

Facility-Level Factors Affecting Implementation of the Option B+ Protocol for Prevention  
of Mother-to-Child Transmission of HIV (PMTCT) in Kilimanjaro, Tanzania

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Thesis submitted in partial fulfillment of  
the requirements for the degree of  
Master of Science in the Duke Global Health Institute  
in the Graduate School of Duke University

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ABSTRACT

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## Abstract

**Background:** In 2013, Tanzania adopted the Option B+ protocol for prevention of mother-to-child-transmission (PMTCT) of HIV, whereby all HIV-positive pregnant women initiate lifetime antiretroviral therapy (ART). Option B+ holds great promise for improving women's health and moving towards an "AIDS-free generation". This study aimed to evaluate the implementation of Option B+ in selected sites in Kilimanjaro region of Tanzania using the Consolidated Framework for Implementation Research (CFIR). **Methods:** Data were obtained through semi-structured observations, review of clinic records, and key informant interviews (KIIs) with healthcare providers across the PMTCT care cascade. 35 hours of observation and 30 KIIs were conducted at three healthcare facilities from May 2017 to July 2017. **Findings:** The data revealed key themes in relation to CFIR domains. Considering the intervention characteristics, the protocol was adaptable as it was observed in three healthcare facilities with different staffing and flows of care. Considering the outer setting, providers noted that stigma and lack of partner involvement were key patient-level factors hampered implementation. Interconnectedness of facilities helping implementation, but poor referral systems existed. The maladies of the underlying health system hindered optimal implementation. Considering the individual (provider) characteristics, knowledge about the protocol varied depending on training and level of experience. There was consensus

that Option B+ was effective in preventing vertical HIV transmission. However, considering the process of implementation, fidelity of implementation varied across clinics and over time, determined by providers present, clinic set-up, time of day and patient volume. As observed, the burden of record keeping appeared to hamper focused provider-patient interactions. **Discussion:** Future success in implementation of the Option B+ protocol in Tanzania requires additional training of providers on the guidelines, including counseling and patient-centered care. Community education focusing on stigma reduction and uptake of HIV testing among men will provide a more supportive implementation context. Implementation activities extending beyond the clinical setting, including home-based care, are needed. Electronic medical records may decrease the burden of redundant documentation, help track women lost to follow-up at the clinic level and improve the quality of care.

## **Dedication**

I dedicate this thesis to my family, especially my children Jerop and Kibet for enduring the absence of their mother throughout this journey to a graduate degree. Your resilience and unwavering love kept me going every day.

I also dedicate this thesis to the healthcare providers in sub-Saharan Africa, and especially Tanzania where the study was located, for their persistence and resilience in providing care to many, despite the strained resources and less than ideal working environments.

# Contents

|   |      |
|---|------|
| Abstract .....  | iv   |
| List of Tables .....  | x    |
| List of Figures .....   | xi   |
| Acknowledgements .....  | xiii |
| 1 Introduction.....   | 1    |
| 1.1 HIV and global priorities.....  | 1    |
| 1.1.1 Elimination of new HIV infections among children (eMTCT) by 2015 and<br>keeping their mothers alive ..... | 1    |
| 1.1.2 The 90-90-90 goals .....  | 2    |
| 1.1.3 Current statistics.....   | 2    |
| 1.2 Prevention of mother-to-child transmission (PMTCT) of HIV .....   | 4    |
| 1.2.1 Mother-to-child transmission of HIV .....   | 4    |
| 1.2.2 PMTCT evolution.....  | 5    |
| 1.2.3 PMTCT Option B+.....  | 8    |
| 1.2.4 Comprehensive PMTCT services.....   | 8    |
| 1.3 PMTCT Option B+ implementation .....  | 9    |
| 1.3.1 PMTCT Option B+ in Tanzania .....   | 10   |
| 1.4 Implementation research.....  | 11   |
| 1.4.1 PMTCT Option B+ implementation research.....  | 12   |
| 1.5 Study goals and objectives .....  | 15   |
| 2 Methods .....   | 16   |

|     |   |    |
|-----|---|----|
| 2.1 | Overview .....  | 16 |
| 2.2 | Conceptual Model .....  | 16 |
| 2.3 | Setting.....  | 20 |
| 2.4 | Procedures .....  | 21 |
|     | 2.4.1 Observation procedures .....  | 22 |
|     | 2.4.2 Interview procedures.....   | 26 |
| 2.5 | Data analysis .....   | 27 |
| 3   | Results .....   | 28 |
| 3.1 | Intervention characteristics .....  | 29 |
|     | 3.1.1 Origin of the Option B+ protocol of the PMTCT guidelines .....          | 29 |
|     | 3.1.2 Superiority of the Option B+ protocol of the PMTCT guidelines.....      | 29 |
|     | 3.1.3 Adaptability of the Option B+ protocol of the PMTCT guidelines .....    | 31 |
| 3.2 | Outer setting.....  | 34 |
|     | 3.2.1 Patient centeredness of the implementation .....                        | 35 |
|     | 3.2.2 Inter-facility relations.....   | 39 |
|     | 3.2.3 Overarching health system .....   | 42 |
| 3.3 | Inner setting.....  | 44 |
|     | 3.3.1 Structural characteristics .....  | 44 |
|     | 3.3.2 Network and communication.....  | 46 |
|     | 3.3.3 Facility commitment and input into implementation.....                  | 48 |
| 3.4 | Individual (provider) characteristics .....                                   | 51 |
|     | 3.4.1 Knowledge and beliefs on the Option B+ protocol of PMTCT guidelines.... | 51 |

