%)	33 (70%)	466	2,440	407	336	133

Notes: AD = adherence counseling; RH = reproductive health; TD = tracing defaulters; HCW = healthcare worker. Topic discussions were reported by health staff; only on occasion was someone from the research team able to monitor the meetings directly.

3. Data collection methods

3.1 Ethical approval

This study was approved by the Amref Health Africa Institutional Review Board in Tanzania, as well as the Committee for Protection of Human Subjects at the University of California, Berkeley (CPHS 2014-12-6992).

3.2 Data collection

3.2.1 Sample size determination and power calculation

We initially powered the study for the outcome of retention in care 90 days postpartum. In our preliminary analysis of pregnant women in Shinyanga, we found that more than 36 per cent of HIV-infected pregnant women who initiated ART were lost within 100 days (Andersen, Njau and McCoy 2014). Thus, we conservatively assumed that in the comparison communities, 67 per cent of women would remain in care at 90 days postpartum. For logistical and budgetary reasons, and especially given the rapid nature of the impact evaluation, we powered the study to follow 15 sites in each arm (treatment and intervention, respectively).

We assumed an intracluster correlation coefficient of 0.04 and that the intervention would increase the proportion of women retained in care postpartum from 67% to 80% (minimal detectable effect size of 13 percentage points, or 20%). We therefore would require at least 39 observations per community, or 537 observations from the treatment and control groups, to have 80 per cent power to reject the null hypothesis of no effect.

We hypothesized that obtaining data from at least 36 HIV-infected women per facility would be well within the normal volume of clients at RCH clinics, as many RCH clinics initiate an average of 11 HIV-infected women on ART or ARVs per month. With at least six intervention months in each community, we assumed we could meet this goal.

3.2.2 Identification and treatment assignment

Inclusion criteria

The research team assigned treatment status at the health facility level, stratified by facility size. Of the 56 health facilities in the Shinyanga region, 37 sites were included in the sampling frame for this study. Sites that were excluded did not meet the inclusion criteria.

To be included in the study, sites had to be in operation, offer on-site treatment and care for HIV including ART, provide Option B+ services and RCH services, and not be currently participating in another study or program linking CHWs to PMTCT (n = 8 exclusions). Additionally, we excluded sites if they were serving too few female ART patients to reasonably meet the expected sampling goal (cut-off of 75 female ART patients or fewer over the course of one year; n = 11).

Stratified selection and treatment assignment

We split the 37 sites into strata indicating sites with more than 550 ART patients (large sites) and sites with fewer than 550 (small sites). This number corresponds approximately to the 80th percentile mark for total female ART patients. This cut-off point

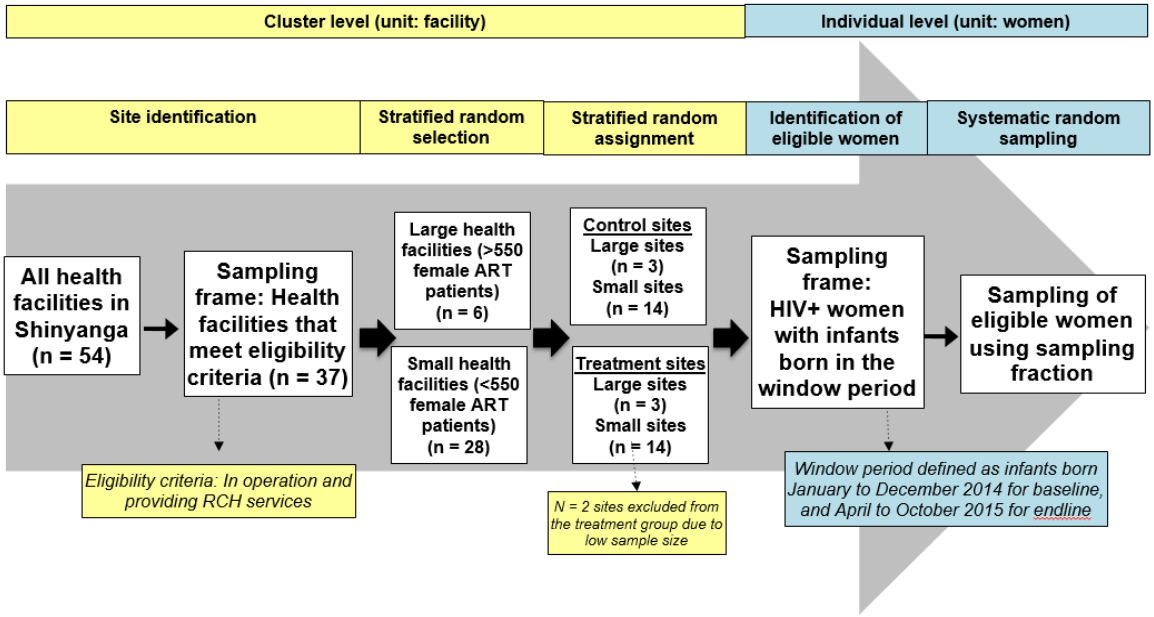
allowed us to stratify by facility type, namely hospitals versus clinics or health dispensaries. The stratification yielded 7 large and 30 small sites.

From the seven large sites, we sampled six, allocating three to the treatment and three to the control conditions. Of the 30 smaller sites, we sampled 28, allocating 14 to the treatment group and 14 to the control group. The resulting stratified assignment was balanced on facility size (number of clients) and client characteristics (total and stratified by age and sex) at baseline.

While we originally planned to allocate 15 sites to treatment and 15 to control (30 total), we added two additional sites to each group (34 total) so that if we encountered issues at a site (e.g. suspension of Option B+ services, not reaching ideal sample number of patients), we would be able to maintain the minimum number of sites originally estimated by the team.

Additional exclusions
Later, we excluded two additional sites, as we found that one did not meet eligibility criteria and the other did not have a sufficient sample size (n < 2).

Figure 3: Sampling strategy flow chart



3.2.3 Sampling women living with HIV at health facilities

At the health facility level, we retrospectively abstracted data from routinely collected information in CHW logs and facility registries. To estimate baseline and endline outcome indicators, we collected data from two six-month cohorts of women. This corresponded to women living with HIV infection who were pregnant and postpartum at key times before the intervention was initiated (baseline) and during the intervention (endline).

Eligibility
Women were considered eligible for inclusion if they were: 1) found in the four sampling sources at the health facility; 2) HIV positive; and 3) had a child born in one of the two cohort window periods (baseline, endline).

The baseline cohort included HIV-infected women who were 90 days postpartum between 1 April 2014 and 31 March 2015; this corresponded to infants born between 1 January and 31 December 2014. These women were unexposed to the intervention.

The endline cohort included HIV-infected women who were 90 days postpartum between 1 July 2015 and 31 January 2016, corresponding to infants born between 1 April and 31 October 2015. These women were exposed to the intervention for 4–9 months of their pregnancy and during their 90-day postpartum period. We hypothesized that this was a reasonable amount of exposure to the intervention given that, on average, women in Tanzania are 5.4 months pregnant at their first ANC visit when they have the first opportunity to initiate ART (National Bureau of Statistics [Tanzania] and ICF Macro 2011).

