

SUPPORTING THE IMPLEMENTATION OF GUIDELINES TO PREVENT MOTHER-
TO-CHILD-TRANSMISSION OF HIV IN MALAWI: A QUALITATIVE DESCRIPTIVE
CASE STUDY

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ABSTRACT

Chifundo Colleta Zimba: Supporting the implementation of guidelines to prevent mother-to-child transmission of HIV in Malawi: A qualitative descriptive case study
(Under the direction of Jennifer Leeman)

The burden of human immunodeficiency virus (HIV) on women aged 15–49 years is high in Malawi (13%), resulting in HIV transmission to 12,000 children in 2011. Malawi has adopted the Option B+ guidelines which, if fully implemented, could prevent over 95% of HIV cases in children born to HIV-infected women. Since adoption of guidelines is not enough to move science into practice, the UNC Project—a partner organization to the Malawi government—provided prevention support (e.g., training and technical assistance [TA]), to 134 Malawian clinics between 2011 and 2014 to enhance implementation of the Option B+ guidelines.

This qualitative, descriptive multiple-case study aimed to describe the types of prevention support the UNC Project provided to 4 clinics, how support varied across low- and high-performing clinics, and factors that may explain variations in Option B+ implementation across clinics (N=4). Data were gathered through 21 in-depth interviews with 18 key stakeholders (n=6 TA providers and n=12 care providers). Observation supplemented data from in-depth-interviews. Directed content, thematic, and cross-case analyses were used to analyze data.

The study found that the UNC Project used the following prevention support strategies: off-site trainings of the service providers; ongoing, onsite TA that employed collaborative and audit and feedback approaches; tools such as standard operating procedures

(SOPs); and resources such as HIV testing kits. Variations occurred in TA dose (i.e., time TA providers spent on guidelines activities in the clinic and community) and on TA focus (i.e., the unit where TA providers spent more hours).

All four clinics reported full implementation of most of the Option B+ guideline core components. Implementation gaps were found on community mobilization, documentation, and components done during the post-delivery period. Staffing and transportation emerged as the most salient contextual factors influencing TA delivery while size of the clinic staff, service space/infrastructure, stocks of the HIV testing kits, and magnitude of the served population explained differences in guideline implementation between low- and high-performing clinics.

Results of this study can help advance understanding of the way prevention support enhances implementation of new evidence-based interventions and contextual factors that may need to be addressed.

This dissertation is dedicated to my only son Blessings Chitaniimba, who from the age of four years was deprived of motherly care while I was studying. Throughout his life, Blessings has known his mother as a student. As he grows and turns into a young boy, he happens to be the only person who has wholeheartedly supported me to complete my PhD. May God Almighty continue blessing him with more wisdom and understanding and a lovely mind.

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LIST OF ABBREVIATIONS

AIDS	Acquired immune deficiency syndrome
ART	Antiretroviral treatment therapy
ARVs	Antiretroviral drugs
AZT/ZDV	Zidovudine
CDC	Centers for Disease Control and Prevention
DBS	Dried blood spot
DHO	District health office/r
DNA	Deoxyribonucleic acid
EFV	Efavirenz
EBSIS	Evidence-based system for innovation support
HIV	Human immunodeficiency virus
HP	High performing clinic
HTC	HIV testing and counseling
HSAs	Health surveillance assistants
ISF	Interactive systems framework
LP	Low performing clinic
NMT	Nurse/midwife technician
NSO	National Statistical Office
NVP	Nevirapine
PCR	Polymerase chain reaction
PMTCT	Prevention of maternal/mother to child transmission of HIV
SOP	Standard operating procedure
TA	Technical assistance
TDF	Tenofovir

UNAIDS Joint United Nations Programme on HIV/AIDS
UNC University of North Carolina
USAID United States Agency for International Development
WHO World Health Organization
3TC Lamivudine

CHAPTER 1. AN OVERVIEW OF THE STUDY

Introduction

Malawi is heavily affected by the human immunodeficiency virus (HIV) and acquired immune deficiency syndrome (AIDS). Almost 11% of the 13 million people in Malawi are infected with HIV (National Statistical Office [NSO] & Macro, 2011). The burden of HIV is higher among Malawian women and children than among the general population. In 2011, 13% of reproductive-age women (15–49 years) and 10.6% of pregnant women were infected with HIV, resulting in maternal transmission of HIV to 12,000 children (Malawi Ministry of Health [MoH], 2012a). Use of antiretroviral treatment therapy during pregnancy and breastfeeding can help prevent over 95% of these infections and potentially save many lives (Chasela et al., 2010; Joint United Nations Programme on HIV/AIDS [UNAIDS], 2012a). However, for several years in Malawi, use of antiretroviral drugs to prevent mother-to-child transmission of HIV has been very low. For example, between July 2010 and June 2011, only 45% of all HIV-infected pregnant women received a short course antiretroviral treatment therapy regimen and only 11% received a lifelong course of the regimen to prevent mother-to-child-transmission of HIV (MoH, 2012a).

To increase uptake of the antiretroviral treatment therapy among HIV-infected women and prevent HIV transmission to children exposed to HIV, the Malawi Ministry of Health developed and implemented new Malawian integrated antiretroviral treatment therapy and prevention of mother-to-child-transmission (PMTCT) of HIV guidelines that provide all HIV-infected pregnant and breastfeeding women with access to lifelong antiretroviral drugs

regardless of their immunity level that can be measured by individuals' CD4 count(i.e., a count of the type of white blood cells that are destroyed by the HIV) or their World Health Organization (WHO) clinical stage (Malawi MoH, 2011). These guidelines are commonly known as the “Option B+” in Malawi and worldwide. To scale up, enhance, and promote the implementation of the Option B+ guidelines in the Central and Western zones of the Malawian Ministry of Health healthcare delivery system, the University of North Carolina (UNC) Project, an organization that works in collaboration with the Malawi Ministry of Health, provided three years (2011–2014) of technical assistance (TA) and other support strategies to clinics in five districts—Lilongwe, Dedza, Ntcheu, Mchinji, and Dowa. Support strategies such as TA have the potential to improve clinics' implementation of the Option B+ guidelines and increase the proportion of women receiving recommended care, yet very little was known about the way TA and other support strategies were delivered and used in Malawi. In addition, data from the Malawi Ministry of Health indicate that key indicators of the implemented Option B+ guidelines varied across clinics in the districts that received TA. Among the districts that received TA between October 2012 and September 2013, the proportion of pregnant women tested for HIV in the antenatal clinic ranged between 62.5% in Mchinji district and 90% in Lilongwe district. Making sure that women are tested and know their HIV status is critical in the implementation of the Option B+ guidelines because it is only when a woman is known to be HIV-infected that she can have access to antiretroviral treatment therapy. This study explored whether this variation is related to the delivery or use of technical assistance (TA) or due to other contextual factors.

Purpose of this Study

The purpose of this qualitative, descriptive multiple-case study (Parse, 2001; Yin, 1994, 2013) was to describe how prevention support such as technical assistance (TA) varied across low- and high-performing clinics and to explore factors that might explain variations across the selected clinics (N=4). Cases for this study were defined as the Malawi Ministry of Health Primary Health Centers that received TA support from the UNC Project.

Specific Aims

Aim 1: To describe the prevention support (e.g., training, technical assistance) that the UNC Project provided and how it was used by two high- and two low-performing clinics of the Malawi Ministry of Health.

Aim 2: To identify contextual factors that may explain variation in the delivery and use of technical assistance (TA).

Aim 3: To identify contextual factors that may explain variation in the implementation of Option B+ guidelines in the two high- and low-performing clinics of the Malawi Ministry of Health.

Background and Significance

The burden of HIV on women and children is high in Sub-Saharan Africa, where Malawi is situated. In 2011, about 60% of all women living with HIV lived in Sub-Saharan Africa (UNAIDS, 2012). As mentioned above, in Malawi, 13% of reproductive-age women (15–49 years) and 10.6% of pregnant women were infected with HIV in 2011, resulting in maternal transmission of HIV to 12,000 children (Malawi MoH, 2012a). Yet evidence supports that use of antiretroviral drugs can help prevent over 95% of these infections and potentially save many lives (Chasela et al., 2010; Jamieson et al., 2012; UNAIDS, 2012a, 2012b; WHO, 2012). Antiretroviral treatment therapy prevented 409,000 children from

acquiring HIV between 2009 and 2011 worldwide (UNAIDS, 2012a, 2012b) and can reduce the rate of mother-to-child HIV transmission from 45% to less than 5% (Chasela et al., 2010; Jamieson et al., 2012; UNAIDS, 2012a; WHO, 2012). Use of antiretroviral treatment therapy to prevent maternal transmission of HIV is effective, but its implementation is limited in Malawi and in the rest of Sub-Saharan Africa. Between July 2010 and June 2011, only 45% of all HIV-infected pregnant women received the short-course antiretroviral treatment regimen and 11% received a lifelong course of the regimen to prevent transmission of HIV from mothers to their babies (MoH, 2012a). In addition, prevention-of-mother-to-child-transmission of HIV program evaluations revealed that less than 20% of mother/baby pairs received all aspects of recommended services beyond the antenatal period in Sub-Saharan Africa and in Malawi (Beltman et al., 2010; Manzi et al., 2005; Moses et al., 2008).

Use of prevention support strategies such as TA has the potential to improve clinics' implementation of Option B+ guidelines and increase the proportion of women receiving recommended care, but very little is known about the way prevention support was delivered and used in Malawi. In addition, key indicators for the implemented Option B+ guidelines varied across the clinics that received TA from the UNC Project between 2012 and 2013, and we did not know whether this was due to variation in the delivery or use of TA or due to contextual factors. The UNC Project in Malawi used prevention support strategies such as TA to enhance clinics' implementation of the newly adopted Option B+ guidelines. Implementation of Option B+ activities is critical to improving women's and children's health. Prevention support strategies such as TA are used to build organizations' or individuals' capacity (knowledge, skills, and motivation) to implement evidence-based

interventions (Flaspohler, Lesesne, Puddy, Smith, & Wandersman, 2012; Gregory et al., 2012; Hunter et al., 2009; Wandersman, Chien, & Katz, 2012).

Results from this qualitative multiple-case study contribute to our understanding of how the UNC Project delivered TA and how both the two low- and two high-performing Malawi Ministry of Health clinics used TA and other support strategies to implement the newly adopted Option B+ guidelines. This study advances our understanding of the reasons for variation in provision and use of prevention support and implementation of the Option B+ guidelines across multiple clinics. Findings of this study describe in detail the prevention support that the UNC Project provided, how clinics used that support, and variations in contextual factors influencing the delivery of TA and implementation of the guidelines. The added knowledge from this study will enhance the practice of Option B+ implementation and research aimed at elimination of pediatric HIV infection in Malawi. Results of this study are expected to inform improvements in the science of prevention support and in the implementation of the prevention-of-mother-to-child-transmission of HIV services in Malawi and beyond because mother-to-child transmission of HIV is a global issue.

This qualitative, descriptive, multiple-case study is important because it is the first to describe prevention support such as how TA was delivered and used in low- and high-performing Malawi Ministry of Health clinics. The study was designed to understand how TA varied across low- and high-performing clinics and explore factors that might explain variations across the four selected clinics. It was innovative in its focus on multiple perspectives: interviews were completed with support providers and users. The study included multiple sites; participants were drawn from two different organizations—the Malawi Ministry of Health and the UNC Project—with the focus on support delivery and its

use in high- and low-performing clinics. Use of multiple sites allowed us to explore contextual differences that have been linked to explain variations in TA delivery and in implementation of the Option B+ guidelines in the four study sites. Previous research on prevention-of-mother-to-child-transmission of HIV programs in Sub-Saharan Africa (e.g., Manzi et al., 2005; Mate, Bennett, Mphatswe, Barker, & Rollins, 2009; & Moses et al., 2008) did not consider the influence of contextual factors on TA delivery and use or on the implementation of interventions such as the Option B+ guidelines in Malawi. Although prevention support such as TA is widely used to promote the implementation of evidence-based interventions, little is still known about how best to design support interventions. To advance the science of prevention support, this study took advantage of an existing broad-scale support intervention that the UNC Project used to assist the Malawi Ministry of Health in the Central and Western zones of the Malawi healthcare delivery system to scale up implementation of Option B+.

Brief Background and History of the UNC Project in Malawi

The UNC Project is a partner organization of the Malawi Ministry of Health and started its work in Malawi in 1989 (Mofolo & Chingondole, 2013, unpublished data). The Project's mission is to improve the health of the Malawians by providing service, research, and training. The UNC Project's initial work was funded by Family Health International/United States Agency for International Development (USAID) to create and validate the Malawi Ministry of Health clinical treatment algorithms for sexually transmitted infections. Currently, the UNC Project has several projects that focus on building Malawi's human resource capacity to provide patient care and conduct health services research in priority health areas such as HIV, malaria, obstetrics, gynecology, and pediatrics (Mofolo & Chingondole, 2013, unpublished data).

Within its service arm, the UNC Project in Malawi established the first prevention-of-mother-to-child-transmission of HIV program in 2001, which focused on Lilongwe, the capital city of Malawi, where direct care was provided. By 2002, the program had expanded to four clinics and provided counseling and HIV, hemoglobin, and syphilis testing; offered a single-dose of Nevirapine to both HIV-infected mothers and their babies; and referred all HIV-infected women to a long-term care clinic for antiretroviral drugs (Moses et al., 2008). By 2013, the program expanded to 134 clinics in the Central and Western zones of the Malawian healthcare delivery system (Herce et al., 2015). The UNC Project pioneered various strategies for preventing mother to child transmission of HIV in Malawi. Examples of such strategies include rapid HIV testing, “opt-out” HIV testing, use of lifelong antiretroviral treatment therapy for HIV infected pregnant and breastfeeding women, and use of TA to implement the Option B+ guidelines (Herce et al., 2015)

Research conducted by the UNC Project in Malawi, such as by Chasela et al. (2010); Jamieson et al. (2012); and Cohen, McCauley, and Gamble (2012); contributed to the recommendations included in the WHO’s prevention-of-mother-to-child-transmission of HIV guidelines (2010, 2012), which recommend prolonged antiretroviral therapy in women and their HIV-exposed children (see Table 1). In 2011, the UNC Project received funding from the USAID through a project known as the “Safeguard the Family Program,” which was launched in April 2011 for the specific purpose of providing support such as TA to five districts in the Central and West zones of the Malawian healthcare delivery system. These targeted districts were Dedza, Lilongwe, Mchinji, Ntcheu, and Dowa. In 2011, the targeted districts had 134 health facilities (including the Malawi Ministry of Health clinics, those owned by the Christian hospitals’ association of Malawi, and privately owned clinics) that

served about 3.86 million people and provided antenatal care to approximately 174,000 new pregnant women annually (Herce et al., 2015). For three years (2011 to 2014), the UNC Project's Safeguard the Family Program provided TA and other support strategies to enhance the implementation of the Option B+ guidelines with the goal of reducing mother-to-child-transmission of HIV from 50% to less than 10% at the end of the breastfeeding period (Herce et al., 2015).

The Guiding Framework

The Interactive Systems Framework (ISF) for Dissemination and Implementation (Wandersman et al., 2008, 2012) was applied to describe prevention support and determine how the provision and use of prevention support varied across low- and high-performing clinics and to uncover contextual factors that might explain variations in TA delivery and in the implementation of the Option B+ guidelines in Malawi. According to Wandersman et al. (2008; 2012), the ISF for Dissemination and Implementation includes tasks that are carried out by different individuals or organizations during the process of dissemination and implementation of any evidence-based intervention. These tasks are carried out by three interacting systems: the *Prevention Synthesis and Translation System*, which synthesizes scientific information and translates it into user-friendly interventions that can easily be used by the implementers in their practice settings; the *Prevention Support System*, which provides support services to build individuals' or organizations' capacity to implement the promoted scientific interventions; and the *Prevention Delivery System*, which implements the interventions in their practice settings (Wandersman et al., 2008, 2012).

Figure 1 shows how the ISF for Dissemination and Implementation was applied to guide the development of this research. This framework posits the need for Prevention Support Systems to bridge the gap between evidence and practice to promote improved

outcomes. To enhance the implementation of the Option B+ guidelines in the Central and Western zones of the Malawian healthcare delivery system, the UNC Project in Malawi served as a Prevention Support System and for three years provided training, technical assistance and other supports to the Malawi Ministry of Health clinics. The UNC Project provided support that aimed to build - clinics' capacity to implement the Option B+ guidelines. The Malawian Ministry of Health clinics implemented the Option B+ guidelines and thus served as a Prevention Delivery System. The Malawi Ministry of Health central office and their national stakeholders synthesized the available evidence and developed the innovative Malawian Option B+ guidelines that provide all HIV-infected pregnant and breastfeeding women with access to lifelong antiretroviral treatment therapy regardless of their immunity level (Malawi MoH, 2011). The Malawi Ministry of Health central office, therefore, served as the Prevention Translation and Synthesis System. These systems have been depicted by the three separate gray boxes in Figure 1. The two black double arrows indicate how the UNC Project interacted with the Malawi Ministry of Health central offices and other national stakeholders during the process of developing the Option B+ guidelines and also with the Malawian Ministry of Health clinics to build their capacity to implement the Option B+ guidelines in their practice settings. The Evidence-Based System for Innovation Support (EBSIS) describes the tools, training, TA, and Quality Assurance and Quality Improvement (QA/QI) that the Prevention Support System (i.e., UNC Project) provided to build clinics' capacity. Details about how Wandersman et al. (2012) theorized that the EBSIS functions are presented in Figure 5.

Wandersman et al.'s ISF also depicts how the context in which the clinics are operating may influence the process of delivering TA, its use, and the implementation of the

promoted Option B+ guidelines (Wandersman et al., 2008; 2012). Examples of these contextual factors are those that can personally affect the women and the community such as lack of affordable transportation and distance to the clinic; clinic-level factors such as the age of the clinic, its size, and its magnitude; and socio-structural factors such as workforce problems and the implementation climate. These contextual factors were explored to assess how they might explain variations in TA delivery and its use and in implementation of the Option B+ guidelines in the study sites (Damschroder et al., 2009; Damschroder & Hagedorn, 2011). Attending to contextual factors in a qualitative, descriptive multiple-case study helped this study avoid giving out misleading information or gaining an incomplete understanding of the cases that were studied (Yin, 2013).

This study focused its description on the interaction of the Prevention Support System and the Prevention Delivery System of the ISF and on contextual factors that were present at the patient/community, clinic, and the general Malawian healthcare systems' level that were found to be relevant to explain variation in TA delivery and use and implementation of the Option B+ guidelines (Wandersman et al., 2008; 2012). Factors that arose at community and the general healthcare systems' levels are referred to as the socio-structural factors in this study.

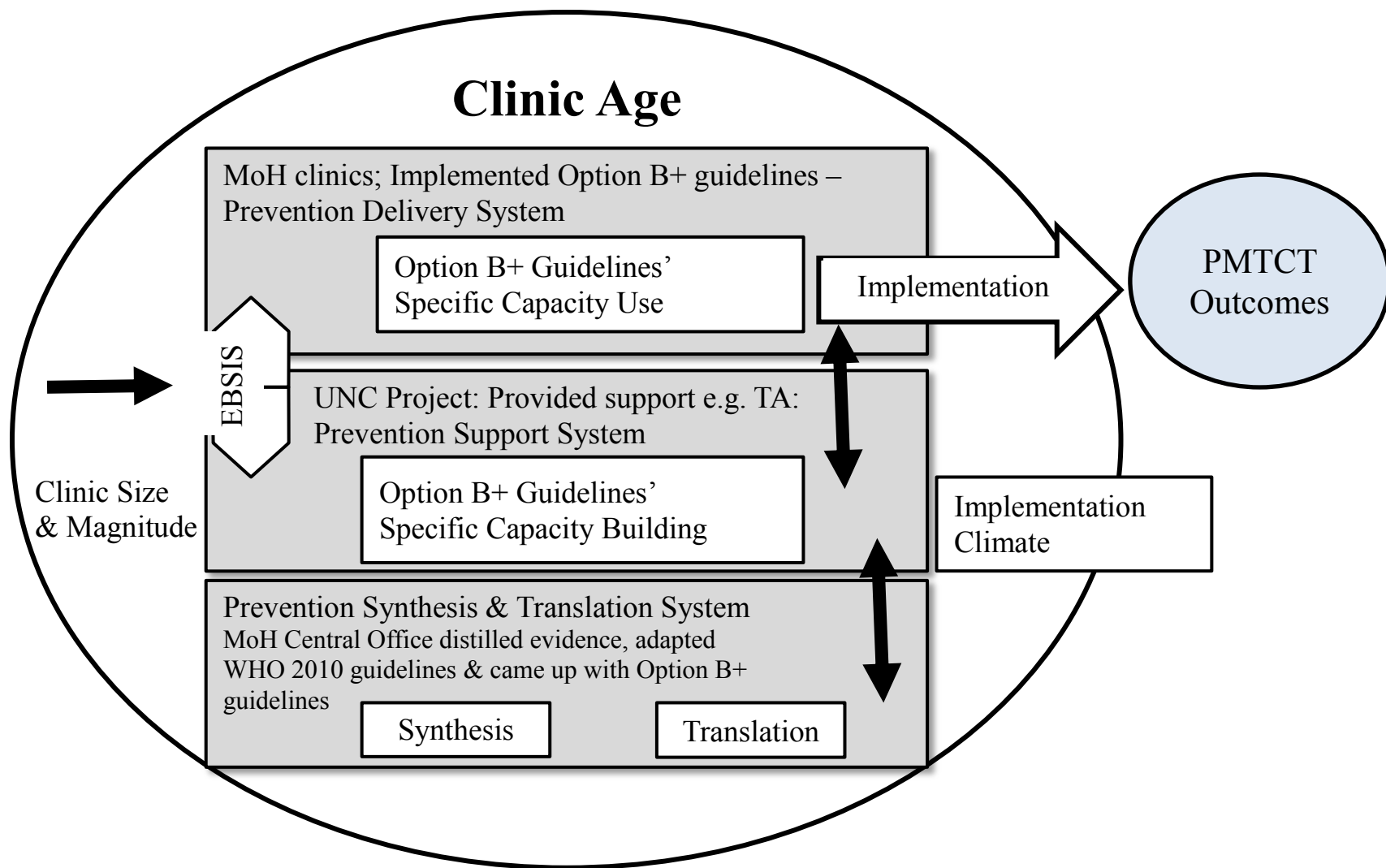


Figure 1. The ISF applied to implementation of the Malawian Option B+ Guidelines.

PMCTC = Prevention of Maternal to Child Transmission; MoH = Ministry of Health; WHO= World Health Organization

CHAPTER 2. LITERATURE REVIEW

Preventing Mother-to-Child Transmission of HIV in Malawi

Human immunodeficiency virus (HIV) and acquired immune deficiency syndrome (AIDS) are issues of global concern. Worldwide, about 34.0 million adults and children were living with HIV in 2011. Of these, 2.5 million reported that they had newly contracted the HIV infection (UNAIDS, 2012a). Although HIV affects all population ages, its burden on women and children is very high. In 2011, among the 34.0 million people who lived with HIV worldwide, about 330,000 were children ages 0 to 14 years (UNAIDS, 2012a). This trend has been similar since 2007, when the World Health Organization (WHO) reported that of the 39.5 million people who lived with HIV and AIDS as of December of 2006 worldwide, approximately 17.7 million were women and 2.3 million were infants and young children below 15 years of age (WHO, 2007).

Geographically, the burden of the HIV pandemic for women and children is worse in poor countries, especially those in Sub-Saharan Africa, where Malawi is located. In 2011, more than 90% of the children who acquired HIV infection through the mode of mother-to-child transmission of HIV worldwide lived in Sub-Saharan Africa (UNAIDS, 2012a). In 2011, approximately 12,000 children in Malawi below the age of 15 years acquired the HIV infection (MoH, 2012a). Although primary prevention of HIV acquisition in parents is the only method to guarantee zero mother-to-child transmission of HIV, every year about 68,000 HIV-infected women worldwide still get pregnant and deliver children who are exposed to HIV (UNAIDS, 2013). However, use of antiretroviral treatment therapy during and after

pregnancy can help prevent over 95% of these infections and potentially save many lives (Chasela et al., 2010; Jamieson et al., 2012; UNAIDS, 2012a, 2013; WHO, 2012). Since the early 2000s, WHO has been a leading organization in guiding low- and middle-income countries on how to implement prevention-of-mother-to-child-transmission (PMTCT) of HIV interventions. Therefore, this chapter discusses a review of the following literature that is related to this study: HIV and AIDS in Malawi, approaches to prevent mother-to-child transmission of HIV, effectiveness of antiretroviral treatment therapy (ART) for PMTCT, history of PMTCT guidelines in Malawi, and problems with implementing interventions to prevent mother-to-child transmission of HIV both worldwide and in Malawi.

HIV and AIDS in Malawi

Malawi is heavily affected by HIV and AIDS. Geographically, Malawi is located south of the equator in Sub-Saharan Africa, which is home to 69% of the 34.0 million people who lived with HIV in 2011 worldwide (UNAIDS, 2012a). With a population of about 13 million people, almost 11% of Malawians are infected with HIV (NSO & Macro, 2011). In 2010 and 2011, about 52,000 (i.e., 33,000 adults and 19,000 children) and 42,000 (i.e., 30,000 adults and 12,000 children) Malawians were newly infected with HIV, respectively (Malawi MoH, 2012a). The distribution of the HIV prevalence varies across Malawi's three administrative regions—the northern (7%), central (8%), and southern (15%) regions (Malawi MoH, 2012a; NSO & Macro, 2011).

Although HIV affects Malawians of all ages, its burden is worse among Malawian women (13.3%) of reproductive age (15 to 49 years) than men (10.2%) and has been persistently higher since 1985, when the first case of HIV was discovered in Malawi (Bello, Chipeta, & Aberle-Grasse, 2006; NSO & Macro, 2011). HIV prevalence is much higher among young Malawian women aged 15–24 years (5.2%) than among their male

counterparts (1.9%) (Malawi MoH, 2012a; NSO & Macro 2011). Stratifying HIV prevalence by gender and place of residence, the pandemic is higher among individuals who reside in urban areas (17%) than those in rural (9%), with the highest HIV prevalence among women who reside in urban areas (22.7%) (NSO & Macro 2011).

Among Malawian women, HIV prevalence is even higher among pregnant women. In antenatal clinics, HIV prevalence in Malawi is at 10.6%, with 10.1% in the north, 10.7% in central Malawi, and 17.2% in the southern part of the country (NSO & Macro, 2011). The high level of HIV among women is a particular concern in Malawi because 44.4% of the country's female population is of child-bearing age (15–49 years), with a high fertility rate of 5.7 births per woman (6.1 in rural and 4.0 in urban areas) and a very low rate of contraceptive use (46.1%). In addition, the desire to have more children regardless of HIV status is also high in Malawi. On average, men and women of reproductive age want 3.9 children and 4.0 children, respectively (NSO & ICF Macro, 2011). Yet, about 20% of all new HIV infections in Malawi occur in newborn babies who contract the HIV infection from their HIV-infected mothers (UNAIDS, 2013). Reports indicate that in Malawi, about 13.8% of infants born to HIV-positive women get infected from their HIV-infected mothers (Malawi MoH, 2012a; NSO & Macro, 2011). In 2011, the high HIV and fertility rate in Malawi contributed to 12,000 HIV infections in children (Malawi MoH, 2012a). Although mother-to-child transmission of HIV is high, there are approaches, such as use of antiretroviral drugs that are known to be effective in preventing HIV infection in children.

Approaches to Prevent Mother-to-Child Transmission of HIV

HIV is a complex phenomenon that requires different and complex approaches to prevent its transmission from one individual to the other. Evidence indicates that most children contract HIV through mother-to-child transmission, and most Malawian women

contract HIV through heterosexual activities (Malawi MoH, 2012a; NSO & Macro, 2011), therefore, there is need for prevention interventions that target the reproductive age population to help reduce HIV acquisition among parents and eventually in children as well. In addition, use of a combination of HIV-prevention strategies that target both parents and children would greatly reduce the HIV infection in the general child population. There are various approaches and interventions that have proved to be effective in preventing primary HIV infections in parents, preventing unintended pregnancies among HIV-infected women, and preventing mother-to-child transmission among HIV-infected women who become pregnant and deliver children exposed to HIV (Malawi MoH, 2011; UNAIDS, 2012a).

Approaches to Prevent Primary HIV Infections in Parents

To prevent primary HIV infections in parents requires implementation of a combination of activities that have proved to be effective in preventing HIV transmission from one individual to the other. Data from Malawi show that about 80% of the HIV infections are contracted through unprotected heterosexual contact (Malawi MoH, 2012a; NSO & Macro, 2011). Therefore, prevention interventions such as promotion of sexual abstinence before marriage, consistent use of condoms, and male medical circumcision may help potential parents prevent HIV acquisition or transmission among sexual partners, thereby preventing HIV transmission to their future children as well. Due to Malawi's low-income status, some researchers have used conditional or unconditional cash transfers as one approach that has proved to be effective in reducing HIV infection among schoolgirls, poor women, and poor men in Malawi (Baird, Garfein, McIntosh, & Ozler, 2012; Heise, Lutz, Ranganathan, & Watts, 2013).

The most influential study on cash transfer, conducted in the Zomba district of Malawi, reported a significant reduction in early marriages, teenage pregnancies, and self-reported sexual activities, which, in turn, led to a decreased HIV prevalence among school-age girls who received cash incentives (0.7%) versus those who did not (3.0%) (Baird et al., 2012). Although evidence from cash-transfer studies has added to the menu of effective HIV prevention interventions, cash transfers are difficult to scale-up and sustain due to Malawi's limited economic resources (Heise et al., 2013; UNAIDS, 2013). In addition, an evaluation of cash-transfer interventions has questioned their effectiveness in the long term and in the general population because the short-term effects indicated that men who received the cash as a reward were 9 percentage points *more* likely, and women were 6.7 percentage points *less* likely, to engage in risky sex (Kohler & Thornton, 2012).

Prevention of HIV infection among parents can also be achieved through correct and consistent condom use. Condoms are the most available and effective way to prevent HIV worldwide (UNAIDS, 2012a, 2012b, 2013). Therefore, condom use is a very important step in combating HIV infection both in the general population and in prospective parents. However, use of condoms and knowledge about their use are still very limited in countries with high HIV prevalence, such as in Malawi. In 2011, condom use with a non-regular sexual partner in Malawi was about 46% (46.8% among the female population and 57.1% among the general male population) while knowledge about condom use was 72% in the general female population and 72.6% in the general male population (NSO & Macro, 2011). Limited supplies of condoms are another barrier to their use in Sub-Saharan Africa, including in Malawi. In 2011, an estimated nine male condoms per every man and one female condom for every 10 women aged 15–49 years were available in the Sub-Saharan region from donations

(UNAIDS, 2012a). For condoms to be consistently and effectively used by both men and women in countries highly affected with HIV such as Malawi, there is a need for both an adequate supply and a demand.

In recent years, evidence has also emerged that male medical circumcision prevents HIV acquisition among heterosexual men. Male medical circumcision has the potential to reduce HIV acquisition among males who engage in sexual activity with women by 20% (UNAIDS, 2012a). Because of this evidence, WHO and UNAIDS recommend male medical circumcision in countries with high rates of HIV infection as one way to prevent HIV (UNAIDS, 2012a). If HIV acquisition among men who engage in heterosexual relationships can be reduced, a considerable reduction of primary HIV infection among parents can be achieved. However, despite the WHO and UNAIDS recommendation on voluntary medical male circumcision, its adoption in the Sub-Saharan Africa is still very low (UNAIDS, 2012a). For example, Malawi achieved less than 5% of its target on voluntary male medical circumcision in 2011 (UNAIDS, 2012a).

Approaches to Prevent Unintended Pregnancies among HIV-Positive Women

In addition to strengthening primary HIV prevention services to reduce HIV infection among parents, UNAIDS and WHO also recognize the value of preventing unintended pregnancies among HIV-infected women as a strategy to prevent mother-to-child transmission of HIV and contribute to the quality of women's lives (UNAIDS, 2012a). Interventions such as the use of modern contraceptive methods and provision of counseling on the use of contraceptives and on the dangers of becoming pregnant while infected with HIV may help women prevent unintended pregnancies, thereby contributing to a reduction of mother-to-child transmission of HIV (UNAIDS, 2012a; Malawi MoH, 2011). In support of the UNAIDS blueprint, preventing unintended pregnancies among HIV-infected women is

one of Malawi's priorities (Malawi MoH, 2011). However, Malawi still has a very high fertility rate (5.7 births per woman) and a very low rate of contraceptive use (46.1%) (Malawi MoH, 2012a; NSO & Macro, 2011). Increasing use of contraceptives as a birth control method among HIV-infected women would help reduce unintended births among this population and thereby prevent the birth to HIV-infected children.

Approaches to Prevent Mother-to-Child Transmission of HIV among HIV-Infected Pregnant and Breastfeeding Women

A combination of effective HIV-prevention interventions is the most effective approach to quickly reduce HIV transmission and acquisition (UNAIDS, 2012a, 2013). These may include interventions such community mobilization for HIV testing and counseling, conducting HIV testing, providing antiretroviral treatment therapy to individuals who test HIV-positive, and promoting condom use among HIV-infected individual and HIV-discordant couples. To effectively implement any HIV prevention combination interventions, both the target population and potential implementers need to be aware of the presence of HIV among them and how to access the HIV test and antiretroviral drugs. Evidence is well established that early HIV testing and counseling, early provision of antiretroviral treatment therapy and psychological support to HIV-infected pregnant women greatly reduces the rate of mother-to-child transmission of HIV (Malawi MoH, 2011, 2012a; UNAIDS, 2012a).

Effectiveness of Antiretroviral Treatment Therapy (ART) for Prevention-of-Mother-to-Child-Transmission (PMTCT) of HIV

Use of a combination of antiretroviral drugs by the HIV infected pregnant and breastfeeding women is one of the interventions used by the global community to fight against HIV infection in children. The goal is to eliminate pediatric HIV worldwide. Antiretroviral drugs are used to prevent transmission of HIV from an HIV-infected mother to her child during pregnancy, labor, delivery, and breastfeeding periods. Literature indicates

that without any intervention, about 15 to 45% of the babies born to HIV-infected women contract HIV infection from their mothers: 5–10% during pregnancy, 10–20% during labor and delivery, and 10–20% during the breastfeeding period (WHO, 2007; 2012). With an antiretroviral treatment therapy (ART) as an intervention, HIV maternal transmission rates can be reduced to levels below 5% (Chasela et al., 2010; Jamieson et al., 2012; WHO, 2012). For example, use of a combination of antiretroviral drugs by HIV-infected women during pregnancy—starting at 28 to 34 weeks' gestation and during the breastfeeding period up to six months after delivery with a planned early breastfeeding cessation, suppressed women's viral load to less than 400 copies per milliliter and reduced mother-to-child transmission of HIV by over 98%, leaving the HIV transmission rate at only 1.1% (Shapiro et al., 2010). Another large study that was conducted in Malawi (N=2,369 HIV-1-positive, breastfeeding mothers) used a combination of antiretroviral drugs with HIV-infected women during pregnancy and breastfeeding periods (up to 28 weeks post-delivery) and a single drug (nevirapine) to their HIV-exposed children for 28 weeks post-delivery. Use of antiretroviral drugs in this study prevented postnatal transmission of HIV-1 by over 97% during the breastfeeding period. The HIV transmission rate in babies whose mothers received ART was 2.9% ($p = 0.009$) and when their infants also received an antiretroviral drug it was 1.7% ($p < 0.001$) (Chasela et al., 2010). However, due to extended breastfeeding after discontinuing antiretroviral drugs, the study found that HIV-infection rates increased up to 4% in both groups (Jamieson et al., 2012). Therefore, in poor countries such as Malawi, where breastfeeding is the norm and the only food available for the baby, use of extended ART throughout the breastfeeding period for both the woman and her child is the most effective intervention to decrease HIV transmission from an HIV-infected woman to her child.

Use of antiretroviral drugs is also effective in preventing HIV transmission in sexual partners. A recent multi-country study found that when an infected partner used antiretroviral drugs, it protected 96% of uninfected partners from being infected with HIV (Cohen, McCauley, & Gamble, 2012). Given the strength of evidence in support of the effectiveness of ART at preventing mother-to-child transmission of HIV, the global community, including Malawi, committed itself to increase the use of ART by the HIV infected pregnant and breastfeeding women with the goal of eliminating new pediatric HIV infections by the year 2015 and improving maternal, newborn, and child survival and health in the context of HIV (UNAIDS, 2012a; Malawi MoH, 2011; WHO, 2012).

Due to the available evidence on the effectiveness of ART at preventing mother-to-child transmission of HIV, WHO and its global partners have been developing guidelines to promote their use, and many countries have been adopting or adapting those guidelines (WHO, 2004, 2007, 2010, 2012).

History and Trend of PMTCT of HIV Guidelines in Malawi

The initial WHO's guidelines for preventing mother-to-child transmission of HIV in low- and middle-income countries, recommended prophylactic ART (short course of antiretroviral drugs) for HIV-infected pregnant and breastfeeding women with high immunity levels (WHO, 2004, 2007, 2012). These guidelines have evolved, and changes have been ongoing based on availability of new evidence. The WHO guidelines recommend that lifelong antiretroviral treatment therapy (ART) be prescribed only after women present with clinical manifestation of AIDS— a low CD4 count or a WHO clinical stage of 3 or 4 . Following this approach many women fail to receive the drugs in time to prevent transmission of HIV to their children. In 2011, Malawi adopted the WHO (2010) guidelines and adapted them to create its own PMTCT guidelines known as Option B+, which call for the provision of

lifelong ART to all HIV-infected pregnant and breastfeeding women regardless of their CD4 count or their WHO clinical stage (Chimbwandira et al., 2013; Malawi MoH, 2011; Schouten et al., 2011; WHO, 2012). The Malawian guidelines have also evolved over time.

The prevention-of-mother-to-child-transmission (PMTCT) of HIV interventions have been implemented in Malawi and other parts of Africa since the early 2000s (Creek et al., 2009; Malawi MoH, 2007). In Malawi, the PMTCT interventions were first implemented in 2001 by the United Nations Children’s Fund a partner organization of the Malawi government (Malawi MoH, 2007). The United Nations Children’s Fund first focused its effort on the northern part of the country. This effort was followed by the Médicines Sans Frontières in the South, and, in 2002, the Elizabeth Glazer Pediatric AIDS Foundation through the UNC Project in Malawi. This was followed with funding support from the USAID in the central region of the country, with more focus on Lilongwe, the capital city of Malawi.

The PMTCT of HIV was launched as a Malawi government initiative in 2003 to fight against HIV infection in Malawian children and called for the provision of comprehensive antenatal care, including HIV testing and counseling and ART to prevent HIV transmission from an HIV-infected mother to her child; comprehensive labor and delivery care; postnatal care; neonatal care; provision of prophylactic ART for the newborn baby; mother and child dyadic follow-up care; provision of family-planning services for the mother; and HIV testing for the baby at six weeks and at the end of HIV exposure (Malawi MoH, 2007; 2011). PMTCT of HIV has been incorporated into all maternal and child healthcare services.