Sampling
We sampled women based on a predetermined sampling fraction, calculated from the number of women at the site considered eligible. In these cases, we sampled using a systematic random sample.

Upon arrival at the clinics, research staff created a list of eligible women using the criteria above. They sampled from four record sources: the mother–child follow-up register, the postnatal register, the delivery register and CTC2 cards. Although we used other registers to determine outcome and process indicators, they were not used in the sampling process because they did not provide the necessary information to determine eligibility (child's date of birth, identification numbers and HIV status).

Table 4: Sampling sources for health facility-based sampling

Source	Description
Mother–child follow-up register	This register is filled out for all HIV-positive women who give birth and come to the clinic for services; it tracks important prevention services, like infant HIV testing.
Postnatal register	This register is filled out during the postnatal visit.
Delivery register	This register is filled out after delivery for all women who deliver at the clinic.
CTC2 cards (PMTCT only)	CTC2 cards are individual medical records used at the clinic to record services received for HIV-positive patients. For our purposes, we used only those from the clinic for PMTCT.

After reviewing all sources and enumerating all eligible women from the sampling registers, the research team counted the sampling frame and determined the sampling fraction. If there were more than 50 women at a site and the sampling fraction was less than one, the team would use the fraction to take a systematic random sample of women from the list.

3.2.4 Data sources and methods
Quantitative data collection
The research team abstracted data from six health facility registers, as well as the CHW logs for each sampled woman. The research team collected data using tablet computers loaded with Qualtrics data collection software. We provided no compensation to the sites or site staff for this specific activity, as we were retrospectively abstracting existing data (Table 5).

Health facility survey

In order to understand the key characteristics of each health facility, the study team also conducted a facility survey during baseline and endline data collection. The comprehensive questionnaire asked facilities about the types of services they provided, number of staff, size and so on. This data was used to check the baseline balance of control and treatment groups (see also Section 3.3.2 Primary specifications).

Table 5: Data collection registers

Source	Description	Relevant measure(s)
1) ANC register	Contains information about all women who booked for ANC	Number of ANC visits
2) ART register	Contains information about HIV-infected pregnant or postpartum women who are initiated on ART at RCH clinics. We matched all HIV-infected women in the baseline or endline cohorts to the ART register to determine whether they initiated ART and at what time relative to their pregnancy	Timing of ART initiation (calculated from the last normal menstrual period)
3) Postnatal register	Contains information relevant to the postnatal clinic visit	Place of delivery, postnatal visit attendance
4) CTC2 cards	Contains individual medical record data for HIV-infected women. We abstracted data from these cards as needed, to supplement data in the ART register	Timing of ART initiation, retention in care postpartum
5) ARV dispensing register	Contains ART pick-up dates and quantity for HIV-infected women	MPR
6) HEI cards	Contains relevant information on HIV-exposed infants	Early infant diagnosis testing
7) CHW logs	Standardized logs, kept by CHWs, of pregnant and postpartum women in their catchment area	Number of CHW visits per woman

Qualitative data collection

To further understand program implementation and to help describe why the intervention did or did not work, we conducted a qualitative study to complement the quantitative impact evaluation. Research staff conducted a total of 35 in-depth interviews with 5 clinic staff members, 10 community health workers and 20 women who received the intervention following established qualitative methods (Weiss 1995).

Interviewee demographics were purposively selected to represent a range of characteristics (presented in Table 6) including years of experience in their field of work, ages and rural or urban clinic settings. Patients were selected for a range of ages, number of live births and rural or urban clinic settings. Interviewees were compensated TZS10,000 (approximately USD3) for their time.

The interviewer used semi-structured interview guides. Interviews covered a range of topics, including CHW and health facility staff working relationships, interactions with and opinions of the ABC, and experiences with ARV adherence.

Table 6: Select qualitative interviewee demographics

	CHWs	Health staff	Patients
N	10	5	20
Age, mean (range)	39.4 (25–50)	47.8 (42–58)	31.2 (21–42)
Sex			
Male	4	0	—
Female	6	5	20
Location			
Rural	8	1	16
Urban	2	4	4
Years in the field, mean (range)	11.8 (2–24)	8.6 (2–20)	—
Parity, mean (range)	—	—	3.8 (2–8)

3.2.5 Quality control and confidentiality

We monitored data quality through periodic data downloading and cleaning. At baseline, we produced error reports using STATA© software to highlight missing or inconsistent data, which were sent back to the data collection team for correction. The team then conducted extended data cleaning after baseline collection. This involved returning to each site and double-checking missing data for key indicators, abstracting additional information on missing women, and gathering data from informal interviews with the health staff about data record keeping at the facilities.

At endline, we followed the same data cleaning protocol in real time; the data collection team received weekly feedback on missing, inconsistent or unmatched data. The team cross-checked data at the site and input changes as needed. Additionally, using tablet computers with Qualtrics survey software significantly cut down on the data errors likely to arise through a paper-based process.

Given the sensitive nature of health records for HIV-positive clients, confidentiality was of the utmost importance during data collection. All clinic staff involved in the project, including CHWs and healthcare workers, adhered to stringent confidentiality guidelines put in place by the Tanzanian Ministry of Health. Research study staff did not collect identifying names or addresses at any point during either quantitative or qualitative data collection, in line with ethical requirements.

Potentially identifiable information was limited to date of birth of the infant, and CTC and ANC patient identification numbers. This information was used only to merge datasets from the different registers. Once the data was merged and cleaned, this information was dropped from analysis datasets. De-identified data, both quantitative and qualitative, was saved securely on Box (the University of California, Berkeley's encrypted online storage system).

3.2.6 Challenges

Sample size

After piloting data collection tools at baseline, it became clear that we would not meet our desired n per site within our original sampling window of six months. We therefore decided to expand the eligibility window at baseline to one year. Unfortunately, due to the short intervention period, we were not able to do the same at endline.

As a result, we sampled more women at baseline (12-month window period, n = 1,154) than at endline (6-month window period, n = 678). We also did not attain the needed number of women per site outlined in the initial power calculation. This may, in turn, affect our ability to detect significant differences between treatment and control groups.

The reason for this under-enrollment was due mostly to an overestimation of the average number of women enrolling in HIV care at each site per month. As outlined in Section 3.2.1 Sample size determination and power calculation, we initially estimated that we would have at least six new HIV-positive pregnant and postpartum women in the sample. This estimate was based on our best available data and turned out to be incorrect. There was no way to estimate the number of incident ANC enrollments by HIV-infected women at the time of study initiation; we were forced to use caseload as a proxy, which turned out to be insufficient.

Finding and linking records across registers

At baseline, the study team encountered significant challenges linking women across registers. This was in part due to differences and inconsistencies in the numbers used to identify women across various registers. Consequently, the team used a 'fuzzy matching' (Christen 2012) process to match the data, using only the strictest match definitions. All data that did not match was re-examined during data cleaning. Research assistants returned to the sites to re-check identifying numbers and determine whether the unmatched women were included in our sample. At endline this was not an issue, as reports were created and fed back to the team in real time.

ANC visit data collection

Although ANC registers collect information about individual women who book ANC, the columns intended to record the *number* of ANC visits per women were generally not completed. We found that the number of ANC visits was generally recorded at the aggregate level, rather than the individual level (the number of women attending four or more ANC visits was a simple tally, not linked to individuals).

Unfortunately, this means that we are not able to measure our process indicator of four or more ANC visits. This was a surprising finding, because clinics are mandated to report this information to the Ministry of Health and Social Welfare and there is a specific place to record it in the ANC register. As a result, ANC register information is not reported for this study.

Infant testing

At baseline, infant HIV testing appeared to be unusually low and the research team informally interviewed clinic staff about this discrepancy. Clinic staff at several sites mentioned that when children tested HIV negative, staff members would not record this

results in the HEI card at the facility. It therefore appeared that fewer children were being tested than in reality.

We have no evidence that this bias is differential by treatment status, and the resulting statistics may still approximate differences between treatment and control groups. However, EID rates are substantially below what has been estimated by other studies (Chiduo et al. 2013).

ART initiation date
The research team found that the ART initiation date in the ART register was sometimes different from the date found on the individual's CTC card. Upon investigation and after discussions with clinicians and ministry staff, the team determined that the CTC card was the most accurate measurement of ART start date and was therefore the primary source used for all analyses. Some women had started and stopped using ARVs prior to their pregnancy under previous PMTCT strategies, including those where ART was discontinued after breastfeeding ended (or six weeks post-delivery if not breastfeeding) (Gamell et al. 2013) and the older date was often recorded in the ART register.

Heterogeneity of impact
To determine effect heterogeneity by the intensity of exposure to CHWs, we initially planned to construct a variable that indicated the number of visits each woman in our sample received from CHWs. Unfortunately, however, many women in our samples were not found in the CHW log forms. We hypothesize that this was because: 1) some women in our sample were not served by the CHWs; and 2) there were significant differences in the level of understanding of the log forms among CHWs that led to errors which prevented matching between the logs and women in the health facility sample.

We received several forms that were missing identifying information that would link the log form to our sample, such as ANC or CTC number. In order to still assess the heterogeneity of impact, we instead examined clinic-level intervention saturation. This measure was an aggregate score of the intensity of each intervention component in each community.

3.2.7 Threats to validity
Contamination
In the urban area of Shinyanga, the treatment and control sites of the intervention are necessarily closer than in the rural areas. Due to their proximity, it is possible that there was some contamination of the intervention into the control catchment areas. Through qualitative interviews, we found high demand for the ABC, and it is possible that, in some cases, the card may have been provided to women outside of treatment areas.

Nevertheless, the implementation team members did their best to orient the site supervisors and CHWs on the importance of giving ABCs only to their clients and not to women from other catchment areas. We collected no evidence from the qualitative interviews that contamination was happening. Additionally, it is possible that other programs were operating in the area without our knowledge.

Positionality and Hawthorne effects
Since the research team abstracted the data directly from clinic records, there is minimal risk of negative effects from positionality of the researchers on the data collection

process. Additionally, the data collection team comprised only native Tanzanians. Qualitative interviews were also carried out exclusively by Tanzanian staff.

There is also minimal risk of Hawthorne effects, since all data was abstracted retroactively from health facility-based medical registers. The data collection team visited sites separately from the intervention activities or monitoring and their goal was expressly to look at health facility records; they did not interact with the CHWs in any way. Nor, in turn, did the implementation staff or CHWs interact with the facility records. During monitoring visits, it was made clear that the purpose of the evaluation was not to evaluate the clinic, the staff or the CHWs themselves, but rather to gain a better understanding of how the intervention worked.

3.3 Analysis methods

3.3.1 Evaluation strategy

Analysis approach

We analyzed outcome indicators using a difference-in-differences approach, whereby the effect of the exposure on the outcome can be 'differenced out' from time-constant effects using the following linear regression equation (adapted from Gertler et al. 2010):

$$E(Y) = \alpha + \beta_1 x_t + \beta_2 x_i + \beta_3 (x_t * x_i) + \varepsilon$$

Where β_1 represents the effect of time, (x_i) and β_2 represent the effect of the treatment (x_t). The effect estimate of the interaction term (β_3) is equivalent to the effect estimate of the difference-in-differences analysis, also denoted by the following equation:

$$\text{Impact} = [(Y|\, x_t = 1, x_i = 1) - (Y|\, x_t = 0, x_i = 1)] - [(Y|\, x_t = 1, x_i = 0) - Y(x_t = 0, x_i = 0)]$$

where the average program effect is equal to the average difference in the outcome between the treatment control groups at endline, minus average difference in the outcome between treatment and control groups at baseline. We used this model to assess effect in both the primary outcome and the process indicators.

All estimates were weighted by clinic for the: 1) probability of selection within strata of large and small sites; 2) probability of selection given the number of eligible women at each site; and 3) probability of response at each site. In addition to these regression equations, we conducted sensitivity analyses, controlling for clinic-level factors that were imbalanced at baseline (Table 7) as well as imbalance of baseline process indicators.

Primary outcomes of interest (Impact)

- Impact indicator 1: timing of ART initiation (n = 787).
- Impact indicator 2: percentage of women retained in HIV care 60–120 days postpartum for the full sample (n = 1,830), and among women with evidence of HIV care (those who had CTC numbers; n = 1,348) since a woman can only fall out of care once she is in the system.
- Impact indicator 3: percentage of women with at least 95% ART adherence at 90 days postpartum, and with at least 80% adherence at 90 days, to be consistent with the existing literature.
- Additional impact indicator: ART initiation during pregnancy or postpartum (had any information listed in an ART register, had an ART start date on a CTC card,

or had evidence of ART or ARVs listed in an ANC register, but not if their ART start date was more than 40 weeks before the expected date of delivery) (286 exclusions; n = 1,544).

Heterogeneity of impact by intervention intensity

To examine effect heterogeneity by the strength of the intervention across intervention communities, we created an aggregate intensity score based on indicators linked to the four intervention components. This included information on:

1. The average number of CHW visits received by HIV-positive women
   Defined as the total number of visits conducted with HIV-positive women, divided by the number of HIV-positive women at each site. Data was retrieved from CHW logs. This indicator was intended to capture the level of contact between CHWs and HIV-infected pregnant and postpartum women, as a proxy for the strength of the ART adherence counseling component of the intervention.
2. The proportion of defaulters that were traced at each site
   Defined as the number of defaulters traced, over the number of total defaulters at each site. Data was collected from the monitoring form used at site visits. This was intended to capture the strength of the tracing defaulters component of the intervention.
3. The average number of HCW or CHW meetings per month at each site
   Defined as the total number of meetings conducted over the number of months of the intervention. Data collected was from meeting forms or meeting minutes filled in by HCWs at the site. This variable intended to capture the strength of the linkage between CHW and community health centers.
4. Average number of ABC cards per HIV-positive woman recorded in the CHW logs
   Defined as the total number of ABC cards distributed, divided by the number of HIV-positive women at each site. This comprised data on ABC distribution collected from the monitoring forms and data on the number of HIV-positive women collected from the CHW logs. Although women should not have received more than one ABC card, this indicator intended to capture the saturation of communities with ABC cards and was superior to using the absolute count of ABC cards distributed alone.