Changes in the Malawian PMTCT of HIV Guidelines over Time

Malawi’s first PMTCT guidelines used *monotherapy*—a single dose of nevirapine to mother at the onset of labor and to baby within 72 hours of delivery. This monotherapy was used in Malawi from the beginning of PMTCT interventions in 2001 until 2006 (MoH, 2007;

2011). Then, in 2007, the country changed to the use of *dual therapy*—a combination of two types of antiretroviral drugs: Zidovudine (AZT or ZDV) starting at 28 weeks’ gestation up to 1 week post-delivery; a combination of single dose Nevirapine, Zidovudine, and Lamivudine (NVP +AZT/3TC) during labor and delivery; and a combination of Zidovudine and Lamivudine (AZT/3TC) to the mother for seven days post-delivery. The current guidelines, which Malawi adopted in 2011, recommend the use of *triple therapy*—a combination of three types of antiretroviral drugs: Tenofovir/Lamivudine/Efavirenz abbreviated as TDF/3TC/EFV and nicknamed the “5A regimen” in Malawi. This therapy is recommended to all HIV-infected pregnant and breastfeeding women and is started as soon as a woman is diagnosed with HIV but after 14 weeks’ gestation if she is she pregnant. It is continued for life (lifelong triple therapy) (Malawi MoH, 2007, 2011; Schouten et al., 2011). The Malawi Ministry of Health followed the World Health Organization guidelines for PMTCT up until 2010 (see Table 1). Malawi’s current guidelines adapt the WHO’s (2010) recommendations and were developed by the Malawi Ministry of Health and its stakeholders in the country (Malawi MoH, 2011; Schouten et al., 2011).

A description of the current Malawian ART/PMTCT of HIV guidelines (the “Option B+”). The basis for the 2011 Malawian Option B+ guidelines are the WHO (2010) guidelines for treating HIV-infected pregnant and breastfeeding women in low- and middle-income countries (see Table 1) (Malawi MoH, 2011; Schouten et al., 2011; WHO, 2012). The WHO (2010) guidelines recommend that all HIV-infected pregnant women with a CD4 cell count of more than $350/\text{mm}^3$ be treated with triple antiretroviral prophylactic drugs that starts at 14 weeks’ gestation and continues throughout pregnancy, labor and delivery, and throughout the breastfeeding period until one week after cessation of all breastfeeding. For

babies born to HIV-infected women, the recommendations call for daily doses of Nevirapine (NVP) or Zidovudine (AZT) from immediately after birth until the child is four to six weeks old regardless of the baby's feeding methods (WHO, 2010, 2012). For women with a CD4 cell count of less than $350/\text{mm}^3$, WHO recommends continuing triple antiretroviral treatment therapy for life. Malawi adapted these guidelines and came up with its own PMTCT guidelines—the Option B+ (Malawi MoH, 2011; Schouten et al., 2011).

Malawi's Option B+ guidelines include the following four prongs: (1) primary prevention of HIV infection in parents, (2) prevention of unintended pregnancies among HIV-infected women, (3) starting lifelong ART for HIV-infected pregnant and breastfeeding women regardless of their CD4 count and/or WHO clinical stage ('Option B+'), provision of nevirapine prophylaxis for babies born to HIV-infected mothers up to age of 6 weeks, safe obstetric practices, and (4) provision of care, treatment and support for HIV-infected women, their children, and their families" (MoH, 2011, p. 2). What is different in the 2011 Malawian Option B+ as compared to the country's previous guidelines is the recommendation for *lifelong* ART to all HIV-infected pregnant and breastfeeding women regardless of their CD4 cell count or WHO clinical stage and the provision of Nevirapine drug to their babies up to six weeks of age.

According to Malawi Ministry of Health (2011), the Option B+ guidelines were adopted based on the following rationale:

1. The country anticipated it as a way of increasing access to ART by making a positive HIV-antibody rapid-test result in pregnant women as the criterion for ART; the antenatal clinics were thought to serve as ideal entry points for accessing ART by HIV-infected women and their families. The antenatal attendance rate for the second

quarter of 2010 was over 90% and availability of HIV rapid testing at all antenatal sites was perceived as a means to high ART coverage of HIV-infected women and as a way to reduce postpartum mortality rates in HIV-infected women. It was observed that high mortality rates were documented in postpartum women with high CD4 counts (>350 cells/mm³ in pregnancy) who were not on ART.

2. ART was seen as a means of reducing transmission of HIV because maternal ART reduces viral load and provides optimal protection to the baby during pregnancy, delivery, and for subsequent pregnancies. This is especially important because of Malawi's high fertility rate. This reduction of maternal viral load enables safe breastfeeding and avoids the need for extended infant ART prophylaxis. Reduction of viral load also reduces HIV transmission to sexual partners, especially for discordant couples.

From the perspective of cost-effectiveness, the Option B+ guidelines provide a policy that has the potential to prevent new HIV infection in children, improve the quality of their mothers' lives, and reduce AIDS-related mortality in HIV-infected women at a low cost over time (Fasawe et al., 2013).

The Option B+ guidelines are supported by the WHO as an approach that offers both clinical and programmatic advantages because of its adoption of the same ART regimen to treat pregnant and breastfeeding women with either HIV or AIDS and also for prevention of HIV transmission from an HIV-infected mother to her child and to her sexual partner (WHO, 2012). Table 1 displays changes in the PMTCT guidelines for both WHO and Malawi since the inception of the PMTCT interventions in Malawi.

Table 1. Trend in Changes of the WHO and Malawian ART/PMTCT of HIV Guidelines

Year	WHO Guidelines	Malawian Guidelines
2000	<p>Monotherapy and dual therapy ART prophylaxis</p> <ul style="list-style-type: none"> For the mother: Zidovudine (ZDV) alone or in combination with lamivudine (3TC) and Nevirapine (NVP). Single-dose NVP at the onset of labor <p>ART prophylaxis for the baby</p> <ul style="list-style-type: none"> Single dose NVP soon after birth 	<p>No PMTCT interventions</p>
2001		<p>Monotherapy ART prophylaxis for the mother</p> <ul style="list-style-type: none"> Single-dose NVP at the onset of labor <p>ART prophylaxis for the baby</p> <ul style="list-style-type: none"> Single-dose NVP soon after birth but within 72 hours of birth
2004	<p>Monotherapy and dual therapy ART prophylaxis for the mother:</p> <ul style="list-style-type: none"> Option 1: ZDV + NVP Option 2: Single-dose NVP at onset of labor <p>ART prophylaxis for the baby</p> <ul style="list-style-type: none"> Single dose NVP within 72 hours of life 	<p>Monotherapy ART prophylaxis for the mother</p> <ul style="list-style-type: none"> Single-dose NVP at the onset of labor <p>ART prophylaxis for the baby</p> <ul style="list-style-type: none"> Single-dose NVP soon after birth but within 72 hours of birth
2006	<p>Dual therapy and triple therapy</p> <p>Mother in need of ART as treatment: Triple therapy recommendation is as follows: During pregnancy period:</p> <ul style="list-style-type: none"> AZT + 3TC + NVP twice daily <p>During labor and delivery period:</p> <ul style="list-style-type: none"> AZT + 3TC + NVP twice daily <p>After delivery:</p> <ul style="list-style-type: none"> AZT + 3TC + NVP twice daily <p>ART prophylaxis for the baby is:</p>	<p>Monotherapy</p> <p>ART prophylaxis for the mother</p> <ul style="list-style-type: none"> Single-dose NVP at the onset of labor <p>ART prophylaxis for the baby</p> <ul style="list-style-type: none"> Single-dose NVP soon after birth but within 72 hours of birth

Year	WHO Guidelines	Malawian Guidelines
2007	<ul style="list-style-type: none"> AZT x 7 days* <p>Mothers in need for ART prophylaxis During pregnancy:</p> <ul style="list-style-type: none"> AZT starting at 28 weeks of pregnancy or as soon as possible after HIV diagnosis <p>ii. During labor and delivery period:</p> <ul style="list-style-type: none"> A combination of single-dose NVP +AZT/3TC <p>iii. After delivery: AZT/3TC for 7 days ART prophylaxis for the baby</p> <ul style="list-style-type: none"> Single-dose NVP + AZT for 7 days 	<p>Dual therapy and triple therapy Mother in need of ART as treatment: Treat with triple therapy as follows:</p> <ol style="list-style-type: none"> During pregnancy: Stavudine (d4T) + 3TC + NVP once daily During labor and delivery : Stavudine (d4T) + 3TC + NVP once daily After delivery: Stavudine (d4T) + 3TC + NVP once daily <p>ART prophylaxis for the baby:</p> <ol style="list-style-type: none"> AZT x 7 days* <p>•Mother in need of ART Prophylaxis During pregnancy:</p> <ul style="list-style-type: none"> AZT starting at 28 weeks of pregnancy or as soon as possible after HIV diagnosis <p>ii. During labor and delivery period:</p> <ul style="list-style-type: none"> A combination of single-dose NVP +AZT/3TC <p>iii. After delivery: AZT/3TC for 7 days ART prophylaxis for the baby</p> <ul style="list-style-type: none"> Single-dose NVP + AZT for 7 days <p>Dual therapy and triple therapy</p> <p>Mother in need of ART as treatment: Treat with triple therapy as follows:</p>
2010	<p>Dual therapy and triple therapy</p> <p>Option A for women Treatment (for women with CD4 count ≤ 350 cells/mm³)</p>	<p>Dual therapy and triple therapy</p> <p>Mother in need of ART as treatment: Treat with triple therapy as follows:</p>

Year	WHO Guidelines	Malawian Guidelines
	<ul style="list-style-type: none"> Triple ARVs starting as soon as diagnosed, continued for life <p>Prophylaxis (for women with CD4 count >350 cells/mm3)</p> <p>During pregnancy:</p> <ul style="list-style-type: none"> AZT starting as early as 14 weeks' gestation <p>During labor and delivery:</p> <ul style="list-style-type: none"> Single-dose NVP and first dose of AZT/3TC at the onset of labor <p>After delivery:</p> <ul style="list-style-type: none"> AZT/3TC daily for 7 days <p>Option A for infants</p> <ul style="list-style-type: none"> NVP daily from birth until 1 week after cessation of all breastfeeding, or, if infant is not breastfeeding or mother is on treatment, NVP should be given until the baby is aged 4 to 6 weeks. <p>Option B for women</p> <p>Treatment (for women with CD4 count of ≤350 cells/mm3)</p> <ul style="list-style-type: none"> Triple ARVs starting as soon as HIV is diagnosed and ART continued for life <p>ART prophylaxis (for women with CD4 count of >350 cells/mm3)</p> <ul style="list-style-type: none"> Triple ARVs starting as early as 14 weeks' gestation and continued throughout pregnancy, labor, and delivery period and throughout breastfeeding period until 1 week after cessation of all breastfeeding <p>Option B for Infants</p> <ul style="list-style-type: none"> NVP or AZT daily from birth up to e age 4 to 6 weeks regardless of infant feeding method. 	<ul style="list-style-type: none"> vii. During pregnancy: viii. Stavudine (d4T) + 3TC + NVP once daily ix. During labor and delivery: x. Stavudine (d4T) + 3TC + NVP once daily xi. After delivery: xii. Stavudine (d4T) + 3TC + NVP once daily <p>ART prophylaxis for the baby</p> <ul style="list-style-type: none"> i. AZT x 7 days* <p>* If the mother receives less than 4 weeks of ART during pregnancy, AZT should be given 4 weeks to the infant.</p> <p>•Mother in need of ART Prophylaxis</p> <p>During pregnancy:</p> <ul style="list-style-type: none"> AZT starting at 28 weeks of pregnancy or as soon as possible after HIV diagnosis <ul style="list-style-type: none"> ii. During labor and delivery period: • A combination of single-dose NVP +AZT/3TC iii. After delivery: AZT/3TC for 7 days <p>ART prophylaxis for the baby</p> <p>Single dose -NVP + AZT for 7 days</p>

Year	WHO Guidelines	Malawian Guidelines
2011		<p>Triple therapy for all HIV-infected pregnant and breastfeeding women (Option B+)</p> <p>ART for women</p> <ul style="list-style-type: none"> Regardless of CD4 count, triple ARVs (e.g., Tenofovir/Lamivudine/Efavirenz abbreviated as TDF/3TC/EFV and nicknamed “5A regimen” in Malawi) starting as soon as diagnosed, (after 14 weeks’ gestation) continued for life. <p>ART for infants</p> <p>Daily NVP from birth through age 6 weeks regardless of infant feeding method</p>
2012	<p>Dual therapy and triple therapy</p> <p>Option A for women</p> <p>Treatment (for CD4 count ≤ 350 cells/mm³)</p> <ul style="list-style-type: none"> Triple ARVs starting as soon as diagnosed, continued for life <p>Prophylaxis (for CD4 count > 350 cells/mm³)</p> <ul style="list-style-type: none"> Antepartum: AZT starting as early as 14 weeks, gestation Intrapartum: at onset of labor, single-dose NVP and first dose of AZT/3TC Postpartum: daily AZT/3TC through 7 days postpartum <p>Option A for infants</p> <ul style="list-style-type: none"> Daily NVP from birth until 1 week after cessation of all breastfeeding, or, if not breastfeeding or if mother is on treatment, through age 4–6 weeks <p>Option B for women</p> <p>Treatment (for CD4 count ≤ 350 cells/mm³).</p> <ul style="list-style-type: none"> Triple ARVs starting as soon as diagnosed, continued for life <p>Prophylaxis (for CD4 count > 350 cells/mm³)</p>	

Year	WHO Guidelines	Malawian Guidelines
	<ul style="list-style-type: none"> • Triple ARVs starting as early as 14 weeks' gestation and continued intrapartum and through childbirth if not breastfeeding or until 1 week after cessation of all breastfeeding <p>Option B for Infants</p> <ul style="list-style-type: none"> • Daily NVP or AZT from birth through age 4–6 weeks regardless of infant's feeding method <p>Option B+ for women</p> <ul style="list-style-type: none"> • Regardless of CD4 count, triple ARVs starting as soon as diagnosed, continued for life <p>Option B+ for Infants</p> <ul style="list-style-type: none"> • Daily NVP or AZT from birth through age 4–6 weeks regardless of infant feeding method 	

*If the mother receives less than 4 weeks of ART during pregnancy, AZT should be given for 4 weeks to the infant.

Source: WHO, 2004, 2007, 2012; Malawi MoH, 2007, 2011; Schouten et al., 2011; WHO, 2012.

Note: The WHO guidelines were first issued in 2000, and revised in 2004, 2006, 2010, and 2012 (WHO, 2004, 2007, 2012). Malawi adopted the WHO guidelines in 2001, 2007, and adapted the WHO 2010 to come up with its own ART/PMTCT (the Option B+) guidelines in 2011, which, in turn, the WHO adopted (Malawi MoH, 2011; Schouten et al., 2011; WHO, 2012).

Problems/Challenges with Implementation of the ART and PMTCT Interventions

Research on the effectiveness of antiretroviral treatment therapy (ART) on prevention-of-mother-to-child-transmission (PMTCT) of HIV has been carried out and ART has proved to be effective. Research has shown that ART alone is not enough to prevent HIV infections in children—there is a need for a combination of HIV-prevention strategies to prevent primary HIV infection in parents, prevent unintended pregnancies in HIV-infected women, and increase use of ART in HIV-infected pregnant and breastfeeding women as a total package of PMTCT of HIV interventions (UNAIDS, 2012a; Malawi MoH, 2011). The field of preventing mother-to-child transmission of HIV has now entered into an era of implementation, where the focus is on how well different types of interventions, such as use of ART to prevent HIV transmission from an HIV infected mother to her child, can be delivered in real-world settings. According to the United States National Institutes of Health (NIH), implementation research focuses on scientific methods that can be used to promote the integration of interventions based on research evidence into healthcare practice and policy (PAR-13-055). Implementation science seeks to understand the behavior of healthcare providers, their settings, and the contexts that surround them in the process of the adoption, implementation, and maintenance of the implemented scientific interventions and guidelines such as the Malawian Option B+ (NIH, PAR-13-055). However, challenges to implementation of ART/PMTCT of HIV interventions in real-world settings still remain.

Although we know that use of effective PMTCT interventions such as ART can greatly reduce HIV infections in children, not all women in Sub-Saharan Africa, including Malawi, access them. Between 2010 and 2011, only about 60% of HIV-infected pregnant women received ART to prevent mother-to-child transmission of HIV in Sub-Saharan Africa (UNAIDS, 2012a). Between July 2010 and June 2011, only 45% of all HIV-infected

pregnant Malawian women received a short course of ART and 11% received lifelong ART to prevent HIV transmission to their babies (Malawi MoH, 2012a). Although in 2011 Malawi adopted new guidelines that allow all HIV infected pregnant and breastfeeding women to have access to lifelong ART, we know that adoption of new guidelines is not sufficient; the guidelines also need to be fully implemented within the Malawian healthcare system.

However, evidence from Malawi and other countries in Sub-Saharan Africa demonstrates that there are gaps in implementation of the previous WHO guidelines, and only 10–19% of mother/baby pairs receive all recommended aspects of interventions to prevent mother-to-child transmission of HIV (Beltman et al., 2010; Manzi et al., 2005; Mate, Bennett, Mphatswe, Barker, & Rollins, 2009; Moses et al., 2008; Van Lettow et al., 2011).

Gaps in Implementation of the World Health Organizations' Guidelines to Prevent Mother-to-Child Transmission (PMTCT) of HIV in the Real-World Setting

The best approach for implementing a successful intervention to prevent mother-to-child transmission of HIV worldwide is yet unknown. There are several gaps that need to be filled to successfully prevent mother-to-child HIV transmission in real-world settings.

Literature reveals that the attrition rate by mother/baby pairs beyond the antenatal period is very high—over 80% (Beltman et al., 2010; Manzi et al., 2005; Mate et al., 2009; Moses et al., 2008; van Lettow et al., 2011). Some of the factors contributing to this high attrition rate have been studied and relate to problems with implementation and the complexity of the healthcare systems in which the interventions are delivered. For example, in countries such as Malawi where ART interventions to prevent mother-to-child transmission of HIV are provided in different units, lack of proper coordination and utilization of the available resources could lead to poor implementation of the interventions. As reported by Braun et al. (2011), poor coordination among the service providers in Malawi led to a very high attrition

rate among babies born to HIV-infected women. Only 53.7% of the HIV-exposed infants were tested for HIV using the deoxyribonucleic acid polymerase chain reaction (DNA PCR) test—an antigen test used to detect HIV infection—and only 29.5% of the 13.8% of HIV-infected children were enrolled into pediatric HIV care (Braun et al., 2011). The literature revealed various barriers to implementation that may contribute to poor outcomes in Sub-Saharan Africa, including Malawi.

Barriers to Implementation of the Antiretroviral Treatment Therapy (ART) Interventions to Prevent Mother-to-Child- Transmission of HIV

Use of antiretroviral treatment therapy (ART) as an intervention to prevent mother-to-child transmission of HIV has been integrated into the existing maternal and child health units in most countries and in Malawi but there are several barriers to its implementation from both healthcare institutions' and patients' perspectives in most countries. Most interventions that healthcare organizations adopt use nurses or nurse midwives as their main workforce, and women are required to travel to these units to access the services (Agadjanian & Hayford, 2009; Beltman et al., 2010; Manzi et al., 2005; Mate et al., 2009; Moses et al., 2008; Uwimana, Jackson, Hausler, & Zarowsky, 2012; van Lettow et al., 2011). From the institutional perspective, the activities to prevent mother-to-child transmission of HIV have increased the workload for nurses, who complain of a lack of incentives, political will, and insufficient leadership support (Agadjanian & Hayford, 2009; Uwimana, Jackson, et al., 2012). In addition, insufficient resources and lack of consultation among units that are involved in implementation of the different activities that aim at preventing mother-to-child transmission of HIV also contribute to implementation challenges that are faced by the practice settings (Agadjanian & Hayford, 2009; Uwimana, Jackson, et al., 2012). We know that failure in healthcare systems can lead to an accumulative attrition rate of mother/baby

pairs and eventually lead to an accumulative rate of HIV infections in children (Barker, Mphatswe, & Rollins, 2011).

From the patients' perspectives, the main barriers include lack of affordable transportation to access the services due to economic difficulties and gender inequities, additional visits to the clinic (apart from the required antenatal visits, HIV-infected women are expected to have additional visits either for further counseling or to pick up ART supplementation); and a feeling of being segregated by staff when HIV infected women are attended to using different lines from that of the HIV uninfected women at the maternal and child health units (Agadjanian & Hayford, 2009; Kasenga, Hurtig, & Emmelin, 2010; O'Gorman, Nyirenda, & Theobald, 2010). In addition, women enrolled in the interventions to prevent mother-to-child transmission of HIV report perceived harsh or threatening attitudes of healthcare workers, and after getting an HIV-positive result, they also face domestic violence, such as conflicts with their sexual partners that may result in divorce, shame, and fear of family disgrace (Kasenga et al., 2010; O'Gorman et al., 2010). These barriers result in women's preferring the traditional birth attendants and not keeping hospital appointments (Kasenga et al., 2010). Traditional birth attendants are village women who are trained outside of the formal education system to conduct deliveries in their communities (Wanyu, Diom, Mitchell, Tih, & Meyer, 2007). Looking critically at the Malawian healthcare system, there are several socio-structural factors that may contribute to gaps in implementation.

Structure of the Malawian healthcare system, leadership, resource availability, and its distribution channels that affect implementation of activities to prevent mother-to-child transmission of HIV. Malawi has an area of 118,484 km², is divided into 28 districts, and has a healthcare delivery system that is centralized (Malawi MoH, 2010).

Levels of the healthcare delivery system in Malawi are defined as primary, secondary, and tertiary (see Figure 2). As shown in Figure 2, the village clinic, health post, dispensary, and health centers provide primary healthcare; community/rural hospitals and district hospitals provide secondary care; and central hospitals provide tertiary care. The majority of patients, including HIV-infected pregnant and breastfeeding women and their families, are first seen at a health center (Malawi MoH, 2012b). Of the 516 government health facilities, 85% offer primary care, 10% secondary care, and only 1% tertiary care (Malawi MoH, 2012b).

However, due to its centralized structure, there is inequity in the distribution of human and material resources within the Malawi Ministry of Health (Malawi MoH, 2012b). Although the majority of patients are first seen at a health center, more resources are channeled to higher levels of care (Malawi MoH, 2012b). Although services to prevent mother-to-child transmission of HIV are conducted on almost all levels of care, most of them are done at the health center level, which benefits least from resources. This mal-distribution of resources adversely affects implementation of the activities that are designed to prevent HIV transmission from an HIV infected mother to her child across all clinics in Malawi.

The administration of human and material resources related to implementation of the activities to prevent mother-to-child transmission of HIV in Malawi follows a well-established bureaucracy within the Ministry of Health (see Figures 2 and 3). As an organization, the Malawi Ministry of Health has a centralized structure that allows the decisions about the implementation of the PMTCT services to be done at the central level and passed down through its well-structured hierarchical levels. The Ministry has dedicated the PMTCT-specific administrative work to the national PMTCT program coordinator, who is located at the central level, and to the district PMTCT program coordinators, who are located at the

district levels while the service work is assigned to the PMTCT service providers who are located in the clinics that are involved in the implementation of the activities to prevent mother-to-child transmission of HIV. Within this bureaucracy, the service providers who work in the clinics are controlled and supervised by the district PMTCT coordinators, who are also controlled and supervised by the national PMTCT program coordinator (Figure 3).

For general administration, the Malawi Ministry of Health has devoted the HIV and AIDS section in the office of the president and cabinet to be responsible for HIV/AIDS policy development, the National AIDS Commission to be responsible for leadership and coordination of HIV and AIDS activities, and the HIV/AIDS unit as an office that oversee the implementation of all HIV and AIDS activities. A human resources office is responsible for hiring, deploying ,and firing service providers who work within the entire system and the procurement office is responsible for buying all necessary material resources for the entire system while the central medical stores have been assigned the responsibility of distributing material resources to the central and district hospitals, which are expected to further distribute them to the primary health centers that are located within their districts (Mrs. Mkangama, director of HIV and AIDS services in the office of the president and cabinet, personal communication, July 10, 2013). This centralized structure enables all the managerial decisions to be made by the top-level managers, who are located at the central offices within the Ministry of Health and allows the primary health centers to be controlled and supervised by the district hospitals, which are also controlled and supervised by the central offices. This hierarchical organizational structure may negatively affect implementation of the ART/PMTCT activities at the delivery point (clinic level). In this type of organization, collaboration of activities across units is limited because decision making is done by top-

level managers, who assume authority over coordination and control in an organization (Daft, 2010). The structure is able to create distance between top-level managers and the service providers and prevents service providers from succeeding in developing their management skills (Daft, 2010). For example, in sections that are involved in implementation of interventions to prevent mother-to-child transmission of HIV within the Malawi Ministry of Health healthcare delivery system, decisions about policy changes are done at the central level—the office of the president and cabinet, coordinated by the National AIDS Commission and the HIV/AIDS Unit and their national stakeholders. The service providers at the delivery point (in clinics) then are simply informed about the changes. In a centralized organization like that of the Malawi Ministry of Health, there is little coordination at the local level—decisions and authority belong to the top-level managers. There is less consideration given to social context and the needs of the service providers, thereby neglecting helpful actions that could improve service providers' motivation and their productivity in the implementation of interventions to prevent mother-to-child transmission of HIV in their clinics (Daft, 2010).

A negative result of the centralized decision making in previous changes of the PMTCT guidelines in Malawi was confusion among service providers, who failed to effectively implement the new guidelines in their clinics (Chinkonde, Hem, & Sundby, 2012). In Malawi and across the globe, PMTCT policy changes depend on availability of evidence, which most of the time is not accessible to most Malawian service providers who work directly at the clinic level. Therefore, engaging service providers in the process of policy development may help effectively transfer knowledge that could be used to enhance the implementation of the activities to prevent mother-to-child transmission of HIV. However,

the centralized leadership and decision-making system prevents the service providers from being fully engaged in policy development and in making decisions about what they are expected to implement in their clinics. If policy makers simply impose guidelines on the service providers who work in the clinics, the result may well be frustration and abandonment of the intervention that is being promoted. It is also known that in centralized structures, the hierarchy becomes overloaded and the top-level managers fail to respond to the ever-changing environment, such as the HIV and AIDS pandemic in Malawi surrounding the clinics where activities to prevent mother-to-child transmission of HIV are implemented (Daft, 2010). Creation of horizontal structures may help to create an effective workflow that may lead to service providers' self-directed teams who could be effectively involved in managerial tasks (Daft, 2010). In such a structure, service providers may be empowered to work together as teams across clinics to share about their opportunities and help solve the problems they may face without waiting for decisions from the top-level authorities. If clinics in Malawi are empowered to make implementation decisions specific to their clinics, variation in implementing future evidence based interventions may be avoided.

Decentralization of roles like hiring of staff and purchase of vital resources may help develop service providers who can handle leadership roles within their clinics and thereby improve implementation. Organizations that aim at quality implementation continuously develop their service providers and provide a setting in which service providers are largely self-managed and motivated (Schulz III, 2011). An adoption of self-directed and collaborative leadership may promote collaborative practice at the service delivery point rather than the centralized type of leadership that could lead to providers' failure to accept their tasks at times (Bush, 2011). In addition, use of teams may help promote communication and collaboration among

the top-level managers, middle-level managers, and service providers in identifying HIV-related problem-solving strategies, thereby enabling the Malawi Ministry of Health to continuously improve its prevention of mother-to child transmission of HIV implementation capabilities.

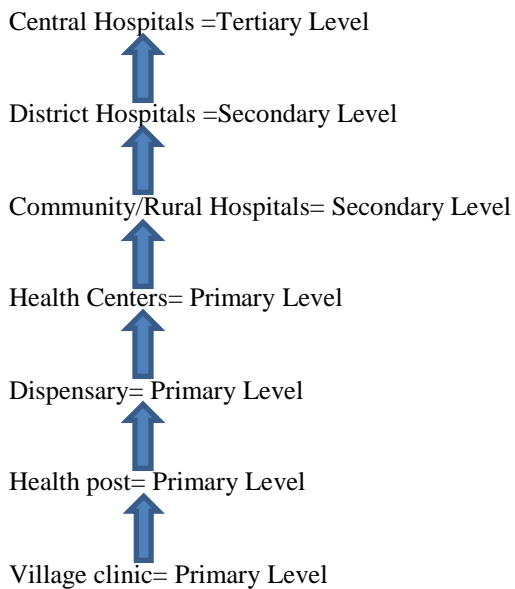


Figure 2. The Malawian healthcare delivery system and flow of patient referrals.

In Figure 2, the village clinics, health posts, dispensaries, and health centers provide primary healthcare; community/rural and district hospitals provide secondary care; and central hospitals provide tertiary care. However, primary care is also delivered at all levels in Malawi. The majority of patients, including HIV-infected pregnant and breastfeeding women and their families who come direct from their homes, are seen at health centers while the village clinics and health posts are mostly used as outreach clinics for maternal and child health services but not for PMTCT services (Malawi MoH, 2010).

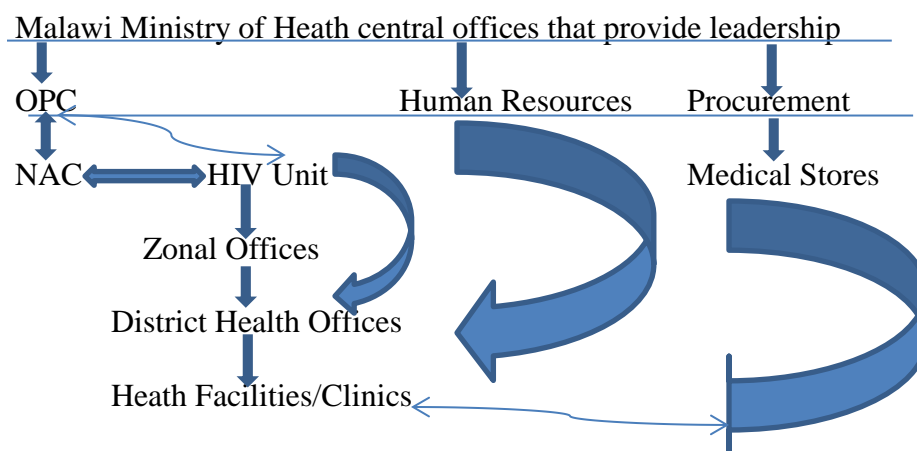


Figure 3. The flow of leadership and administrative authority within the Malawian HIV/PMTCT healthcare delivery system.

In Figure 3, OPC represents the Office of the President and cabinet and NAC represents the National AIDS Commission.

General resource availability and its distribution channels in the Malawian healthcare delivery system. Apart from being in a region of high HIV prevalence, Malawi is one of the most resource-constrained countries in the world. More than 52% of its population lives below the poverty line, and 22% of them are in extreme poverty (World Bank, 2006). Due to high poverty rates, the Malawi government has subsidized its healthcare system, including the ART/PMTCT services, in such a way that all Malawians are eligible to access care in its health facilities at no cost. However, due to the centralized design of the Malawi Ministry of Health’s delivery system, healthcare resources are not equitably distributed; hence the barriers to implementation in some clinics while others benefit, which leads to variation in implementation of many services (Malawi MoH, 2012b). For example, due to lack of resources in the Malawian ART/PMTCT services in 2011, only 544 out of 1,028 health facilities provided PMTCT services as part of antenatal care, only 517 facilities provided ART, and only 200 facilities were able to collect blood from HIV-exposed babies

for HIV testing (Malawi MoH, 2012b). In 2010, about 56% of Malawian women did not access healthcare due to long distances to a health facility, 54% due to lack of transportation, 47% were concerned that they would not find any service providers at a facility, and 61% were concerned that they would not find any drugs at hospital pharmacies (NSO & Macro, 2011).

The distribution of resources from the central level to the delivery point (Figure 3) negatively influences implementation of the ART/PMTCT services in other ways. Due to the poverty that affects the country, road networks are not good. Health facilities that are close to well-paved roads are likely to have a greater access to resources such as HIV test kits and antiretroviral drugs than facilities that are not connected. In addition, communication between health facilities and central offices may take time and could lead to women, their children, and their family members not being able to access the needed services to prevent mother-to-child transmission of HIV at their nearest health facility. Effective use and engagement of non-governmental organizations and community workers who already travel to the served communities could help solve this problem (Uwimana, Jackson, et al., 2012; Uwimana, Zarowsky, Hausler, & Jackson, 2012). Although access to the few resources that Malawi has is a problem for most women, their children, and family members; Malawi is also facing a big problem of financing the healthcare services, including those that are designed to prevent mother-to-child transmission of HIV.

Financial resources is one of the major contextual factors that can affect implementation (Chinman et al., 2008; Durlak & DuPre, 2008; Gregory et al., 2012; Wandersman, Chien, & Katz, 2012; Wandersman et al., 2008), and Malawi is one of the poorest countries and cannot afford to fund its own ART/PMTCT activities alone (UNAIDS,

2012a). Funding is critical not only to delivering ART/PMTCT services but is also required for the delivery of the TA and other activities that are necessary to support service providers who do implement the services. In addition, funding is required to procure ART/ PMTCT supplies such as HIV testing kits, and antiretroviral drugs.

Despite its financial constraints and concerns about sustainability, Malawi has been a pioneer in the provision of lifelong ART to all HIV-infected pregnant and breastfeeding women in the Sub-Saharan African region (Malawi MoH, 2011; Schouten et al., 2011; UNAIDS, 2013; WHO, 2012). Although we know that resources are required for lifelong ART to be fully implemented in the country, Malawi is still far from the self-reliance that is required to implement services as stipulated in the 2011 Option B+ guidelines (Malawi MoH, 2011). About 40% of Malawi's national budget relies on the international donor community, and for the 2011–2012 fiscal year almost 100% of HIV/AIDS activities were funded by international donors (UNAIDS, 2012a; Malawi MoH, 2012a). This over-reliance on donations can negatively affect the implementation of the Option B+ guidelines at all levels in Malawi. If donors decide not to fund the HIV and AIDS interventions, implementation will cease and the sustainability of such interventions will be jeopardized. Therefore, collaboration among health departments, Ministry of Health offices, and non-governmental partners is important to cover all aspects of prevention-of-mother-to-child transmission (PMTCT) of HIV across the country (Uwimana, Jackson, et al., 2012; Uwimana, Zarowsky, et al., 2012). This collaboration and effective engagement of PMTCT implementation stakeholders may also help boost prevention support activities such as TA in Malawi. Above all, to survive in good and bad times, Malawi must have responsive and capable human resources to help with the coordination and development of sustainable plans for funding

sources within the country (Kagan, Kane, Quinlan, Rosas, & Trochim, 2009; Schulz III, 2011). Although Malawi is being praised for pioneering in the implementation of the Option B+ guidelines that mandate use of lifelong ART by all HIV infected pregnant and breastfeeding women, plans for sources of critical resources could have been co-opted to promote effective implementation, sustainability of the services, and uniform implementation among different clinics.

Workforce in the Malawian healthcare delivery system. Malawi's Ministry of Health has come up with staffing standards. For example, primary health centers are expected to have at least two Clinical Technicians, four Medical Assistants, fourteen nurses, and one community health nurse (Malawi MoH, 2013). However, Malawi is constrained in its supply of healthcare providers, and maintaining the recommended minimum human resources levels is a challenge. In 2011, the country had fewer than 100 registered physicians and about 3,000 nurses serving 1,028 health facilities across the country (Malawi MoH, 2012b). Thus, in 2011 in Malawi, there was an average of three nurses per health facility and less than one physician per 10 health facilities. In other words, less than one full-time physician is responsible for 130,000 patients while one nurse is responsible for 4,333. This shortage of staff is in part the result of poor working conditions in Malawian health clinics, which lead to many Malawi-trained physicians and nurses leaving the country to practice (Malawi MoH, 2012b). This country-wide shortage of nurses and physicians has a negative impact on implementation of services that are designed to prevent mother-to-child transmission of HIV because most healthcare organizations in Malawi use nurses to implement the adopted interventions (Kasenga, Hurtig, & Emmelin, 2007; Kasenga et al., 2010; Manzi et al., 2005; Moses et al., 2008). If a facility is understaffed, the probability of underperformance is

high—many will be overworking. They may develop burn-out and abandon implementation of their assigned activities. However, the Malawi government recognizes the need to strengthen healthcare systems through training more healthcare providers, creation of other cadres to work within the healthcare systems, and improvements to the equity and efficiency of resource distribution as outlined in its Malawi Health Sector Strategic Plan 2011–2016 (MoH, 2010). If this plan can be implemented as designed, the problem of service providers in Malawi may be lessened and future implementation of guidelines to prevent mother-to-child transmission of HIV and delivery of prevention support programs such as TA may be improved. To follow the pathway of the prevention of mother-to-child transmission of HIV field of science, the identified problems can be improved to effectively implement the ART/PMTCT activities in real-world settings through use of implementation strategies such as technical assistance (TA). The Interactive Systems Framework (ISF) that is described in the following section identifies the need for prevention support such as training and TA to improve implementation of any evidence-based intervention such as the Option B+ guidelines in the Malawian clinics.

CHAPTER 3. CONCEPTUAL FRAMEWORK

The Interactive Systems Framework (ISF) for Dissemination and Implementation

This descriptive qualitative multiple-case study was guided by a conceptual model of Prevention Support that was derived from the Interactive Systems Framework (ISF) for Dissemination and Implementation (Wandersman, Chien, & Katz, 2012; Wandersman et al., 2008) and other literature that is relevant to this study. The ISF includes tasks that are carried out by different individuals or organizations during the process of dissemination and implementation of any scientific intervention. These tasks are carried out by three interacting systems—the Prevention Synthesis and Translation System, which synthesizes scientific information and prepares it into user-friendly interventions that can easily be used by the implementers in their practice settings; the Prevention Delivery System, which implements the scientific interventions in their practice settings; and the Prevention Support System, which builds delivery systems' capacity to use the promoted scientific interventions (Wandersman et al., 2012; Wandersman et al., 2008) (see Figure 4).

Synthesis and Translation

Wandersman et al. (2008) define synthesis as a “process of compiling and summarizing information about innovations” while “translation is the process of converting (translating) scientific knowledge into practitioner-friendly products to be used for implementation” (p. 175). The ISF assumes that when interventions are translated into a format that is accessible, user-friendly, and clear, the likelihood of their successful dissemination and implementation will be high (Wandersman et al., 2012; Wandersman et

al., 2008). Since it is known that scientific knowledge may be available but not ready for the service providers to use, the synthesis process filters the available scientific knowledge and prepares it to be disseminated and implemented. The goal of synthesis is to identify effective interventions that will address priority problems while the goal of translation is to communicate those interventions in a format that meets the needs and the context of specific setting and healthcare providers (Wandersman et al., 2012; Wandersman et al., 2008).

Prevention Support/Capacity Building

According to Wandersman et al. (2012; 2008), the distilled and translated user-friendly interventions prepared by the Prevention Synthesis and Translation System are not enough to move science into practice. To enhance implementation, the ISF identifies the Prevention Support System as a key element to provide support that can build service providers' and/or their settings' capacity to implement the promoted intervention in their practice settings.

Capacity comprises the knowledge, skills, attitude, motivation, and resources to implement and maintain interventions at individual and collective levels (Flaspohler, Lesesne, Puddy, Smith, & Wandersman, 2012; Wandersman et al., 2012). Prevention support consists of activities that are implemented by the Prevention Support System to support the Prevention Delivery System in order for them to implement interventions with quality (Durlak & DuPre, 2008; Wandersman et al., 2012; Wandersman et al., 2008).

According to Wandersman et al. (2008, 2012), capacity building is the core component of the ISF framework. Prevention support can build two types of capacities: (1) intervention-specific capacity—the knowledge, skills, motivation, and resources necessary to implement a specific intervention, and (2) general capacity—the skills and motivation of service providers an infrastructure of delivery settings.

Evidence-Based System for Innovation Support (EBSIS). The Prevention Support System uses four primary EBSIS strategies to build the capacity of Prevention Delivery Systems: tools, training, technical assistance (TA), and quality assurance and quality improvement (QA/QI) (see Figure 5) (Wandersman et al., 2012). The ISF posits that the integrated use of support strategies will increase capacity and lead to quality implementation of the adopted evidence-based intervention (Wandersman et al., 2012).

Tools are resources such as manuals and guidelines that communicate guidance and other information to implementers of the interventions (Wandersman et al., 2012). Training is a planned, instructional, interactive activity that is organized to enable the learners to acquire knowledge, skills, and attitudes specific to helping them improve their performance (Chinman et al., 2008; Wandersman et al., 2012). Training is mainly offered in a group setting and is done to help service providers understand how the interventions work and how they might effectively implement interventions in their practice settings (Chinman et al., 2008; Durlak & DuPre, 2008). Technical Assistance (TA) is an individualized, hands-on consultation that is generally provided after training to reinforce understanding of knowledge and skills of the interventions' implementers and to enhance quality implementation of the interventions in the practice settings (Chinman et al., 2008; Hunter et al., 2009; Wandersman et al., 2012). "Quality assurance (QA) involves the use of tools and logic to assess quality performance while quality improvement (QI) is the use of methods to enhance quality performance; therefore, QA/QI is an integrative process for identifying current levels of quality and for improving quality performance" (Wandersman et al., 2012, p. 453). With the aim of bridging the gap between science and practice, experts from within or outside the implementing organization might provide prevention support such as training, tools, TA, and

QA/QI so that interventions are adopted, integrated into routine practice, and implemented with fidelity (Brownson, Colditz , & Proctor, 2012; Fixsen, Blase, Naoom, & Wallace, 2009; Norton, Amico, Cornman, Fisher, & Fisher, 2009; Rycroft-Malone et al., 2012). Of all the EBSIS strategies stated by Wandersman et al. (2012), TA and training are among the most used components in the capacity-building literature.

Technical assistance (TA) can be an ongoing or temporary activity and can be delivered through various media such as on-site consultation, e-mail communication, and via telephone (Chinman et al., 2008; Hunter et al., 2009; Wandersman et al., 2012). Examples of TA mechanisms are re-training, provision of emotional support, monitoring of the implementation of the intervention, and assisting the service providers who directly deliver the intervention in their practice settings so their intervention-specific capacity are improved or maintained. TA is also used to help boost the morale of the interventions' implementers such as by appreciating their commitment to the delivery of the implemented intervention and helping them solve the problems they face (Chinman et al., 2008; Duffy et al., 2012; Durlak & DuPre, 2008; Firesheets et al., 2012; Hunter et al., 2009). TA activities may also be used to help organizations choose the proper intervention, to advise on how the intervention can be adapted to fit the practice settings, and to build intervention-specific capacity, monitoring, and evaluation skills (Chinman et al., 2008; Hunter et al., 2009; Wandersman et al., 2012).

Effectiveness in Support of the Evidence-Based System for Innovation Support (EBSIS). There is evidence that use of EBSIS such as tools, training, TA, and QA/QI increases capacity, adoption, and implementation of interventions in the practice setting both at the individual and at a collective level. Various studies that applied ISF and used EBSIS

reported that tools, training, and TA enhanced the capacity of the interventions' implementers and have demonstrated that capacity building interventions promote skill acquisition in disease prevention and health promotion programs like teen pregnancy prevention and substance abuse prevention programs (Chinman et al., 2008; Colarossi et al., 2013; Durlak & DuPre, 2008; Firesheets et al., 2012). Some studies that used training, tools, and TA as capacity-building strategies indicated that capacity (measured as knowledge, self-efficacy, and behavior) and performance (measured as participation or intent to participate in implementation of the promoted intervention) were higher in organizations or service providers who received training and TA as compared to those who did not, and both significantly increased with an increase in TA hours over time (Chinman et al., 2008; Durlak & DuPre, 2008). The effectiveness of more TA hours is evident when ongoing and temporary TA models are compared. The ongoing-TA model is reported to be more effective than that of a temporary model in building intervention-specific capacity (Spath, Clair, Greenberg, Redmond, & Shin, 2007). For example, more hours of TA were positively correlated with improvements in implementation such as in achievement of set program goals (Chinman et al., 2008). In addition, if TA is continuously provided, implementers of the intervention use the interventions' information with more confidence (Wandersman et al., 2012). As reported in a meta-analysis of 20 studies that used training and TA, capacity of individuals who engaged in implementation of various prevention programs significantly increased after they were trained and supported with TA as compared to before getting any support (Durlak & DuPre, 2008). Furthermore, the study found that retraining of service providers doubled the fidelity of implementation to over 85% among those who had implementation problems at the beginning of their projects (Durlak & DuPre, 2008). Self-reports from organizations and

individuals that received training and TA up to the end of the project also provide evidence that collective performance in various project activities increased due to interaction between the Prevention Support System and the Prevention Delivery System during the process of training and TA provision (Chinman et al., 2008; Duffy et al., 2012; Firesheets et al., 2012).

Because it is known that prevention support is a key to successful implementation, training and TA and other prevention supports are required when organizations are introduced to new interventions or in case of staff turnover (Duffy et al., 2012; Durlak & DuPre, 2008; Wandersman et al., 2012). Prevention support is especially important when a new prevention program such as the implementation of the Malawian 2011 ART/PMTCT (Option B+) guidelines in clinics is introduced. These guidelines were introduced at a system level, affecting the country, district, health facility, and community levels. Therefore, service providers who are involved in its implementation needed to be trained and require continued TA support to acquire the capacity to adopt and implement the guidelines and maintain their use as a routine practice in their clinics (Chinman et al., 2008).

In HIV prevention studies conducted in Africa and elsewhere, training and TA are used in combination with other methods as a bundled intervention. For example, the Zambian Ministry of Health provided a bundle of PMTCT support interventions such as building human resource capacity and improving facility capacity and effectively increased the proportion of women who were counseled, tested, and received results about their HIV status (Torpey et al., 2010). Likewise, use of a partnership support intervention that provided an expert to train program managers in systems' improvement design and quality improvement in South Africa resulted in reducing the HIV infection rate from 7.6% to 5% within 1 year in children who were born to HIV-infected women (Youngleson et al., 2010).

Implementation. For implementation of any scientific intervention to occur, the Prevention Delivery System (organizations, communities, or the service providers) must have the capacity to carry out tasks that are important to implementation of the promoted scientific interventions in their delivering settings. Although the ISF acknowledges that levels of the existing capacities of the Prevention Delivery System required to implement the promoted scientific intervention into their practicing settings differ, if capacity of the Prevention Delivery System is properly supplemented and built, interventions will successfully be implemented and the intended outcomes will be achieved (Wandersman et al., 2012; Wandersman et al., 2008).

In summary, the ISF assumes that if the capacity of the implementers of any scientific intervention is built, it can be used to enhance implementation of the promoted scientific intervention in the practicing setting, thereby leading to an achievement of the desired outcomes (see Figure 4). The framework emphasizes the importance of interaction among its three systems for implementation of any intervention to occur. For example, for the distilled and translated user-friendly scientific intervention to be implemented in the delivering settings, the capacity of the implementers must be built and used. For the implementation process to effectively occur, the Prevention Synthesis and Translation System has to involve the intended users—the Prevention Support System and the Prevention Delivery System—throughout the synthesis and translation process to increase the probability of its usage (Wandersman et al., 2012; Wandersman et al., 2008). Likewise, the Prevention Support System must collaborate with the Prevention Delivery System for it to learn about the gaps in implementers' capacity that may be filled with support that can fit the needs of the Prevention Delivery Systems (Wandersman et al., 2012; Wandersman et al., 2008). If the

systems are not interacting well, the likelihood of effective implementation will be compromised. This interaction among all the three systems is depicted by two double black arrows in Figure 4.

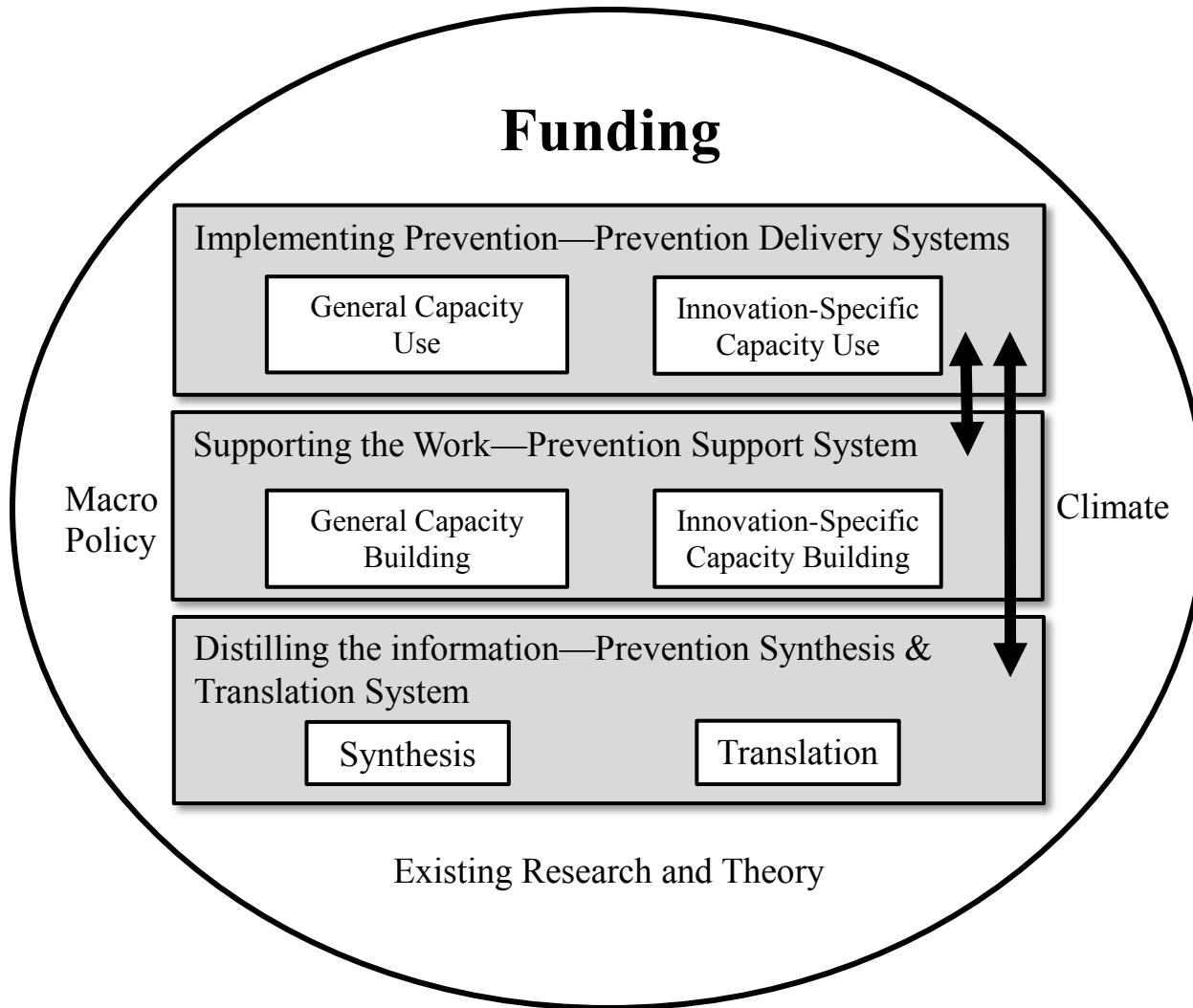


Figure 4. The original Interactive Systems Framework (ISF) for dissemination and implementation.

Source: Wandersman et al. (2008, p. 174)

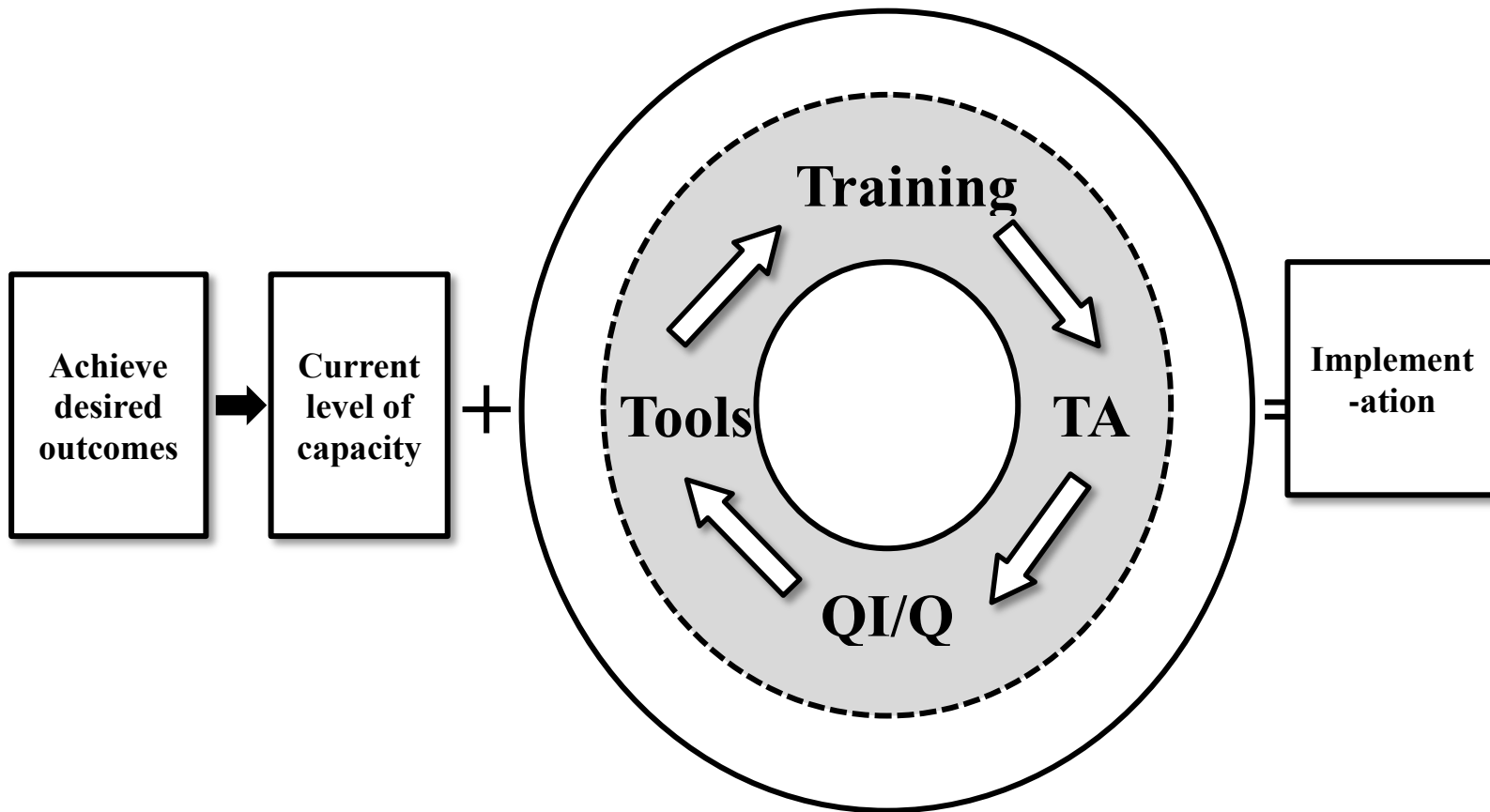


Figure 5. The capacity-building and utilization logic model.

Adapted from Wandersman et al. (2012)

Application of the ISF to this Dissertation Study

Figure 4 presents the original ISF for dissemination and implementation, Figure 5 shows how the Prevention Support of the ISF uses tools, training, TA, and QA/QI to build capacity of the Prevention Delivery System to improve implementation. Figure 6 has been derived from the ISF and from the literature review related to this study and is the conceptual framework of Prevention Support that guided this study to describe how the provision and use of prevention support varied across low- and high-performing Malawi Ministry of Health clinics and to uncover contextual factors that might explain variations. As discussed previously, the ISF posits the need for Prevention Support Systems to bridge the gap between evidence and practice to promote improved outcomes. To enhance the implementation of the Malawian 2011 ART/PMTCT guidelines in the Central and Western zones of the Malawian healthcare delivery system, the UNC Project in Malawi provided a three-year support program that involved use of EBSIS such as tools, training, and TA to support the Malawian Ministry of Health clinics to build service providers' and organizational capacity (skills, knowledge, attitude, behavior, and motivation) that enhance implementation of ART/PMTCT activities at a clinic level. However, TA dose and relationship between the Prevention Support System and the Prevention Delivery System may also influence both individual and organizational capacity.

Evidence suggests that contextual factors may influence the process of delivering prevention support such as TA, its usage, and the implementation of the promoted guidelines in clinics and other settings (Wandersman et al., 2012; Wandersman et al., 2008; Yin, 2013). This dissertation study therefore, included exploration and description of other contextual factors at patient/community, clinic, and socio-structural/systems' level (see Figure 6). These contextual factors show their influence on both the work of the Prevention Support System

and on implementation of activities at a clinic level. The inclusion of these contextual factors in this framework guided and focused exploration on specific factors that helped explain variations in TA delivery and its use and in implementation of the Option B+ guidelines in the four study sites/cases. Since this dissertation study used a qualitative descriptive multiple-case study design method, inclusion of these contextual factors in the conceptual framework was in line with Yin (2013), who in his discussion consistently reported that it is very important to attend to contextual factors when conducting case studies to avoid a misleading or incomplete understanding of the cases that are being studied.

This framework was designed to help this study have an in-depth understanding of how the provision and use of TA varied across the two low- and the two high-performing Malawian Ministry of Health clinics and to uncover contextual factors that helped this study explain variations in TA delivery and use from the perspectives of both the capacity-builders/TA providers (the UNC Project) and the users (the Malawian Ministry of Health clinics). The ISF indicates that use of Prevention Support strategies such as tools, training, and TA build capacity such as knowledge, skills, resources, and motivation of the implementers that leads to performance—participation or intent to participate in implementation of the intervention. Therefore, exploration on how provision and use of TA varied across the study cases, and uncovering contextual factors that helped this study explain variations in study cases' performance was based on the prevention support strategies that were provided, how they were used, and the influence of the identified contextual factors. With the guidance of this framework, this study drew the informants for the in-depth interviews from both the prevention support providers (the UNC Project) and users (the Malawian Ministry of Health clinics). This approach helped researchers of this study

understand how and why the provision and use of prevention support varied across the two high- and two low-performing selected clinics of the Malawian Ministry of Health.

Operational Definitions of the ISF Constructs Used in this Dissertation Study

To respond to this study's objectives, the main ISF constructs that were applied to the study and therefore operationalized in the following section include: prevention support strategies, use of prevention support, implementation of Option B+ components, and contextual factors— clinic age, size, and magnitude.

Prevention Support Strategies

As described in previous sections, prevention support comprises activities that are delivered with the goal of achieving a performance standard from the time any scientific-based intervention is disseminated to the time of its maintenance in its practice setting (Durlak & DuPre, 2008; Wandersman et al., 2012; Wandersman et al., 2008). In this dissertation study, the UNC Project used prevention support to build the Malawi Ministry of Health clinics' ART/PMTCT guidelines-general and -specific capacity to implement the guidelines. Support-provision literature indicates that TA is one of the most commonly used methods to build organizations' and/or service providers' capacity to implement the scientific-based interventions in their organizations (Chinman et al., 2008).

Prevention support strategies as described by Wandersman et al. (2012) include tools, training, TA, and QA/QI. In this dissertation study, prevention support was defined as organized activities that were conducted by the UNC Project to help the Malawian Ministry of Health clinics effectively implement the Malawian 2011 ART/PMTCT (the Option B+) guidelines in their practice settings. Therefore, specific activities that were done by the UNC Project to enhance the implementation of the implemented guidelines were used as observable data for capacity building. Specifically, TA hours and activities that were spent

on ART/PMTCT guidelines' activities that were done at community level where women and their families live, TA hours and activities that were done and spent at the antenatal clinic where most ART/PMTCT guidelines' activities are offered, TA hours and activities that were done and spent on maternity activities where women deliver their babies and where HIV-exposed children are started on ART prophylaxis (if born at a clinic), and TA activities and hours that were done and spent at under-five clinics where HIV-exposed children and their mothers are followed up were used as operational definitions of capacity building (Malawi MoH, 2011). An under-five clinic is a place where PMTCT activities that ascertain the HIV status of the HIV-exposed children are carried out (MoH, 2011). These TA activities and hours helped this study understand if TA support (capacity building) varied and how it varied among the four studied clinics/cases.

Implementation of Option B+ Components

Implementation as a major construct that characterizes the action of the Malawian Ministry of Health clinics (the Prevention Delivery System) was another focus of this dissertation study. Implementation involves carrying out tasks that are important to implement the promoted scientific interventions in the practice settings (Wandersman et al., 2012; Wandersman et al., 2008). Implementation—according to prior studies that used TA and were guided by the ISF— is the actual behavior that is displayed by the individuals/organizations that are delivering the promoted intervention. In this dissertation study, implementation was defined as the actual behavior that was displayed by the Malawian Ministry of Health clinics that informed this research about the clinics'/individuals' involvement in the implementation of the Malawian 2011 ART/PMTCT (the Option B+) guidelines at the four study sites. This behavior was observed through the clinics' perceived performance—the Malawian Ministry of Health clinics' participation in the implementation

of the Malawian 2011 ART/PMTCT guidelines (Chinman et al., 2008). The specific Malawian Ministry of Health clinics' behaviors of focus for this research included the extent to which the study clinics were doing the following PMTCT guidelines' activities:

Community PMTCT activities

- Conduct community sensitization and mobilization activities about the implemented ART/PMTCT guidelines at their clinic and in communities that surround their clinic.

Antenatal and maternity unit PMTCT activities

- Ascertain HIV status at each visit
 - Checking for an HIV status on page 6 of the antenatal woman's health passport to determine the HIV status at each visit.
 - Routine offer of an HIV test through provider-initiated HIV testing and counseling to all pregnant and breastfeeding women who seek health care services at the study clinic.
- Offer of ART/PMTCT services
 - Conduction of health education that is designed to inform the HIV-infected women and their family members that once antiretroviral drugs (ARVs) are started, they must be taken every day for life.
 - Initiation of lifelong combined ART regardless of CD4 count and/or clinical stage to all identified HIV-infected pregnant and breastfeeding women on the day of or within 7 days of HIV diagnosis unless they opt out.

- Supply of 3x25mls-bottle of nevirapine (NVP) syrup to HIV-infected women for their HIV-exposed babies at first opportunity when the woman is known to be HIV-infected unless the woman opts out.
- Initiation of integrated mother/infant follow-up scheduling.

Under-five PMTCT activities

- Ascertaining of HIV status for all the HIV-exposed children —collection of at least one Deoxyribonucleic acid-Polymerase Chain Reaction (DNA-PCR) sample from each HIV-exposed child from the age of 6 weeks unless the mother opts out.

General PMTCT activities

- Proper documentation of all rendered PMTCT activities in correct registers or cards. (Malawi MoH, 2011)

Contextual Factors

To avoid getting misleading results, this dissertation study included contextual factors as one of the ISF constructs that were explored. There are several factors reported in literature that may contribute to variation in TA delivery, use and in the implementation of the PMTCT activities at the clinic level. This study explored community-, clinic-, and systems-level factors that might affect women and their family members to access the ART/PMTCT services at the study sites. There is evidence from literature that socio-structural issues such as workforce shortages and the hierarchical structures such as that of the Malawian Ministry of Health may influence variation in TA delivery and use and in implementation of ART/PMTCT activities at the clinic level. In addition, clinic-level factors such as age, size, and magnitude of the clinic and implementation climate may affect TA provision, its use, and the implementation of the Malawian ART/PMTCT guidelines in both

low- and high-performing Malawian Ministry of Health PMTCT clinics (see Figure 1).

Therefore, the following section provides operational definitions of these clinic-level factors which were used to collect clinics' descriptive information:

1. Age of the clinic:
 - a. The number of years the clinic has been operating its primary healthcare services.
 - b. The number of years/months the clinic has been implementing the Malawian 2011 ART/PMTCT guidelines (the Option B+).
2. Size of the clinic:
 - a. The total number of employees who are involved in the implementation of the ART/PMTCT guidelines' activities at the clinic.
3. Magnitude of the clinic: Because size is related to magnitude (Daft, 2010), the PMTCT study clinics' data of the Fiscal Year 2012–2013 were used to operationalized magnitude as:
 - a. The total catchment area that is served by the study clinic.
 - b. The total annual number of antenatal women served by the study clinic.
 - c. The total annual number of deliveries at the study clinic.
 - d. The HIV prevalence rate faced by the study clinic.

This study assumed that TA provision, TA use, and the implementation performance varied between the old and the young clinics and also between the bigger and smaller clinics.

4. Implementation climate: This study also explored implementation climate as one of the inner contextual factors that might explain variation in TA provision and use and in the implementation of the guidelines. According to Weiner, Belden,

Bergmire, & Johnston (2011), implementation climate refers to the extent to which service providers perceive that the intervention is expected, supported, and rewarded. Therefore, for this dissertation study, implementation climate was operationalized as: the within-group agreement in both the TA providers and the Malawian Ministry of Health PMTCT service providers' perceptions specific to the implemented PMTCT guidelines and to the TA support. This information helped this study understand the service providers' perceptions at the clinic level on whether they felt that the ART/PMTCT guidelines and the TA were needed and if ever they felt supported to implement the Malawian ART/PMTCT (the Option B+) guidelines. This information was collected by asking the within-group collective views of the informants on how they perceived the extent to which the people working at the study facility agreed with and supported the implementation of activities based on Option B+ guidelines and also how they perceived their support from both the TA providers and from the Malawi Ministry of Health central, zone, and district offices.

The assumption of this study was that the service providers who recognized the need for the TA support at their clinics believed that TA would help their clinics implement the Option B+ guidelines and that more of the clinics where these providers work effectively used TA than those who did not.

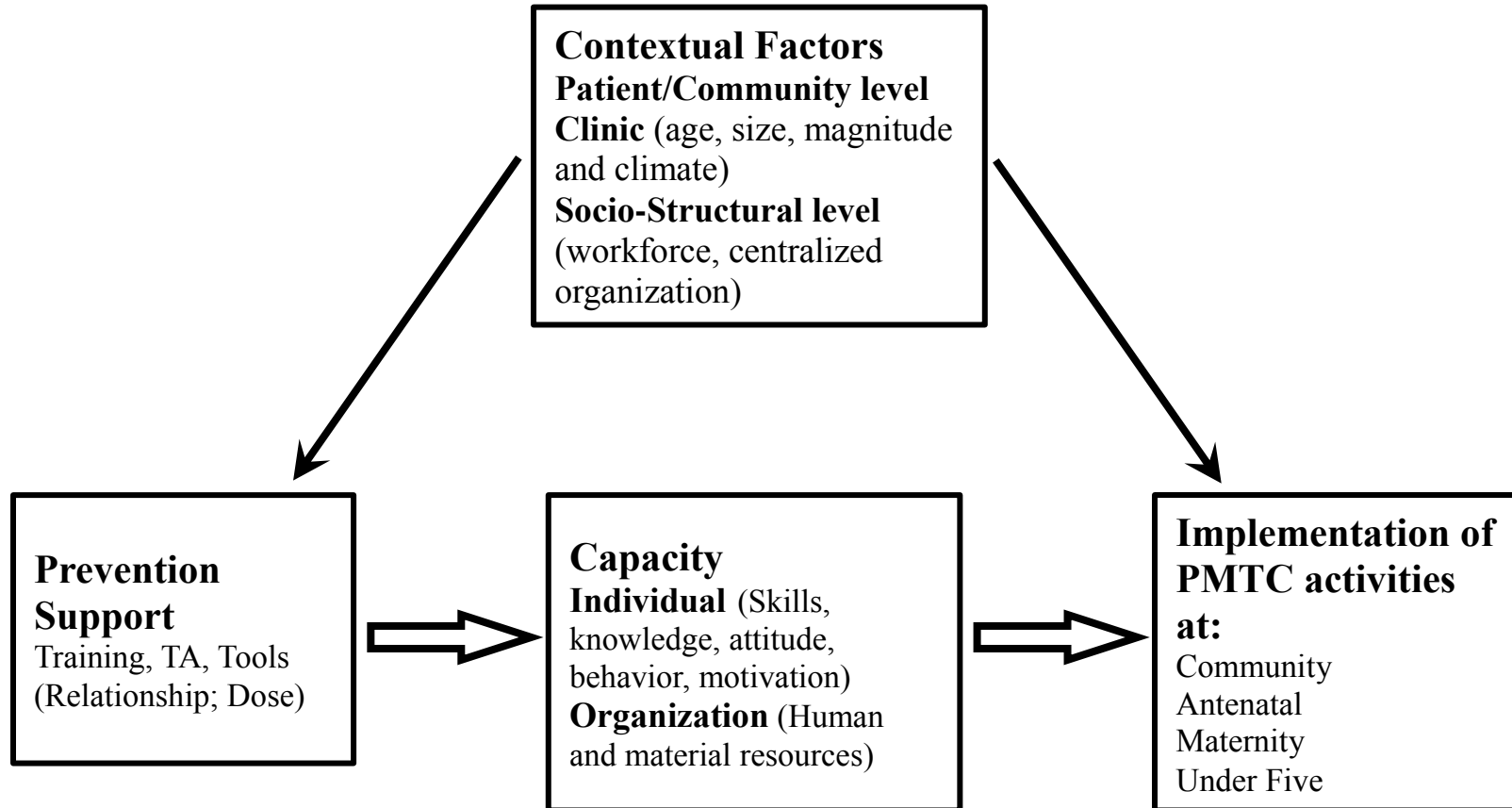


Figure 6. Study's conceptual model of prevention support.

Application of the Interactive Systems Framework (ISF) for Dissemination and Implementation by Prior Researchers

Although the development of the ISF came from literature specific to child maltreatment and youth violence in the United States, this framework can be applied to different types of disciplines whose work is focused on dissemination and implementation and can guide an understanding of a wider range of programs, policies, and processes in areas of adolescent reproductive health, HIV and AIDS prevention, youth development, and employment promotion (Flaspohler et al., 2012; Saul et al., 2008; Wandersman et al., 2008). The ISF has been applied by various researchers in different areas such as teen pregnancy prevention (Chinman et al., 2008; Lesesne et al., 2008; Ray, Wilson, Wandersman, Meyers, & Katz, 2012); HIV and sexually transmitted infection prevention programs (Gregory et al., 2012; Lewis et al., 2012), prevention of children's mental health and violence (Flaspohler et al., 2012), breast cancer prevention (Rapkin et al., 2012), and substance abuse prevention programs (Firesheets, Francis, Barnum, & Rolf, 2012).

The ISF was first applied by the Division of Violence Prevention at the Centers for Disease Control and Prevention (CDC) of the United States to guide their planning project in search of strategies that could be used to move child maltreatment and youth violence science into practice (Flaspohler et al., 2012). This demonstrated how the CDC as a funder applied the framework to bridge the gap between science and practice in the field of child maltreatment and youth violence science. According to the second special issue of the ISF, most studies that used ISF to guide their research focused on both understanding and facilitating the implementation of science-based programs by theorizing, assessing, or evaluating the work of part or all of the three framework systems (Flaspohler et al., 2012).

Specific examples of the Prevention Support System intervention studies include Chinman et al. (2008), which developed the Getting to Outcomes support intervention which includes manuals, training, and TA to build service providers' capacity and program performance of the community-based substance abuse prevention coalitions, and Ray et al. (2012), which used trainer-of-trainers and TA prevention support strategies in its CDC-funded "health teen network" project where trainer-of-trainer support was provided to state and regional grantee organizations who later provided TA to local community partners—the implementers of the evidence-based teen pregnancy programs to youth—to implement the evidence-based programs. These studies provided information that with support tailored to implementation of the specific evidence-based programs, individual and/or program capacity can be effectively built and implementation of the intended interventions could result and could lead to intended interventions' outcomes.

In the HIV and AIDS prevention field, the ISF has been applied and adapted to guide the interaction among different stakeholders in the process of moving science into practice. For example, Gregory et al. (2012) adapted the ISF to disseminate the culturally adapted research-based substance abuse and mental health treatment and adherence information to the local community agencies that served the HIV-infected population. In Gregory et al.'s (2012) study, the university distilled scientific information and provided training and TA support (acted as both the Prevention Translation and Synthesis System and the Prevention Support System) to the local community agencies (the Prevention Delivery System) for them to implement the evidence-based substance abuse and mental health programs while serving individuals who were infected with HIV. Another illustration of the HIV prevention study includes a study done by the Division of Reproductive Health at the CDC of the United

States. This CDC division (the Prevention Synthesis and Translation System) in its multi-site capacity-building project used the ISF to engage the local partners (the Prevention Delivery System) and their grantees organizations (the Prevention Support System) that provided training and TA to local partners to build their capacity with the aim of implementing a science-based approach to teen pregnancy prevention (Lesesne et al., 2008). This approach demonstrated how all three systems of the ISF interacted to move the science of HIV and teen pregnancy prevention into practice. Lesesne et al.'s (2008) study was designed to be an example to program managers in the fields of teen pregnancy and HIV and STI prevention on how different stakeholders could be engaged in one project to move science into practice.

Most of the studies that used ISF as a framework and training and TA as prevention support strategies found that capacity (knowledge, self-efficacy, and behavior) and performance (participation or intent to participate in evidence based interventions' implementation) was higher in organizations or service providers who received training and TA as compared to those who did not, and both significantly increased with an increase in TA hours over time (Chinman et al., 2008; Firesheets et al., 2012; Ray, Wilson, Wandersman, Meyers, & Katz, 2012). Individual capacity was also shown to be increased after training and TA as compared to before in 20 of the 59 studies that were included in the meta-analysis that involved training and TA (Durlak & DuPre, 2008). Self-reports from organizations and individuals that received training and TA up to the end of the project also provide evidence that performance in various project activities increased due to interaction they had with training and TA providers (Chinman et al., 2008; Duffy et al., 2012; Firesheets et al., 2012; Ray et al., 2012).

In summary, prior studies provided awareness that the ISF could be applied to guide a project that has a focus on dissemination and implementation of science-based prevention programs. The ISF emphasizes a system-wide approach if science is to be moved from just being research results into practice where the research results may have a greater impact on humankind. Therefore, the framework was suited to be used to either examine or understand the work of the systems that were involved in the process of dissemination and implementation of a specific science-based intervention such as the TA interaction that the UNC project and the Malawi Ministry of Health had as they implemented the 2011 ART/PMTCT (the Option B+) guidelines in Malawi.

CHAPTER 4. RESEARCH METHODOLOGY

Introduction

This study used a qualitative, descriptive, multiple-case study design (Parse, 2001; Yin, 1994, 2013) to (1) describe the Prevention Support (e.g., training, technical assistance) that the UNC Project provided and how it was used by both the two high- and low-performing clinics of the Malawi Ministry of Health; (2) identify contextual factors that may explain variation in the delivery and use of TA; and (3) identify contextual factors that may explain variation in the implementation of ART/PMTCT services in the two high- and two low-performing clinics of the Malawi Ministry of Health (N=4 clinics). A qualitative, descriptive, multiple-case study design is used when the study intends to respond to “how” or “why” questions, when the behaviors of the potential study participants cannot be manipulated or controlled, and if the study intends to uncover contextual factors that a researcher believes are related to the issue that is under study (Baxter & Jack, 2008; Yin, 2013). To comply with the research methods that comprise several actions that researchers must take to move from the research question to its answers (Brink & Wood, 1998; Polit & Beck, 2008; Yin, 2013), the following section details the study design, sampling methods, procedures, methods of data collection, and data analysis and its management for this study. Maintaining the rigor of this study is also described under this section.

Study Design

A qualitative, descriptive, multiple-case study design was used (Parse, 2001; Yin, 1994, 2013). As described by Yin (2013), a case study is an empirical approach that is used

mostly by researchers whose goal is to answer “how” or “why” questions about an existing issue (the case) over which a researcher has little or no control. A qualitative multiple-case study design was suited to respond to “how” or “why” questions because this study was conducted to understand how and why the provision and use of prevention support varied across low- and high-performing clinics, as well as why there was variation in the implementation of the prevention of mother-to-child-transmission (PMTCT) of HIV services in the clinics that received support from UNC Project.. A qualitative, descriptive, multiple-case study design helps researchers describe and investigate an issue of interest in the real-world setting in which it occurs (Baxter & Jack, 2008; Parse, 2001; Yin, 2013), in this case, provision of prevention support such as TA and its use in the Malawi Ministry of Health clinics.

Sampling Methods and Study Setting

The cases for this study were sampled from a population of Malawian Ministry of Health primary health centers that received TA support from the UNC Project to implement the Option B+ guidelines. Four cases were purposively selected from a list of clinics that received TA from the UNC Project: Mkanda Health Center located in Mchinji district, Chitowo and Mtakataka Health Centers located in Dedza district, and Nathenje Health Center located in Lilongwe district. Informants for the in-depth interviews were sampled from two collaborating healthcare organizations—the UNC Project and the Malawi Ministry of Health through use of a snowball sampling technique (Miles & Huberman, 1994).

Inclusion Criteria for Cases in this Study

The primary inclusion criteria for the cases in this study were Malawian Ministry of Health primary health centers that (1) received TA and other prevention support strategies from the UNC Project; (2) had adopted and implemented the Malawian 2011 ART/PMTCT

(the Option B+) guidelines for a period of at least one year by December 2013; (3) provide antenatal, labor and delivery, postnatal, and under-five services; and (4) meet the minimum staffing norms—two nurses/midwives, two clinicians (either clinical technicians or medical assistants), one assistant environmental health officer, and one health surveillance assistant/1000 households (Dr Kachala, verbal communication, July 10, 2013).

Eleven health centers—Mkanda in Mchinji district; Chitowo, Golomoti, Lobi, and Mtakataka in Dedza district; and Area 25, Chadza, Kawale, Chileka, Area 18, and Nathenje in Lilongwe district—met the primary inclusion criteria for this study. From this list, a nonprobability purposive sampling method (Patton, 2002) was used to select “cases,” that is, clinics, for this study. To sample the study clinics, two steps were followed. First, PMTCT program performance data for Fiscal Year (FY) 2012-2013 from the clinics that received and used TA was assessed to determine the clinic’s level of performance as either high ($\geq 80\%$) or low ($\leq 60\%$) for the percentage of pregnant women are accessing PMTCT services. Making sure that at least 80% of all pregnant women are accessing PMTCT services is consistent with United Nation’s goals for 2010 (WHO, 2007). Clinic performance data were then used to identify two high- and two low-performing clinics. Clinics were selected based on the proportion of pregnant women tested for HIV in the antenatal clinic because it showed the most variation across clinics. Figure 7 displays the proportion of pregnant women tested for HIV at antenatal clinics per district, which ranged from 62.5% in Mchinji to 90% in Lilongwe district between October 2012 and September 2013.

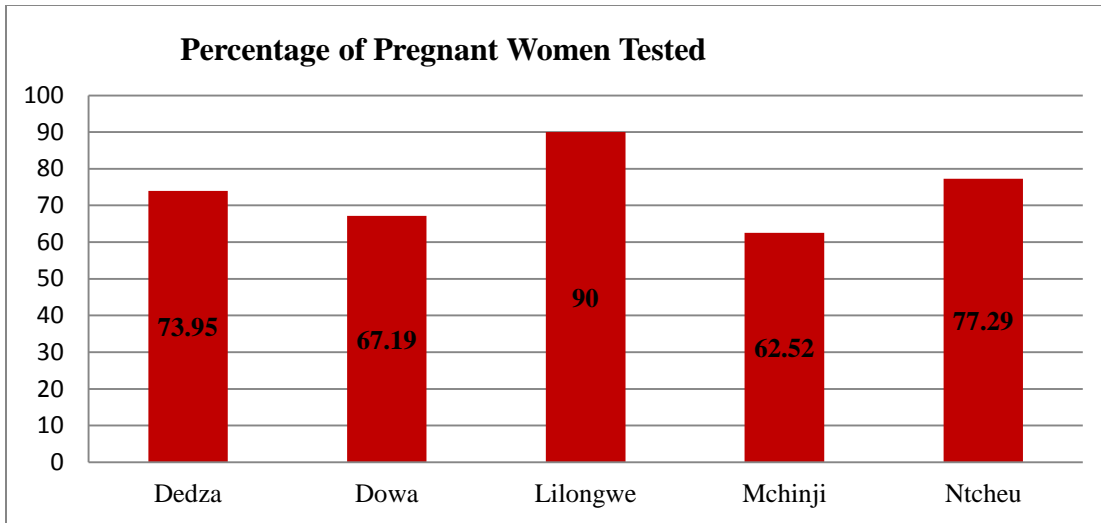


Figure 7. Proportion of pregnant women tested for HIV at antenatal clinics in the five supported districts between October 2012 and September 2013.