We ran two analyses with this score, using the same regression approach noted above, utilizing both a binary categorization and the continuous score. In the first analysis, we ranked each indicator (from 1 to 15, with 1 being the lowest score and 15 being the highest) and then averaged ranks to create a summary score. When values were equal, the score took on the median value between the ties (e.g. if twelfth and thirteenth place were the same value, they took the rank value of 12.5.

The resulting average score across the four components was then analyzed as: 1) a continuous variable; and 2) part of a three-level treatment variable, grouped into ‘high performing’ (above the median) and ‘low performing’ (at or below the median) treatment groups (0: comparison, 1: low-performing intervention and 2: high-performing intervention sites).

Note that our original plan to link *individual* CHW-client visits in the community to clinic medical records was not feasible. In addition to the major data quality issues in the CHW

logs (described in Section 3.2.6 Challenges), CHWs were also often unable to record the client ID on their logs, which was the sole linkage to medical records. This precluded linking single visits to individuals at health facilities. The heterogeneity analysis described above circumvented this problem by relying on aggregate data at the community level.

Qualitative data

Interview transcripts were transcribed and translated by Tanzanian staff. Transcripts were then analyzed using Atlas.ti survey software. Coding consisted of three levels: 1) organizational or structural; 2) deductive; and 3) inductive. The organizational codes correspond to the different parts of the intervention, e.g. organizational codes include 'ABC cards' if the ABC card was discussed and 'tracing defaulters' if the quote related to the process of tracing those defaulting from care.

We derived and adapted deductive codes from existing literature on CHW interventions in Sub-Saharan Africa (Chinkonde, Sundby and Martinson 2009; Nuwagaba-Biribonwoha et al. 2007; Turan and Nyblade 2013). We developed codes both deductively, using prior literature and knowledge of barriers and facilitators to using services in the PMTCT cascade, and inductively, incorporating codes that emerged from the data. We then aggregated codes into sub-themes and themes and examined narratives for theme saturation across interviews.

3.3.2 Primary specifications

Balance tables

The research team collected data on services provided at the clinics. Table 7 outlines these characteristics and tests for balance across treatment and control clinics at baseline. All clinic-level characteristics were balanced at baseline, with the exception of the mean number of CHWs.

Table 7: Facility-level baseline balance

	Treatment sites mean (SE)	Control sites mean (SE)	Mean difference	p-value
Total number of sites	15	17	—	—
Clinic characteristics				
Type of facility (%)				0.27
Government health center	53.2	76.2	—	—
Government dispensary	25.8	23.8	—	—
Religious or voluntary hospital	6.4	0	—	—
Religious or voluntary health center	14.6	0	—	—
Estimated population in catchment area	16,321 (1,895)	17,015 (2,896)	–693	0.84
Number of staff	16.0 (1.7)	18.8 (3.4)	–2.8	0.50
Average number of CHWs per site mean (SE)	15.2 (2.6)	9.2 (1.0)	6.0	0.03*
Average number of CHWs per capita in the catchment area	0.07	0.13	0.06	0.11
Frequency of CHW meetings (%)				
1–2 times per month	0	6.0	—	—
3–4 times per month	34.5	35.6	—	—
> 4 times per month	65.6	58.0	—	—
Service provision				
Number of days per week ANC services are open (mean SE)	4.2 (0.4)	4.9 (0.3)	–0.7	0.14
Provision of ART services, including Option B+ services (%)	100	100	—	—
Provision of postnatal services (%)				0.35
At health facility	100.0	94.4	—	—
Referral to another facility	0	5.6	—	—
Provision of delivery services (%)				0.25
At health facility	83.3	100.0	—	—
Referral to another facility	11.3	0	—	—
Both	5.6	0	—	—
Adherence counseling provided (%)				0.95
Every ANC visit	38.7	33.7		—
Every CTC visit	54.9	60.6		—
Treatment initiation only	6.4	5.6		—
Other attributes				
Mean number of missing women from baseline sample	4.7 (1.5)	2.7 (0.62)	2.0	0.12
HEI testing (from process indicators (Table 10)	37.6 (3.4)	28.9 (1.9)	8.7	0.03*

* Significant at the $\alpha = 0.05$ level.

Notes: SE = standard error. Estimates are weighted by site size. Mean difference calculated for continuous variables only. Statistical significance determined using chi-square for categorical and t-tests for continuous variables.

Data cleaning
As described in Section 3.2.5 Quality control and confidentiality, data was checked as it was entered into Qualtrics. Data cleaning for baseline took place from October through December 2015 and focused on the primary outcome indicators and linkages across registers. At endline, data cleaning and data collection occurred concurrently; cleaning reports were sent to the field team at least on a weekly basis.

Notable exclusions
We identified that 20 per cent of the baseline sample consisted of HIV-infected women who had their infant's date of birth as the only other identifying information (i.e. no ANC or CTC number to link to other registers). To better understand why this was happening, we spoke with clinic health staff and found that some staff would not write in the CTC or ANC number for a woman, particularly if she came to the clinic that day without her identifying paperwork. This was evidence that women without a CTC or ANC number may actually still be receiving care.

We identified these women as 'missing' and 'untraceable' and therefore excluded them from the baseline analysis (n = 123) because there was no way to collect any information on them from any register. During endline data collection, we modified the protocol so that these women would no longer be considered eligible.

To ensure that this exclusion did not introduce bias, we generated and compared a variable for the mean number of missing women by treatment status. Treatment facilities did not have a significantly different mean number of missing women compared with control facilities; there was no evidence of heterogeneity by the mean number of missing women (Table 7).

Deviations from original protocol
The above protocol differs from the original proposal in a few key ways. Firstly, after piloting the data collection tools, we realized that six months was not a sufficient time window to achieve our sample size goals. Subsequently, for baseline, we enlarged the window period to a full year rather than six months. Furthermore, we did not originally specify that sampling of HIV-infected pregnant women would use the CTC card. Through our initial pilot, however, we realized that this was a valuable resource that would allow us to capture more eligible women and therefore added it to the protocol. This has been a particularly important strategy for endline data collection, where the window period is only six months.

Furthermore, the research team discovered that some health facilities had databases of patient records – a finding that we did not initially account for in the protocol. This positive discovery was an additional source of HIV care information that we utilized, when available, at baseline and endline. Finally, due to the lack of identifying information in the CHW log forms, in order to assess heterogeneity of impact, we examined clinic-level intervention saturation rather than the number of visits per woman (see also Section 3.2.6 Challenges).

4. Results

Baseline and endline data collection yielded a total sample of 1,830 pregnant and postpartum women – 1,152 from baseline (infants born in 2014) and 678 from endline (infants born in 2015). For each of the primary outcomes calculated, we subsetted to women who met the inclusion criteria (as outlined in Section 3.3.1 Evaluation strategy). We calculated timing of ART initiation by gestational week among women with an ART initiation date who began ART after conception. We determined retention in care among the full sample as well as among women with evidence of HIV care (a CTC number). We calculated adherence measures among women with complete ARV dispensing data.

4.1 Trends over time, control group only

From baseline to endline, we observed improvements in PMTCT service utilization, including initiation of ART, retention in care and MPR (Figure 4; Table 8). With the exception of an MPR of at least 95 per cent, all primary outcome indicator differences were statistically significant at the p = 0.05 level.