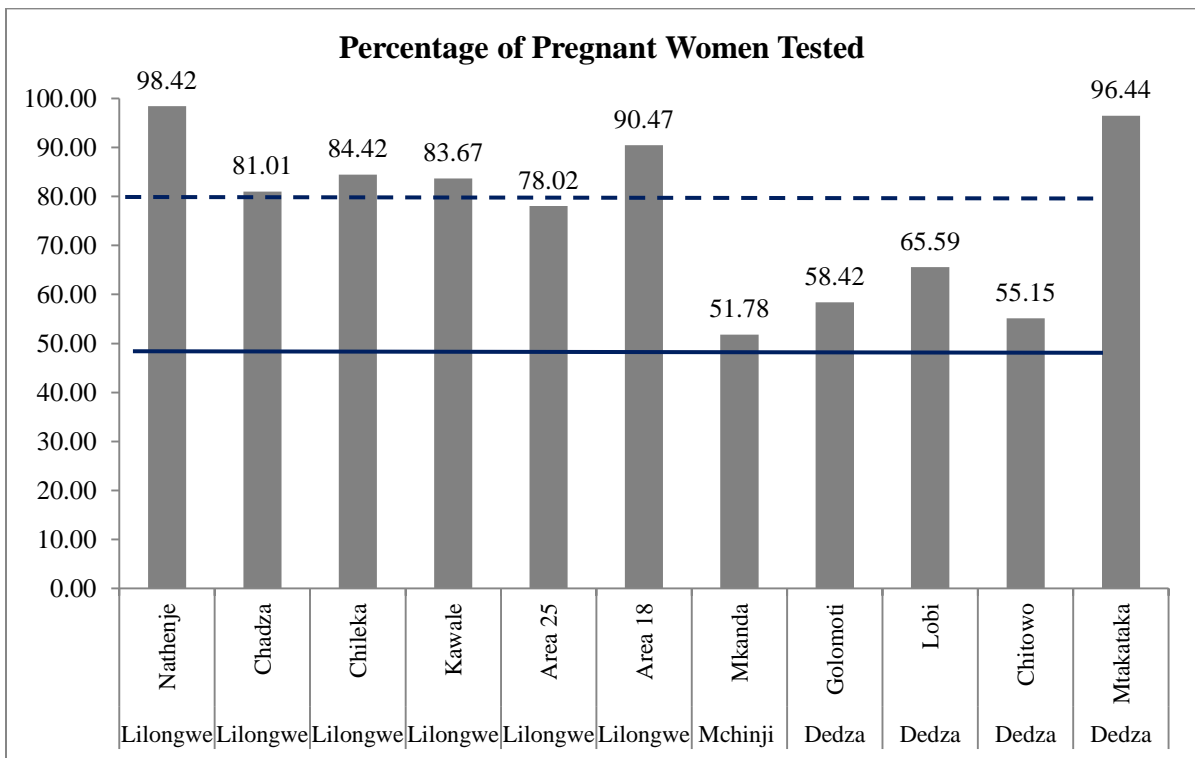


Figure 8. Proportion of pregnant women tested for HIV at antenatal clinics between October 2012 and September 2013 in 11 clinics that met the primary eligibility criteria.

Figure 8 displays the proportion of pregnant women tested for HIV in the antenatal clinic at each of the 11 eligible clinics, which ranged from 51.8% at Mkanda Health Center in Mchinji district to 98.4% at Nathenje Health Center in Lilongwe district between October 2012 and September 2013. Chitowo, in Dedza district, which tested 55.2% of all pregnant women at its antenatal clinic, and Mtakataka, also in Dedza district, which tested 96.4% of all pregnant women at its antenatal clinic, were purposefully selected together with Mkanda and Nathenje Health Centers to be cases for this study. Mkanda and Chitowo fell in the lowest quartile, hence low-performing, and Mtakataka and Nathenje fell in the highest quartile, hence high-performing. HIV testing is the most important step in the ART/PMTCT continuum of care because it provides an entry point to either HIV prevention or treatment care for the women, their children, and their family members. In addition, the impact of healthcare on mother-to-child-transmission of HIV is a cumulative one (Barker, Mphatswe, & Rollins, 2011). Therefore, when close to half of pregnant women in low-performing selected cases are not tested in the antenatal clinic, the opportunity is lost to impact the HIV-transmission rate from the HIV-infected women to their children. See Figure 9 for an overview of the process used to sample these study cases. Use of low- and high-performing clinics helped to select information-rich cases on the causes of variation in the implementation of ART/PMTCT of HIV services such as HIV testing at the antenatal clinics. Use of multiple cases helped this study to better investigate social units such as clinics that received TA and other prevention support strategies in Malawi, and findings are regarded to be more robust than using a single case study (Yin, 2013). We kept N=4 clinics (n=2 low- and n=2 high-performing) as a back-up sample in case the selected ones declined. However, all the sampled cases agreed to participate in this study.

After determining the study cases, N=21 in-depth interviews were planned and done with N=18 informants. Twelve (12) informants were selected from the Malawian Ministry of Health and six (6) from the UNC Project. Of the twelve Ministry of Health staff, eight (8) were service providers at the study clinics (2 per clinic) and four (4) were the ART/PMTCT district coordinators (1 or 2 per district). The study cases were sampled from three districts: Lilongwe, Dedza, and Mchinji. Each district had one ART/PMTCT coordinator except Lilongwe, which had two coordinators. Lilongwe district is the biggest among the five districts that received TA and other support strategies from the UNC Project in Malawi. Dedza's PMTCT coordinator was interviewed, once for each of the two selected cases in the district. The PMTCT district coordinators acted as the program champions, participated in TA visits, and provided supportive supervision to the service providers in the clinics. All six informants from the UNC Project were individuals whose job was to provide technical assistance (TA) directly to the selected clinics. Each of the two TA providers whose job was to support Dedza district were interviewed two times (n=4 in-depth interviews), once for each of the selected cases in the district. To find informants for this study, a snowball sampling technique was used (Miles & Huberman, 1994). The District Health Officers and the UNC Project Director and their representatives helped identify the ART/PMTCT district coordinators and the UNC Program Manager, respectively, who thereafter helped identify the service providers and the TA providers as other key informants for this study. Because the principal investigator of this study had connections with both the UNC Project and the Malawi Ministry of Health, all the key informants were easily identified.

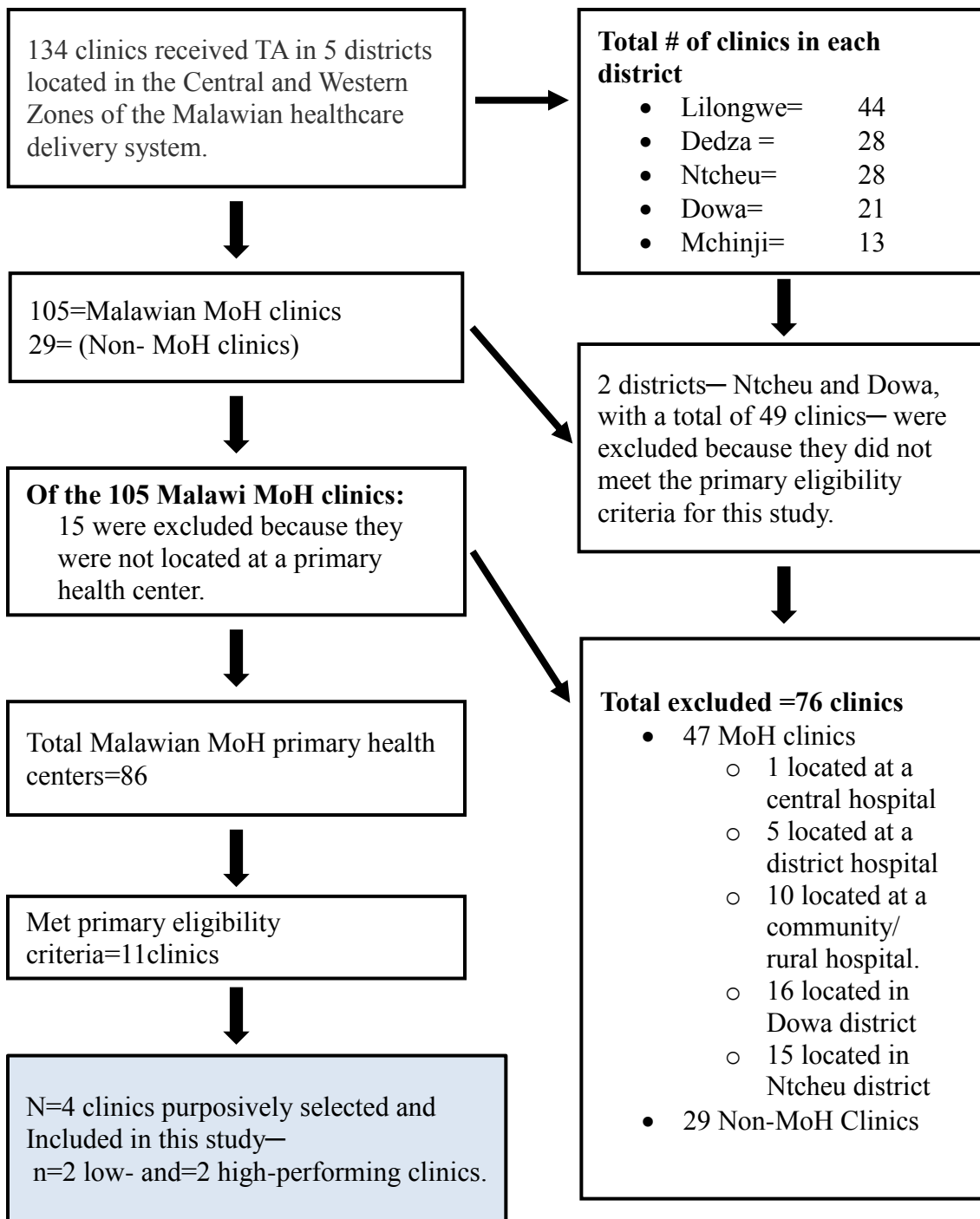


Figure 9. Sample screening: Process of clinics’ screening included as cases for this study.

Procedures

This study was approved by two Institutional Review Boards: The UNC-Chapel Hill Institutional Review Board (IRB) Research and Ethics Committee and the Malawi National Health Sciences Research and Ethics Committee. The UNC-Chapel Hill IRB Research and Ethics Committee reviewed this dissertation study and determined that the submission did not constitute human subjects research as defined under federal regulations [45 CFR 46.102 (d or f) and 21 CFR 56.102(c)(e)(1)] and, therefore, did not require IRB approval. The review by the UNC-Chapel Hill IRB Research and Ethics Committee was done in May 2014. The Malawi National Health Sciences Research and Ethics Committee approved it in August 2014. Due to the requirements by the Malawi National Health Sciences Research and Ethics Committee, this study was renewed and approved for continuation in June 2015. To comply with the Health Insurance and Portability and Accountability Act (HIPAA), the PI of this study did the HIPAA online training at UNC-Chapel Hill and the Good Clinical Practice and the human subjects trainings through the Collaborative Institutional Training Initiative (CITI) program at Miami University prior to data collection. The UNC-Malawi Project is a member of the CITI program, therefore, this training was a pre-requisite for the principal investigator of this study to use and conduct research within the UNC Project premises. In addition, all the research assistants (RAs) including the transcribers did the Good Clinic Practice and the human subjects trainings through the CITI program at the UNC Project in Malawi prior to their involvement in this research. The RAs served two important functions of a qualitative case study: (1) helped with data collection, transcription, and management and (2) helped build rapport. Apart from the RAs whose work is based in Malawi, the principal investigator of this study also had full knowledge of the Malawi healthcare system and study settings due to her involvement in PMTCT work with both the UNC Project and the Malawi Ministry of

Health. The RAs were trained on the study protocol with emphasis on the overview, objectives, consenting process, data collection instrument, and the meaning of all abbreviations and medical terminologies that are used in this study before their involvement into its conduct. The RAs were also trained on data transcription specific for this study.

Permission to conduct the study was sought from the national HIV/AIDS unit office and district health officers in the districts where this study was conducted and from the director of the UNC Project. Permission was also sought from all the participating study clinics through their directors/managers. Informed consent was sought from all the individual informants. All clinics provided permission and all individual informants provided written informed consent prior to participating in the study. The consent form was available in English, Malawi's official language, and Chichewa, Malawi's national language.

The principal investigator of this study, who is a bilingual Malawian, developed both the English and Chichewa versions of the consent form. A second bilingual Malawian read through both versions of the consent form for clarity and accuracy. A Chichewa version of the consent form was included in case some of the study informants would prefer it. All key informants were English literate and preferred an English version of the consent form. Education is given in English in Malawi and all informants had an education of more than 12 years.

Methods of Data Collection and Management

Data Collection

Data collection was done between October 2014 and January 2015. In-depth interviews using a semi-structured questionnaire were the main method of data collection for this study. The first part of the questionnaire had open-ended questions and was used to collect information to describe characteristics of the study cases including contextual factors

such as clinic age, size, and magnitude. The clinics' descriptive information also included the catchment area, number of operational years, years/months the clinic had been implementing the 2011 ART/PMTCT guidelines (Option B+), number of PMTCT service providers, and clinic HIV prevalence for the fiscal year 2012-2013. The clinics' descriptive information provided some of the information on the clinic level contextual factors that helped explain variation among the study cases on both support provision and use and on implementation of the PMTCT services. Data on context was also collected as part of the in-depth interview guide, which included space to accommodate interviewers' observations and emerging issues that needed interpretation or follow-up (see Appendices 1 and 2). Partial observation of the environment surrounding the study cases supplemented the in-depth interviews. Interviews and observation are among the most common methods of data collection for qualitative research (Creswell, 2007; Parse, 2001; Polit & Beck, 2008; Spradley, 1979). Moreover, the qualitative multiple-case design that this study used is flexible enough to use multiple data sources (Yin, 2013).

Prior to data collection, dry runs (mock interviews) were done in two PMTCT clinics in two different districts: Kasinje Health Center in Ntheu district and at Lumbadzi Health Center in Lilongwe district. These clinics were involved in the process of TA provision and use but were not eligible to be included in the study. The survey and interview guide were revised based on findings from the pilot study.

We went to the field and conducted twenty-one (N=21) in-depth interviews. These in-depth interviews were completed with eighteen (N=18) key informants—TA providers (n=6), PMTCT service providers at the study clinics (n=8), and the ART/PMTCT district coordinators from the districts where the study cases were sampled (n=4). In total, nineteen

(19) individuals consented to be interviewed. One service provider was terminated from being interviewed because he was not actively involved in the TA program. Qualitative literature indicates that the focus of any qualitative study is to have an in-depth understanding of the issue that can be provided by a relatively small sample (Patton, 1990, 2002; Sandelowski, 1995). In addition, most qualitative studies that explored the use of TA conducted between 7 and 20 interviews (Hightow-Weidman et al., 2012; Hunter et al., 2009; Stetler et al., 2006). Therefore, with the assumption that in descriptive, qualitative, multiple-case study design, “humans do create social networks, can describe retrospective and prospective life events and patterns and themes can be drawn from the studied phenomena” (Parse, 2001, p. 57), our twenty-one (21) total in-depth interviews provided us with the thick, rich data that this study needed. This study used multiple sources of data collection— the in-depth interviews, clinics’ descriptive information, and a partial observation of the environment that surrounded the study clinics.—These data sources made the collected data thicker for our description and helped us reach the theoretical data saturation point.

Of the 21 in-depth interviews that this study conducted, twenty (20) and a half (1/2) of them were completed face-to-face and only half (1/2) of one interview was completed via telephone. All the in-depth interviews were conducted at a place and time chosen by the informants. Three (3) in-depth interviews were done in the informants’ homes, three (3) at a motel, two and a half (2 1/2) at one of the UNC Project offices, twelve (12) in the informants’ working offices, and half (1/2) of one was completed via telephone. All the in-depth interviews were done using a combination of both English and Chichewa languages. Seventeen (17) in-depth interviews were mostly done in English and four (4) mostly in Chichewa. The in-depth interview guide was available in both English and Chichewa (see

Appendices 1 and 2). The rights and dignity of the study informants were respected and observed by allowing them to seek clarification throughout the process of data collection.

As discussed previously, these in-depth interviews were guided by an interview guide with semi-structured, open-ended questions (Spradley, 1979). The questions on the interview guide were descriptive, broad, and constructed to capture the concepts as described in Figure 6 and allowed the researcher of this study to learn about the study informants' view on their prevention support such as TA provision or use and their experiences about their daily activities in the implementation of the Malawian 2011 ART/PMTCT of HIV (the Option B+) guidelines (Marshall & Rossman, 2011). Formulation of questions in the in-depth interview guide was guided by the study's conceptual model of Prevention Support (Figure 6), which was developed out of the Interactive Systems Framework (ISF) (Wandersman, Chien, & Katz, 2012; Wandersman et al., 2008) and from the reviewed literature. The ISF indicates that use of prevention support such as TA, training, and tools, build the capacity of the implementers who later use that capacity (e.g., skills, knowledge, and motivation) to implement the interventions in their practice settings (Wandersman et al., 2012). Therefore, there were questions in the in-depth interview related to TA, training, and tools as capacity-building methods and how the clinics used capacity to implement the Option B+ guidelines in their clinics. The ISF emphasizes the interaction between the Prevention Support System and the Prevention Delivery System during the process of support provision and implementation of the interventions in the implementing sites. Therefore, this study also explored the relationship between the TA providers and users as one that may vary and may influence implementation. In addition, prior studies that have studied TA to implement scientific interventions suggest that TA may vary in its dosage (e.g., more hours versus less hours,

temporary versus ongoing) and that these variation may result in differences in implementation (Wandersman et al., 2012; Chinman et al., 2008). Therefore, variation in TA dose and TA focus were explored in this study.

According to reviewed literature, other factors such as human and material resources may also vary and might lead to variation in both TA delivery and use and also in the implementation of the guidelines at the clinic level (Malawi MoH, 2012b). Therefore, interview questions explored contextual factors that may influence the delivery of prevention support and/or the implementation of the Option B+ guidelines at the patient/community, clinic and systems level. Examples of clinic-level factors that this study explored are size of the clinic, magnitude of the clinic, and workforce issues. The explored factors helped this study to describe how the prevention support and Option B+ implementation varied between the two low- and high- performing study clinics.

The procedure for developing the in-depth guide followed the same process as that of the consent form; that is, the PI developed the guide and a second bilingual Malawian read it for clarity and accuracy. Throughout data collection, notes were taken using note pads and audio recorders. Two digital audio recorders were used to record each in-depth interview, where one served as a source and the other as a back-up in case data from the first were lost. These field notes and in-depth interviews were transcribed verbatim, typed in a Word document on the same day of each data collection (Creswell, 2007; Miles & Huberman, 1994). We used F4 transcription software and a foot pedal to aid transcription of our data. To follow suit with most research studies in Malawi that provide participants with incentives valued at about \$5, this study provided \$5 cash incentives to show appreciation to this study's key informants for their time and effort.

Data Management

A team of seven researchers was directly involved in data management of this research. The team included the principal investigator (PI), the dissertation chair, a consultant with qualitative expertise, and four well-trained qualitative research assistants with a vast experience qualitative HIV-prevention research in the settings where this study was conducted. One of research assistants who had a bachelor's degree in mass communication and journalism helped with both data collection and transcription. The other three helped with data transcription and included a professional counselor, a research nurse, and a final-year student at a local technical college studying rural and community development. Data from the mock interviews was used to train the RAs on how to transcribe data specific for this study. The PI of this study, who directly involved herself in data collection, transcription, and translation, checked all 21 transcripts for completeness and clarity. Data captured in Chichewa were transcribed verbatim and then translated into English by both the PI and the RAs so the team had consensus on the translated transcript. Two of the RAs—the nurse and the professional counselor—helped with translation of the data that was transcribed in Chichewa.

Data from all sources were embedded by integrating them so that one case-description data set was created for each clinic. A qualitative case-study design allows for data triangulation—use of multiple data sources—and then enables these data to converge so the researcher can understand the study cases better (Baxter & Jack, 2008; Creswell, 2007; Yin, 2013). Moreover, qualitative case-study researchers believe in a constructivism philosophical viewpoint—they accept that realities can be constructed in different ways (Creswell, 2007; Polit & Beck, 2008; Yin, 2013). Researchers on this study, therefore, shared the belief that knowledge can be constructed through inquiry and that reality can be

understood through both objective (observation) and subjective (in-depth interviews) ways of knowing. It was the responsibility of both the RAs and PI to collect all the information and if it happened that more information was needed from the study informants, data collectors returned to them to seek more information or clarity. For easy management, a common database was created in a secured computer to store all the collected data. Back-up data was kept using a secured external hard drive.

To promote safety, confidentiality, and anonymity, the interview guides did not capture names of the informants; the informants were identified by a unique number. The computer and the backup hard drive in which the study data were stored are both encrypted by a password known only to the PI of this study, and they, together with audio files, field notes, and all other study materials, were kept in a locked, fireproof safe cabinet in a locked office in the UNC Project building in Malawi or the UNC School of Nursing in the United States with key access by the PI only. Recorded data were erased from the recorder after data entry into a computer.

Methods of Data Analysis and Interpretation

A directed content analysis approach was used to code and analyze most of the data from the interviews (Hsieh & Shannon, 2005). A thematic analysis approach was used to code and analyze contextual factors that emerged that either influenced TA delivery or implementation of the Option B+ guidelines. According to Braun and Clarke (2006), a thematic analysis approach is used to isolate patterns or themes within data that can be reported and it is described as an important research analytical tool that helps researchers organize and describe their data to produce rich and detailed interpretations.

As described by Hsieh and Shannon (2005), directed content analysis starts with a theory and findings from prior studies, which then guide the initial codes. Therefore, initial

codes for this study were derived from a conceptual model of the Prevention Support (see Figure 6) and the ISF for Dissemination and Implementation (See Figures 1 and 5). This approach helped explore and describe how the Prevention Support methods such as TA was delivered and used by the study clinics. A deductive use of the conceptual model of Prevention Support in coding helped compare results across the study cases by exploring specific contextual factors that might explain variation in TA delivery, use, and implementation of guidelines' activities at the community, clinic, and socio-structural levels, (Hsieh & Shannon, 2005). This was coupled with an inductive approach to isolate themes that emerged related to contextual factors that influenced both TA delivery and implementation of the guidelines at the study clinics (Braun & Clarke, 2006).

Data analysis was done concurrently with data collection (Baxter & Jack, 2008) following the steps described by Miles and Huberman (1994). This process was completed between October 2014 and October 2015. As explained above, this study used both a directed content analysis and thematic analysis approaches. A deductive theory application was used to identify our initial codes for the themes that emerged from each clinic (Hsieh & Shannon, 2005). The initial codes were then iteratively revised to fully capture data and more codes were added using an inductive thematic approach (see appendix 3 for a final list of codes). Atlas.ti 7.5.7 qualitative data analysis software was used to assist in the organization of data for analysis. Thereafter, data was coded with the purpose of reducing and retaining relevant data (Miles & Huberman, 1994). Either the RA and the PI or two RAs independently transcribed each transcript. The PI and the dissertation chair of this study independently coded multiple transcripts and then met to closely examine the transcribed data to come up with the emerging themes and consistent approaches to coding (Yin, 2013). Themes were

guided by the questions that were asked during the interviews and were chosen based on a consensus between the two involved analyzers. The PI and the dissertation chair met bi-weekly on Skype while the PI was in Malawi and met weekly face-to-face while the PI was in Chapel Hill to discuss study issues and the emerging themes. Using the agreed-upon emerging themes, a matrix (codebook) was developed. Topics were organized by their relation to emerging themes (data display). Data was interpreted through a reflexive process to include only data obtained from the study informants and from the observations that were made, including the meanings that were attached to them (Creswell, 2007; Miles & Huberman, 1994). A summary description of each clinic (case) was then developed, which, in turn, was used for cross-case synthesis (Yin, 1994, 2013).

In order to explore similarities or differences within, between, and among cases (Yin, 2013), two separate word tables were created and displayed data from each case to capture findings from the two high-performing and the two low-performing cases. The first cross-case analyses were between the two low-performing cases followed by that between the two high-performing cases. Another word table was then created to display data from the combined low- and high-performing cases to capture findings from all four clinics/cases (Yin, 2013). Last, a final cross-case synthesis of data from the combined low- and high-performing clinics was then done. A qualitative analysis of the word tables allowed this study to draw cross-case conclusions from the whole study via more focused thoughts on whether the study cases are similar or different in some of the findings (Yin, 2013). This case and cross-case analysis process is in line with Yin (2013), who indicated that a case study using qualitative methods can study multiple cases and then draw a final “cross-case” conclusion that will create a thick description of the case under study. Throughout the data collection

and analysis process, the RA, the PI, and the chair and the committee of this dissertation study were meeting periodically via Skype or face-to-face to discuss and review emerging issues.

Methods of Maintaining Rigor

Rigor in any qualitative study is assessed by its credibility, confirmability, dependability, and transferability (Baxter & Jack, 2008; Polit & Beck, 2008). Use of a qualitative, multiple-case study design contributed to the rigor of the results of this study because of its design flexibility, which allowed use of multiple data sources (Baxter & Jack, 2008; Yin, 2013). To maintain credibility, this study used a team of experienced researchers and research assistants. I, the principal investigator of this study, am a Malawian registered nurse/midwife and have extensive experience in PMTCT research and service. For many years, I worked as a research nurse, a PMTCT trainer, and a service provider in Malawian clinics. The five dissertation committee members are distinguished, associate and assistant professors, chaired by a public health specialist who has experience in translation, dissemination, and implementation research. The chair of this dissertation committee is also an expert in mixed-methods research—that is, using both qualitative and quantitative methods. The four research assistants have extensive experience in PMTCT of HIV qualitative research in Malawi, where this study was done. Using data that was collected during the mock interviews, the RAs were trained on transcription and coding of data specifically for this study. After data collection, data-management procedures as described under data management section were used to maintain the credibility of the data. Throughout data analysis, both the PI and the chair of this dissertation were involved in the coding of each transcript independently and then would compare and discuss on the emerging themes on a weekly basis (Baxter & Jack, 2008). A theme was maintained if the two agreed

(Sandelowski & Barroso, 2003). Then, confirmability will be achieved by asking the key informants to review the draft of the case descriptions and the final report (member checking) before any dissemination of the results (Baxter & Jack, 2008). To ensure the reliability and dependability of the data that this study collected, the study protocol was used throughout the study (Yin, 2013). The description that this study includes in Chapter 5 carries views of the TA providers, the service providers at the study clinics, and that of the ART/PMTCT district coordinators as a representation of the study clinics. These views may be transferred to other clinics that are implementing the Option B+ guidelines and received TA and other support strategies from the UNC Project in Malawi but were not included as part of cases for this study.

The chair of the dissertation committee under which this study was conducted carried the role of the chief consultant and acted as an editor to review and help with the research process to ensure valid findings. Other dissertation committee members were consulted periodically throughout the research process. In addition, a qualitative expert from Odom Institute, a free resource for students at UNC-Chapel Hill, was used as study consultant whenever necessary. This whole process made the findings of this study to be trustworthy.

CHAPTER 5. RESULTS

Introduction

This section presents a report of the findings of the descriptive qualitative multiple-case study that was done at four rural Malawian Ministry of Health primary health centers located in the central region of the country. All four health centers have been offering primary care services to a population that lives in their defined catchment areas for at least three decades (30–35 years). All centers have been implementing the antiretroviral therapy/prevention-of-mother-to-child-transmission of HIV (ART/PMTCT) guidelines that are known as Option B+ since 2011, and all but one received support from the UNC Project for three years. The fourth health center received support from the UNC Project for five years. Table 2 displays characteristics of the study cases in detail. To respond to the study aims, 21 in-depth interviews were completed with 18 key stakeholders who were either service providers at the clinic, ART or PMTCT coordinators at the district where the study clinics are located, or the technical assistant (TA) providers who were actively involved in the support program that the UNC Project provided to the study clinics. The clinic service providers and the district coordinators were employees of the Malawi Ministry of Health while the TA providers were either employees or former employees of the UNC Project. All the informants were actively involved in the UNC Project support program. Table 3 displays descriptive characteristics of the study informants. Of the 18 informants, 17 (94.4%) were nurse/midwives and 1 (5.6%) was a Medical Assistant. Of the 17 nurse/midwives, 15 (88.2%) were nurse/midwife technicians (NMTs) and 2 (11.8%) were registered

nurse/midwives. Classifying informants in terms of gender, 9 (50%) were males and 9 (50%) were females. Professional work experience ranged from 4 to 45 years with the majority working less than 20 years.

Results presented in this section respond to each of the study aims. Aim 1 describes the prevention support that the UNC Project provided to the study clinics; Aim 2 describes contextual factors affecting delivery of technical assistance (TA) and how it varied between the low- and high-performing clinics; and Aim 3 describes contextual factors affecting implementation of the core components of the Option B+ guidelines and how they varied between the low- and high-performing clinics.

Table 2. Characteristics of the Study Cases

Characteristics	LP-1	LP-2	HP-1	HP-2
Clinic Age:				
• Year Opened	1983 (31 years)	1984 (30 years)	1979 (35 years)	1984 (30 years)
• Years Implementing Option B+	3 years	3 years	3 years	3 years
• Years receiving TA	3 years	3 years	5 years	3 years
Clinic Location				
• Distance from Ministry of Health central office	66.93 km (41.59 miles)	135.1 km (83.95 miles)	28.66 km (17.81 miles)	146.14 km (90.81 miles)
• Distance from its district health office	50.03 km (31.09 miles)	36.93 km (22.95 miles)	23.02 km (14.31 miles)	138.81 km (86.25 miles)
• Distance from a well-paved road	12 km (7.8 miles)	10 km (6.4.miles)	Just off a well-paved road.	Just off a well-paved road
• Distance from other health facilities	Surrounded by facilities that do not offer maternity, ART services and are not implementing the Option B+ guidelines	Surrounded by facilities that do not offer maternity and ART services and are not implementing the Option B+ guidelines	Surrounded by facilities that do offer maternity, ART services and are also implementing the Option B+ guidelines	Surrounded by facilities that do offer maternity and ART services and are also implementing the Option B+ guidelines. Is also surrounded by other 3 facilities that serve the same population
• Distance from other countries	Borders with another country	Borders with another country	Inside country	Inside country
• Developmental environment	Very remote area	Very remote area	Rural area	Rural area

Characteristics	LP-1	LP-2	HP-1	HP-2
Magnitude				
• Catchment Area	37,571+ other people from other facilities and from another country	51,289 + other people from other facilities and from another country	69,562	19,595 Minus those served by 3 other health facilities (1 public, 1 private, 1 owned by Christian hospitals association of Malawi).
• 2012-2013 FY # Pregnant women seen at a facility	1530	2693	3496	873
• 2012-2013 FY # annual deliveries at a facility	936	1817	1152	325
• 2012-2013 FY Overall HIV prevalence rate at a facility	Couldn't be established	7.7%	7%	Couldn't be established
Clinic Size				
• # of staff trained in Option B+	2 Nurses (NMTs) 11 HSAs 3 counselors 1 Statistical Clerk	2 Nurses (NMTs) 1 Medical Assistant 2 HSAs 4 counselors	7 Nurses (1=RN; 6 NMTs) 1 Medical Assistant 7 HSAs 2 counselors	3 Nurses (NMTs) 2 Medical Assistants 8 counselors 1=Volunteers
• # of staff involved in implementation of Option B+	2 Nurses (NMTs) 3 Counselors 1 Statistical Clerk	2 Nurses (NMTs) 1 Medical Assistant 2 HSAs 4 Counselors	7 Nurses (1RN; 6 NMTs) 1 Medical Assistant 7 HSAs 2 Counselors + other staff deployed by other partner organizations	3 Nurses (NMTs) 2 Medical Assistants 2=HSAs 8= Counselors + other staff deployed by other partner organizations

LP = Low Performing clinic, HP = High Performing clinic, NMTs= Nurse/Midwife Technicians, RN= Registered Nurse, HSAs= Health Surveillance Assistants, TA= Technical Assistance, Km= Kilometers.

Table 3. Characteristics of the Study Informants

Clinic & Informant Code	Role in the UNC Project Support Program	Gender	Professional Experience (Year)	Professional Cadre
LP-1				
Informant 1	TA Recipient (Coordinator at a district level)	Female	11	Nurse Midwife technician (Community Health Nurse Technician)
Informant 2	UNC Project TA Provider	Female	10	Nurse Midwife Technician
Informant 3	UNC Project TA Provider	Male	10	Nurse Midwife Technician
Informant 4	TA Recipient(Service Provider at the clinic level)	Male	22	Nurse Midwife Technician
Informant 5	TA Recipient (Service Provider at the clinic level)	Female	4	Nurse Midwife Technician
LP-2				
Informant 1	TA Recipient (Coordinator at a district level)	Female	6	Registered Nurse/Midwife
Informant 2	UNC Project TA Provider	Female	10	Nurse Midwife Technician
Informant 3	UNC Project TA Provider	Male	7	Nurse Midwife Technician
Informant 4	TA Recipient (Service Provider at the clinic level)	Male	4	Nurse Midwife Technician
Informant 5	TA Recipient (Service Provider at the clinic level)	Male	8	Medical Assistant
HP-1				
Informant 1	TA Recipient(Coordinator at a district level)	Female	20	Nurse Midwife Technician
Informant 2	TA Recipient(Coordinator at a district level)	Male	10	Registered Nurse/Midwife
Informant 3	UNC Project TA Provider	Female	25	Nurse Midwife Technician
Informant 4	UNC Project TA Provider	Male	11	Nurse Midwife Technician
Informant 5	TA Recipient (Service Provider at the clinic level)	Male	7	Nurse Midwife Technician
Informant 6	TA Recipient (Service Provider at the clinic level)	Female	45	Nurse Midwife technician
HP-2				
Informant 1	TA Recipient (Coordinator at a district level)	Female	11	Nurse Midwife Technician (Community Health Nurse Technician)
Informant 2	UNC Project TA Provider	Female	10	Nurse Midwife Technician
Informant 3	UNC Project TA Provider	Male	10	Nurse Midwife Technician
Informant 4	TA Recipient (Service Provider at the clinic level)	Male	5	Nurse Midwife Technician
Informant 5	TA Recipient (Service Provider at the clinic level)	Female	6	Nurse Midwife Technician

LP = Low Performing clinic; HP = High Performing clinic.

Aim 1: Prevention Support

Prevention Support is a concept used by Wandersman et al. (2008, 2012) to include all the strategies that a supporting organization provides to a delivery system to build individual or organizational capacity to implement the promoted scientific interventions. According to Wandersman et al. (2012), Prevention Support includes four types of support strategies: tools, training, technical assistance (TA), and quality assurance and quality improvement (QA/QI). Although we anticipated variation in the types of support strategies that the UNC Project used in low- versus high-performing clinics, with the exception of TA, this study found little variation in the way prevention support was delivered across the four study clinics. As detailed in the following tables, in addition to the support strategies described by Wandersman et al. (2012), the UNC project also provided study clinics with a range of resources. Table 4 provides definitions and examples of the different types of support strategies and Table 5 displays ways in which TA varied between high- and low-performing clinics.

Table 4. Types, Definitions and Examples of the Prevention Support Strategies that the UNC Project Used to Build Clinics' Capacity to Implement the Option B+ Guidelines

Types	Definition and Examples
Training	<p>“Training is a planned, instructional activity that is intended to facilitate the acquisition of knowledge, skills, and attitudes in order to enhance learner performance and is often performed in group settings” (Wandersman et al., 2012, p. 449).</p> <p>In reference to this study, training is a planned, instructional, interactive activity that aimed at building service providers’ capacity (knowledge, skills, and attitudes) to implement the Option B+ guidelines (Wandersman et al., 2012).</p> <p>The following four types of trainings were funded and organized by the UNC Project and were provided to different types of service providers. With the exception of the one-day orientation course, all courses required staff to travel off site.</p> <ul style="list-style-type: none"> • Two week ART/PMTCT training course for nurses and clinicians new to ART/PMTCT. Content covered how to implement all guideline components. • One week ART/PMTCT refresher course for nurses and clinicians who were previously trained. Content covered how to implement all guideline components. • One week early infant diagnosis training course for the Health Surveillance Assistants. Content covered how to identify and collect and process HIV samples from HIV-exposed children. • One day orientation course for data assistants who worked as data clerks at the clinics. Content covered how to properly document the implemented ART/PMTCT guidelines’ activities for purposes of monitoring and evaluation.
Tools	<p>“Tools refer to informational resources designed to organize, summarize, and/or communicate knowledge” (Wandersman et al., 2012, p. 448).</p> <p>Examples of tools are manuals and guidelines that communicate guidance and other information to implementers of the interventions (Wandersman et al., 2012). The UNC Project used the following tools:</p> <ul style="list-style-type: none"> • Malawi Ministry of Health ART/PMTCT manuals and guidelines to train service providers. • Standard operating procedures (SOPs), flow charts, and posters that had information to help clinics fully manage the women and their family members.

Types	Definition and Examples
Resources	<p>Resources are materials other than tools that were supplied by the UNC Project to enhance the study clinics' implementation of the Option B+ guidelines.</p> <p>Examples of material resources supplied to study clinics in times of shortage included: Contrimoxale drugs, HIV testing kits, water guard, vital meal, transportation, and other miscellaneous resources such as printing services.</p>
Technical Assistance (TA)	<p>“TA is an individualized, hands-on approach to building an entity’s capacity for quality implementation of innovations, usually following training” (Wandersman et al., 2012, p. 449).</p> <p>In reference to this study, TA is an individualized, hands-on consultation that the UNC Project provided to clinics after training to reinforce understanding of knowledge and skills of the clinics as implementers of the Option B+ guidelines and to enhance quality implementation of the guidelines in the practice settings (Wandersman et al., 2012).</p> <p>TA focus includes areas of emphasis on the practice of the UNC Project’s TA providers on where they were trying to change at a study clinic. The frequency and an amount of time spent on each unit by the TA providers’ determined TA focus at that specific clinic.</p> <p>Different areas of focus: Community activities (e.g., mobilization and follow-up, antenatal care, labor and delivery, early infant diagnosis, HIV testing and counseling for pregnant and breastfeeding women, initiation and retention of HIV-infected women on antiretroviral drugs, and documentation of all rendered ART/PMTCT of HIV care.</p>
Collaborative Delivery of Services	<p>The UNC Project used a collaborative approach as an aspect of TA (Wandersman et al., 2012)</p> <p>For this study, collaboration includes all activities that were done in conjunction by both the UNC Project and the Malawi Ministry of Health staff and aimed at helping the clinic staff implement the Option B+ guidelines with quality. The UNC Project:</p> <ul style="list-style-type: none"> • Collaborated with district coordinators on quarterly basis to deliver TA to clinics. • Conducted collaborative community sensitization and mobilization activities about the implemented Option B+ guidelines in communities surrounding the clinics together with the district and clinic staff. • Collaborated with clinic staff to implement clinic-level core components of the Option B+ guidelines such as provision of health education, examining pregnant women, HIV testing and counseling, documentation of the rendered care, and compiling different types of reports.
Audit and	<p>The UNC Project used Audit and Feedback as an aspect of TA. Audit and Feedback is one of the quality</p>

Types	Definition and Examples
Feedback	<p>improvement strategies used to improve service providers' practice (Jamtvedt et al., 2006). Audit and Feedback is a concept related to Wandersman et al.'s Quality Assurance and Quality Improvement (QA/QI). "QA involves the use of tools and logic to assess quality performance while QI is the use of methods to enhance quality performance. QA/QI is an integrative process for identifying current levels of quality and for improving quality performance" (Wandersman et al., 2012, p. 453). For this study, Audit and Feedback includes all activities that were done by the UNC Project's TA providers that helped them assess quality performance of the clinics on the implementation of the Option B+ guidelines and thereafter give feedback on both the strengths and on areas that needed improvement. Audit and Feedback is a strategy that was commonly used by the UNC Project's TA providers as they provided their onsite and ongoing TA to clinics.</p> <p>Examples of Audit and Feed back: data collection and providing feedback.</p> <p>Ways of data collection for Auditing purposes: direct care observation using a standardized checklist, checked the clinics' monitoring and evaluation tools, and collected monthly and quarterly clinic reports.</p> <p>Ways of providing feedback: TA providers convened immediate meetings after a direct care observation, called for a one-day briefing meeting involving several clinics, or went to a specific clinic where clinic staff were gathered and briefed on their implementation rates.</p>

HP= High-performing clinic; LP= Low-performing clinic; UNC= University of North Carolina; ART= Antiretroviral Treatment Therapy; PMTCT= Prevention-of Mother-to Child-Transmission

Training

In the year 2011, Malawi adopted the new Option B+ guidelines mandating that all HIV-infected pregnant and breastfeeding women receive lifelong antiretroviral drugs regardless of their level of immunity. To implement the Option B+ guidelines, the Malawi Ministry of Health and its implementing partners at the national level developed different types of curricula to train service providers at the clinic level. Prior to training the clinics, Malawi Ministry of Health trained trainers-of-trainers who were drawn both from its implementation partner organizations such as the UNC Project and the Malawi Ministry of Health district offices.

Training of the clinic-level service providers was funded and organized by the UNC Project in collaboration with the Malawi Ministry of Health. The aim of training was to provide clinic staff with knowledge, skills, and attitudes required to implement the adopted guidelines and to improve their performance. As indicated in Table 4, there were four types of trainings that targeted different types of service providers. Except for the one-day orientation course for data assistants, all other types of trainings required service providers to travel off site to a centralized location within the district where they were housed for the duration of the training. The UNC Project paid for housing for both trainers and trainees and also allowances to trainees for their meals. Both the UNC Project and the Malawi Ministry of Health provided trainers. The Malawi Ministry of Health provided training curricula. The study found no variation in how training was conducted across the study clinics. Study participants identified training as one of the support components that promoted clinics' adoption and implementation of the Option B+ guidelines in their practice settings.

Training effects on implementation of the Option B+ guidelines. Although training facilitated clinics' adoption of the Option B+ guidelines, it created staff shortages and left implementation gaps at the clinics at times when service providers were withdrawn from their work places to attend to residential trainings. Staff responsible for implementing the Option B+ guidelines often had responsibility for other services as well. This study found that program coordinators at the district level did not coordinate how and when to withdraw staff from the clinics to attend different types of trainings related to different interventions that clinics implemented. Due to lack of coordination, clinics suffered a critical shortage of staff when more than one staff member was withdrawn to attend training at the same time.

The study also found that there was lack of training for the clinic support staff such as hospital administrators, environmental health officers, drivers, and hospital attendants. Lack of training left knowledge gaps among some of the personnel key to implementing the Option B+ guidelines. For example, clinics used the existing Malawi Ministry of Health ambulance drivers to transport HIV specimens to laboratories that were located at either the district or central hospitals, and yet drivers had no knowledge of how to care for the specimens while transporting them. Drivers were also used to carry HIV test results from the laboratories back to the clinics where the specimen came from. Hospital administrators supervised the drivers and data clerks, and the environmental health officers supervised the Health Surveillance Assistants (HSAs) who were used as HIV counselors, Under-Five service providers, and outreach workers, yet administrators and environmental health officers had no knowledge about the extra work that implementation of the Option B+ guidelines created for their staff. Lack of knowledge on the Option B+ guidelines by this critical group

of health workers contributed to problems faced by the clinics in fully implementing the guidelines.

Tools

Tools as described in Table 4 are among the Prevention Support strategies that the UNC Project used to help the clinics implement the Option B+ guidelines. The UNC Project used the Malawi Ministry of Health Option B+ manuals, guidelines, and curricula to train the clinic staff. The manuals, guidelines and curricula integrated changes of antiretroviral treatment therapy and prevention of mother-to-child transmission (ART/PMTCT) of HIV information. Trainers provided copies of the manuals and guidelines to all individual training participants and clinics for reference. To enhance implementation of the Option B+ guidelines at the study clinics, the UNC Project developed and provided standard operating procedures (SOPs), flow charts, and posters as additional tools (see Table 4). The SOPs, flow charts, and posters had information to help clinics fully manage the women and their family members who accessed HIV, ART, and PMTCT care at the study clinics. The UNC Project gave these tools to clinics and the clinics hung them on the walls. TA providers and clinics valued the SOPs, flow charts, and posters because they reminded service providers about what they learned during their training on how to manage women and their family members who sought ART/PMTCT care at their clinics. These tools helped service providers and built their capacity to implement the Option B+ guidelines at their practice settings. In the words of a TA recipient who coordinated ART/PMTCT activities at a district level:

With the coming of the partners to the ministry, it assisted a lot in the implementation of Option B+ because, with the assistance from the UNC Project technical office we developed SOPs which we shared to health centers so they put them in their labor maternity ward so that they should know what they are supposed to do whenever they have this mother who tested HIV positive.

From one district coordinator speaking on behalf of service providers:

UNC Project provided us with guidelines..... on issues of EID [early infant diagnosis], they provided us with posters which have been pasted all over to say, how do you collect DBS [dried blood spot] sample, how do you go about with an HIV pregnant mother...so it's like we have the resources which can make us capable to implement the Option B+.

A clinic service provider described the tools at the clinic:

...they brought some posters..... in EID [early infant diagnosis], there are flow charts of how we can manage an infant born to an HIV positive mother...it's like a guide ... It stipulates when we are to take samples and how to take them and how to follow up the infant.

Resources

As part of prevention support, the UNC Project provided the following material resources to the study clinics whenever they ran short of them: drugs, HIV testing kits, water guard, vital meal, transportation, and other miscellaneous resources such as printing services, mosquito bed nets, and point-of-care and blood pressure machines. These material resources were supplied to enhance continued implementation of the Option B+ guidelines in the study clinics when their supplies ran out.

Whenever clinics experienced a shortage of cotrimoxazole—an antibiotic drug that is used for prophylaxis to prevent opportunistic infections in HIV-infected or -exposed infants—the UNC Project supplemented clinics with such drugs. The UNC Project also brought HIV testing kits to supplement the clinics in times of shortage. All clinics had phone contacts for the TA providers and were able to inform them when the HIV testing kit stock would not last them a week; in response, the TA providers provided clinics with the needed kits. The following quote illustrates how the TA providers responded when informed about shortages of HIV testing kits:

When we were informed that the test kits would not last that particular week, we would rush and provide them with test kits.....UNC Project sometimes had to procure some test kits because they were sometimes out of stock in some health facilities.

Water guard and vital meal are resources indirectly related to the implementation of the Option B+ guidelines that the UNC Project provided to study clinics. Water guard is used to reduce diarrhea cases in the general population and was given to HIV-infected women and their family members. Vital meal helps improve nutritional status and was given to HIV-exposed infants after six months of life—the time when supplementary feeding is recommended in Malawi. Since the water guard was in the form of a powder, the UNC Project also supplied clinics with pails for clients to use when dissolving it and for water storage. In addition, clean pieces of cloth were supplied for water purification. Clinic staff were taught how to educate HIV-infected women on the use of supplied resources.

Another material resource that the UNC Project provided to the study clinics was transportation. In all the study clinics, TA providers either used their vehicles or motorcycles to support clinics' implementation activities. The TA providers' offices were located at the district health office which enabled them carry resources such as drugs, HIV testing kits, stationery, and HIV results from the district, central, or UNC Project laboratories whenever they visited the study clinics they. From the clinics, TA providers transported patients' samples to the laboratories to be tested. None of the study clinics had laboratory capacity to test HIV using the polymerase chain reaction/deoxyribonucleic acid (PCR/DNA) test— an antigen test that is used to test HIV infection of the HIV exposed children. In addition, those TA providers who were using vehicles as their means of transport to visit the clinics were able to release their vehicles to be used as an ambulance to ferry patients to the district hospitals if the clinics' ambulance was not available at the time of their TA visit. The UNC

Project also provided transportation for the coordinators during their quarterly joint clinic supervisory visits because the district health office lacked consistent transportation for the district coordinators to regularly supervise the study clinics.. In addition, TA providers lobbied for bicycles from the United Nations Children’s Fund and gave them to some health centers to be used as means of transportation when tracing clients who missed their scheduled clinics’ visits. Among the study clinics, only one clinic (HP-1) benefited from bicycle support.

The UNC Project also supported study clinics with miscellaneous resources such as printing services, mosquito bed nets, and blood pressure and point-of-care machines. Clinics did not have printing services and got all their printed stationery either from the district health office or at the central office of the Malawi Ministry of Health, which had limited funding to buy materials such as paper and toner. As part of its support service, the UNC Project helped with printing required materials such as registers and data collection and reporting forms. Due to high prevalent of malaria in Malawi and because the effects of malaria are potentially fatal especially in HIV-infected individuals, the UNC Project provided the clinics with mosquito bed nets, until the Malawi government took this role over as part of its safe motherhood initiative program. Lastly, whenever the TA providers found that clinics lacked vital resources such as blood pressure or point-of-care machines, they reported to their management, who were able to buy the necessary resource for the needy clinic. All clinics encouraged male involvement in HIV services. Therefore, point-of-care machines were supplied to clinics to test the CD-4 cell count of HIV-infected women’s sexual partners who accompanied them to clinic. In addition to supporting clinics with material resources, TA providers helped with implementation activities and thereby acted as

additional human resources in times of clinics' shortage of staff. TA providers also assisted in leveraging for more staff through lobbying from the district health office of the Malawi Ministry of Health. Among the study clinics, two clinics (HP-1 and LP-2) benefited.

Technical Assistance (TA)

As experts in the HIV, ART, and PMTCT fields, the UNC Project supported clinics with three years of ongoing, on-site TA to enhance their capacity (e.g., skills, knowledge, and motivation) to implement the adopted Option B+ guidelines (see Table 4 for more details). The UNC Project's TA program was also referred to as a mentorship program or the "Safe Guard the Family" program by both the TA providers and the study clinics. Therefore, mentorship and TA are used synonymously in this report. In all four study clinics, TA aimed to reinforce what clinics learned during their ART/PMTCT trainings so that the guidelines would be adopted, integrated into routine maternal and child health care practice, and implemented with fidelity. Among all the support strategies that the UNC Project used, only TA showed some variation in the way it was delivered across the study clinics (see Table 5). TA took two forms: audit and feedback and collaborative delivery of services.

Audit and feedback. Audit and feedback is a concept related to Wandersman et al.'s (2012) concept of quality assurance and quality improvement (QA/QI). Table 4 provides a definition of audit and feedback and a detailed account of how the UNC Project used it as a TA strategy. Auditing involves assessing the quality of clinics' performance on the implementation of the Option B+ guidelines. Feedback involves providing clinics with information of both strengths in their performance and areas that need improvement. In their description of TA, study informants virtually always referred to either audit and/or feedback as the primary strategies TA providers used. Therefore, for this study, audit and feedback comprise most activities that were done by the UNC Project's TA providers. The UNC

Project's audit and feedback activities typically involved direct care observation and physical data collection followed by the provision of feedback.

Auditing. To audit implementation, TA providers used three methods: direct care observation to assess individual staff performance using a standardized checklist; review of the clinics' monitoring and evaluation tools such as registers, cards, and clients' health passport booklets; and review of the clinics' monthly and quarterly reports using the standardized Malawi Ministry of Health's reporting forms (see also Table 4).

During direct care observation, TA providers observed how care was being delivered to clients and assessed individual-level performance, which helped them give feedback to the observed service provider. This method also assisted the TA providers to check if clinics were delivering the ART/PMTCT services and, if so, that they were done according to standards set in the Option B+ guidelines. If gaps were observed during direct care observation, TA providers were able to mentor the service provider on how to manage clients according to the Option B+ guideline standards. A standardized checklist was used to assess how an individual service provider was performing. This checklist had information on all sections/units that were involved in the implementation of the Option B+ guidelines at the clinic.

Study findings include various innovations in the way TA providers audited implementation through direct care observation. First, TA providers sometimes assisted with direct care provision while observing the service provider on her/his care skills; second, at other times, they acted as an observer while the service provider was doing a procedure; and third, at one clinic (HP-1), toward the end of the TA program, TA providers would go to this clinic and observe a specific service provider—most often a nurse—for four (4) consecutive

weeks. If the TA providers assessed that the nurse's performance was according to standards, they could leave him/her and start to observe another service provider, but if he/she was not performing according to the set standards, they continued to observe him/her on a quarterly basis. In all the study clinics, direct care observation was also done during quarterly joint supervisions that were done by the TA providers from the UNC Project in collaboration with the district health staff (the ART and the PMTCT coordinators) from the Malawi Ministry of Health. Following any of the different observation approaches, the TA providers would demonstrate the correct methods in response to any shortfalls identified. In the following quote a TA provider describes direct care observation:

We could check how the counselor was counseling the client, if the procedure she was doing was correct or not; how that counselor was giving the results, is it the way they are taught or not and if something was wrong we could correct after the client is out of the room.

Audit and feedback was described as an aspect of TA by one district coordinator:

When I say mentoring, it's like when the ministry developed those policies on Option B+, nurses and clinicians were trained on how to manage clients. So, they [UNC Project's TA providers] were going there [clinics] to strengthen those policies so that the clinics should practice according to standards set by the ministry.....They would be in uniform like this one, go there on clinic days, the staff at the clinic would conduct the normal clinics, so this mentor would sit by and observe what is happening, after that they were able to give feedback on whether they did well or not.

Another method that the TA providers from the UNC Project used to audit implementation was to check the clinics' monitoring tools such as registers, cards, and clients' health passport booklets, which contain patients' health profiles. All the tools that were used by the clinics to monitor implementation were developed by the Malawi Ministry of Health. Monitoring tools helped the TA providers have a sense of how the Option B+ guidelines were being implemented at the study clinics. In addition, the approach helped

them assess whether clinics were collecting the data clinics need to monitor and improve their own performance and their patients' receipt of the components of Option B+. For example, TA providers reviewed antenatal and maternity registers to check on clients who missed their scheduled visits. This helped the TA providers collaborate with the service providers and devise a system to track down defaulters who had been initiated on the lifelong antiretroviral therapy (ART) but were not reporting back to care. The following quotes illustrate how clinic monitoring tools were used to audit implementation:

From the TA provider:

[W]e were checking in the registers and see how they are documenting so if the documentation is not good at the end we could sit down with the staff trying to explain and reason with them on how we can best document in the registers.

The district coordinator's perspective was:

...because they will tell you on how the programme is performing, like in the antenatal, if you go to its register you may have 50 women registering in that month and per policy we were supposed to test all the 50 women and you have not tested may be 30 of them, it will show you that you have a gap in ascertain for the HIV status using those reporting tools. And out of the ones tested, you would see that such figure tested HIV positive and how many of them did actually start treatment, so with those reporting tools you could be able to see all those and see the gaps which you can now rework on according to this stand.

Collection of the clinics' monthly and quarterly reports was another data collection method that was used by the UNC Project's TA providers to audit implementation of the Option B+ guidelines at the study clinics. On a monthly basis, TA providers went to clinics to collect data by themselves and on a quarterly basis they collaborated with the district coordinators (e.g., either the ART or PMTCT coordinators) from the Malawi Ministry of Health. Data was collected from various clinic registers such as the antenatal, maternity, antiretroviral treatment therapy, HIV testing and counselling, and early infant diagnosis, aided by the

standardized monthly or quarterly reporting forms that were designed by the Malawi Ministry of Health to assess clinics' performance. After data were collected, TA providers took the reports with them to their office for analysis to come up with a report that was later used to give feedback to the study clinics. The following quotes illustrate how TA providers audited through collection of clinics' reports from the perspectives of the TA providers:

...at the end of each quarter, we were collecting data. In fact all the information that we needed was found in those registers so it was like getting data for UNC Project at the same time the same data was used by them....

Feedback. Ways of providing feedback are listed in Table 4. After an analysis of the collected data, TA providers gave feedback by inviting service providers who were involved in the implementation of the Option B+ guidelines to participate in a one-day, offsite briefing on their implementation strengths and gaps. TA providers also gave bimonthly feedback to individual clinics on their performance.

A TA provider talked about how feedback was done:

We were going together with the DHO [district health office] staff and then we divided ourselves to different units like ART [antiretroviral therapy], EID [Early Infant Diagnosis], Antenatal and Maternity to see their performance at a health center level. Then at the end, we then write a report on how each clinic has performed. After that we go for the feedback.

We were calling them together,... the HSAs[Health Surveillance Assistants], nurses, environmental health officers, their bosses' clinician. We had to meet and give them the feedback, that the data we collected has shown that you have done better in such-such section like antenatal, HTC [HIV Testing and Counseling] or maternity. And we were also finding out the gaps in all the areas and how we can fill them....

A district coordinator, as a representative of the clinic, explained:

They were giving us feedback to say this is how you are performing and sometimes they would give us feedback comparing to other facilities where they were supporting as well.

TA collaboration in service delivery. TA providers not only provided audit and feedback, they also directly assisted clinic staff with delivering components of the Option B+ guidelines (see Table 4 for details). TA providers collaborated with service providers to provide both community and clinic health services that were helpful for the clinics to deliver components of the Option B+ guidelines with quality. Examples of community- and clinic-based activities where the TA providers participated in the actual hands-on care provision include:

- **Community sensitization and mobilization activities.** To support clinics with community activities, the UNC Project funded community mobilization activities to inform community members about the Option B+ guidelines. TA providers collaborated with the district coordinators and the clinic service providers to conduct the community sensitization and mobilization activities. In the Malawian context, the community comprises key stakeholders such as the traditional authority chief of a given area, a leader of the specified area; the group village headmen; the village headmen; volunteers; different village-level committees; leaders of different organizations in that specific area; and all the people who live in that specified area. TA providers together with the district coordinators and the clinic service providers either went to the community or called the community leaders to the clinics and educated and explained to them about the Option B+ guidelines through dramas and role plays. At these community mobilization meetings, both district and clinic staff from the Malawi Ministry of Health and TA providers from the UNC Project encouraged males to be involved in maternal and child health, including general HIV, ART and PMTCT services, by engaging

themselves in couple HIV testing and counseling and supporting their sexual partners to fully access all the components of the Option B+ guidelines. “Male involvement” is a concept that is used to allow men to participate in maternal and child health activities. Male involvement was included in community mobilization activities to gain the support of men and enhance implementation of the adopted Option B+ guidelines at the clinics through holistic family care.

- **Antenatal care.** TA providers collaborated with nurses and counselors to provide the following antenatal care:
 - Provision of health education as a means of disseminating the Option B+ guidelines to all pregnant and breastfeeding women and their family members who sought care at the study clinics. Health education also aimed at informing the HIV-infected women and their family members that once antiretroviral (ARVs) drugs are started, they must be taken every day for life.
 - Checking in women’s health passport books to determine the HIV status of pregnant and breastfeeding women.
 - HIV testing and counseling of the pregnant and breastfeeding women and their family members (e.g., spouses and children) who sought care at clinics on TA visit days.
 - Initiation of lifelong combined ART to all identified HIV-infected pregnant and breastfeeding women.

- Supplying three bottles of 25mls each of nevirapine (NVP) syrup to identified HIV-infected women for their HIV-exposed babies at the first opportunity once the woman was known to be HIV-infected.
- Health and physical assessment including fundal palpation of the pregnant women who sought care at study sites during TA visit days.
- Initiating the integrated mother/infant follow-up scheduling.
- Documentation of all rendered PMTCT activities in correct registers and on cards.
- Report writing.
- **Early infant diagnosis (EID).** To help with EID activities, which are done as part of the Under-Five care, TA providers collaborated with health surveillance assistants (HSAs) and counselors to provide the following care:
 - Checking in women's and children's health passport books to identify the HIV-exposed children.
 - Collection and processing of the dried blood spot samples from HIV-exposed children and transporting them to the laboratories.
 - Counseling of mothers and guardians on their childrens' HIV status when sample results were available at the clinic but not given to the mother/guardian.
 - Helping HSAs with defaulter tracing of all clients enrolled into the ART/PMTCT program through devising a tracing system and use of support groups that were formed of HIV-infected women from within the communities.

- Documentation of all rendered EID activities in correct registers and on cards.
- Report writing.
- **In all other maternal and child health departments** such as at maternity labor ward and family planning, including the general ART clinic, TA providers helped with identification of clients in need of the HIV testing, gave health education, counseled and tested clients for HIV, and helped staff with documentation issues including report writing.
- **TA providers/district coordinators collaborative quarterly supervision.** At the district level, TA providers collaborated with the coordinators and provided joint supportive supervisions on a quarterly basis to the study clinics.

In the words of the TA provider, the following quote illustrates how TA providers collaborated with the study clinics to implement the Option B+ guidelines:

We helped with the actual antenatal care provision, specifically HIV counseling and testing and documentation in the registers.

In the words of the district coordinators, this is how TA providers collaborated with the study clinics:

.....together with the staff there, it was like they were showing them how to ascertain the HIV status, so we were together checking and if the child is due for DBS [dried blood spot] sample, then the counselor was taking that one for sample collection...

On community mobilization, we were choosing the traditional authority through the HSAs but we were communicating to them through the health center... so the HSAs [Health Surveillance Assistants] were taking part in that..... they could go there with the district coordinator and the other team members to give them information. They were meeting the community leaders, traditional birth attendants, village leaders and giving them information on PMTCT, on the importance of going together [to the clinic] on the first visit with the husband to get health education.

TA collaboration in service delivery is one of the support components that clinics valued most. There was a consensus from all the study informants that TA strengthened implementation through TA providers' involvement in implementation of the guidelines' core components at the clinic and community level. In addition, TA providers' frequent visits to the study clinics helped the service providers gain confidence and motivation to implement the Option B+ guidelines with fidelity. Service providers' skills were also reported to have strengthened because of regular reminders that the TA Providers gave to the service providers on the skills that they learned during training.

Most Valuable Support Strategies

Across study clinics, there was agreement that tools, TA, and the resources that the UNC Project provided helped most with the implementation of the Option B+ guidelines. Tools such as SOPs, flow charts, and posters reminded service providers about what they learned during their training sessions and acted as an available resource for reference when managing women and their family members who sought HIV, ART, and PMTCT care at their clinics.. In addition to tools and TA, clinics valued all resources such as HIV testing kits that were supplemented to them in times of shortages. Supplemental resources helped clinics continuously implement the core components of the Option B+ guidelines even in times when the country faced great shortages of them.

In conclusion, the UNC Project supported all four study clinics with training, technical assistance (TA), tools, and resources. As indicated in Table 4, four types of training were funded and organized by the UNC Project and provided to different types of service providers. Although training was reported as a single support that built clinics' initial capacity and helped clinics adopt the Option B+ guidelines, it caused shortages of staff in the short run, which had negative effects over implementation of the adopted guidelines. To

support clinics with TA, the UNC Project's TA providers used two forms: audit and feedback and collaborative delivery of services approach. The UNC Project supported clinics with tools such as SOPs and flow charts and supplemented various resources such as HIV testing kits when clinics ran short of them. Among the support provided by the UNC Project, clinics valued TA, tools, and resources most.

Aim 2 and 3: Description of Contextual Factors

This section describes contextual factors that either influenced the UNC Project's TA delivery or implementation of the Option B+ guidelines at the study clinics. The identified contextual factors include environmental issues that were either facilitators/enhancers or barriers/inhibitors to TA delivery or to implementation of the Option B+ guidelines and occurred at the clinic, patient/community, or systems level. Factors that occurred at the clinic level are hereafter referred to as inner contexts while those that occurred at community and systems levels are outer contexts. The first part of this section describes contextual factors that influenced delivery of TA and second are those factors that influenced implementation of the Option B+ guidelines at the study clinics. Variation in which identified contextual factors influenced either TA delivery or implementation of the Option B+ guidelines between the low- and high-performing study clinics are discussed after each section.

Aim 2: Contextual Factors That Influenced Delivery of the Technical Assistance (TA)

Contextual factors that either enhanced or hindered TA are described here. The section describes ways in which TA varied across the study clinics and variation in contextual factors that influenced TA delivery. Table 5 displays ways in which TA varied and Table 6 shows the variation in contextual factors that emerged as influencers of TA delivery between the low- and high-performing clinics.

Ways in which technical assistance (TA) varied. The UNC Project's TA delivery varied across the four study clinics in the way it strengthened implementation, in the TA providers' area of focus, and in its dose (i.e., the time in hours that were spent by TA providers on guidelines' activities in clinics or communities).

Strengthening implementation. At HP-1 clinic and LP-2 clinic, TA was reported to have strengthened implementation mostly through hands-on consultations and feedback meetings. At HP-1 clinic, TA was also reported to have strengthened implementation through the conduct of several collaborative community mobilization activities. In addition, at both HP-1 and LP-2 clinics, TA assisted in leveraging for more staff through lobbying from the district health office and through hands-on care. This was not the case at the HP-2 and at LP-1 clinics, where TA was reported to have strengthened implementation mostly through feedback meetings and did not assist in leveraging for more staff.

Focus and dose. TA focus encompasses the frequency and approximate amount of time spent on each unit or activity by the TA providers. TA dose was determined by calculation of the approximate amount of time in hours overall that were spent on guidelines' activities at the clinics or in communities each month.

Although TA focus varied from clinic to clinic, this study revealed that all TA providers focused most on documentation issues such as proper documentation of the rendered ART and PMTCT care in various clinic registers and cards and on report writing. TA providers varied in how much they focused on other areas. At HP-1 clinic, TA providers focused their effort on antenatal care and ensuring that pregnant women got HIV testing and if tested positive, were initiated on the lifelong antiretroviral therapy (ART). At HP-1 clinic, TA providers' observations centered on nurses' work in the antenatal clinic. At HP-2 and at

LP-1 clinics, TA providers focused on early identification and diagnosis (EID) of the HIV-exposed infants. Contrary to other study clinics, TA providers at LP-2 clinic focused on all units that were involved in implementation of the Option B+ guidelines. The following quotes illustrate how TA focus varied across the study clinics:

From TA providers at HP-1 clinic:

The technical assistance is not usually rendered in maternity and also in family planning because we are concentrating much on antenatal, HTC [HIV Testing and Counseling] and exposed infants.

We helped with the actual antenatal care provision specifically HIV counseling and Testing, and documentation in the registers.

From the district coordinator for HP-2 clinic:

They were doing supportive supervision and mentorship mainly in the EID [early infant diagnosis]....supportive supervision mainly focused on capacity building especially to the service providers. They could go through the pink card together and then through the log books. So, it was like a walk through the EID programme.

In the words of the TA provider for LP-1 clinic:

...this mainly focused on DBS [dried blood spot], though other information for antenatal is there but it was not much information, but mostly we were following up the babies for DBS.

The TA provider for the LP-2 clinic said:

What I was doing it's like today I go for maternity, so I will be assisting in maternity for the whole day, next week I will go for antenatal and the other day I go for HTC [HIV testing and counseling].

And the service provider at LP-2 clinic explained:

.....most of the times their supervision visits targeted areas where the PMTCT activities are done, up to the place where infants are taken their samples as well as the follow ups.

There was a wide range of variation in TA dose at clinic level across all the four study clinics (approximately from 1 ½ hours once per month at LP-1 to approximately 6 hours, one to two times per month, at LP-2). TA dose on collaborative community

mobilization activities ranged from one full day once at the beginning of the UNC Project's support program at LP-2 clinic to several times each quarter at HP-1 clinic.

Although variation occurred in the way TA was delivered, this study did not find any variation in types of the prevention support strategies that can help to explain variation in implementation of the Option B+ guidelines between the high- and low-performing study clinics.

Table 5. Ways in which Technical Assistance (TA) Varied

TA indicator	Clinic Code			
	HP-1	HP-2	LP-1	LP-2
How TA strengthened implementation	Hands-on consultations Feedback meetings Collaborative community mobilization activities Lobbied for more staff	Feedback meetings	Feedback meetings	Hands-on consultations Feedback meetings Lobbied for more staff
TA Focus	Antenatal care and documentation (6/6)	EID (4/5) and documentation (5/5)	EID (4/5) and documentation (5/5)	All ART/PMTCT units and documentation (5/5)
TA Dose at clinic	Approx. 5hrs, 1 to 2/month (4/6)	Approx. 3 hrs., 1/month (4/5)	Approx. 1 ½ hrs., 1/month	Approx. 6 hrs., 1-2/month (5/5)
TA Dose at community	One full day, once every quarter (2/6) to several times of collaborative community mobilization activities (4/6)	Collaborative community mobilization activities' dose couldn't be established	Collaborative community mobilization activities' dose couldn't be established	One full day of collaborative community mobilization activities, once at the beginning of the TA support (5/5)

EID= Early infant diagnosis, LP-1= Low Performing clinic 1, LP-2= Low Performing clinic 2; HP-1= High Performing clinic 1 and HP-2= High Performing clinic 2; Numbers in parentheses indicate a proportion of informants who agreed to the point

Contextual factors that influenced delivery of the technical assistance (TA).

Staffing and transportation emerged as the most salient contextual factors influencing TA delivery (see Table 6).

Staffing. Staffing emerged from all informants as an inner and outer contextual factor that influenced delivery of the TA to all four study clinics. **Shortage of staff who worked as TA providers from the UNC Project and of those who worked as the service providers at the clinics negatively influenced TA provision.** For the three-year period 2011–2014, the UNC Project employed 1 or 2 TA providers to work with each of the three districts. Although there was no variation in the number of TA providers between the high- and low-performing clinics, almost all informants reported that shortage of TA providers was a barrier to delivering all the planned TA visits per day. This is because TA providers had to visit more than one clinic per day for them to deliver TA to all clinics that were located within their assigned districts per month. The following quotes illustrate shortage of TA providers and how it affected TA delivery. In the words of one of the TA provider at HP-clinic:

...at first I was the only one, and then my friend [a colleague] joined me nine months before the end of the project.

In the words of the service provider at one of the LP- clinics,

[T]hey should at-least have a reasonable number of such officers so that they should be scattered all over because he was alone by then so it was a challenge for him to cater for the whole district.

Variation occurred in how shortage of clinic staff affected delivery of TA between the high- and low-performing clinics. **Periodic staff reassignments were the main cause of shortage of staff at both high-performing clinics while a critical shortage of staff was reported to have existed in both low-performing clinics and to negatively affect TA.** Both high-performing clinics reported having enough staff across all health professionals

who were involved in the implementation of the Option B+ guidelines. At both high-performing clinics, most staff except the Health Surveillance Assistants (HSAs), who also worked as the HIV counselors and Under-Five service providers, were described as available at clinics and received most of the planned TA. The general cause of shortage of service providers at both high-performing clinics was staff reassignments to other duties outside of their respective clinics. Examples of staff reassignments included attending to residential trainings and conducting community outreach activities. TA providers could not find some of the nurses, clinicians, or HSAs at the clinics because they were attending to other duties outside their practice clinics. The most affected units were the Under-Five and HIV testing, where TA providers could not often find the HSAs who were the only cadre that was trained on early infant diagnosis (EID) of the HIV-exposed infants. The HSAs were mostly living and working in their respective communities and yet clinics trained and used them as Under-Five service providers and counselors in general HIV and in ART/PMTCT of HIV. Another reason why TA providers failed to meet with service providers, especially the HSAs at both high-performing clinics, was a failure to share the TA visit schedule with the clinics. Because service providers at the clinics did not know when TA providers would visit their clinics, they often planned to attend to other duties on the same dates. Another staff reassignment example that had negative effects over TA provision was transferring out of the clinic staff that was trained to implement the Option B+ guidelines and replacing them with untrained ones. The negative effects came in because untrained staff had no capacity to implement the Option B+ guidelines that TA providers were supporting.

In addition to staff reassignment causing shortage of staff, there was an existing critical shortage of staff across all cadres at both low-performing clinics. For example, a

critical shortage of nurses often meant that TA providers could not meet with the clinic staff because nurses were either busy serving patients or out of the clinic to attend to other duties. Instead of delivering TA, TA providers ended up helping with implementation of the Option B+ guidelines' activities. The following quotes illustrate how staffing at the study clinics affected TA delivery and how it varied between the high- and low-performing clinics. In direct words of the TA provider whose job was to deliver TA at one of the high-performing clinics:

Often times we were able to find them, but to the exposed infants, the HSAs [Health Surveillance Assistants] could not be found regularly...also at HTC [HIV Counseling and Testing] we could not find the responsible personnel regularly as well.

In direct words of the district coordinator representing one of the high-performing clinics:

...there are two counselors and there is a provider every time; both of them are never absent at the same time...

In contrast to the previous quotes, the following are quotes from informants who represented the low-performing clinics:

In direct words of the TA provider:

...sometime we could not find them, they could have gone to work shops and most of the times there is one nurse and one clinician and if one has gone for other services it meant some services suffered....

In direct words of the service provider at one of the low-performing clinics:

...but this problem still related to shortage of human resource because if someone is alone like the way I am, that means there is no other person to relieve me.....if I go out or else all of us [nurses and clinicians] are called at the district, it means all the services will not be done because people who are wanted at the district are the same people who are supposed to work here...

Transportation to clinics. TA providers' ability to transport themselves to clinics was affected by fuel availability, their mode of transportation, distance to clinic, and quality of the roadways. Transportation emerged as a contextual factor that varied in the way it

influenced delivery of TA between the high- and low-performing clinics. First, all TA providers complained of fuel problems and inadequate means of transportation to deliver TA to the study clinics. Shortage of fuel was a country-wide problem at the beginning of the UNC Project's support program. Variations occurred on the distance TA travelled from their offices to clinics, their mode of transportation as it related to the location of the clinics, and the quality of the roadways TA providers used to travel to the study clinics.

TA providers' offices were located within or close to the district health offices at the district level. The distance between the district office and clinics does not explain variation in TA delivery between the high- and low-performing clinics. TA providers who delivered TA to the two high-performing clinics traveled 23.02 km (14.31 miles) to HP-1 and 138.81 km (86.25 miles) to HP-2. Distances travelled by TA providers who delivered TA to the two low-performing clinics ranged from 36.93 km (22.95 miles) to 50.03 km (31.09 miles) to LP-2 and to LP-1, respectively. All TA providers reported travelling long distances from their offices to clinics and between clinics because they were required to deliver TA to more than one clinic per day. Long distance travelled by TA providers from clinic to clinic affected TA delivery in that much time was spent travelling and the first clinic visited each day got more time than the second.

TA mode of transportation as it related to the location of the clinics showed some variation between the high- and low-performing clinics. TA providers who supported three of the study clinics (one high- and two low-performing) used a motorcycle to deliver TA to supported clinics in their districts while to the fourth clinic, TA providers used a car. Although one of the high-performing clinics used a motor car and the other a motorcycle, both clinics are located along a well-paved road. The well-paved roads enabled TA providers

to support both high-performing clinics with all the planned TA throughout the support period regardless of their mode of transportation. However, those who used motorcycles to deliver TA to both low performing clinics had more limited access when unpaved roads became muddy and impassable during the rainy season (December through April). During the rainy season, TA providers reported traveling either with the Malawi Ministry of Health district management team during their supervisory visits or borrowing a car from the UNC Project central office to deliver TA. However, they were not always able to do so.

Table 6. Contextual Factors that Influenced TA Delivery

Contextual factors	High-performing clinics	Low-performing clinics
Staffing	<ol style="list-style-type: none"> 1. Shortage of TA providers <ul style="list-style-type: none"> • At most, 2 TA providers were assigned to deliver TA to 28 and 43 clinics respectively within the districts where the study clinics were located per month. 2. Relatively, both clinics had enough staff to implement the Option B+ guidelines (6/11). <ul style="list-style-type: none"> ➤ Most staff except HSAs were available at clinics and received most of the planned TA. • Periodic staff reassignment to other duties caused shortage of staff (11/11). <p>Examples of staff reassignments:</p> <ul style="list-style-type: none"> ➤ Attending to a residential training ➤ Conducting community outreach activities • Staff transfers. Staff trained to implement the Option B+ guidelines were replaced by untrained staff. • Failure to share TA visit schedule with the clinics was another reason why TA providers failed to often meet the HSAs at both clinics. 	<ol style="list-style-type: none"> 1. Shortage of TA providers <ul style="list-style-type: none"> • At most, 1 to 2 TA providers were assigned to deliver TA to 13 and 28 clinics respectively within the districts where the study clinics were located per month 2. Extreme shortage of clinic service providers (10/10) <ul style="list-style-type: none"> ➤ Extreme shortage of staff often meant that TA providers could not meet with the clinic staff. ➤ Instead of delivering TA, TA providers ended up helping with implementation of the Option B+ guidelines' activities. • Shortage of housing (6/10) and period staff reassignment (10/10) to other duties caused extreme shortage of staff <p>Examples of staff reassignments:</p> <ul style="list-style-type: none"> ➤ Attending to a residential training ➤ Conducting community outreach activities ➤ Staff transfers. Staff trained to implement the Option B+ guidelines were replaced by untrained staff. • Failure to share TA visit schedule with the clinics was another reason why TA providers failed to often meet the HSAs at both clinics.

Contextual factors	High-performing clinics	Low-performing clinics
Transportation to clinics	<p>TA transportation to clinics was affected by:</p> <ul style="list-style-type: none"> • Fuel availability <ul style="list-style-type: none"> ➤ At the beginning of TA program, there was a country wide shortage of fuel in Malawi • TA providers' mode of transportation <ul style="list-style-type: none"> ➤ 1 used a car and the other used a motor cycle • Distance to clinic from TA offices <ul style="list-style-type: none"> ➤ 1 clinic was 23.02 km (14.31 miles) away ➤ and the other was 138.81 km (86.25 miles) away • Quality of the roadways from TA offices to clinics <ul style="list-style-type: none"> ➤ Both were well paved with tar mark 	<p>TA transportation to clinics was affected by:</p> <ul style="list-style-type: none"> • Fuel availability <ul style="list-style-type: none"> ➤ At the beginning of TA program, there was a country wide shortage of fuel in Malawi • TA providers' mode of transportation <ul style="list-style-type: none"> ➤ Both used motor cycles • Distance to clinic from TA offices <ul style="list-style-type: none"> ➤ 1 clinic was 50.03 km (31.09 miles) away ➤ and the other was 36.93 km (22.95 miles) away • Quality of the roadways from TA offices to clinics <ul style="list-style-type: none"> ➤ Both were along dusty/Muddy roads ✓ 1 clinics was located 12 km (7.8 miles) away from a well paved tar mark road ✓ And the other was 10 km (6.4.miles) away from a well paved tar mark road

TA=Technical Assistance; HSAs= Health Surveillance Assistants; Km= Kilometers; Numbers in parenthesis= a total number of informants who agreed to the theme.

Aim 3: Contextual Factors that Influenced Implementation of the Option B+ Guidelines

Contextual factors that either enhanced or hindered implementation are described next. First, the section describes implementation of the components of the Option B+ guidelines and then variation in the inner and outer contexts that influenced guidelines' implementation among the two high- and two low-performing clinics. Table 2 displays variation in characteristics of the study clinics/cases and Table 8 displays variation in themes that emerged as either inner or outer contexts between the low- and high-performing clinics.