Table 8: Control site baseline–endline comparison of primary outcome indicators

		Control sites		
	N	**Baseline**	**Endline**	**Difference (CI)**
Total (N)	964	590	374	—
Timing of ART initiation by gestational week, mean (SE)	438	27.3 (0.6)	24.3 (1.2)	–3.0 (–5.2, –0.8)*
Women retained in care postpartum (%) — full sample	964	34.6	47.3	12.7*
Women retained in care postpartum (%) — those with evidence of CTC care	727	46.4	59.0	12.6**
MPR over the 90 days postpartum, mean % (SE)	456	58.6 (2.5)	65.4 (2.4)	6.9 (3.5, 10.3)**
Women with MPR ≥ 95% (%)	456	21.2	22.8	1.6

* Significant at the α = 0.05 level; ** significant at the α = 0.01 level.
Notes: Continuous outcomes tested through t-test; categorical outcomes tested through chi-square tests; CI calculated for continuous variables only. All estimates weighted for selection, site size and, at baseline, missing women.

4.2 Outcome indicators

4.2.1 Impact indicator 1: timing of ART initiation

We determined the timing of ART initiation among HIV-infected pregnant women according to their gestational week (computed from the expected delivery date). This analysis was limited to women with an ART initiation date who had not begun ART prior to pregnancy (n = 787). Though there was a general decrease over time between baseline and endline (Table 8), the treatment group started ART 2.5 weeks later than the control, on average, over time (CI: –1.6, 6.5; Table 9). While on average all sites reduced their average week of commencing gestational ART, the treatment group did not improve relative to the control group.

4.2.2 Impact indicator 2: percentage of women retained in HIV care 60–120 days postpartum

Among the full sample (n = 1,830), we found a non-significant –2.6 percentage-point decrease in the effect difference between treatment and control groups, controlling for time-constant effects (CI: –16.3, 10.9; Table 9).

Among women with evidence of HIV care (those who had CTC numbers; n = 1,348), we found a five percentage-point increase when comparing treatment and control groups, controlling for time-constant effects (CI: –5.9, 15.9; Table 9). While among the full sample we saw little effect, among women already in care we saw a sizable (five percentage-point) improvement in retention in the treatment group. Women with evidence of care is a more intuitive denominator for the outcome, since a woman can only default or fall out of care once she is in the system.

Table 9: Difference-in-differences estimates of intervention effect on primary outcome indicators, Tanzania, 2014–2015

Outcome among pregnant women living with HIV		Baseline (births in 2014)			Endline (births in 2015)				
	N	**Treatment**	**Control**	**Diff**	**Treatment**	**Control**	**Diff**	**Unadjusted DiD (CI)**	**Adjusted DiD (CI)**
Total	1,830	562	590	—	304	374	—	—	—
Timing of ART initiation (n = 787), mean (SE)	787	27.2 (0.8)	27.3 (0.6)	–0.1	26.7 (1.3)	24.3 (1.1)	2.4	2.5 (–1.6, 6.5)	2.0 (–2.0, 6.0)
Women retained in care postpartum, full sample (n = 1,830) (%)	1,830	35.3 (1.9)	34.6 (2.6)	0.7	45.3 (4.6)	47.3 (8.6)	–1.8	–2.7 (–16.3, 10.9)	–4.5 (–17.5, 8.6)
Women retained in care postpartum, evidence of CTC (n = 1,830) (%)	1,348	47.9 (3.0)	46.4 (2.6)	1.5	65.6 (3.4)	58.8 (4.4)	6.8	5.0 (–5.9, 15.9)	0.9 (–11.8, 13.7)
MPR, mean (SE)	820	57.1 (3.3)	58.5 (2.4)	–1.4	67.3 (4.0)	65.4 (2.3)	1.9	3.4 (–5.2, 12.0)	1.7 (–7.0, 10.5)
Women with MPR ≥ 95% (%)	820	16.2 (3.8)	21.2 (3.1)	–5.0	29.1 (4.8)	22.8 (3.1)	6.3	11.3 (–0.7, 23.3)*	9.5 (–2.9, 22.0)
Women with MPR ≥ 80% (%)	820	27.8 (4.1)	34.9 (4.4)	–7.2	46.7 (5.9)	41.6 (4.2)	5.1	12.2 (–0.7, 25.1)*	8.9 (–3.2, 21.1)
Number of women initiating ART during pregnancy	1,544	52.3 (3.5)	61.6 (3.2)	–9.3*	46.3 (3.6)	49.2 (5.1)	–2.9	6.4 (–3.1, 16.0)	4.5 (–3.2, 12.3)

* significant at the α = 0.10 level.

Note: Estimates were weighted for selection, site size and, at baseline, missing women. DiD estimate adjusted model additionally adjusted for factors imbalanced at baseline (HEI diagnostic testing and number of CHWs at the clinic).

4.2.3 Impact indicator 3: percentage of women with at least 95 per cent ART adherence (MPR ≥ 95%)

We calculated ART adherence as measured by the MPR among women who had ARV dispensing records (n = 820). There was only a 0.03 shift in the continuous MPR distribution (CI: –0.05, 0.12). However, there was an increase in the proportion of HIV-infected women achieving at least 95 per cent MPR by 11.3 percentage points compared with women in control sites over time (CI: –0.7, 23.3; Table 9).

The proportion of HIV-infected women achieving at least 80 per cent adherence also increased by 12.2 percentage points over time (CI: –0.7, 25.1; Table 9). Though MPR does not seem to significantly improve in the treatment group, over time the proportion of women with high adherence appeared to improve in the treatment group, compared with the control group.

4.2.4 Additional impact indicator: initiation of ART during pregnancy

Among women who did not begin ART prior to pregnancy, there was a 6.4 percentage-point increase in ART initiation in the treatment group compared with the control group, over time (CI: –3.1, 16.0; Table 9). This estimate, though not statistically significant (p = 0.18), suggests that the intervention had a positive effect on the percentage of women who initiated ART during pregnancy.

It is also worth noting, however, that in this outcome the effect estimates from both treatment and control groups actually decrease over time. This is a surprising finding, considering the positive trends in service use observed in the rest of the data. It is possible that this is because indicators for retention and adherence are limited to women with adherence or retention data. By including all women (other than those who initiated ART before pregnancy), this outcome examines a larger sample population.

This finding could also be due to changes in recording practices with the scale-up of Option B+. While Option B+ scale-up has likely led to the rapid absorption of women into ART, as the program stabilizes, service use reaches a saturation point and this estimate will subsequently stabilize. Since our data collection period coincided with the Option B+ scale-up period, it is possible that that was the driver of this trend (more women have already initiated ART through Option B+).

4.2.5 Adjustment for baseline imbalance

To examine changes in the effect estimates when controlling for baseline imbalances, we conducted a sensitivity analysis. In the analysis, we used the same regression models described above for the primary outcome indicators with adjustment for: 1) HEI diagnostic testing (binary variable from process indicators; and 2) the average number of CHWs per capita at the clinic (Table 7). Effect estimates for MPR $\geq$ 95 and MPR $\geq$ 80 outcomes remained sizable (DiD = 9.5 and 8.9, respectively – see Table 9), though were no longer statistically significant (p = 0.13; Table 9).