Implementation of core components of the Option B+ guidelines. To determine implementation of the core components of the Option B+ guidelines, this study assessed clinics' implementation fidelity to the guidelines. According to Brownson, Colditz, and Proctor (2012), "implementation fidelity is the degree to which an intervention is implemented as it is prescribed in the original protocol" (p. 35). Therefore, implementation for this study refers to the extent to which clinics carried out the core components of the Option B+ guidelines. Option B+ guidelines' core components were used to compare with what is implemented at the practice setting in terms of adhering to the Option B+ guidelines and the quality of the program delivery (Brownson et al., 2012). Table 7 summarizes clinics' reports of their perceived implementation of each of the core components. To come up with the presented summary, all the study informants were asked to what extent the study clinics were carrying out each of the listed core components. Responses were ranked from 0 to 3, with 0 assigned when the interviewee reported that the component was not implemented, 1 assigned when implemented only minimally, 2 assigned when implemented most of the time, 3 when implemented all the time as specified by the Option B+ guidelines. Each clinic's responses were then averaged for each item to create a final score.

Clinics reported full implementation of most of the core components. Although all four clinics reported that they were implementing most of the Option B+ guidelines' core components, a few variations occurred in how the study clinics rated their perceived implementation. An outstanding performance in self-report of almost all the core implementation components was reported to have occurred at high-performing clinic 2 (HP-2 clinic) with an overall score of 2.8 on a scale of 3.0. Perceived implementation at both low-performing clinics was at 2.3 on a scale of 3.0.

Among the core components, all clinics reported doing well on identifying women in need of an HIV test, offer of and provision of an HIV test, initiation of recommended antiretroviral drugs (ARVs) to all HIV-infected women, supplying Nevirapine syrup to them on the day of their HIV diagnosis, and conduction of health education to inform HIV-infected women and their family members that once ARVs are started they must be taken every day for life (see Table 7). To comply with implementation of the stated core components, all the study clinics made sure that pregnant and breastfeeding women and their family members (e.g., sexual partners/spouses) who sought care at these clinics were made aware of the Option B+ guidelines through clinic-based routine health education. Clinics made sure that all pregnant and breastfeeding women and their family members (i.e., sexual partners/spouses and children) received an HIV test by either what most informants called “mandatory” or routine offer of the test to them. Clinics were able to check on page 6 of all women’s health passport books to determine the women’s HIV status at each visit. They made sure that pregnant and breastfeeding women who tested HIV-positive were initiated on the first line antiretroviral drugs such as a one-pill combination of Tenofovir/Lamivudine/Efavirenz (known as 5A regimen in Malawi) on the same day of their

HIV diagnosis. Clinics also made sure that HIV-infected women and their family members were educated that the antiretroviral therapy (ART) that was initiated on them was life-long. Almost all HIV-infected pregnant and newly delivered women were supplied with three bottles of 25mls each of Nevirapine syrup for their HIV-exposed children on the same day of their HIV-positive diagnosis.

However, an assessment of perceived implementation revealed that activities related to community sensitization and mobilization, documentation and on ascertaining HIV status for the HIV-exposed children at 6 weeks, 12 months, and 24 months were the components that some clinics did well while others did not (see Table 7). All but HP-2 clinic minimally conducted community sensitization and mobilization activities; all but the LP-1 clinic reported documentation problems; and neither of the low-performing (LP) clinics fully identified and ascertained the HIV status of the HIV-exposed children at 6 weeks and 12 and 24 months.

Table 7. Study Informants' Perceptions of Implementation

Activity	HP-1	HP-2	LP-1	LP-2
1. Community sensitization and mobilization activities.	1	3	0.2	1
2. HIV testing of all pregnant and breast-feeding women at each visit.	2.6	3	2.4	3
3. Checking health passport to determine HIV status at each visit.	2.6	3	3	3
4. Routinely offering an HIV test through provider-initiated HIV testing and counseling to all pregnant and breastfeeding women who seek health care services at this clinic.	2.8	3	2.4	2.6
5. Conducting health education that is designed to inform the HIV-infected women and their family members that once antiretroviral drugs (ARVs) are started, they must be taken every day for life.	3	3	3	3
6. Initiation of lifelong combined ART, such as Tenofovir/Lamivudine/Efavirenz (5A regimen), to all identified HIV-infected pregnant and breastfeeding women on the day of or within seven days of HIV diagnosis regardless of woman's CD4 count or her clinical stage.	3	3	3	3
7. Supplying three bottles of 25mls each of Nevirapine (NVP) syrup to all HIV-infected women for their HIV-exposed babies at first opportunity once the woman is known to be HIV-infected.	3	3	3	3
8. Initiating the integrated mother/infant follow-up scheduling.	2	2.6	3	2.6
9. Ascertaining HIV status for all the HIV-exposed children by, collecting at least one deoxyribonucleic acid-polymerase chain reaction (DNA-PCR) sample from each HIV-exposed child from the age of six weeks?	3*	2.6*	1.8*	1.4
10. Ascertaining HIV status for all the HIV-exposed children by collecting all the recommended HIV tests for the HIV-exposed children?	2.6*	3*	2.2*	1.6
11. Proper documentation of all rendered PMTCT activities in correct registers or cards.	1.5	2	3	1
Overall rating	2.5	2.8	2.3	2.3

(Scale of 0-3 with 0=Not implemented; 1=Implemented minimally; 2= most; 3= all the time)

LP = Low Performing clinic, HP = High Performing clinic; *= for those babies who reported to the facility

Variations in contextual factors that influenced implementation of the Option

B+ guidelines. There were several factors that were identified as either facilitators/enhancers or barriers/inhibitors to implementation of the Option B+ guidelines that were common across all four study clinics. This section describes variation in the identified contextual factors among the two low- and two high-performing clinics. Table 2 displays characteristics of the clinics/cases as part of the outer and inner contexts and how they varied across all the study clinics. Table 8 summarizes patterns of themes in contextual factor variations across the high- and low-performing clinics. As indicated in Tables 2 and 8, the magnitude of the served population (outer context), size of the clinic staff, service space/infrastructure, and stocks of the HIV test kits (inner contexts) emerged as contextual factors that varied most between the high- and low-performing clinics.

Magnitude of the served population. Magnitude of the population each clinic served was determined not only by the clinic's official catchment area, total number of pregnant women seen, and annual deliveries at a facility but also by the clinics' location as it related to other bordering countries and facilities that also adopted and implemented the Option B+ guidelines. Catchment area is an estimated total number of people who live in the communities from which clinics' patients/clients are drawn to receive healthcare services at a specific health facility. In the Malawian context, the communities that make up specific catchment areas comprise areas ruled by the Traditional Authority chiefs. Magnitude therefore was operationalized as the total catchment area served by the study clinics, the total number of pregnant women seen, the total deliveries at the study clinics, and the total HIV prevalence rate of the study clinics during the Fiscal Year 2012-2013. Magnitude was one of the contextual factors that showed the most variation between the low- and high-performing

clinics (See Table 2 and Table 8). Although the Malawi Ministry of Health has established official catchment areas for every health center (i.e., a total number of people to be served by each clinic), location/site of the study clinic contributed much to the magnitude of the population the clinics served. Even though all the study cases were located in the central region of Malawi, a cross-case comparison showed that the site-specific location of the two low- and two high-performing clinics had some similarities between them but greatly varied across them (see Table 2 and Table 8).

Both high-performing clinics were located in rural areas and were surrounded by other health facilities that also implemented the Option B+ guidelines and offered maternity and ART services. One of the high-performing clinics is also surrounded by 3 other health facilities (1 public, 1 private and 1 that belongs to Christian Hospitals' Association of Malawi) that serve the same population the high-performing clinic does. Since all the other surrounding health facilities also implemented the Option B+ guidelines, one of the high-performing clinics served only a population that lives within its designated catchment area while the other served less people than its designated official catchment area. This is because women and their family members could choose among the four health facilities in their area where to access care to prevent mother-to-child transmission of HIV.

In contrast, both of the low-performing clinics were located at a very remote area, at the border between Malawi and other countries, and both were surrounded by facilities that did not implement the Option B+ guidelines and had no maternity and ART services. Since both of the study clinics implemented the Option B+ guidelines and had maternity and ART services, women and their family members from facilities that did not have the services accessed all the needed care at these study clinics, causing both of the low-performing clinics

to serve a higher population than what was designated to them. This is because both clinics bordered with other countries that led to women and their family members from other countries accessed maternity, HIV, ART and all services that are offered to prevent mother-to-child transmission of HIV at the study clinics. All services that are offers at Malawian Ministry of Health facilities are free and Malawi does not have a national identification measure that can help identify Malawians from non-Malawians from surrounding countries. In addition, people in the borders share similar culture, language, and even disease patterns that prohibited both of the study clinics denying care to women and their family members from other countries. It is also a medical requirement that any person seeking care at a health facility has to be treated. Due to clinics' overpopulation, both the low-performing clinics suffered work overload and frequent shortages of resources that hindered implementation of the Option B+ guidelines. A detailed example of how work overload and frequent shortage of resources hindered implementation of the Option B+ guidelines is described under size of the clinic staff and stocks of HIV test kits below.

A cross-case comparison of the magnitude of the population served by the study clinics using the Malawi Ministry of Health established catchment areas showed that the high-performing (HP) clinic 1 had the largest official catchment area (69,562) among all the four study clinics. However, this clinic only served the people from within its catchment area. The HP clinic 2 had the smallest catchment area among the four study clinics—it together with 3 other health facilities served a total catchment area of 19,595 people. Critical analyses of both low-performing (LP) clinics indicated that the populations they served were bigger than that of both the high-performing clinics. This is because the LP-1 clinic served an established total catchment area of 37,571 and the LP-2 clinic served 51,289 people but both

served an additional population from other facilities and countries. An example of how much smaller both HP clinics were is given by the total annual number of pregnant women who accessed care and the total number of deliveries conducted during the Fiscal Year 2012-2013 at each of the study clinics (see Table 2).

Size of the clinic staff. As an inner context, size of the clinic staff was operationalized as the total number of clinic staff who were trained to implement the Option B+ guidelines and the actual total number of clinic staff who were involved in the implementation of the Option B+ guidelines. Staffing emerged as one of the contextual factors that varied most in the way it influenced implementation of the Option B+ guidelines between the high- and low-performing clinics.

Although the previous section on magnitude of the served population indicates that both low-performing clinics served larger populations than the high-performing clinics, the size of the clinic staff measured by the total number of staff trained and involved in implementation of the Option B+ guidelines was much smaller for both low-performing clinics than that of the high-performing clinics (See Table 2). For example, HP-1 clinic trained and used 7 nurses; the HP-2 clinic trained and used 3 nurses; both low-performing clinics trained and used only 2 nurses to implement the Option B+ guidelines. In addition, both HP clinics received additional staff from other partner organizations that helped with hands-on implementation of the Option B+ guidelines at either the community (at HP-2 clinic) or clinic (at HP-1 clinic) level while both of the LP clinics used only the existing staff employed by the Malawi Ministry of Health. For example, HP-1 clinic received 2 additional HIV and testing counselors from one of its partner organizations and at least two additional clinicians (i.e., medical assistants or clinical officers) from two other partner organizations to

help with implementation of the Option B+ guidelines and to serve patients on ART. The HP-2 clinic received additional outreach workers from a partner organization to help with continuous community mobilization and outreach activities about the implemented Option B+ guidelines in communities served by the clinic. The additional outreach workers worked hand-in-hand with the clinic as they helped with dissemination of the implemented Option B+ guidelines and follow-ups of the HIV-infected women and their HIV-exposed infants to keep them in care.

From thematic analysis, variation in clinic size was evident because staffing arose as a factor that enhanced implementation of the Option B+ guidelines at both high-performing clinics but hindered its implementation at both low-performing clinics (see Table 8).

Although staff reassignments to other duties other than implementation of the Option B+ guidelines at the clinics caused shortage of staff across all four study clinics, staff was described as adequate at both high-performing clinics while a critical shortage of staff was reported to have existed at both low-performing clinics. Staff were adequate at both high performing clinics as at least one provider was present at each unit that served patients/clients on antiretroviral therapy (ART) or those seeking interventions to prevent mother-to-child transmission of HIV. Availability of staff at the clinic made women and their family members access most of the care at both high-performing clinics.

In contrast, a critical shortage of staff was reported to have existed over a long period at both low-performing clinics, which had negative effects over implementation of the Option B+ guidelines. It was a general outcry from all 10 study informants (i.e., the TA providers, district coordinators, and service providers at both clinics) that both the low-performing clinics had suffered a critical shortage of staff since the adoption of the

implemented Option B+ guidelines and continue to do so. Due to shortage of staff, the whole facility was manned by only one or two nurses and a medical assistant; hence both clinics failed to fully implement the Option B+ guidelines according to the set standards. A critical shortage of staff meant that a high volume of patients were attended to by few staff, leading to staff work overload, lack of motivation, and burnout. Due to high workload, patients waited hours to receive the HIV, ART, and services required to prevent mother-to-child transmission of HIV, leading some women and their family members to abscond from their care. These overloaded clinics sometimes used support staff such as cleaners and watchmen to help with implementation of the guidelines' activities (e.g., documentation and ART drug resupply) or else women and their family members were turned away from accessing the care they needed to prevent HIV transmission to their children. Although use of unprofessional staff was the only option that was available to boost staffing numbers by both of the low-performing clinics, this approach compromised the quality of the implemented Option B+ guidelines and led to poor performance outcomes. The most cited cause of an existing shortage of staff at both clinics was lack of staff housing to accommodate more staff. In addition, both clinics were located at a very remote area where staff could hardly access the rental housing in surrounding communities, so staff used to refuse to be deployed to such facilities. Lack of housing led the managers at the district level to fail to deploy more staff to both of the low-performing clinics.

In addition to the existing shortage of staff at both low-performing clinics, staff reassignments to other duties outside of their respective clinics caused additional shortage of staff and hindered implementation of the Option B+ guidelines across all the four study clinics. Examples of staff reassignments are attending to an off-site residential training and to

community outreach activities and transferring out of staff that were trained to implement the Option B+ guidelines to other clinics and replacing them with untrained ones. When staff was out of his/her respective clinics to attend to other duties, it either caused shortage of staff at high-performing clinics or temporarily closing of the clinics at both low-performing clinics. Transferring out of staff hindered implementation because the untrained staff who replaced those who were already trained had no capacity to implement the guidelines.

In conclusion, variation in size of the clinic staff verses clinic' magnitude of the served population areas provides partial explanation as to why there was variation in implementation of the Option B+ guidelines between the low- and high-performing clinics. The following quotes illustrate how staffing varied in the way it influenced implementation of the Option B+ between the high- and low-performing clinics: From the service providers at the high-performing clinics:

...to be honest as a health center, we have adequate staff. I can compare with other health centers which have just one nurse; but we have three nurses, two clinicians... We also have [name of the organization withheld] staff that follow pregnant women up to time of delivery. They ask the women if they started antenatal clinic and if they got tested for HIV. They also sensitize them on the importance of HIV testing; and that has helped because the women are coming...

[W]e have adequate staffand I feel that this is a great strength, because you know that whenever you are away from the facility, you are assured of continuity of the services...

From service providers at the low-performing clinics:

...[T]he workload here is high, it is very high but staff that are supposed to do the job are very few....it is a very big challenge because the work that is done here require more people than we are....Monday to Sunday, 24/7, we [nurses and clinicians] are found at this facility because patients do come any time to seek for help, so we do not have time to rest....the HSAs [Health Surveillance Assistants] also have a lot of work. As a result [care for] the HIV positive woman is withheld until all babies who come for immunizations are assisted. As the time go by, that woman just leaves the facility without being assisted.

....it's a big challenge because there is always one individual on duty. For example I am the one on duty and I am working day and night. You know labor ward is always very busy I will not manage to attend to the labor ward, Antenatal, Family Planning and OPD [Out Patient Department]. The result is that some other clients are sent away...

[T]here is no way I can help the woman fully if there is less staff....For example am working day and night, so there is no way I can help the woman fully as per guidelines..... because, when it is day time; I am the very same person who needs to attend to family-planning women, antenatal women and labor ward.....sometimes am too busy, too tired, at the end of the day, I may leave the woman because I was too tired.

[T]he issue of human resource is a long standing problem and we do not even know if it will be solved---we do not know if a day will come that this facility will have additional staff. Always when this problem is presented, the immediate answer is 'if we deploy other staff there, where are they going to live?' So the issue goes back to lack of housing, they [district managers] say there are no houses here for them to deploy other staff members.... nurses are graduating, medical assistants are graduating in numbers but now the challenge is with housing....

As described above, staff reassignment was one of the common causes of shortage of staff across all the study clinics but varied in the way it influenced implementation of the Option B+ guidelines between the high- and low-performing clinics. In both high-performing clinics, the most affected units by staff reassignment were those mostly managed by the Health Surveillance Assistants (HSAs) while all units were affected at both low-performing clinics. The following quotes show how staff reassignment affected implementation: In direct words of the TA providers at the high-performing clinics:

[M]ost of the HSAs [Health Surveillance Assistants] were working in the community and so whenever there is an activity in the community they could go....and the HTC [HIV counseling and testing] services would suffer.

Most of the times we could not find HSAs because they were conducting outreach clinics or at their respective health posts and so the mothers at under-five clinic could not be tracked very well.

In the words of the TA provider at one of the low-performing clinics,

[W]hen you do not find a nurse, you were also finding that the services are not offered because there was only one nurse.... And we could find some HSAs [Health Surveillance Assistants] had gone for campaigns, like the immunization campaign, nobody was there to provide HIV counseling and testing.

From a service provider at one of the low-performing clinics,

[I]t is happening that you are in training, you are being called to another trainingFor example the past six weeks I was out....while I was there, I was also called to attend one week training in PAC [Post Abortal Care]..... I made an excuse but they said they wanted me. So I was forced to continue..... but my friend [a colleague at the clinic] was alone. The end result was that she got tired and... was not attending to family planning, antenatal clinic.....she could not do otherwise because she reported to the bosses and the bosses could not assist.... So we just agreed that 'let you just attend to the labor ward and send away those for other services.'

Service space/infrastructure. Availability of service space/infrastructures that accommodated all units that implemented the Option B+ guidelines was another theme that emerged as an enhancer to implementation of the Option B+ guidelines at both high-performing clinics while limited space at both low-performing clinics was identified as something that hindered quality implementation of the Option B+ guidelines (see Table 8).

Although both high-performing clinics described space as not adequate for all services that are offered at the facility, both clinics reported to have space to implement the Option B+ guidelines. All maternal and child healthcare services (i.e., antenatal, labor and delivery, family planning, and Under-Five services), including HIV counseling and testing, ART and all services that clinics offered to prevent mother-to-child transmission of HIV were either offered under one roof or just in the adjacent buildings. In addition, all activities in the prevention of mother-to-child transmission of HIV continuum of care (e.g., HIV counseling and testing, ART initiation, antenatal care, labor and delivery care, Under-Five and early infant diagnosis care) had at least a room where service providers used to offer the services to women and their family members. Availability of space and the design of the

clinics' infrastructure were described as enhancers to implementation of the Option B+ guidelines by both high-performing clinics because they aided women and their family members to easily access all the HIV-related care without being delayed or getting lost at the clinic. Availability of space led clinics to care for their HIV-infected and affected patients in private and confidential rooms. Availability of space coupled by adequate staff also aided the clinics to offer all the HIV-related activities on daily basis, leading many women and their family members to access care at their convenience, hence maintaining them in care. In addition, HP-1 clinic had a big maternity waiting home with a capacity of about 100 women and their family members who wished to stay over and wait for labor and delivery at the facility. The maternity waiting home enhanced implementation of the Option B+ guidelines such that women and their family members who resided far from the facility accessed the required services that are designed to prevent HIV transmission to their children during the labor and delivery period.

In contrast, both low-performing clinics reported to have very limited space to effectively implement the Option B+ guidelines. Almost all services related to implementation of the Option B+ guidelines were provided in either one or two rooms. Lack of service space caused long waiting time for patients/clients and led to lack of privacy and confidentiality that made some of the women and their family members abscond from accessing their HIV-related care. Due to inadequate space coupled by a critical shortage of staff with a high volume of patients, both low-performing clinics failed to offer all the services that are designed to prevent mother-to-child transmission of HIV on a daily basis, leading to some women and their family members missing their clinic appointments because they had to frequently return to the clinics to fully access the HIV-related care such as ART,

counseling and HIV testing for their children. The following quotes illustrate how service space/infrastructure varied in the way it influenced implementation of the Option B+ guidelines between the high- and low-performing clinics:

In the words of the TA providers at the high-performing clinics:

[T]he structure itself; it is user friendly in the sense that everything is done under one roof, like the HIV Testing and Counseling, antenatal, initiation of ART and even vaccinations were done under one roof. So there was no discrimination because every antenatal mother went through all the rooms...unlike other health facilities where you have a separate room for ART initiation, and an antenatal room and HTC [HIV testing and counseling] far apart from each other.

[T]hey have a structure which normally has the HTC [HIV testing and counseling], the ART clinic room at the same structure and the antenatal services in that same structure.....so, chances of missing the mothers are very slim.

A district coordinator who represented one of the high-performing clinics said:

I can say they [ART/PMTCT services] were properly structured because it is the same building whereby the women get to one room and screened, from there to another room in the same building for antenatal services, HTC [HIV testing and counseling], they come back then are given ART in the same room.

In contrast, the following quotes illustrate how service space/infrastructure hindered implementation of the Option B + guidelines at both low-performing clinics:

From district coordinators:

In terms of client flow it was not all that good because HTC [HIV testing and counseling] was like a stand-alone, there is antenatal on one side and there is HTC on the other side.... so it is easy for the women to run away or skip other services. But if the services were provided at one place then I think it would have been much better.

The issue is the building, especially the one that is used for PMTCT; it is not all that conducive because if we look at the room is just too small... I can say we have a room where they use for antenatal services and it's where the drugs are being given.... and that antenatal room that I'm saying is just too small, it's just next to the waiting area and the more you delay there, people who are outside think something about you.

A service provider at one of the low-performing clinics said:

We do not have rooms to use for these services at this facility. We don't have ART clinic room...we do borrow an OPD [Out Patient Department] room or here at the ANC [antenatal clinic]...what happens currently is that we sit here discussing such issues, you will see someone enters the room which is not on, so the woman doesn't feel comfortable.

Stocks of the HIV testing kits. Stocks of the HIV testing kits emerged as a theme that varied in the way it influenced implementation of the Option B+ guidelines between the high- and low-performing clinics. HIV testing kits are among the HIV commodities that are essential to implement the Option B+ guidelines at clinic level. All four study clinics reported to have received their HIV commodities (i.e., the antiretroviral drugs, HIV testing kits, and Cotrimoxazole antibiotic) direct from the HIV/AIDS unit of the Malawi Ministry of Health central office. The HIV commodities were transported to all individual clinics by the Central Medical Stores as a contracted organization by the HIV/AIDS unit of the Malawi Ministry of Health.

Among the enhancers to implementation of the Option B+ guidelines, availability of all types of HIV testing kits and a good supply chain management of the HIV commodities was one of the salient factors reported by both high-performing clinics. Almost all high-performing clinics' informants reported that HIV testing kits were mostly available. One of the high-performing clinics (HP-1) reported to have never experienced stock-outs of the HIV commodities including the HIV testing kits because it was used as a *hub* center by the HIV/AIDS unit. A hub center is a clinic that is supplied with more HIV-related resources than what it can actually use so that when nearby clinics run short of them, they should easily access them from there. Although the second high-performing clinic (HP-2) reported to have experienced stock-outs of the HIV testing kits, it was not often. However, whenever the clinic ran short of the HIV testing kits, it easily accessed them from its district hospital, from

partner organizations such as the UNC Project, and from 3 other neighboring clinics that also implemented the Option B+ guidelines.

In contrast, both low-performing clinics reported to have experienced frequent stock-outs of the HIV testing kits. There are several reasons cited by informants that contributed to this. First, the supply of all HIV commodities is calculated using figures recorded on the clinics' reports that the HIV/AIDS unit of the Malawi Ministry of Health receives from each clinic. If the report is inaccurate, all supplies for that clinic will be inadequate. Under-reporting of the work done by both clinics contributed to both clinics' receiving less supply, leading to frequent stock outs of the HIV testing kits. Second, to come up with each clinic's resource distribution plan, the Malawi Ministry of Health uses the clinics' catchment areas as the basis for that clinics' magnitude, and yet both of the low-performing clinics served a higher population than what is documented as their catchment areas. As described previously under magnitude of the served population, both low-performing clinics were surrounded by other clinics that were not implementing the Option B+ guidelines and both bordered with other countries, leading to more women and their family members accessing the HIV, ART, and any other care that is designed to prevent HIV transmission from an HIV infected mother to her HIV-exposed child from the study clinics.

Although stocks of the HIV testing kits varied in the way it influenced implementation of the Option B+ guidelines between the high- and low-performing clinics, all informants reported to have liked the supply chain management that allowed the Central Medical Stores to transport the HIV commodities direct to the clinics without supplying them through their district health offices as it used to be before clinics adopted the Option B+ guidelines. The following quotes illustrate how stocks of the HIV testing kits varied in the

way it influenced implementation of the Option B+ guidelines between the high- and low-performing clinics: From district coordinators who represented the high-performing clinics:

[A]t any time, you can access the services because test kits; ARVs [antiretroviral drugs] have never been out of stock ever since the programme started... we have not had any stock outs.

[A]t times the facility does run out of resources like the testing kits,that was in 2012 and this problem is corrected...but when they call [name of the facility withheld] as their hub site or maybe they call the district hospital they get assistance.

A service provider at one of the high-performing clinics said:

[W]e do not have the stock outs of the drugs..... We also receive a lot of test kits and we rarely have stock outs.

In contrast, a TA provider who represented one of the low-performing clinics reported:

[T]he most barrier was also shortage of test kits. A person may come to seek for HIV testing services but if there are no test kits, he/she cannot be tested...nowadays we cannot run away from the truth, shortage of drugs in government hospitals is a very big problem but when we talk of PMTCT drugs such as Bactrim and ART, they are there... but HIV test kits still it's a problem..... the catchment area is big but there are also other health centers which do serve a bigger population but they do not experience as frequent run out of test kits as [name of the clinic withheld] does. So about shortage of test kits, it is a big problem.

A district coordinator of one of the LP- clinics aid:

[T]hey were under-reporting and because of under-reporting, supply of test kits and other supplies is also very low...because the more you test, the more you are able to get the supplies but for [name of the clinic withheld], it's like we are testing few women which resulted in low supply of the test kits...this could be an assumption to say maybe there are a few number of pregnant women who are supposed to be tested.

And a service provider at one of the low-performing clinics stated:

[S]hortage of reagents can also badly affect this program because sometimes reagents are out of stock.... currently, this has changed a bit but in the past, it was happening often because they were supplying us with less resources than what we were using.... because more people do come here to seek for HIV test as a result those resources

were lasting for less than a month.... so for us to press an order and for them to process it, it was taking long time.

In summary, the following were identified as contextual factors that varied in the way they influenced implementation of the Option B+ guidelines between the low- and high-performing clinics: Magnitude of the served population, size of the clinic staff, service space/infrastructure, and stocks of the HIV test kits. Both high-performing clinics identified most of the above described factors as enhancers/facilitators while both low-performing clinics identified them as barriers/inhibitors to implementation of the Option B+ guidelines.

Conclusion

This chapter described the prevention support strategies that the UNC Project used to support implementation of the Option B+ guidelines at four Malawian Ministry of Health primary health centers, contextual factors that influenced delivery and use of technical assistance (TA) as a support strategy that the UNC Project used, perceived implementation of the core components of the Option B+ guidelines, and variation in contextual factors that influenced implementation of the Option B+ guidelines between the two high- and low-performing clinics of the Malawi Ministry of Health.

The UNC Project used the following support strategies to build the clinics' capacity to implement the Option B+ guidelines: training, tools, resources and technical assistance (TA). TA as a support strategy used two approaches: collaborative and audit and feedback. Among the support strategies used by the UNC Project, clinics valued most the on-going, on-site TA; tools such as SOPs, flow charts, and posters; and resources such as HIV testing kits. Little variation occurred in the way TA was delivered, and where there was variation it was mostly in areas where TA providers had put much of their focus and on time they spent on various TA activities (dose). Across all four study clinics, TA focused mainly on proper

documentation of the rendered Option B+ activities but varied in other areas of their focus. At HP-1 clinic, TA focused also on antenatal care; at HP-2 clinic and LP-1 clinic, the additional focus was put on early infant diagnosis (EID) ; and at LP- 2 clinic, TA focused on all units that implemented the Option B+ guidelines (see Table 5).

All the study clinics reported to have adopted and were implementing the Option B+ guidelines. On a scale of 0 to 3, overall perceived implementation ratings of the core components of the Option B+ guidelines ranged from 2.3 at both low-performing clinics to 2.8 at high-performing clinic 2 (see Table 7). Among the core components, all clinics except HP-2 clinic reported minimal implementation of the community sensitization and mobilization activities; all clinics except the LP-1 clinic reported having problems with proper documentation of all rendered Option B+ activities in correct registers or cards; and both LP clinics reported not fully ascertaining of the HIV status for all the HIV-exposed children as recommended by the Option B+ guidelines.

Staffing and TA transportation to clinics emerged as the most salient contextual factors influencing TA delivery. Shortage of staff who worked as TA providers from the UNC Project and of those who worked as the service providers at the clinics negatively influenced TA delivery especially at both low-performing clinics. In addition, TA providers' ability to transport themselves to clinics was affected by fuel availability, their mode of transportation, distance to clinic, and quality of the roadways. Use of motorcycles as a mode of transportation by TA providers at both low-performing clinics hindered consistent TA delivery during the rainy season (December through April) when dusty roads to both clinics become muddy and impassable.

Emerging contextual factors that varied most in the way they influenced implementation of the Option B+ guidelines between the two high- and two low-performing clinics include: magnitude of the served population that causes differences in clinics' workload; size of the clinic staff (i.e., number of staff involved in the implementation work); and availability of adequate service space/infrastructure and stocks of the HIV test kits. At both high-performing clinics, all the identified factors facilitated while at both low-performing clinics they hindered implementation of the Option B+ guidelines.

Table 8. Patterns of Emerging Themes in Contextual Factor Variations Related to Implementation of the Option B+ Guidelines Between High- and Low-Performing Clinics

Contextual Factors	High Performing	Low Performing
Magnitude of the served population.	Relatively smaller	Relatively bigger
-Catchment area	<p>Both HP clinics were surrounded by other health facilities that also implemented Option B+ guidelines, had maternity and offered ART services</p> <ul style="list-style-type: none"> • HP-1 clinics' catchment area= 69,562 <ul style="list-style-type: none"> ✓ HP-1 clinic served people from within its designated catchment area only • HP-2 clinics' catchment area= 19,595 <ul style="list-style-type: none"> ✓ HP-2 clinics' served fewer people from within its designated catchment area ✓ Other people from its designated catchment area were served by 3 other health facilities (1= public; 1= owned by the Christian hospitals association of Malawi; 1= private). 	<p>Both LP clinics were surrounded by other health facilities that did not implement Option B+ guidelines, had no maternity and did not offer ART services. Both borders with other countries.</p> <ul style="list-style-type: none"> • LP-1 clinics' catchment area = 37,571 • LP-2 clinics' catchment area = 51,289 <ul style="list-style-type: none"> ✓ Both clinics served people from within their designated catchment area plus others from surrounding facilities and countries that did not have maternity, HIV and ART services.
-2012-2013 FY # Pregnant women seen at a facility	<ul style="list-style-type: none"> • 3496 pregnant women seen at HP-1 • 873 pregnant women seen at HP-2 	<ul style="list-style-type: none"> • 1530 pregnant women seen at LP-1 • 2693 pregnant women seen at LP-2
-2012-2013 FY # annual deliveries at a facility	<ul style="list-style-type: none"> • 1152 deliveries were conducted at HP-1 • 325 deliveries were conducted at HP-2 	<ul style="list-style-type: none"> • 936 deliveries were conducted at LP-1 • 1817 deliveries were conducted at LP-2

Contextual Factors	High Performing	Low Performing
Size of the clinic staff	Bigger	Smaller
Staffing	<p>Both clinics used the Ministry of Health plus other staff from their partner organizations to implement the guidelines (see Table 2 for specific numbers).</p> <p>Both clinics had adequate staff (6/11)</p> <ul style="list-style-type: none"> • Staff though limited, was described to be available at each unit where the Option B+ guidelines were implemented. • All staff was trained in the Option B+ guidelines • Both clinics had additional staff from partner organizations who helped with hands on services to implement the Option B+ guidelines (7/11) <p>Challenges about staffing</p> <ul style="list-style-type: none"> • Staff reassignment to other duties caused shortage of staff (11/11). 	<p>Both clinics used the Ministry of Health staff only to implement the guidelines (see Table 2 for specific numbers).</p> <p>Both clinics faced an extreme shortage of staffing (10/10)</p> <ul style="list-style-type: none"> • For example there was always one nurse or one medical assistant who covered almost all units at a facility) (10/10) • Not all staff was trained in Option B+ guidelines. • Used Malawi Ministry of Health staff only to implement the Option B+ guidelines. <p>Other factors that contributed to extreme shortage of staff at both clinics:</p> <ul style="list-style-type: none"> • Staff reassignment to other duties caused extreme shortage of staff (10/10) • Lack of housing to accommodate staff caused shortage of staff (6/10). • Clinic location (at a very remote area) caused shortage of staff because staff used to refuse to be deployed to such places (8/10).
Service space/ infrastructure	<p>Adequate and well structured</p> <p>In general the infrastructure accommodated all HIV, ART and PMTCT related activities.</p> <ul style="list-style-type: none"> • The clinics have rooms to accommodate all the Option B+ guidelines' services (11/11) 	<p>Inadequate</p> <p>In general, both clinics had very limited space to implement the Option B+ guidelines.</p> <ul style="list-style-type: none"> • Space is very limited (10/10) • One room was used for various services e.g. nurses office, antenatal examination, HIV

Contextual Factors	High Performing	Low Performing
Stocks of the HIV testing kits	<ul style="list-style-type: none"> All the Option B+ guidelines' services i.e. the MCH, counseling, ART/PMTCT services were done under one roof or just in an adjacent building (11/11) HP-1 clinic had a big maternity waiting home that accommodated about 100 patients and their guardians who wished to await labor at the clinic. <p>HIV testing kits were mostly available (8/11)</p> <ul style="list-style-type: none"> HP-1 clinic had never experienced shortage of HIV testing kits since adoption of the Option B+ guidelines (6/6). HP-1 clinic was used as a hub center HP-2 clinic when run out of stock, it easily gets supplemented from its surrounding clinics that also implement the Option B+ guidelines or from its district health office and partner organizations (5/5) 	<p>counseling, initiation of ART, waiting room for women in labor.</p> <ul style="list-style-type: none"> Other services such as EID were done under the tree or in the hall way/corridor/veranda. <p>Frequent stock outs of HIV testing kits (10/10) Reasons contributing to frequent stock outs of HIV testing kits at both clinics:</p> <ul style="list-style-type: none"> Under-reporting (6/10) Both clinics served a large catchment area (10/10) ✓ Both clinics served an additional population from other facilities and countries that did not have maternity, HIV, PMTCT and ART services Both clinics are located far from the Malawi Ministry of Health central office and also from their hub centers where stocks do come from. ✓ When submit an order, it takes about two weeks before clinics are resupplied (5/10)

LP = Low Performing clinic; HP = High Performing clinic; EID= Early infant diagnosis; MCH= Maternal and child health; ART= antiretroviral therapy; PMTCT= prevention of mother-to-child- transmission; HIV= Human Immunodeficiency Virus; PMTCT= Prevention-of-Mother-to-Child-Transmission of HIV

CHAPTER 6. DISCUSSION AND CONCLUSIONS

Introduction

This qualitative, descriptive multiple-case study described the prevention support strategies that the UNC Project in Malawi used to support implementation of the Option B+ guidelines at four (4) primary Malawi Ministry of Health clinics. This study also described perceived implementation of the core components of the Option B+ guidelines and identified contextual factors that may explain variations in the delivery of technical assistance (TA) and implementation of guidelines between two low- and high-performing clinics that received support from the UNC Project. Data were collected through in-depth interviews, observation, and a short questionnaire that collected descriptive characteristics of the study clinics/cases. Twenty-one (21) in-depth interviews were completed with eighteen (18) informants who worked as TA providers, service providers, and district coordinators at the time the UNC Project supported clinics to implement the Option B+ guidelines. This chapter presents a summary and synthesis of main study findings; implication for theory, policy, and practice; suggestions for further research; a discussion of the study limitations; and conclusions.

Summary and Synthesis of Findings

Figure 10 displays a revised Model of Prevention Support (see Figure 6) that has incorporated the main findings of this study. As displayed in Figure 10, the synthesis of findings for the current study focused on three concepts: prevention support, implementation, and contextual factors. Capacity, though not fully assessed in this study, is included in Figure 10 as part of the model to hypothesize how prevention support affects implementation.

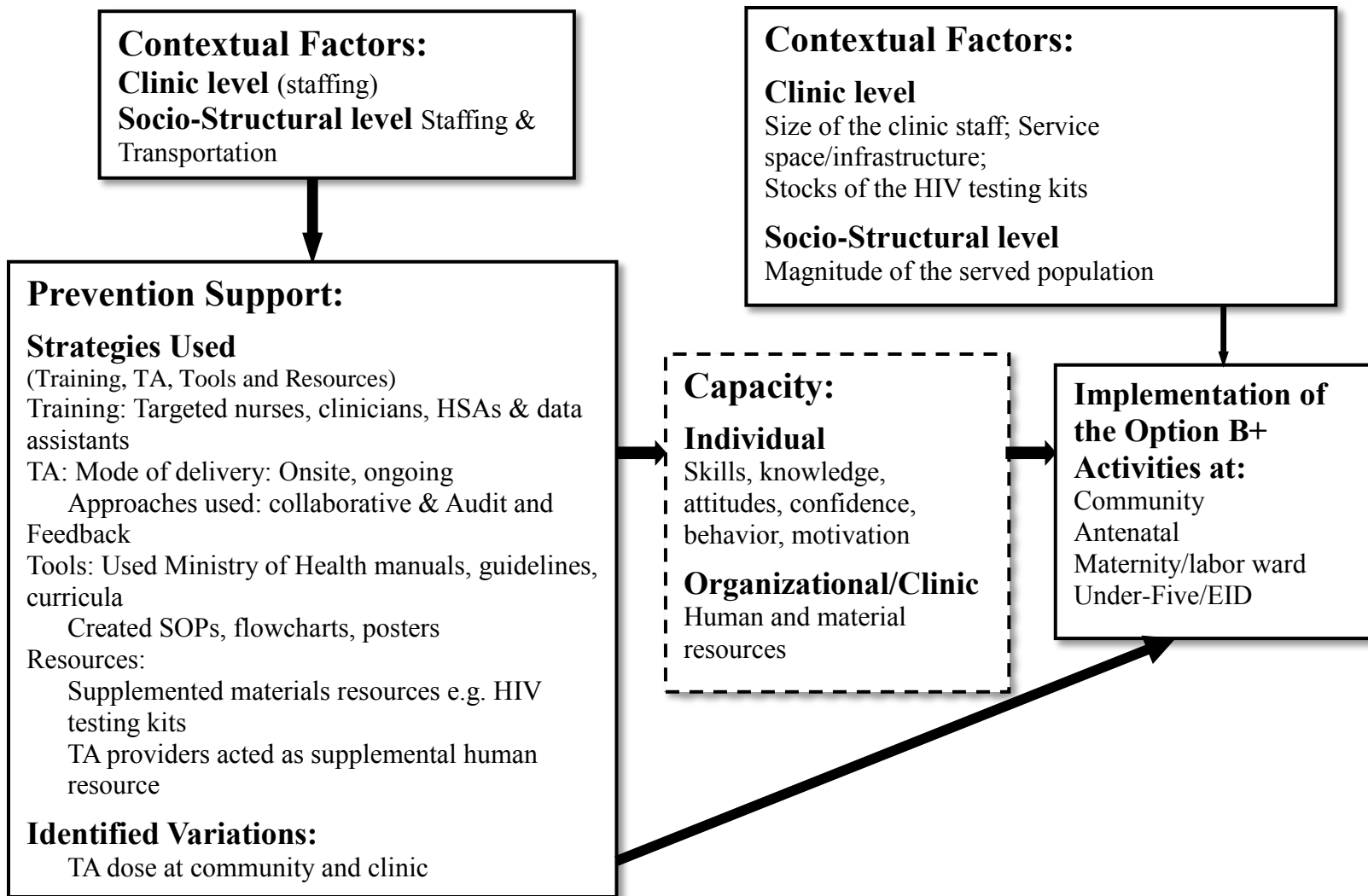


Figure 10. The revised model of prevention support.

Prevention Support

This study found that the UNC Project used the following prevention support strategies to support implementation of the Option B+ guidelines in all the four study clinics: training, TA, tools, and resources. The UNC Project collaborated with Malawi's Ministry of Health to deliver four types of **trainings** for the clinic service providers (see Table 4). Three of the four trainings were residential and required staff to be away from their practicing clinics for 5 to 10 days. To further support all the study clinics, the UNC Project delivered three-years of onsite **technical assistance (TA)**. Two approaches—collaboration and audit and feedback—were used to deliver TA. At each visit, TA providers collaborated with clinic staff to implement community- and clinic-level components of the Option B+ guidelines. All community mobilization activities were funded by the UNC Project but were done by both the TA providers from the UNC Project and staff from the Malawi Ministry of Health. Examples of clinic-level activities that TA providers mostly did in conjunction with the clinic service providers include documentation and report writing. To meet their primary goal of reinforcing quality of the implemented Option B+ guidelines, TA providers were able to remind the service providers on how to better implement the guidelines' activities by collaborating with clinic staff through on-the-job consultations. TA providers were also able to help with implementation of the core components of the Option B+ guidelines by acting as additional staff members, giving health education to pregnant women, providing HIV testing to women and their family members, and initiating the lifelong antiretroviral treatment therapy (ART) to women who tested HIV-positive in units where clients were found unattended to. This is because of the shortage of staff that affected almost all clinics at times due to staff reassignments to other duties such as to attend to an off-site residential training or to an outreach activity. TA providers used audit and feedback approaches to assess and

provide guidance on clinics' implementation of Option B+ guidelines. TA providers mostly audited clinics' performance through analyzing data collected about the implemented activities and then conducted feedback meetings at individual clinics or a group of clinics that met together at one place to find solutions to the identified implementation gaps. Audit and feedback is what Wandersman et al. (2012) call Quality Assurance and Quality Improvement (QA/QI). To further support clinics, TA providers used **tools** such as the Malawi Ministry of Health manuals, guidelines, and curricula and created the standard operating procedures (SOPs), flowcharts, and posters and distributed them to all the study clinics. The SOPs, flowcharts, and posters captured important implementation information and specified implementation procedures that clinics used as referent tools when engaging themselves in guidelines' implementation activities. Last, the UNC Project supported clinics with **resources** that clinics required to effectively implement the Option B+ guidelines. Both material resources (e.g., supplemental HIV testing kits when clinics run out of stock) and human resources (e.g., use of TA providers to help with various implementation activities) were used as part of the prevention support strategies.

Among the prevention support strategies, **variation** occurred in how TA was delivered. **TA dose** (i.e., overall amount of time spent by TA providers providing TA in clinics and in communities) and **TA focus** (i.e., the unit where TA providers spent more time) varied across clinics. TA dose was highest at LP-2 clinic, where TA providers spent an average of 6 hours once to two times per month. Although earlier studies related greater TA dose to better outcomes (Wandersman et al., 2012; Chinman et al., 2008), the findings of this study suggest that greater TA dose is also related to low performance. The greater TA dose in this study may imply that TA providers intensified TA at LP-2 clinic to help improve its

capacity, which may lead to improved performance. TA dose in collaborating on community mobilization activities ranged from one full day once at the beginning of the support program at LP-2 to quarterly at HP-1 clinic. On TA focus, all clinics focused most on documentation (i.e., checking clinic registers, cards, and report writing). However, variation occurred on other areas of TA focus. At HP-1, TA providers focused more than at other clinics on antenatal activities to ensure that all pregnant women who accessed care were informed of the implemented Option B+ guidelines, were offered an HIV test, and if tested positive were initiated on lifelong ART and given Nevirapine syrup for their HIV- exposed babies. At HP-2 and LP-1, TA providers focused more than at other clinics on early infant diagnosis. At LP-2 TA providers focused equally across all units that implemented the Option B+ guidelines. The identified variations in TA did not explain differences in clinics' implementation of the B+ guidelines.

Study findings have some similarities and differences with prior capacity-building studies. Similar to the support strategies that are presented in Wandersman et al.'s (2012) Evidence-Based System for Innovation Support (EBSIS) and to those strategies identified in a systematic review of innovation support interventions (Leeman et al., 2015), the current study identified training, TA, tools, and audit and feedback as support strategies that the UNC Project used. In contrast to Wandersman et al., (2012), we identified audit and feedback as a component of TA rather than a standalone support strategy. In addition, study findings augment Wandersman et al.'s (2012) model by identifying specific examples of tools such as SOPs, flow charts, and posters that were created by the UNC Project as unique to this study. Study findings also identified an additional support strategy— resources.

Implementation

As described in Figure 10 and displayed in Table 7, the current study found that the four clinics differed in level of implementation of the Option B+ guidelines' core components. On a scale of 0 to 3.0, overall self-rating of perceived implementation ranged from 2.3 to 2.8. Perceived implementation ratings were higher at high-performing clinics (2.5 and 2.8.) than at low-performing clinics (2.3 and 2.3). All clinics performed well on Option B+ implementation components that are done during antenatal through the labour and delivery periods (e.g., initiation of recommended lifelong antiretroviral drugs [ARVs] to HIV-infected pregnant and breastfeeding women on the same day of their HIV diagnosis). Clinics performed less well on components that are done during the post-delivery period such as early identification and diagnosis of HIV-exposed children to ascertain their HIV status at 6 weeks and at 12 and 24 months (see Table 7 for details). With the exception of HP-2, clinics failed to fully conduct community sensitization and mobilization activities and all but LP-1 failed to properly document all the rendered activities in the correct registers and cards.

Findings of this study support results from earlier studies that were done in similar environments. HIV testing and initiation of lifelong ART to HIV-infected pregnant and breastfeeding women are two major successes that are reported by most studies of Malawi's implementation of the Option B+ guidelines. For example, one year after adoption of the Option B+ guidelines, Malawi registered an increase in ART uptake of 748% (i.e., 1,257 before the second quarter of 2011 to 10,663 in the third quarter of 2012 [Chimbwandira et al, 2013]). A study by the WHO (2014) revealed that over 80% of women who tested HIV-positive in Malawi received lifelong ART following implementation of the Option B+ in the country. Similarly, a study done in five districts from which the current study drew its cases reported increased HIV testing and counseling uptake from 66% to 87%, ART uptake from

23% to 96%, and infant Nevirapine uptake from 1% to 100% from baseline to end of the support project (all $p < 0.001$) (Herce et al., 2015). Likewise, UNAIDS (2015) reported that lifelong ART uptake for HIV-positive pregnant and breastfeeding women in Malawi increased from 11% in 2011 to 64% by the end of 2014.

The implementation gaps that the study identified also are supported by findings from earlier studies. In 2014, only 18% of all HIV-exposed children in Malawi received a virological test within the first two months of their lives (UNAIDS, 2015). In the districts from which this study drew its cases, only 20% of the HIV-exposed children accessed the virological test between 2011 and 2014 (Herce et al., 2015). Research evidence supports that effort in implementation of the activities to prevent mother-to-child transmission of HIV in Malawian clinics is higher in maternity units than units that manage postnatal women and their children. Less effort in managing postnatal women and their children may be the cause of higher postpartum rates of mother-to-child-transmission of HIV. In 2014, 7% of children born to mothers with HIV were HIV-positive at six weeks post-delivery in Malawi. The percentage increased to 17% at age 12-18 months, indicating that many children are being infected post-delivery (UNAIDS, 2015). If Malawi is to join the global effort of eliminating new pediatric HIV infections, there is need for the implementation clinics to enhance implementation of the activities that are designed to prevent mother-to-child transmission of HIV during the post-delivery period.

Contextual Factors

Aims 2 and 3 of this study were to describe variation in contextual factors that were either barriers or facilitators to TA delivery or to implementation of the Option B+ guidelines between the two high- and low-performing study clinics. Figure 10 displays contextual factors in two separate boxes, of which one contains factors that influenced TA delivery and

the other those that influenced implementation. Contextual factors in Figure 10 are further separated within each box to indicate those that arose at the clinic- and socio-structural levels. Clinic-level factors are environmental issues that informants identified as coming from within the study clinics. Socio-structural factors are environmental issues that informants identified as either coming from the communities where women and their family members lived or government and higher levels of both the Malawi Ministry of Health and the UNC Project organizations as they interacted to enhance implementation of the Option B+ guidelines at the study clinics.

Variation in contextual factors that influenced TA delivery. As displayed in Figure 10, **TA delivery** was affected by staffing and transportation. **Staffing** was the primary factor that affected TA at the clinic level. An existing shortage of service staff at both low performing (LP) clinics limited TA providers opportunity to meet with service providers and much of the TA visit time was spent helping with implementation of the Option B+ guidelines. However, because both high performing (HP) clinics had sufficient staff to implement the guidelines, TA providers managed to deliver most of the planned TA to both clinics. Staffing was also a factor at the socio-structural level. A shortage of TA providers influenced TA delivery across all the study clinics. UNC Project used either 1 or 2 TA providers who were assigned to districts that had 13, 28, or 44 clinics. Shortgae of TA providers led all TA providers to schedule TA visits to more than one clinic each day, which caused the clinics to receive fewer TA hours than they needed. In addition to staffing, TA providers' mode of **transportation** in relation to quality of the roadways to clinics also influenced TA delivery between the high- and low-performing clinics. TA providers who supported three of the study clinics (HP-2 and both LP) used motorcycles and one clinic (HP-

1) used a car, but both HP clinics received all planned TA because the roads that connected clinics and district areas where TA providers resided were well-paved and allowed TA providers to travel to clinics all year round without facing transportation problems. However, use of motor bikes to travel to both LP clinics that were located away from well-paved roads (i.e. about 12 km [7.8 miles] away to LP-1 clinic and 10 km [6.4.miles] away to LP-2) limited TA providers' access to clinics when unpaved roads became muddy and impassable during the rainy season (December through April). Due to clinics' ability and inability to be reached all year round by the TA providers, the amount of TA that was delivered to high-performing clinics was more than that of the low-performing clinics.

Variation in contextual factors that influenced implementation of the Option B+ guidelines. The left top box of Figure 10 displays contextual factors that influenced implementation of the Option B+ guidelines at either the clinic level (i.e., size of the clinic staff, service space/infrastructure, stocks of the HIV test kits) or socio-structural level (i.e., magnitude of the served population). Both high-performing clinics reported having enough clinic staff to implement the guidelines' activities, had service space/infrastructure to accommodate all units that were involved in implementation of the Option B+ guidelines, never or rarely experienced shortage of the HIV testing kits since clinics adopted the Option B+ guidelines, and served a population whose magnitude was either equal to or less than their official designated catchment area as mandated by the Malawi Ministry of Health. However, the above stated factors emerged as barriers to implementation of the guidelines' activities at both of the low-performing clinics. Both low-performing clinics reported a critical shortage of staff, limited service space/infrastructure to accommodate all units that implemented the Option B+ guidelines, frequent stock-outs of the HIV testing kits (a

resource that is critical if clinics are to determine the HIV status of individuals in need of the Option B+ services), and a higher magnitude of the population served as compared to their official designated catchment area as mandated by the Malawi Ministry of Health. The higher magnitude of the clinics' served population at both low-performing clinics comprised of people from their formal designated catchment areas, others from the surrounding clinics that did not adopt the Option B+ guidelines at that time and had no maternity and ART services, and also people from other countries that border Malawi.

In support of Wandersman et al. (2008; 2012), the current study found that contextual factors do influence the work of organizations that either support or implement innovations. In line with Yin (2013), identification of the previously described contextual factors helped us understand why both of the high-performing study cases/clinics performed well and both of the low-performing clinics performed badly on one of the core components of the Option B+ guidelines' implementation (i.e., proportion of women tested for HIV at their clinics) after two years of adoption and implementation of the Option B+ guidelines while getting support from the UNC Project.

Implications for Theory, Policy, Practice, and Research

Supporting the implementation of the guidelines to prevent mother-to-child-transmission of HIV in Malawi at the time when the country had just adopted the new evidence-based Option B+ guidelines was required to enable clinics to successfully implement the activities. There are several implications to theory, policy, practice, and future research that arose out of this study and are discussed next.

Implication for Theory

Findings of the current study confirm and extend key elements of Wandersman et al.'s Interactive Systems Framework (ISF) for Dissemination and Implementation and Evidence-Based System for Innovation Support (EBSIS) (2012). The study's findings support use of tools, training, and technical assistance (TA) as the prevention support strategies as presented in the EBSIS. However, the current study suggests that "audit and feedback" need to be incorporated within TA rather than used as a stand-alone quality assurance/quality improvement (QA/QI) strategy as indicated in the EBSIS. TA involved several activities such as consultations, practical teaching by showing clinic service providers how certain procedures (e.g., collection of dried blood samples from HIV-exposed children) were supposed to be conducted, and auditing and giving feedback on performance of the core components of the Option B+ guidelines' activities. In addition, the current study identified resources as a new strategy that may be added to expand the Wandersman et al.'s EBSIS model. In all study clinics, provision of supplemental resources such as HIV testing kits helped the clinics implement the guidelines even in times of national shortages of such resources. Addition to material resources, the current study found that TA providers acted as additional human resources because they helped with implementation of guidelines' activities in times of clinic staff shortages.

The ISF for dissemination and implementation includes contextual factors as one of the main constructs that influence the work of the three interacting systems (Wandersman et al., 2008, 2012). Study findings confirm the influence of funding and macro policy; two types of contextual factors identified by Wandersman et al. (2012). Although the present study did not directly address the issue of funding, it identified contextual factors influencing the work of both prevention support and delivery systems that are highly related to funding—

staffing (i.e., shortage of clinic staff and TA providers), non-availability of staff housing, clinic space and infrastructure, stocks of HIV testing kits, and TA providers' mode of transportation. As described in further detail in the next section, macro policy influenced resource allocation to all the study clinics. Both material and human resources at all clinics came from either the Malawi Ministry of Health central or district office. In addition, all clinics used same resources to implement different services. Therefore, shortage of service providers and critical shortage of material resources were as a result of the policies that the Malawi Ministry of Health used.

Implications for Policy

Malawi Ministry of Health is a centralized healthcare organization with most decisions made by the top-level managers (top-down approach). The Malawi Ministry of Health functions hierarchically with offices at central, zone, district, and health facility levels. In contrast, the Malawian Ministry of Health uses a bottom-up patient referral system (i.e., patients enter at the level of the health center and are then referred to district and then central hospitals). This can lead to a mismatch between the way resources are allocated from the top down as compared to the rate at which patients enter the system. Although the study cases (i.e., the health centers) fall nearly at the bottom of the Malawian Ministry of Health healthcare delivery system (see Figure 2), the majority of patients, including the HIV-infected pregnant and breastfeeding women and their families, are first seen at health centers (MoH, 2010, 2012). As a result of the top-down leadership approach and the bottom-up patient referral system that the Malawi Ministry of Health uses, most resources (both human and material resources) are allocated at higher levels of care than they are at health centers in Malawi. In addition to implementation of the Option B+ guidelines, the current study found

that each of the study clinics implemented multiple different initiatives and each of those initiatives was overseen by different district-level managers. All the different district managers had power to control the work of the same clinic service providers who were involved in the implementation of the Option B+ which led them be able to withdraw clinic staff to attend to different types of training related to different types of interventions that clinics implemented. Study findings suggest the need for policies to foster more equitable distribution of resources from top to bottom and also increase coordination among district level managers and the programs that they oversee.

There is need for revised resource distribution policies within the Malawi Ministry of Health. The study findings suggest the need for a resource distribution policy that should be put in place to guide the Malawi Ministry of Health to allocate both material and human resources based on the actual patient population seen by the facility and not based on what the Ministry designates as facilities' official catchment areas. The study found that the Malawi Ministry of Health's designated catchment areas often did not reflect the actual population that clinics served (see Tables 2 and 8). Both low-performing study clinics were surrounded by other health facilities that did not adopt the Option B+ guidelines and lacked maternity and ART services. Furthermore, both clinics bordered other countries. As a result they served a larger population than was estimated as their official catchment areas and a population that also was larger than that served by either high-performing clinic. Both low-performing clinics suffered greater shortages of material and human resources as compared to the high-performing clinics because they served a larger population than they were funded for. Study findings also revealed that lack of housing to accommodate staff at both low-performing clinics further contributed to the shortage of staff. Although the Malawi Ministry

of Health (2013) has established standards for the number of staff to be deployed at each healthcare facility, without construction of additional housing, the established staffing standards will not be met and clinics will continue to suffer staff shortages.

There is need for inter-programs' training and coordination policy within the Malawi Ministry of Health. The study identified training as an important prevention support strategy that helped clinics gain the initial capacity to implement the Option B+ guidelines. Training is essential in the field of HIV to engage clinics in implementing interventions that are known to prevent mother-to-child-transmission of HIV. A central challenge to the field of HIV and prevention of mother-to-child-transmission (PMTCT) of HIV is that guidelines frequently change following emerging evidence. For example, in just one decade, both the World Health Organization and Malawian PMTCT guidelines have changed three times (see Table 1). Recently, the United Nations (UN)—of which Malawi is a member state—has just adopted what they believe to be sustainable development goals to ensuring healthy lives and promoting well-being for all ages, one of which is ending AIDS by 2030 (WHO, 2015). It is evident therefore that any change that healthcare organizations adopt requires that service providers be trained to implement the changes in their practice setting. Due to lack of reliable Internet in Malawi, residential training that is offered in a form of a traditional classroom is one of the best options.

However, the study found that residential training caused staff shortages and hindered implementation of the Option B+ guidelines in the short run across all four study clinics. Almost all trainings that clinics received required staff to be withdrawn from their practice settings for 5 to 10 days (see Table 4). In addition, at times, different types of trainings were organized concurrently by different program coordinators or their implementing partners at

either the district or central levels. As a result, multiple staff were out of the clinic at the same time. Therefore, there is need for an inter-program's training and coordination policy within the Malawian Ministry of Health to govern different program leaders and their implementing partner organizations who withdraw service providers from clinics to attend to different types of residential trainings. One option to effectively govern trainings without causing shortage of clinic staff would be for the Malawi Ministry of Health to create a training officers' position at the district level to act as a training liaison officer among different programs (both within and outside the Malawi Ministry of Health) that withdraw clinic staff to train or update them about various changes and thereafter use them to implement the adopted interventions at their work settings. The training office would be informed of all planned training schedules within the district which could prevent concurrent trainings. The training office would also be responsible to liaise with other managers who directly supervise clinic staff to help with relief staffing if more than one clinic service provider is required to attend to an important training and thereby avoid staff shortages at the clinic. Offering trainings on weekends is another option that would avoid staff shortages. Because of the continuous changes that Malawian clinics adopt and implement, there is need for the Malawi Ministry of Health to consider including training of the inter-professional healthcare students and their various teachers such as those in nursing, medical, and clinical colleges so that when students graduate from college, they would have the capacity to implement any evidence based intervention at clinics where they may be deployed. Training of students and their teachers in health sciences colleges is expected to reduce withdrawing of service providers from their practice settings once students join the healthcare workforce.

The study findings also suggest a need for additional training curricula and amendments and integration of some of the existing training curricula that are used by the Malawi Ministry of Health to train service providers who are involved in implementation of activities that are designed to prevent mother-to-child transmission of HIV at their practice settings. The training gaps that current study identified, such as lack of training of other support staff (e.g., the environmental health officers, administrator, drivers, watchmen, and cleaners), might be address through a general HIV training curriculum to orient this key group of health workers. To minimize the frequency of withdrawing staff from clinics while maximizing their ART/PMTCT capacity, an integration of the early infant diagnosis (EID) training curriculum into both the ART/PMTCT training curriculum for nurses and clinicians and that of the HIV counseling and testing for the lay HIV testing and counseling counselors would help to enhance the early infant diagnosis (EID) capacity of nurses, clinicians, and HIV testing and counseling counselors who work full time at the clinics to fully implement the guidelines' activities at their practice settings.

Implications for Practice

Implication for prevention support systems. The UNC Project was one of the first organizations to provide prevention support to assist clinics in adopting and implementing the Option B+ guidelines in Malawi, but the prevention support system they created was not tailored to best fit Malawi. Study findings suggest that prevention support needs to provide adequate staffing and appropriate transportation. Prevention support also needs to employ strategies that promote sustainable change. For Malawian health centers such as the study clinics, it is important for the supporting organizations to plan for more TA providers who could be distributed to deliver TA to all clinics that need such support. In addition, the supporting organizations need to plan for a proper mode of transportation that can withstand

various Malawian roadways throughout all the weather seasons if the onsite and ongoing TA is to be effectively delivered in Malawi. Findings of this study revealed that use of motorcycles as TA mode of transportation to clinics that are connected through use of dusty/muddy roads was a barrier to TA delivery during rainy season. Therefore, a situational analysis of the roadways to help the prevention support organizations plan for a proper mode of transportation for TA providers is recommended if organizations plan to use ongoing and onsite TA prevention support strategies in Malawi.

The current study also found that some of the prevention support strategies such as direct use of supplemental material resources (e.g., HIV testing kits) and use of TA providers to help with implementation of the guidelines that the UNC Project used left the question of sustainability of the implemented Option B+ guidelines across all the four study clinics. TA that the UNC Project used to enhance implementation of the Option B+ guidelines was part of its three-year support project. If clinics were able to better implement the guidelines only because of additional human and material resources with which the UNC Project supplemented them, this means from the time the support project phased out, the level of implementation at the study clinics went down. The aim of the prevention support (the work of the UNC Project) is to build capacity of the delivery system (i.e., capacity of clinics and their service providers) to enhance implementation of the adopted interventions and sustain them once the supporting organization was no longer able to act as a safety net (Wandersman et al., 2012).

Implications for the prevention delivery system. The study findings reveal that implementation of the Option B+ guidelines brought a lot of changes in service providers' roles. Due to shortage of skilled staff such as nurses and clinicians, clinics and their non-

governmental partner organizations used Health Surveillance Assistants to implement most interventions. For example, clinics used the Health Surveillance Assistants as the HIV testing and counseling counselors, and they were the sole managers of the Under-Five clinics including identification and management of the HIV-exposed infants under the early infant diagnosis (EID) program. Health Surveillance Assistants are trained outside of the formal education system and— were instituted by the Malawi Ministry of Health to serve communities as outreach workers with the aim of disease prevention and health promotion. At the time of this study, all Health Surveillance Assistants lived and worked in their respective communities and only visited the clinic to manage children at the Under-Five clinics under a specific work schedule. Findings identified low self-ratings in implementation of all core components of the Option B+ guidelines that were done in units that were managed by the Health Surveillance Assistants (e.g., community mobilization activities and ascertaining of HIV status of the HIV-exposed children at the age of 6 weeks and 12 and 24 months). Therefore, redefining the roles of the Health Surveillance Assistants in areas related to antiretroviral therapy (ART) and prevention of mother-to-child transmission (PMTCT) of HIV would help improve implementation of the Option B+ guidelines across the study clinics. Community health education/mobilization and tracing of missed clients are the only Option B+ core implementation activities that need to be done by the Health Surveillance Assistants. This is because Health Surveillance Assistants' core duties are already in the community. The Health Surveillance Assistants' roles as the counselors and early infant diagnosis service providers need to be transferred to the HIV testing and counseling lay counselors. Integrating the early infant diagnosis activities into the general HIV testing and counseling services may help all the study clinics improve implementation of the guidelines'

core components that are done in the post-delivery period. The good thing is that all the clinics have a well-established cadre of lay HIV testing and counseling counselors who work closely with nurses and clinicians at clinics and their main job is to provide HIV counseling and testing to all clients in need of the services.

The findings also provide specific contextual factors (see Figure 10) that have been linked to high and low performance of the implemented Option B+ guidelines. There is need therefore for organizations such as the Malawi Ministry of Health that plan to adopt and implement new evidence based interventions to start assessing contextual factors that may either be barriers or facilitators before adopting any change to avoid performance differences among different participating sub-units of the organizations such as the clinics.

Implications for Future Research

The findings of the current study suggest that the work of prevention support (i.e., the work of the UNC Project) that aimed at building capacity of the service providers and clinics specific to implementation of the Option B+ guidelines in Malawi was moderated by the following contextual factors: size of the clinic staff, service space/infrastructure, stocks of the HIV testing kits, and the magnitude of the served population. We therefore hypothesize that with everything equal, prevention support will enhance capacity of both service providers (individuals) and clinics (organization); but the performance will be higher at clinics that have more staff, have space to implement the interventions, have sufficient stocks of required resources such as the HIV testing kits, and serve a less populated area than at the clinics that have staff shortages, have no or inadequate service space, frequently run out of required resources such as the HIV testing kits, and serve a bigger population. There is need therefore for future studies to examine such moderators when designing prevention support programs and also when exploring the effects of prevention support on capacity of service providers

and organizations that have just adopted new evidence based interventions and how that capacity may affect implementation (see Figure 10).

The study also found some gaps/weak links in the implementation of the Option B+ guidelines' core components. Among the lowest rated in implementation were community mobilization and all core components that are conducted during the post-delivery period (see Table 7). Although every year Malawian colleges produce community health nurses at both technician and registered nurse levels who could have helped with community mobilization activities, there were none among the clinic service providers who worked as community health nurses at any of the four study clinics. A survey is needed to find out where the Malawian community health nurses are and what roles they take after graduating with their community health nursing qualification. Future exploratory studies are also needed to find out why there is higher performance in prevention of mother-to-child transmission of HIV activities that are done during antenatal through labour and delivery period than those that are done during post-delivery periods in Malawi. The findings of this study suggest the need for future studies to invest in implementation strategies that would help enhance implementation of activities that are expected to be fully conducted after the delivery period. Such implementation activities need to be tailored to enhance adherence of mother/baby pairs to care. When the mother/baby pair remains in care, all HIV-exposed children will have a chance of getting an HIV test to ascertain their HIV status from the age of 6 weeks up to the end of their HIV exposure and their mothers will continue getting the lifelong antiretroviral drugs (ARVs) that will help keep them healthy and thereby able to care for their children. The post-delivery period is critical in the fight of prevention of maternal transmission of HIV because it is the time to intensify counseling services to all HIV-positive mothers on how to

effectively use ARVs to reduce their HIV viral load, which will reduce the rate of mother-to-child-transmission of HIV.

Study Limitations

This qualitative descriptive multiple-case study included public health centers only as cases and left out bigger and non-public health facilities such as district and central hospitals as well as those owned by private practitioners and by the Christian Hospital Association of Malawi. Therefore, findings of this study may not apply to all health facilities. The study also interviewed TA and service providers only and left out their managers, thereby potentially missing out on other contextual factors that affected the process of delivering the prevention support such as TA or that of implementation of the Option B+ guidelines at the study clinics. However, this study achieved its purpose of describing the prevention support strategies that the UNC Project used, was able to determine how TA varied, and managed to explore factors that have been linked to variations in either TA delivery or implementation of the Option B+ guidelines between the two low- and high-performing study clinics. Although the qualitative, multiple-case design that this study used helped us come up with thick descriptions of the study cases that might be relevant to clinics that also received prevention support from the UNC Project and are implementing the Option B+ guidelines, generalizability of results from any qualitative method is limited (Creswell, 2007; Polit & Beck, 2008).

Conclusion

This qualitative multiple-case study described the prevention support (e.g., training, technical assistance) that the UNC Project provided and how it was used by the two high- and low-performing clinics of the Malawi Ministry of Health. The study also identified

contextual factors that may explain variation in the delivery and use of technical assistance (TA) and variation in the implementation of the Option B+ guidelines in the two high- and low-performing clinics of the Malawi Ministry of Health. Four Malawi Ministry of Health primary health centers were drawn from three districts as cases of this study. At two high performing cases, the proportion of pregnant women who test for HIV during the Fiscal Year 2012-13 was over 96% while at two low performing clinics, it was about 50%.

In response to aim 1, this study found that the UNC Project supported the Malawi Ministry of Health clinics with training, tools, TA, and resources as the prevention support strategies. The study found little variation on how TA was delivered across all the study clinics with most variation found on TA dose and TA focus (see Table 4 for definitions). To determine how clinics used the prevention support that they received from the UNC Project, this study assessed individual clinics' perceived implementation. Table 7 summarizes clinics' reports of their perceived implementation of the core components of the Option B+ guidelines. On a scale of 0 to 3.0, clinics' overall self-ratings ranged from 2.3 at both low-performing clinics to 2.8 at high-performing clinic 2. Findings of this study revealed that all clinics performed well in components that are done during antenatal through labour and delivery periods but did not perform well in components that are done during the post-delivery period. Results also show that clinics did not perform well on community mobilization and documentation activities as they related to implementation of the Option B+ guidelines (see Table 7). In response to aim 2, this study identified staffing and transportation as contextual factors that influenced TA delivery between the high- and low- performing clinics (see Figure 10). Shortage of TA providers was a common barrier to TA delivery while shortage of clinic staff affected TA delivery to both low-performing clinics. Use of motor

bikes as means of transportation to travel to both low-performing clinics that were connected by unpaved roadways limited TA providers' access to clinics during the rainy season, when unpaved roads became muddy and impassable. In response to aim 3, this study identified size of the clinic staff, service space/infrastructure, stocks of the HIV testing kits, and magnitude of the served population as contextual factors that influenced implementation of the Option B+ guidelines between the high- and low- performing clinics (see Figure 10). At both high-performing clinics, all the above identified factors facilitated implementation while at both low-performing clinics were identified as barriers to implementation of the Option B+ guidelines. Findings of this study have advanced implementation science.

APPENDIX 1. AN IN-DEPTH INTERVIEW GUIDE (ENGLISH VERSION)

An In-depth Interview Guide to be Completed by the Informants From the Malawian Ministry of Health Clinics and Technical Officers From the University of North Carolina (UNC) Project

1.	Date of Interview:	_ _ _ / _ _ _ _ / _ _ _ (DD/MMM/YY)
2.	Interviewer initials:	_ _ _ _ _
3.	<u>Informant ID Number:</u>	_ _ _ _ _ _ _
4.	Start time of interview	
5.	End time of interview	

Note to Interviewer

This in-depth interview guide should be used for informants who are the technical officers, service providers, and PMTCT coordinators who were actively involved in the delivery or use of technical assistance activities at the specific study clinic.

Introductory text

Thank you for taking the time to talk to me today. I am here to learn about your experience with the University of North Carolina (UNC) Project’s technical assistance program and with implementing the antiretroviral treatment/prevention of mother-to-child- transmission of HIV (ART/PMTCT) “Option B+” guidelines.

As I said during the consent process, your participation is confidential and you are here to represent (*name the clinic*). This interview should last for about 45 to 60 minutes. This is meant to be a dialogue between you and me. This dialogue will be audio-tape recorded. However, you will see me writing notes at times. These notes are meant to remind me of an issue that I think needs further questioning or follow-up. Please feel free to stop me at any time if you want to ask a question, add something to the conversation, or stop the interview.

Part 1: Study-clinic demographic information

Clinic name _____

1. Informant’s role in the technical assistance program and in the PMTCT of HIV care
 - Technical assistance provider (RN, NMT, CO, MA, HSA, HTC Counselor, other: specify.....)
 - Technical assistance recipient/PMTCT service provider at the clinic (RN, NMT, CO, MA, HSA, HTC Counselor, other: specify.....)

- Technical assistance recipient/PMTCT coordinator (RN, NMT, CO, MA, other: specify.....)

Note to Interviewer: *Question 2 to 7 in Part 1 of this interview guide should be completed once for each study clinic.*

2. For how many years has this clinic (health center) been operating its primary health care services? On what day did the health center open?

Answer:

_____ Months or _____ years
 Date _____ Month _____ Year _____

3. For how many years/months has this clinic been implementing the Option B+ guidelines? On what date did this clinic start implementing the Option B+ guidelines?

Answer:

_____ Months or _____ years
 Date _____ Month _____ Year _____

4. When did this clinic start receiving technical assistance from the UNC Project?

Date _____ Month _____ Year _____

5. What is the total number of employees who are involved in the implementation of the Option B+ guideline activities at this clinic? ***Include everyone in all PMTCT units BUT EXCLUDE all who were just trained but are not yet involved in the actual activities' implementation.***

RNs= NMTs= COs= MAs= HSAs=
 HTC Counselors= Volunteers= others, specify=

6. What is the total catchment area that is served by the study clinic?

7. Answer the following questions using the PMTCT clinic's data from fiscal year 2012–2013:

- a) What was the total annual number of antenatal women served by the study clinic?

- b) What was the total annual number of deliveries at the study clinic?

- c) What was the overall HIV prevalence rate in the study clinic?

Part 2: In-depth interviews on provision and use of technical assistance to promote implementation of the Option B+ guidelines at the study clinic

The goal of this dialogue is to learn how (*name the clinic*) interacted with the UNC Project during the process of providing technical assistance and how this clinic used the knowledge from the assistance it received. Please be honest in your responses, as I can learn from what this clinic found useful and what needs to be improved in future technical assistance programs. Some of the questions may seem repetitive, but I want to fully understand the technical assistance provision, its usage, and how this clinic is implementing PMTCT activities.

1. Please describe the activities of the technical officers from the UNC Project at (*name the clinic*) between the years 2011 and 2014.

Probes: How often did the technical officers from UNC Project conduct these activities? **Notes section**

2. What do you remember most clearly about the technical assistance that the UNC project provided to help (*name the clinic*) implement the Malawian 2011 ART/PMTCT (Option B+ guidelines)?

Please discuss any technical assistant provided related to services provided at the community level, antenatal clinic, maternity units, and at the under-five clinic. Please approximate the number of hours or minutes the technical officers from the UNC Project spent on PMTCT activities at this clinic per month? What about hours or minutes spent on activities done at the community level?..... the antenatal clinic?.... the maternity unit?..... the under-five clinic? How often were the technical assistance providers able or not able to meet with the individual responsible for implementing PMTCT guidelines?..... What were the barriers to meeting with those individuals?

Notes Section

3. Reflect on all activities that were done by the UNC Project between the years 2011 and 2014. What do you remember most clearly about the UNC technical assistance program?..... What parts of the technical assistance from the UNC Project do you think most helped (*name the clinic*) implement the Option B+ guidelines?

What tools were used or developed by the technical assistance providers from UNC Project that you believe helped this clinic to implement the Option B+ guidelines? What other support do you think would have helped this clinic to better implement the guidelines beyond what was provided by the UNC Project?

If (*name the clinic*) could be involved in a technical assistance program again, what would you suggest that the technical assistance providers to do differently?

Notes Section

4. Try to remember what you believe were the barriers to (*name the clinic*) implementation of PMTCT guidelines before the UNC Project supported it with technical assistance. Tell me more about those barriers.

Probe: Which of these barriers did the UNC Project's technical assistance assist (*name the clinic*) dealt with?

Tell me how the technical assistance addressed those issues.Once this clinic began receiving technical assistance from the UNC Project, what do you believe this clinic found helpful?..... What was not helpful?Tell me about things that the UNC technical assistance did NOT address.How do you think these issues could have been addressed by the technical assistance team in order to enhance implementation of PMTCT activities at this clinic?

5. Think about the community that surrounds this clinic and the clinic itself. What do you think were facilitators or barriers to this clinic's implementing the PMTCT activities based on the Option B+ guidelines?

Probe on how easy it is for women and their family members to easily access the services at the clinic and availability of resources, such as staff and materials, to aid implementation of PMTCT activities at the clinic.

Notes Section

6. How are the PMTCT services structured at (*name clinic*) ?..... ...On what days does (*name clinic*) delivers PMTCT activities such as HIV counseling and testing, antenatal services, under five services, ART services and community services?Are these days the same as the days that the technical officers from UNC Project were visiting (*name the clinic*)?

Probes: How far apart are the antenatal, labor and delivery, postnatal, under-five and ART units at (name the clinic).....What about availability of space for the PMTCT services such as space for HIV testing, counseling, storage for antiretroviral drugs, HIV testing kits, dispersion of antiretroviral drugs?

Notes Section

7. Now think about all issues that could arise from the Malawian health care system in general, including the Ministry of Health as a mother organization of this clinic. What do you think are the facilitators or barriers to this clinic implementing PMTCT activities based on the Option B+ guidelines?

Probe on resource distribution, such as deployment of workforce, distribution of HIV-testing kits, and antiretroviral drug, stock outs, trainings for workforce (i.e., taking them out of clinic).

Notes section

Note to Interviewer: *Let informant know that questions 8 and 9 are about implementation of PMTCT activities based on the Option B+ guidelines at (name the clinic).*

8. To what extent do the people working in this clinic agree with and support the implementation of activities based on Option B+ guidelines?

Notes Section

9. Please describe to me to what extent (*name the clinic*) is carrying out the following PMTCT activities? *Probe on answers for each activity.*

- Conducting community sensitization and mobilization activities about the implemented Option B+ PMTCT guidelines at this clinic and in communities that surround this clinic.

Probe: If not doing fully, probe on why not.

- Ascertaining of HIV status for all pregnant and breast-feeding woman who access care at this clinic on each visit.

Probe: If not doing fully, probe on why not.

- Checking on page 6 of the antenatal woman's health passport to determine the HIV status at each visit.

Probe: If not doing fully, probe on why not.

- Routinely offering an HIV test through provider-initiated HIV testing and counseling to all pregnant and breastfeeding women who seek health care services at this clinic.

- *Probe:* If not doing fully, probe on why not.

- Conducting health education that is designed to inform the HIV-infected women and their family members that once antiretroviral drugs (ARVs) are started, they must be taken every day for life.

- *Probe:* If not doing fully, probe on why not.

- Initiation of lifelong combined ART, such as Tenofovir/Lamivudine/Efavirenz (5A regimen), to all identified HIV-infected pregnant and breastfeeding women on the day of or within seven days of HIV diagnosis regardless of woman's' CD4 count or her clinical stage.

Probe: If not doing fully, probe on why not.

- Supplying three bottles of 25mls each of Nevirapine (NVP) syrup to all HIV-infected women for their HIV-exposed babies at first opportunity once the woman is known to be HIV-infected.
Probe: If not doing fully, probe on why not.
- Initiating the integrated mother/infant follow-up scheduling.
Probe: If not doing fully, probe on why not.
- Ascertaining HIV status for all the HIV-exposed children, that is, collecting at least one deoxyribonucleic acid-polymerase chain reaction (DNA-PCR) sample from each HIV-exposed child from the age of six weeks.....What about all the recommended HIV tests for the HIV-exposed children?
Probe: If not doing fully, probe on why not.
- Proper documentation of all rendered PMTCT activities in correct registers or cards.
Probe: If not doing fully, probe on why not.

Notes Section

10. How would you describe the working relationship between the UNC Project technical providers and (*name the clinic*)? *Probe on both positive and negative relationships and how the positives can be reinforced and the negatives can be overcome.*

What about the working relationship between this clinic and the Malawi Ministry of Health as a mother organization? *Probe on both positive and negative relationships and how the positives can be reinforced and the negatives can be overcome.*

Notes Section

11. Is there anything else you'd like to tell me about how (*name the clinic*) received and used technical assistance from the UNC Project to implement the Option B+ guidelines? Or suggestions for additional technical assistance that would be helpful?
Probe on the answers.