Figures 4 and 5: Percentage of women adherent to ART, from baseline to endline, stratified by treatment status

Figure 4: Percentage of women at least 95 per cent adherent (MPR ≥ 95%)

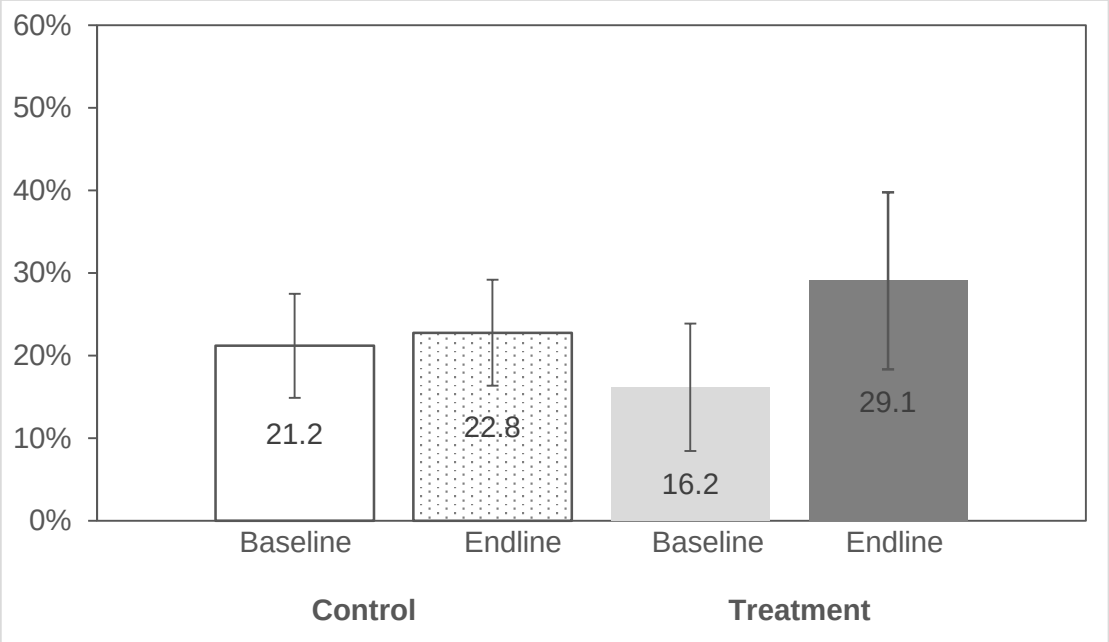
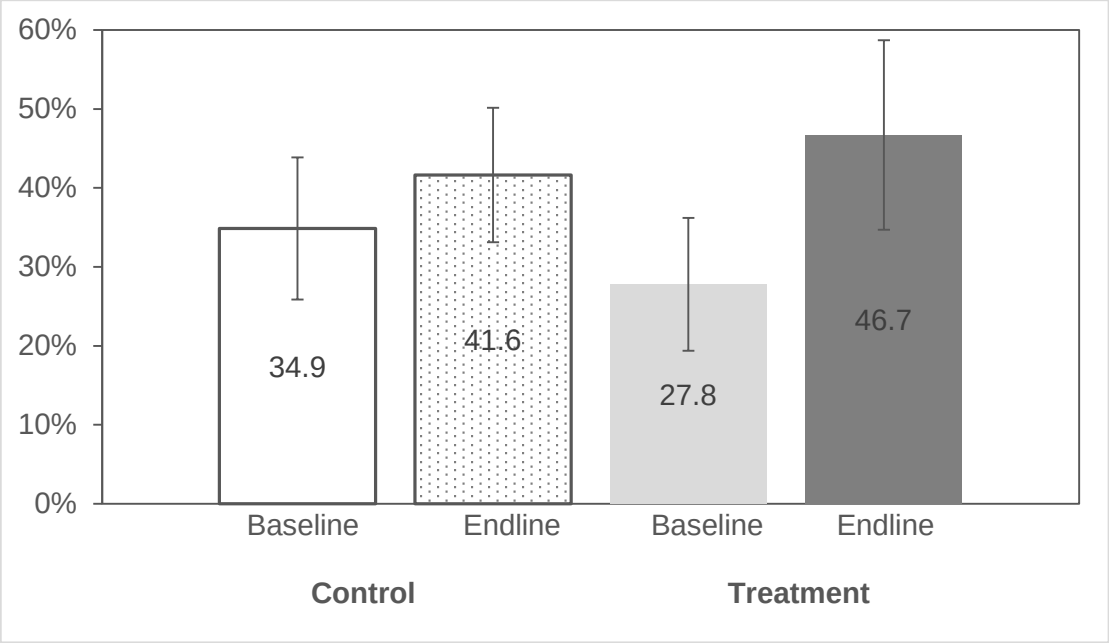


Figure 5: Percentage of women at least 80 per cent adherent (MPR ≥ 80%)



4.3 Process indicators

We present baseline and endline results, stratified by treatment status, below. The intervention did not appear to have an effect on any of the process indicators. We were unable to report the outcome of ANC registration because of aforementioned issues with data recording at the clinics.

Table 10: Process indicators for the impact evaluation

	Baseline			Endline			
	Treatment % (SE)	Control % (SE)	Diff.	Treatment % (SE)	Control % (SE)	Diff.	DiD estimate (CI)
Women delivering in a health facility	42.4 (3.4)	39.5 (2.3)	2.9	45.9 (3.8)	49.6 (8.2)	–3.7	–6.7 (–23.2, 9.9)
Women attending a postnatal visit	22.8 (3.0)	13.7 (2.3)	9.1	27.1 (3.2)	24.1 (3.0)	3.0	–6.1 (–16.3, 4.1)
HEI testing	37.6 (3.4)	28.9 (1.9)	8.7**	35.1 (4.1)	22.7 (2.5)	12.4**	3.7 (–9.9, 17.3)

** significant at the $\alpha = 0.05$ level

Note: Data calculated among the full sample (n = 1,830), weighted for selection, site size and, at baseline, missing women

4.4 Heterogeneity of impact

In order to examine heterogeneity of impact by community-level intervention intensity, we used aggregated data from the communities. We analyzed the site-level rank score as: 1) a continuous variable (taking values between 5.125 and 13.125); and 2) a categorical variable (cutting the rank score at the median, the categorical variable taking the values of 0, 1 or 2). Seven sites were classified as ‘high’ saturation (above the median rank score) and the remaining eight were classified as ‘low’ saturation (at or below the median).

We found heterogeneity of impact for women with MPR of at least 95%, women with MPR of at least 80%, and the percentage of women initiating ART (Table 11). The sites with a high treatment saturation score had a larger effect estimate than the low treatment score, and the treatment effect for the high saturation group was statistically significant. This pattern held when treatment was analyzed as a continuous variable; the treatment effect remained significant for all three outcomes (MPR $\geq$ 95%, MPR $\geq$ 80% and the percentage initiating ART).

Table 11: Primary outcome indicators stratified by treatment intensity among women in Tanzania, 2014–2015

		Baseline (births in 2014)			Endline (births in 2015)					
		Treatment intensity			Treatment intensity			DiD categorical		DiD continuous (CI)
	N	High	Low	Control	High	Low	Control	High	Low	
Total	1,830	171	391	590	94	210	374	—	—	—
Timing of ART initiation	787	27.9	26.7	27.3	23.3	29.3	24.3	–3.4	5.1***	0.6 (–0.5, 0.6)
Women retained in care postpartum – all	1,830	35.0%	35.6%	34.6%	48.6%	42.6%	47.3%	0.9	–5.6	–0.2 (–1.8, 1.4)
Women retained in care postpartum – evidence of CTC	1,348	51.5%	45.3%	46.4%	70.2%	61.9%	59.0%	6.1	4.0	0.4 (–0.7, 1.6)
MPR	820	61.4	54.0	58.6	69.2	65.7	65.4	0.9	4.8	0.4 (–0.5, 1.2)
Women with MPR ≥ 95%	820	18.8%	14.3%	21.2%	34.8%	24.1%	22.8%	14.3**	8.2	1.4 (0.4, 2.4)***
Women with MPR ≥ 80%	820	33.2%	24.1%	34.9%	52.5%	41.8%	41.6%	12.6*	11.0	1.5 (0.3, 2.7)**
Women initiating ART during pregnancy	1,544	45.3%	58.4%	61.7%	47.8%	45.2%	49.2%	15.0***	–0.7	0.9 (0.0, 1.9)**

* Significant at the α = 0.10 level; ** significant at the α = 0.05 level; *** significant at the α = 0.01 level.

Note: Estimates were weighted for selection, site size and, at baseline, missing women

4.5 Qualitative data

The qualitative data collected during the study contributed to a better understanding of the intervention components. It also revealed several new themes regarding the utility of CHWs in the context of the broader healthcare system in Tanzania. For further details on the demographic characteristics of the stakeholders who were interviewed, see Table 6.

Several themes emerged from the interviews, particularly how CHWs played a role in supporting women by building trust as well as identifying barriers and helping women to overcome them. One woman reported:

> *I feel good because [the CHW] is helping me with so many things. Sometimes I am lazy and don't feel like going to the clinic for my medications but he comes and insists me to go there. He is really helping me with so many things.* (Patient 20)

As one CHW explained:

> *We agree on the day she will come to clinic and I escort her here. I talk to the nurse about that specific client, [explaining] that she has no spouse and we have to help her.* (CHW 7)

Formally linking CHWs to health clinics
In general, most CHWs and healthcare staff interviewed reflected positively on their relationships. CHWs reported feeling satisfied about the mentorship the healthcare staff provided, while healthcare staff reported gratitude for the CHWs' help at clinics.

While reports of satisfaction may fall victim to social desirability bias, this is nevertheless an encouraging finding. As intended, most of the CHWs reported meeting with the clinic staff on a weekly basis. However, one of the CHWs mentioned that, at their clinic, they met only monthly. Given that the CHW was at a treatment site, this may reveal that most, but not all, clinics were faithful to the weekly meeting schedule.

ABCs
A prerequisite for the qualitative interviews was that the women had to have received an ABC. This purposeful selection was to ensure that we could collect information about how ABCs were used. There was some heterogeneity of how the ABCs were used; some read it multiple times, while others not at all. This differential use of ABCs is to be expected.

Adherence counseling
Adherence counseling was a key part of the intervention. Almost all interviewed patients reported that the CHW reminded them of the importance of regularly taking ART. There was often little detail in these accounts, but it is important to note that the women who did not report much detail were also the ones who reported not having any issues with adhering to their medication daily. It is possible that these women did not require extra support and therefore did not receive the full extent of adherence counseling. We interviewed two women who reported having issues with ART adherence. One of these women reported:

> *I took those medications as I was supposed to but I was waking up late and very tired … He [the CHW] advised me to keep on taking them and that I will feel some changes after 14 days. I listened to him and kept on taking them. I kept on taking the medications and I was feeling okay. After two months, it was like taking water.* (Patient 15)

Tracing defaulters

The tracing defaulters component of the intervention seemed to be ubiquitously understood across CHW and health staff interviews, though the level of detail at which the process was explored varied across interviewees. Among those who did explain the process, one CHW reported:

> *They inform us to follow up on a specific person if she has not shown up for a week. Therefore, you get the information that you need and you will know where to start looking for her. You will talk to her and she will share with you why she stopped taking her medications. Some may have had two tins so they have not shown up at the clinic because they still have the medications. We do get such cases.* (CHW 5)

Other interviews emphasized the importance of going to the homes of people who had disengaged from HIV care and speaking to them about the importance of returning to the clinic. This evidence suggests that the tracing defaulters protocol was followed as expected at the clinics.

CHWs in this study appeared to play an essential and unique role in the lives of women by encouraging shared trust, and subsequently enabling women to receive clinic-based care and adhere to their medication.

5. Discussion

5.1 Interpretation of results

5.1.1 Temporal changes in key outcomes

Tanzania began rolling out Option B+ in September 2013. Its goal is to improve HIV-related services for pregnant mothers by diagnosing HIV during pregnancy and initiating all HIV-infected women on lifelong ART regardless of clinical stage. Our health facility-based survey results – from a random sample of facilities representing 58 per cent of all 55 facilities providing MNCH services in Shinyanga region – indicate that, by 2014, all facilities in the study sample had the capacity for HIV testing and ART initiation. This finding is consistent with the scale-up of Option B+ throughout Tanzania.

The temporal changes in our outcome indicators in the control group are encouraging. They suggest that Option B+ (and/or other health system strengthening activities) may be related to the increases in women's access to, and use of, services. This may arise by overcoming operational barriers at the clinic or by increasing demand in the community. Specifically, we found that timing of ART initiation, retention in care and adherence improved over the one-year timeframe from 2014–2015.

However, this data was collected from a subset of sites in the region, and is not representative of Option B+'s impact nationally. Nor can the changes be directly and

causally attributed to the Option B+ policy without further study. Nevertheless, these indicators are key steps in the PMTCT cascade and provide a preliminary signal of success in the national program's implementation.

5.1.2 Changes in key outcomes

This study evaluated the short-term impact of a multi-pronged intervention that integrated CHWs into PMTCT services. The intervention included linking CHWs to clinics, using CHWs to trace those defaulting from HIV care and providing ART adherence counseling and ABCs to HIV-infected pregnant women. The intervention was inexpensive and acceptable to health facility staff, CHWs and HIV-positive pregnant women.

Using a cluster-randomized design in 32 health facilities, we found that the intervention resulted in improvements in all primary outcome indicators compared with comparison facilities after a short period of time. In particular, we found an 11.3 percentage-point increase in the percentage of women who were at least 95 per cent ART adherent over time. We measured this using the MPR (a proxy for ART adherence) in the 90-day window after delivery, which was significant at the alpha = 10 per cent level. After adjustment for baseline imbalance, the effect estimates for these outcomes remain sizable, although no longer statistically significant. Notably, the short period of exposure to the intervention (six months) and smaller sample size preclude statements about the intervention's effect on other outcomes.

Qualitative findings support the hypothesis that CHWs are key in linking women to healthcare (see also Section 4.5 Qualitative data). CHWs play an important role in the Tanzanian health system. Patients build trust with them and interact with them in different ways than they do clinic staff. CHWs are uniquely positioned to support women through their pregnancy by providing information and suggestions, reminding them to take medication and advocating for their receipt of services in ways not possible for facility staff.