Notes Section

APPENDIX 2: AN IN-DEPTH INTERVIEW GUIDE (CHICHEWA VERSION)

An In-depth Interview Guide to be Completed by the Informants From the Malawian Ministry of Health Clinics and Technical Officers From the University of North Carolina (UNC) Project

6.	Date of Interview:	_ _ _ / _ _ _ _ / _ _ _ (DD/MMM/YY)
7.	Interviewer initials:	_ _ _ _
8.	Informants' ID Number:	_ _ _ _ _ _ _
9.	Start time of interview	
10.	End time of interview	

Note to Interviewer

This in-depth interview guide should be used for informants who are the technical officers, service providers, and PMTCT coordinators who were actively involved in the delivery or use of technical assistance activities at the specific study clinic.

Mau Oyamba

Zikomo pokhala ndi nthawi kuti tikambirane ndi ine lero. Ndili pano kuphunzira za zomwe munamukana nazo mu ndondomeko ya chithandizo cha upangili (*Technical assistance program*) chomwe a bungwe la University ya North Carolina (UNC) inapeleka ku chipatala cha (*name the clinic*) pokhazikitsa ndi kulimbikitsa ndondomeko ya chithandizo cha mankhwala— oyamba kumwa nthawi yomwe mayi wapakati kapena oyamwitsa akangopezeka ndi kachilombo ka HIV mosayanganira kuchuluka kwa chitetezo cha m'thupi la mayiyo kapena kudwala matenda ena obwera chifukwa chotsika kwa chitetezo chanthupi— omwe amathandiza kuchepetsa kufalikira kwa ka chilombo ka HIV kuchokera kwa mayi kupita kwa mwana (ART/PMTCT “Option B+” guidelines).

Monga ndinanenera pa nthawi yolandira chivomerezo, kutenganawo mbali kwanu ndi kwachinsinsi ndipo muli pano kuimira chipatala cha (*name the clinic*). Mafunsowa ayenera kutenga pafupifupi ola limodzi (45-60 minutes). Izi zikutathauza kuti tidzikambirana pakati pa inu ndi ine. Kukambiranaku kudzitepedwa. Komabe, mudzindiona ndikulemba nthawi zina. Zolembazi ndi zoti zindikumbutse pa kanthu kena kake kamene ndikuganiza kuti kakufunika mafunso oonjezera kapena kubwerelamonso. Chonde masukani kundiimitsa pa nthawi ina ili yonse ngati mukufuna kufunsa funso, kuonjezera china chake kuzokambirananzi, kapena kuyimitsa mafunsowa.

Part 1: Study-clinic demographic information

Dzina la Chipatala _____

1. Ntchito ya opereka uthenga mu ndondomeko yopeleka chithandizo cha upangili yomwe a bungwe la UNC linapereka komanso mu chithandizo chofuna kuchepetsa mpata wa kufalikira kwa ka chirombo ka HIV kuchokera kwa mayi kupita kwa mwana.
 - Opereka chithandizo cha upangili (RN, NMT, CO, MA, HSA, HTC Counselor, Ena: tchulani.....)
 - Olandira chithandizo cha upangili / Ogwrira nthito za chithandizo chofuna kuchepetsa mpata wa kufalikira kwa ka chirombo ka HIV kuchokera kwa mayi kupita kwa mwana pa chipatala (RN, NMT, CO, MA, HSA, HTC Counselor, Ena: tchulani.....)
 - Olandira chithandizo cha upangili / wamkulu wa ntchito yofuna kuchepetsa mpata wa kufalikira kwa ka chirombo ka HIV kuchokera kwa mayi kupita kwa mwana m'boma lomwe muli chipatalachi (RN, NMT, CO, MA, Ena: tchulani:

Note to Interviewer: *Question 2 to 7 in Part 1 of this interview guide should be completed once for each study clinic.*

2. Kodi chipatalachi chakhala chikugwira nthito ya zaumoyo kwa zaka zingati? Kodi chipatalachi chinatsegulidwa tsiku lanji?

Yankho :

Miyezi _____ kapena Zaka _____

Tsiku _____ Mwezi _____ Chaka _____

3. Kodi ndi kwa zaka kapena miyezi ingati chipatala chino chakhala chikugwiritsa nthito ya ndondomeko ya chithandizo cha mankhwala— oyamba kumwa nthawi yomwe mayi wapakati kapena oyamwitsa akangopezeka ndi kachilombo ka HIV mosayanganira kuchuluka kwa chitetezo cha m'thupi la mayiyo kapena kudwala matenda ena obwera chifukwa chotsika kwa chitetezo chanthupi— omwe amathandiza kuchepetsa kufalikira kwa ka chilombo ka HIV kuchokera kwa mayi kupita kwa (ART/PMTCT “Option B+” guidelines)?

Yankho :

Miyezi _____ kapena Zaka _____

Tsiku _____ Mwezi _____ Chaka _____

4. Kodi chipatala chino chinayamba liti kulandira chithandizo cha upangili kuchokera ku bungwe la UNC?

Tsiku _____ Mwezi _____ Chaka _____

Kuphatikiza pamodzi, kodi ndi ogwira ntchito angati amene amagwira nawo nthito ya kulimbikitsa ndondomeko ya chithandizo cha mankhwala— oyamba kumwa nthawi yomwe mayi wapakati kapena oyamwitsa akangopezeka ndi kachilombo ka

HIV mosayanganira kuchuluka kwa chitetezo cha m'thupi la mayiyo kapena kudwala matenda ena obwera chifukwa chotsika kwa chitetezo chanthupi—omwe amathandiza kuchepetsa kufalikira kwa ka chilombo ka HIV kuchokera kwa mayi kupita kwa mwana (ART/PMTCT “Option B+” guidelines)? *Muwawerenge onse amene amagwira nthito ku madera onse a ndondomeko ya chithandizo chofuna kuchepetsa mpata wa kufalikira kachilombo ka HIV kuchokera kwa mayi kupita kwa mwana koma musawerenge amene anangophunzitsidwa ndipo sagwirira nawo nthitoyo.*

RNs= NMTs= COs= MAs= HSAs=
 HTC Counselors= Anthu wongozipereka (Volunteers) = Ena
 ,tchulani=

5. Kodi ndi dera lalikulu bwanji limene likuthandizidwa ndi chipatala cha (*name the clinic*)? _____
6. Yankhani mafunso otsatirawa pogwiritsa ntchito zotsatira za chaka cha pakati pa 2012 ndi 2013 za ku ntchito za chithandizo chofuna kuchepetsa mpata wa kufalikira kwa ka chilombo ka HIV kuchokera kwa mayi kupita kwa mwana.
 - a) Kodi ndi amai oyembekezera angati amene anathandizidwa pa chipatala cha (*name the clinic*) m'chakachi? _____
 - b) Kodi ndi amai angati amene anachirira pa chipatala cha (*name the clinic*) m'chakachi? _____
 - c) Kodi kuphatikiza pamodzi, ndi anthu angati pa anthu makumi khumi alionse amene anapezeka ndi kachilombo ka HIV pa chipatala cha (*name the clinic*) m'chakachi? _____

Part 2: In-depth interviews on provision and use of technical assistance to promote implementation of the Option B+ guidelines at the study clinic

Cholinga cha zokambiranazi ndi kuphunzira m'mene chipatala cha (*name the clinic*) chinagwirira nthito ndi a bungwe la UNC munthawi yomwe a bungweli amapereka ndondomeko ya upangili, komanso m'mene chipatalachi chinagwiritsira ntchito nzeru zochokera ku ndondomeko ya upangiliwu umene chinalandira. Chonde khalani a chilungamo m'mayankho ano, chifukwa nditha kuphunzirapo pa zomwe chipatalachi chinazona kuti ndizothandiza, komanso zimene zikufunika kukhonza mundondomeko ya kupereka chithandizo cha upangili mutsogolo muno. Mafunso ena atha kuoneka ngati ndi obwerezabwerezwa, koma ndikufunitsitsa kuti ndimvetsetse za kaperekedwe ka ndondomeko ya upangili, kagwiritsidwe ntchito kake, komanso m'mene chipatala chino chikugwirira ntchito za chithandizo chofuna kuchepetsa mpata wa kufalikira kwa kachilombo ka HIV kuchokera kwa mayi kupita kwa mwana.

1. Chonde fotokozani ntchito za anthu amene amagwira ntchito mundondomeko yaupangili amene amachokera ku bungwe la UNC kuchokera mu chaka cha 2011 kufikira chaka cha 2014 pa chipatala cha (*name the clinic*)

Probes: Ndimowirikiza bwanji anthu amenewa a ku bungwe la UNC amagwira ntchito zimenezi?

Notes section

2. Ndi chiyani chimene mukukumbukira kwambiri chokhudzana ndi nthito ya chithandizo cha upangili imene a bungwe la UNC anapereka pothandiza chipatala cha (*name the clinic*) pa kukhazitsa ndi kulimbikitsa ndondomeko ya chithandizo cha mankhwala— oyamba kumwa nthawi yomwe mayi wapakati kapena oyamwitsa akangopezeka ndi kachilombo ka HIV mosayanganira kuchuluka kwa chitetezo cha m'thupi la mayiyo kapena kudwala matenda ena obwera chifukwa chotsika kwa chitetezo chanthupi— omwe amathandiza kuchepetsa mpata wa kufalikira kwa ka chilombo ka HIV kuchokera kwa mayi kupita kwa mwana imene boma la Malawi linakhazikitsa m'chaka cha 2011 (*Malawian 2011 ART/PMTCT "Option B+" guidelines*)?

Chonde yankhulani za ndondomeko ya upangili wina ulionse okhudzana ndi nthito zomwe zimaperkedwa m'madera ndi m'mamidzi ozungulira chipatala chino, ku sikelo ya a mayi a pakati, ku chipinda chochilira, ndi kuchipatala cha ana osakwana zaka zisanu (kusikelo ya ana).

Chonde tangoyerekezani nambala ya ma ola kapena m'mphindi pa mwezi ulionse a/zimene ogwira ntchito yopeleka chithandizo cha upangili ochokera ku bungwe la UNC amakhala ndikugwira ntchito za chithandizo chofuna kuchepetsa mpata wa kufalikira kwa ka chilombo ka HIV kuchokera kwa mayi kupita kwa mwana pa pachipatala pano?

Nanga ndi ma ola angati kapena mphindi zingati z/omwe anthu amene amapereka chithandizo cha upangili a ku bungwe la UNC amatha kukhala akugwira nthito zomwe zimagwidwa m'madera ndi m'mamidzi ozungulira chipatala chino,..... ku sikelo ya a mayi a pakati,..... ku chipinda chochilira,..... ndi kuchipatala cha ana osakwana zaka zisanu (kusikelo ya ana)?

Ndi mowirikiza bwani kumene opereka chithandizo chaupangiliwa amakwanitsa, kapena samakwanitsa kukumana ndi anthu amene amagwira nthito ya chithandizo chofuna kuchepetsa mpata wa kufalikira kwa ka chilombo ka HIV kuchokera kwa mayi kupita kwa mwana?..... Kodi panali zipysinjo zanzi zomwe zimatha kulepheretsa kukumana ndi anthuwo?

Notes Section

Ganizirani nthito zonse zimene a bungwe la UNC anazichita pakati pa zaka za 2011 ndi 2014. Kodi ndi ziti zimene mukukumbukira kwambiri zokhudza bungwe la UNC ndi ndondomeko yao ya chithandizo cha upangili ?..... Kodi ndi magawo ati a chithandizo cha upangili wochokera ku bungwe la UNC amene mukuganiza kuti anathandiza kwambiri chipatala cha (*name the clinic*) kukhazitsa ndi kulimbikitsa ndondomeko ya chithandizo cha mankhwala— oyamba kumwa nthawi yomwe mayi wapakati kapena oyamwitsa

akangopezeka ndi kachilombo ka HIV mosayanganira kuchuluka kwa chitetezo cha m'thupi la mayiyo kapena kudwala matenda ena obwera chifukwa chotsika kwa chitetezo chanthupi— omwe amathandiza kuchepetsa kufalikira kwa ka chilombo ka HIV kuchokera kwa mayi kupita kwa mwana (Option B+ guidelines)?

Ndi zipangizo ziti zimene zimagwiritsidwa nthito, kapena zinapangidwa ndi anthu amene amapeleka chithandizo cha upangili a ku bungwe la UNC zimene mukukhulupirira kuti zinathandiza chipatalachi kukhazitsa ndi kulimbikitsa ndondomeko ya chithandizo cha mankhwala— oyamba kumwa nthawi yomwe mayi wapakati kapena oyamwitsa akangopezeka ndi kachilombo ka HIV mosayanganira kuchuluka kwa chitetezo cha m'thupi la mayiyo kapena kudwala matenda ena obwera chifukwa chotsika kwa chitetezo chanthupi— omwe amathandiza kuchepetsa kufalikira kwa ka chilombo ka HIV kuchokera kwa mayi kupita kwa mwana (Option B+ guidelines)?

Ndi thandizo lina liti limene mukuganiza kuti likanathandiza chipatala chino kukhazitsa ndi kulimbikitsa ndondomeko kuposera zimene zinaperekedwa ndi a bungwe la UNC?

Ngati chipatala cha (*name the clinic*) chingakhale nso nawo mu ndondomeko ya chithandizo cha chaupangili, kodi mukanaperekapo maganizo anji kuti anthu opereka chithandizo cha upangili adzapange mosiyana?

Notes Section

3. Tayeserani kumbukira zimene mukukhulupirira kuti zinali ziphyinjo ku chipatala cha (*name the clinic*) pogwirira nthito ya chithandizo chofuna kuchepetsa mpata wa kufalikira kwa ka chilombo ka HIV kuchokera kwa mayi kupita kwa mwana, m'nthawi ya m'mbuyo a bungwe la UNC asanathandizire ndi chithandizo cha upangili.

Ndiuzeni zambiri za zophyinjazi.

Probe: *Ndiziti pa zipyinjazi ndi zomwe a bungwe la UNC anathana nazo?*

Tandiuzeni m'mene chithandizo cha upangili chinathandizira kuthana nazo zinthuzo.

..... Pamene chipatala chino chitayamba kulandira chithandizo cha upangili kuchokera ku bungwe la UNC, ndichiyani chimene mukukhulupira kuti chipatala chino chinaona kuti ndi chothandiza?..... Nanga zomwe zinali zosathandiza?

.....Tandiuzeni za zinthu zimene a bungwe la UNC ndi pologalamu yawo ya chithandizo cha upangili sanathane nazo Inu mukuganiza kuti zinthu zimenezi a gulu lopeleka chithandizo cha upangili akanathana nazo bwanji kuti apititse patsogolo kagwiridwe ka nthito ya chithandizo chofuna kuchepetsa mpata wa kufalikira kwa kachilombo ka HIV kuchokera kwa mayi kupita kwa mwana pa chipatala pano?

Notes Section

4. Taganizirani za madera ozungulira chipatala chino komanso chipatala chenichenichi. Kodi inu mukuganiza kuti ndi zinthu ziti zimene zinali zopititsa patsogolo kapena zolepheretsa/ zophyinja kuti chipatalachi chigwire nthito za chithandizo chofuna kuchepetsa mpata wa kufalikira kwa kachilombo ka HIV kuchokera kwa mayi kupita kwa mwana monga momwe ndondomeko ya chithandizo cha mankhwala oyamba kumwa nthawi yomwe mayi wapakati kapena oyamwitsa akangopezeka ndi kachilombo ka HIV mosayanganira kuchuluka kwa chitetezo cha m'thupi la mayiyo kapena kudwala matenda ena obwera chifukwa chotsika kwa chitetezo chanthupi inalembedwera?

Probes: *Kodi ndi nzothekera/nchapafupi bwanji kuti amayi ndi banja lawo alandire chithandizo pachipalachi?.....Nanga zipangizo zogwirira nthito ya chithandizo chofuna kuchepetsa mpata wa kufalikira kwa kachilombo ka HIV kuchokera kwa mayi kupita kwa mwana zimapezeka?Nanga anthu ogwira nthito za chithandizo chofuna kuchepetsa mpata wa kufalikira kwa kachilombo ka HIV kuchokera kwa mayi kupita kwa mwana amakhalapo nthawi zonse pachipatalachi?*

Notes Section

5. Kodi nthito za chithandizo chofuna kuchepetsa mpata wa kufalikira kwa kachilombo ka HIV kuchokera kwa mayi kupita kwa mwana zinagawidwa mwadongosolo lotani pachipatala cha (***name the clinic***)? ...Kodi ndi masiku ake ati amene chipatala cha (***name the clinic***) chimagwira nthito za chithandizo chofuna kuchepetsa mpata wa kufalikira kwa kachilombo ka HIV kuchokera kwa mayi kupita kwa mwana monga: kupereka uphungu ndi kuyesa magazi a kachilombo ka HIV?..... sikelo ya amai a pakati?chithandizo komanso sikelo ya ana ochepera zaka zisanu?chithandizo cholandiritsa mankhwala a ma ARV?..... ndi nthito zogwirira kumadera ndi m'mamidzi ozungulira chipatala chino.?Kodi masiku amenewa ndi omweonso amene opereka chithandizo cha upangili ochokera ku bungwe la UNC amayenderanso chipatala cha (***name the clinic***)?

Probes: *Kodi ku sikelo ya amayi a pakati, ku chipinda chochirira, ku chikuta, ku sikelo ya ana osakwanira zaka zisanu ndi komwe amalandilitsirako mankhwala a ma ARV ndikotalikirana bwanji pa chipatala cha (***name the clinic***)?.....Nanga malo ogwirirako nthito za chithandizo chofuna kuchepetsa mpata wa kufalikira kwa kachilombo ka HIV kuchokera kwa mayi kupita kwa mwana monga malo: oyeserako magazi a ka chilombo ka HIV, operekerako uphungu, osungirako mankhwala a ma ARV, osungirako zipangizo zoyesera magazi a ka chilombo ka HIV, ndi malo operekerako mankhala a ma ARV alipo pa chipatala cha (***name the clinic***)?*

Notes Section

6. Tsopano taganizirani zinthu zonse zimene zingathe kutumphukira/kuchokera ku nthambi ina iliyonse yoona kayendetsedwe ka nchito ya za umoyo M’Malawi muno, kuphatikizapo unduna wa zaumoyo ngati make wa chipatala chino. Kodi inu mukuganiza kuti ndi zinthu zANJI zomwe zikupititsa patsogolo kapena kulepheretsa chipatala chino kugwira nthito za chithandizo chofuna kuchepetsa mpata wa kufalikira kwa kachilombo ka HIV kuchokera kwa mayi kupita kwa mwana monga zinalembedwera mu ndondomeko ya chithandizo cha mankhwala— oyamba kumwa nthawi yomwe mayi wapakati kapena oyamwitsa akangopezeka ndi kachilombo ka HIV mosayanganira kuchuluka kwa chitetezo cha m’thupi la mayiyo kapena kudwala matenda ena obwera chifukwa chotsika kwa chitetezo chanthupi —omwe amathandiza kuchepetsa kufalikira kwa ka chilombo ka HIV kuchokera kwa mayi kupita kwa mwana (Option B+ guidelines)?

Probes: Kodi zipangizo zogwirira nthito ku chipatala cha (**name the clinic**) monga zoyesera kachilombo ka HIV, komanso mankhala a ma ARV zimachokera kuti?.... ndipo zimakafikako bwaji?.....Nanga anthu ogwira nthito pa chipatala cha (**name the clinic**), amatumizidwako kuchokera kuti?.... ndipo zimatengera chiyani kuti atumizeko anthu ogwira nthito ku chipatala cha (**name the clinic**)?Kodi pa chipatala cha (**name the clinic**) pali nthawi ina imene zipangizo zogwiririra nthicho zimapezeka kuti palibe?.....Monga zipangizo ziti? Nanga pa chipatala cha (**name the clinic**) pali nthawi ina yomwe pamapezeka kuti ogwira nthito za chithandizo chofuna kuchepetsa kufalikira kwa ka chilombo ka HIV kuchokera kwa mayi kupita kwa mwana panalibe?Ngati ogwira nthito amapezeka kuti pamakhala kuti panalibe, kodi amapita kuti?.....Kodi ndinthawi yochuluka bwanji imene ogwirira nthito za chithandizo chofuna kuchepetsa mpata wa kufalikira kwa ka chilombo ka HIV kuchokera kwa mayi kupita kwa mwana amapita ku maphunziro a china chake m’paka kukagonera komweko?.....Nanga amatha kukakhalako nthawi yayitali bwanji?..... Nthawi imeneyi, kodi nthito za chithandizo chofuna kuchepetsa mpata wa kufalikira kwa ka chilombo ka HIV kuchokera kwa mayi kupita kwa mwana zimaima kaye?

Notes Section

Note to Interviewer: Let informant know that questions 8 and 9 are about implementation of PMTCT activities based on the Option B+ guidelines at (**name the clinic**).

Mafunso kuyambira la chisanu ndi chitatu (8) ndi la chisanu ndi chinayi (9) ndi okhudza kagwiridwe ka nchito za chithandizo chofuna kuchepetsa mpata wa kufalikira kwa kachilombo ka HIV kuchokera kwa mayi kupita kwa mwana kutengera ndi ndondomeko ya chithandizo cha mankhwala oyamba kumwa nthawi yomwe mayi wapakati kapena oyamwitsa akangopezeka ndi kachilombo ka HIV mosayanganira kuchuluka kwa chitetezo cha m’thupi la mayiyo kapena kudwala matenda ena obwera chifukwa chotsika kwa chitetezo chanthupi omwe amathandiza kuchepetsa kufalikira kwa ka chilombo ka HIV kuchokera kwa mayi kupita kwa mwana pa chipatala cha (**name the clinic**)?

7. Kodi munganene kuti ndi kochuluka bwanji komwe anthu amene amagwira ntchito pa chipatala cha (*name the clinic*) akuvomerezana ndi kugwirizana nazo nchito za chithandizo chofuna kuchepetsa mpata wa kufalikira kwa kachilombo ka HIV kuchokera kwa mayi kupita kwa mwana m'mene zinalembedwera m'ndondomeko ya chithandizo cha mankhwala oyamba kumwa nthawi yomwe mayi wapakati kapena oyamwitsa akangopezeka ndi kachilombo ka HIV mosayanganira kuchuluka kwa chitetezo cha m'thupi la mayiyo kapena kudwala matenda ena obwera chifukwa chotsika kwa chitetezo chanthupi?

Notes Section

8. Chonde ndifotokozereni m'mene chipatala cha (*name the clinic*) chikugwirira ntchito za chithandizo chofuna kuchepetsa mpata wa kufalikira kwa kachilombo ka HIV kuchokera kwa mayi kupita kwa mwana zomwe zili m'nsizi? *Probe on answers for each activity.*

- Kugwirira ntchito zosonkhanitsa ndi kumawaunikira anthu okhala m'mamidzi ndi m'madera ozungulira chipatala chino zokhudza ndondomeko ya chithandizo cha mankhwala— oyamba kumwa nthawi yomwe mayi wapakati kapena oyamwitsa akangopezeka ndi kachilombo ka HIV mosayanganira kuchuluka kwa chitetezo cha m'thupi la mayiyo kapena kudwala matenda ena obwera chifukwa chotsika kwa chitetezo chanthupi— omwe amathandiza kuchepetsa kufalikira kwa ka chilombo ka HIV kuchokera kwa mayi kupita kwa mwana yomwe ikugwitsidwa ntchito pa chipatala pano ndi m'madera ena ozungulira chipatala chino?

Probe: If not doing fully: *Inu mukuganiza kuti ndi chifukwa chiyani chipatalachi sichikugwira ntchitozi kapena sichikugwira nchitozi kwambiri?*

- Kuona ndi kutsimikiza za zotsatira za kachilombo ka HIV za mzimayi wina aliyese wapakati komanso oyamwitsa amene amalandira chithandizo pa chipatala chino pa ulendo wina uli onse.

Probe: If not doing fully, *Inu mukuganiza kuti ndi chifukwa chiyani chipatalachi sichikutha kuona ndi kutsimidza za zotsatira za kachilombo ka HIV paulendo wina uli onse umene a mayi amabwera kudzalandira chithandi pachipatala cha (*name the clinic*).*

- Kuona pa tsamba 6 la khadi ya sikelo ya amayi a pakati kuti atsimikizire za zotsatira za kachilombo ka HIV pa ulendo wina uli onse omwe amayi amabwera kudzalandira chithandizo pa chipatala cha (*name the clinic*).

Probe: If not doing fully: *Inu mukuganiza kuti ndi chifukwa chiyani chipatalachi sichikutha kuona pa tsamba 6 ulendo wina ulionse kutsimikizira za zotsatira za kachilombo ka HIV ka a mayi omwe amathandizika pa chipatala cha (*name the clinic*)?*

- Kupereka chithandizo cha uphungu ndi kuyesa magazi a kachilombo ka HIV chimene ogwira ntchito a pachipatala ayenera kuyambitsa nthawi zonse kuti amayi apakati kapena oyamwitsa amene amalandira chithandizo cha zaumoyo pa chipatala cha (*name the clinic*) ayezetse magazi awo a kachilombo ka HIV?

Probe: If not doing fully: Inu mukuganiza kuti ndi chifukwa chiyani chipatalachi sichikutha kupereka uphungu ndi kuyesa magazi a kachilombo ka HIV nthawi zonse zomwe amayi apakati kapena oyamwitsa amapita ndi kukalandira chithandizo cha za umoyo pa chipatala cha (*name the clinic*)?

- Kuphunzitsa amayi amene ali ndi kachilombo ka HIV komanso mabanja awo kuti munthu akayamba kumwa mankhwala a ma ARV, ayenera kumwa tsiku lirilonse kwa moyo wake onse?

Probe: If not doing fully: Inu mukuganiza kuti ndi chifukwa chiyani chipatalachi sichikutha kupereka chiphunzitso cha kamwedwe ka mankhwala a ma ARV moyenerera?

- Kuyambitsa amayi onse a pakati komanso oyamwitsa amene apezeka ndi kachilombo ka HIV mankhwala a ma ARV omwe munthu a mamwa kwa moyo wake onse, monga mankhwala a Tenofovir/Lamivudine/Efavirenz (5A regimen) tsiku lomwelo lomwe munthu wapezekerera ndi kachilombo ka HIV kapena pasanathe masiku asanu ndi awiri mosayang'anira kuchuluka kwa chitetezo cha m'thupi la mayiyo kapena kudwala matenda ena obwera chifukwa chotsika kwa chitetezo chanthupi?

Probe: If not doing fully: Inu mukuganiza kuti ndi chifukwa chiyani chipatalachi sichikutha kuyambitsa amayi onse a pakati komanso amayi onse oyamwitsa mankhwala a ma ARV tsiku lomwelo lomwe apezekerera ndi kachilombo ka HIV kapena pasanathe masiku asanu awiri?

- Kupereka ma botolo atatu a nevirapine wa madzi wa mlingo okwana ma mililita makumi awiri ndi mphambu zisanu (25mls) pa botolo liri lonse amene ali wa mwana amene anabadwa kapena akuyembekezera kubadwa kwa a mayi amene ali ndi kachilombo ka HIV kwa amai onse pa tsiku loyamba lomwe amayiwo adziwikira kuti ali ndi kachilombo ka HIV?

Probe: If not doing fully: Inu mukuganiza kuti ndi chifukwa chiyani chipatalachi sichikutha kupereka nevirapine wamwanayu kwa amayi onse amene ali ndi kachilombo ka HIV mwa ndondomeko yake?

- Kuyambitsa ndondomeko yakuti amai ndi mwana adzitsatiridwa kapena adzipita kuchipatala pa masiku ofanana.

Probe: If not doing fully: Inu mukuganiza kuti ndi chifukwa chiyani chipatalachi sichikutha kuyambitsa kuti amayi onse amene ali ndi kachilombo ka HIV adzitsatiridwa kapena adzipita kuchipata pa masiku ofanana ndi ana awo?

- Kuonesetsa kuti ana onse obadwa kwa amayi amene ali ndi kachilombo ka HIV akuyezedwa ka chilombo ka HIV. Izi zikuthandauza kuti, kutengako ndi kukayesa magazi ngakhale kamodzi kokha a mwana aliyese amene anabadwa kwa amayi amene ali ndi kachilombo ka HIV kuyambira mwana atakwana milungu isanu ndi umodzi yakubadwa (DNA-PCR sample).....Nanga zoyesa zonse zimene zikufunika kuyesedwa pa mwana aliyense amene anabadwa kwa a mayi amene ali ndi kachilombo ka HIV?

Probe: If not doing fully: Inu mukuganiza kuti ndi chifukwa chiyani chipatalachi sichikutha kutenga ndi kukayesa magazi a mwana aliyese amene anabadwa kwa a mayi amene ali ndi kachilombo ka HIV mwa ndondomeko yake?

- Kulemba ntchito zonse zomwe za gwiridwa za chithandizo chofuna kuchepetsa mpata wa kufalikira kwa kachilombo ka HIV kuchokera kwa mayi kupita kwa mwana m'mabuku (registers) kapena m'ma khadi oyenerera.

Probe: If not doing fully: Inu mukuganiza kuti ndi chifukwa chiyani chipatalachi sichikutha kulemba ntchito zonse zomwe za gwiridwa m'mabuku (registers) kapena m'ma khadi oyenerera?

Notes Section

9. Kodi mungafotokoze bwanji za ubale wakagwiridwe ka ntchito umene unalipo pakati pa anthu amene amapereka chithanzo cha upangili ochokera ku bungwe la UNC ndi chipatala cha (**name the clinic**)?

Probes: Kodi inu mukuganiza kuti ndi ubale wabwino wotani umene unalipo pakati pa anthu amene amapereka chithanzo cha upangili ochokera ku bungwe la UNC ndi chipatala cha (**name the clinic**)?..... Inu mukuganiza kuti ubale wabwinowu ungate kupitsidwa patsogolo bwanji?.....Nanga ubale osakhala bwino umene unalipo pakati pa anthu amene amapereka chithanzo cha upangili ochokera ku bungwe la UNC ndi chipatala cha (**name the clinic**)?..... Nanga ubale osakhala bwinowu, ungatekuthetsedwa bwanji?

Nanga ubale wakagwiridwe ka ntchito pakati pa chipatala chino ndi aunduna wa zaumoyo ngati make wa chiptala chino ndiotani?

Probes: Kodi inu mukuganiza kuti ndi ubale wabwino wotani umene ulipo pakati pa chipatala cha (**name the clinic**) ndi unduna wa zaumoyo?..... Inu mukuganiza kuti ubale wabwinowu ungate kupitsa patsogolo bwanji?.....Nanga ubale osakhala bwino umene ulipo pakati pa chiptatala cha (**name the clinic**) ndi unduna wa zaumoyo ndi otani?..... Nanga ubale osakhalabwinowu, ungatekuthetsedwa bwanji?

Notes Section

10. Kodi pali chinthu china chake chomwe mukufuna kundiuza chokhudzana ndi m'mene chipatala cha (*name the clinic*) chinalandirira, ndikugwiritsira ntchito chithandizo cha upangili chimene a bungwe la UNC anapeleka pa kukhazikitsa ndi kulimbikitsa ndondomeko ya chithandizo cha mankhwala— oyamba kumwa nthawi yomwe mayi wapakati kapena oyamwitsa akangopezeka ndi kachilombo ka HIV mosayanganira kuchuluka kwa chitetezo cha m'thupi la mayiyo kapena kudwala matenda ena obwera chifukwa chotsika kwa chitetezo chanthupi— omwe amathandiza kuchepetsa mpata wa kufalikira kwa ka chilombo ka HIV kuchokera kwa mayi kupita kwa mwana (Option B+ guidelines)?

Probe on the answers.

Notes Section

APPENDIX 3: CODES AND THEIR DEFINITION

Table 9. Codes and their Definition

Codes	Definition
A. Prevention support	<p>Prevention support is any activity that UNC project did to enhance implementation of the Option B+ guidelines at the study clinics. Examples of the prevention support strategies are: tools, training, technical assistance and resources.</p>
<p>1. Tools</p> <ul style="list-style-type: none"> • Reporting forms • Checklists • Registers • Charts • Guidelines • Cards 	<p>Tools are informational resources that were either designed by the UNC Project or the Malawi Ministry of Health to organize, summarize or communicate knowledge to service providers who were actively involved in the implementation of the Option B+ guidelines in the clinics. Examples of such tools are manuals, guidelines, registers, log books, cards, diaries and checklists.</p> <p>Tools are part of support components that are included in the Evidence-Based Systems for Innovation Logic Model (Wandersman, Chien, & Katz, 2012).</p> <ul style="list-style-type: none"> • Reporting forms are tools that both the clinics and the TA providers used. Clinics used reporting form as monitoring and evaluation tools for them to improve care and also as a guide for budgeting for their resources while TA providers used them for Audit and feedback purposes. • Checklists are tools that were used by TA providers only for Auditing purposes. • Registers are tools in a form of a paper based books that both the clinics and the TA providers used. Clinics used registers to store data which later was used for monitoring and evaluation in order for them to improve care and also as a guide for budgeting for their resources. TA providers used registers to audit implementation that helped them to give a proper feedback

Codes	Definition
	<p>to the clinics.</p> <ul style="list-style-type: none"> • Charts are tools that could be either posters/flow charts/ flip chart. These tools were either developed by the UNC Project or the Malawi Ministry of Health to guide health workers on how to deliver a specific procedure or what proper information to give to clients. • Guidelines are tools that consist of policy changes to antiretroviral and prevention of mother to child transmission of HIV care in Malawi. • Cards are tools in a form of a paper based booklets or sheets that both the clinics and the TA providers used. Clinics used cards to store data which later was used for monitoring and evaluation in order for them to improve care and also as a guide for budgeting for their resources. TA providers used cards to audit implementation that helped them to give a proper feedback to the clinics.
<p>2. Training</p>	<p>Training is any activity indicated by the informants that was planned, instructional, interactive that was offered in a group setting and was organized to enable the study clinics to acquire knowledge, skills, and attitudes specific to helping them implement the Option B+ guidelines (Chinman et al., 2008; Wandersman et al., 2012).</p>
<p>3.</p> <p>4. Technical Assistance (TA)</p> <ul style="list-style-type: none"> • Dose • Collaboration • Audit and feedback • Focus 	<p>Technical Assistance (TA) is an individualized, hands-on consultation that was provided by the UNC Project technical officers at the community and clinic level to reinforce understanding of knowledge and skills of the service providers at the clinic and to enhance quality implementation of the Option B+ guidelines in the practice settings (Chinman et al., 2008; Hunter et al., 2009; Wandersman et al., 2012).</p> <ul style="list-style-type: none"> • Dose is the time in hours spent by support

Codes	Definition
	<p>providers on clinic and community based support activities. This excludes time spent on trainings.</p> <ul style="list-style-type: none"> • Collaboration includes all activities that were done in conjunction by both the UNC Project and the Malawi Ministry of Health staff and aimed at helping the clinic staff to implement the Option B+ guidelines with quality. • Audit and feedback includes all activities that were done by the UNC Project technical team that helped them to assess quality performance of the clinics on the implementation of the Option B+ guidelines and there after gave feedback on areas that needed improvement. Strategies such as data collection and providing feedback are examples of Audit and feedback • Focus includes areas of emphasis on the practice of UNC Project TA providers on where they were trying to change at a study clinic. The frequency and an amount of time spent on each unit by the TA providers determine the TA focus at that specific clinic.
<p>5. Resources</p> <ul style="list-style-type: none"> • Drugs • Testing kits • Vital Meal • Water guard • Furniture • Transportation • Insecticides Treated Bed 	<p>Resources are materials other than tools that were supplied by the UNC Project to enhance the study clinics’ implementation of the Option B+ guidelines. Examples of such resources are drugs, HIV testing kits, vital meal, waterguard.</p> <ul style="list-style-type: none"> • Drugs are either antiretroviral drugs or any drug that is used to treat opportunistic infections that are caused by a compromised immunity of an HIV infected person • Testing kits are either antibody or antigen HIV test kits or blood collection kits that are used to determine the presence of HIV infection in the human body. • Vital Meal is a type of nutritious floor that was used as a supplementary food to HIV

Codes	Definition
Nets (ITN)	<p>exposed children from the age of 6 months</p> <ul style="list-style-type: none"> • Water guard is a type of water purification chemical • Furniture includes any type of furniture that was provided by the UNC Project to the study clinics • Transportation includes any means of transportation that was either provided or used to aid delivery of TA or clinics' activities based on Option B+ guidelines • Insecticides Treated Bed Nets (ITN) included mosquito nets that were provided by the UNC Project as part of support to HIV infected women and their family members to prevent malaria which is prevalent and mostly fatal in HIV infected patients.
6. Most valued Support (MVS)	<p>Most valued support includes all the support that informants thought were more important than the rest among the prevention support that was provided by UNC Project.</p>
<p>7. Other Desired support</p> <ul style="list-style-type: none"> • Need more TA visits • Immediate feedback • Mechanisms to reduce defaulters 	<p>Other Desired support includes those types of prevention support that was not provided by UNC Project but was highly recommended by informants as enhancers of prevention support delivery and or use. How informants suggested to improve things at the study sites are included as other desired support</p>
B. Implementation	<p>Implementation refers to how clinics carried out ART/PMTCT of HIV activities in order to achieve quality outcomes of the implemented Option B+ guidelines. Malawi Ministry of Health PMTCT indicators were used to assess implementation of Option B+ guidelines as either fully or partial. Implementation was done at community, antenatal, labor and delivery and Under-Five units.</p>
<p>C. Contextual factors</p> <p>Facilitators</p>	<p>Contextual factors refers to environmental issues that informants identified them as either barriers or facilitators to either TA delivery to</p>

Codes	Definition
Barriers Clinic age Magnitude Clinic Size Staffing (at community, clinic and systems’ level)	<p>implementation of the Option B+ guidelines.</p> <p>Contextual factors arose at community, clinic and systems levels.</p> <p>Facilitators include contextual factors that were perceived by informants as enhancers to either TA provision or implementation of the Option B+ guidelines and arose from the clinics, community or general Malawian health care system.</p> <p>Barriers include contextual factors that were perceived by informants as inhibitors to either TA provision or implementation of the Option B+ guidelines and arose from the clinics, community or general Malawian health care system.</p> <p>Clinic age refers to number of operational years of the study clinic. The age was also calculated based on number of years clinics implemented the Option B+ guidelines.</p> <p>Magnitude was calculated using the following: (1), The clinics’ official catchment areas as designated by the Malawi Ministry of Health; (2) annual number of pregnant women seen at a facility during the fiscal year 2012-2013 FY; (3) annual number of deliveries at a facility during the fiscal year 2012-2013; (4) an overall HIV prevalence rate at a facility; and (5) the workload as described by the informants.</p> <p>Clinic Size was calculated by the number of clinic staff trained in Option B+ and the actual number of clinic staff who are involved in the implementation of the Option B+ activities.</p> <p>Staffing included all emerging workforce issues be it related to TA providers as they deliver TA to clinics or service providers as they implemented the Option B+ guidelines at the study clinics.</p> <p>Community refers to a level of unit where patients and their family members live and were coming from to access care at the clinic. Facilitators and barriers that informants reported to have occurred or arose at community level, are included under this code</p> <p>Clinic refers to a level of unit where Option B+ guidelines were implemented. Facilitators and barriers that informants reported to have occurred or arose at clinic level are included under this</p>

Codes	Definition
D. Mechanisms	<p>code</p> <p>System refers to a level of unit that encompasses all health care divisions including the central Malawian Ministry of Health that were central to implementation of the Option B+ guidelines at the clinic level. Facilitators and barriers that informants reported to have occurred at or arose from the systems' level are included under this code.</p> <p>Mechanisms are intermediates outcomes of TA and these include all outcomes that the informants perceived as mediators between TA provision and implementation of the Option B+ guidelines in the study clinics</p>

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