These relationships help to support HIV-infected women to enter and remain in the PMTCT cascade, including retention in care after birth – the main issue that has threatened the success of Option B+ programs in other settings (Clouse et al. 2014).

Although the effect of the intervention is not conclusive, unadjusted results suggest that at least one component of the intervention may have encouraged women who were already in care to attend their visits on time and consequently have fewer days of medication non-possession. Although the study was not designed to differentiate the effect of the intervention components, we hypothesize (as evidenced through qualitative interviews, see Section 4.5 Qualitative data) that the ABC may have been instrumental in nudging women to attend clinic visits, including HIV care.

CHWs also played a vital role in supporting and encouraging women to attend clinic regularly and to adhere to their medication. Given the short-term nature of the evaluation, these preliminary estimates suggest that a longer follow-up time with a larger sample is warranted to understand these effects better.

Process indicators do not show any suggestive effects. While qualitative interviews suggest that the ABC helped women to make a delivery plan, they may not have been

enough to overcome the significant physical barriers that many women face in receiving key ANC and delivery services.

5.1.3 Impact heterogeneity by treatment saturation

The effect of the treatment on several of the primary outcomes may be heterogeneous by treatment intensity. In particular, the effect estimate of the intervention on treatment adherence (95% and 80% MPR) is larger in the communities that were most successful at implementing the four components of the intervention.

This result in the adherence outcome nevertheless lends further support to the theory that the intervention may be most effective at shifting adherence for those already in care. Additionally, high-performing sites had a strong impact on ART initiation during pregnancy. This provides some evidence that the intervention may have greater impact when implemented with the highest fidelity. Next steps would include evaluating impact heterogeneity on a larger scale and with additional support in order to ensure that all four components are implemented as intended, as well as stronger oversight on monitoring measures (see also Section 6 Conclusions and recommendations).

5.2 Internal and external validity

Internal validity

While the study faced several challenges in collecting and merging the data, extensive data cleaning has ensured that the data was collected accurately. The only threats to internal validity have been difficulties measuring some of the process outcomes, as previously described (see also Section 3.2.6 Challenges). These difficulties were due to record-keeping errors at the clinics and were therefore unavoidable. There is also a small possibility of contamination if women outside of the intervention areas were able to obtain ABC cards and/or received care from a CHW who had been trained to implement the intervention.

External validity

The impact evaluation used a cluster-randomized design, which is appropriate for an effectiveness, rather than efficacy, trial. Thus, the results from the study describe the average population effects of the intervention, rather than the expected effects of the intervention in a given individual.

Furthermore, the study is based in Shinyanga region, a rural region that faces challenges that are commonplace throughout eastern and southern Africa: a shortage of skilled healthcare personnel, poor demand for prevention and care services, and pervasive barriers to ensuring that pregnant women are retained in the PMTCT and HIV treatment cascades. For these reasons, our results have both a high level of external validity as well as policy relevance.

5.3 Cost-effectiveness

The intervention was relatively low cost and therefore has the potential to be implemented on a large scale if deemed effective. The costs of the intervention included the CHW allowance, the ABC cards, the cost of the staff time to meet with CHWs, and training costs. In total, these costs added up to USD51,145 over an 11-month intervention period.

In very simple terms, this investment translates to an overall cost of approximately USD4,525 for every percentage-point increase in 95 per cent medication adherence in our analysis of 820 women. We feel these costs could be justified given the scope and reach of the program, the clinical benefits of high levels of ART adherence for individual women, the potential for PMTCT for current and future pregnancies, and the spillover effects on preventing HIV transmission to others.

5.4 Stakeholder experience

The study findings meet the expectations of the project's different stakeholders at district, regional and national levels. From initial meetings at those levels, stakeholders were interested in the study's potential to produce useful findings that can be used to serve local women and the community at large.

6. Conclusions and recommendations

Despite policy development in Tanzania around CHWs, currently CHW employment is not supported through national policies. Instead, CHW work is viewed as being the responsibility of NGOs and individual volunteerism rather than that of government. In parallel, the country's health sector is facing a workforce crisis (Kwesigabo et al. 2012; WHO Global Health Observatory 2014).

In this context, it is unclear whether the full benefits of Option B+ can be realized. This could accordingly place a large burden on NGOs to fully train and provide appropriate incentives to CHWs, and rollout of such programs is usually small scale and short term. Partly because of this lack of support, maintaining motivation can be an issue in CHW programs, as many CHWs view their work as temporary or a stepping stone to other employment (Schneider et al. 2008). As a result, high turnover subsequently depletes the quality of care.

This study, while inconclusive, highlights how investing in CHWs and increasing their integration into the formal health sector may be a feasible strategy to enhance health outcomes among HIV-infected pregnant and postpartum women. CHWs play a key role in the lives of the women they serve, and may be able to support women to attend clinics and receive ARV medication more regularly.

These are key benchmarks as Tanzania, like other countries in Sub-Saharan Africa, attempts to eliminate MTCT. Furthermore, formalizing the CHW workforce in Tanzania may encourage retention among the CHW workforce, increasing service quality and support – particularly for HIV-infected pregnant and postpartum women.

To further concretize the feasibility of integrating CHWs into PMTCT services in Tanzania, a larger-scale study is needed that can follow a larger cohort of HIV-infected pregnant and postpartum women. In particular, scale-up efforts may consider providing greater infrastructure and monitoring around the intervention (e.g. SMS messages to verify visits). For instance, our monitoring data on CHW visits were self-reported; there is no way yet to verify that these visits actually happened. It produced a high burden of paperwork for the CHWs, who have varying levels of education and comfort with such administrative tasks.

Additionally, quality of supervision of CHWs was not monitored in detail in this study. Future iterations may consider stricter monitoring of CHW visit frequency and length, e.g. via text or electronic tracking, and more frequent and in-depth site monitoring and tracking of healthcare worker and CHW meeting content. Furthermore, the study may consider greater oversight and increased staffing to improve the monitoring and support of the intervention period. These simple tools and strategies will ensure a more even rollout of the program and consequently optimal benefits for HIV-positive women.

Online appendixes

Note to the reader: Online appendixes are provided as received from the authors. They have not been copy-edited or formatted by 3ie.

Online Appendix A: Action birth card can be accessed here:
http://www.3ieimpact.org/media/filer_public/2017/07/13/ie61-appendix_a.pdf

Online Appendix B: Weighting notes can be accessed here:
http://www.3ieimpact.org/media/filer_public/2017/07/13/ie61-appendix-b.pdf

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Despite the proven effectiveness of delivering maternal, newborn and child health (MNCH) and other health services at the community level, there is a paucity of evidence on the effect of integrating MNCH and HIV prevention of mother-to-child transmission (PMTCT) health services using community health workers (CHWs). This impact evaluation of a pilot programme implemented by Amref Health Africa in Shinyanga Region examined whether CHWs can enhance retention in PMTCT services, including retention in HIV care and adherence to antiretroviral therapy. Study findings demonstrate that compared to control sites, there were improvements over time in treatment sites in the timing of antiretroviral therapy initiation, retention in care, and medication possession ratio, though results were not statistically significant.

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