|       |   |    |
|-------|---|----|
| 3.4.2 | Self-Efficacy .....   | 52 |
| 3.4.3 | Individual identification with the facility .....   | 53 |
| 3.4.4 | Other personal attributes that affect implementation of the Option B+ of the PMTCT guidelines .....   | 54 |
| 3.5   | Process of implementation .....   | 57 |
| 3.5.1 | Fidelity of implementing the Option B+ protocol of the PMTCT guidelines                               | 57 |
| 3.5.2 | Other implementation procedures .....   | 60 |
| 3.5.3 | Implementation interventions .....  | 66 |
| 3.5.4 | Reflecting and evaluation.....  | 70 |
| 3.5.5 | Suggestions for improvement .....   | 71 |
| 4     | Discussion.....   | 73 |
| 4.1   | Focus on prevention of vertical transmission while sidelining maternal long-term care engagement..... | 74 |
| 4.2   | Stigma.....   | 76 |
| 4.3   | Counselling.....  | 76 |
| 4.4   | Health workforce .....  | 78 |
| 4.5   | Feedback and quality improvement .....  | 80 |
| 4.6   | Implications for policy and practice .....  | 81 |
| 4.7   | Implications for further research.....  | 82 |
| 4.8   | Study strengths and limitations.....  | 82 |
| 5     | Conclusion.....   | 84 |
|       | Appendix A: Data collection tools.....  | 85 |
|       | References .....  | 91 |

## List of Tables

|  |    |
|--|----|
| Table 1: Statistics relating to prevention of mother-to-child transmission of HIV in Tanzania .....    | 4  |
| Table 2: The evolution of PMTCT guidelines recommended by the WHO.....                                 | 5  |
| Table 3: The Consolidated Framework for Implementation Research as applied to this research study..... | 17 |
| Table 4: Summary of facilities involved in this study.....   | 20 |
| Table 5: Observation of flow of care and implementation of the protocol .....                          | 23 |
| Table 6: Implementation details.....   | 25 |
| Table 7: Summary of participants.....  | 26 |
| Table 8: Resource availability .....   | 49 |
| Table 9: Summary of the report on fidelity of implementing the PMTCT guidelines .....                  | 58 |
| Table 10: Examples of registers present for documentation during a routine PMTCT clinic visit .....    | 60 |

## List of Figures

|   |    |
|---|----|
| Figure 1: Current overall HIV statistics as related to the 90-90-90 goals ..... | 3  |
| Figure 2: Summary of the Tanzanian national PMTCT Option B+ guidelines .....    | 11 |
| Figure 3: Summary of results mapped onto the CFIR framework.....                | 28 |
| Figure 4: PMTCT service delivery points at the three facilities.....            | 45 |

## List of Abbreviations

|        |  |
|--------|--|
| 3TC    | Lamivudine   |
| AIDS   | Acquired immunodeficiency syndrome                 |
| ANC    | Antenatal care                                     |
| ART    | Antiretroviral therapy                             |
| ARV    | Antiretroviral                                     |
| AZT    | Azidothymidine (Zidovudine)                        |
| CFIR   | Consolidated Framework for Implementation Research |
| CTC    | Care and treatment center                          |
| DBS    | Dry blood spot                                     |
| DHMT   | District health management team                    |
| DNA    | Deoxyribonucleotide                                |
| EFV    | Efavirenz  |
| EGPAF  | Elizabeth Glaser Pediatric AIDS Foundation         |
| EID    | Early infant diagnosis                             |
| eMTCT  | Elimination of mother-to-child transmission        |
| HB     | Hemoglobin   |
| HIV    | Human immunodeficiency virus                       |
| HMT    | Health management team                             |
| KCMC   | Kilimanjaro Christian Medical Center               |
| KII    | Key informant interviews                           |
| L&D    | Labor and delivery                                 |
| LPV/r  | Lopinavir/ritonavir                                |
| LTFU   | Loss to follow-up                                  |
| NGO    | Non-governmental organization                      |
| NIMR   | National Institute for Medical Research            |
| NVP    | Nevirapine   |
| PCR    | Polymerase chain reaction                          |
| PMTCT  | Prevention of mother-to-child-transmission         |
| RCH    | Reproductive and child health                      |
| TDF    | Tenofovir  |
| UNAIDS | United Nations Program on HIV and AIDS             |
| VEO    | Village executive officers                         |
| WHO    | World Health Organization                          |

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Above all, thank you God for your guidance and providence through all.

# **1 Introduction**

Initiation of lifelong antiretroviral (ARV) therapy (ART) during pregnancy, as stipulated by the prevention of mother-to-child transmission (PMTCT) Option B+ protocol, is essential for the elimination of mother to child transmission of HIV and the achievement of an AIDS Free Generation. As with any other intervention, how the PMTCT Option B+ protocol is implemented determines the successful achievement of its goals. Given the scarcity of data on the implementation process of Option B+, this thesis aims to identify the healthcare facility-level factors that promote or impede successful implementation in the Kilimanjaro region of Tanzania.

## **1.1 HIV and global priorities**

### **1.1.1 Elimination of new HIV infections among children (eMTCT) by 2015 and keeping their mothers alive**

In 2011, the United Nations Program on HIV and AIDS (UNAIDS), together with other key stakeholders, drafted a plan titled the “Elimination of new HIV infections among children by 2015 and keeping their mothers alive” to reduce HIV infections among children by 90% and reduce maternal deaths from HIV by 50%(UNAIDS 2011). The plan also included a target to reduce mother-to-child transmission of HIV to less than 5% in breastfeeding populations and less than 2% in non-breastfeeding populations(WHO 2012). Twenty-two countries, twenty-one of which were from Africa, were set as priority countries for the attainment of these goals, as they collectively had

90% of HIV positive mothers globally. Tanzania was one of the priority countries(UNAIDS 2011).

### **1.1.2 The 90-90-90 goals**

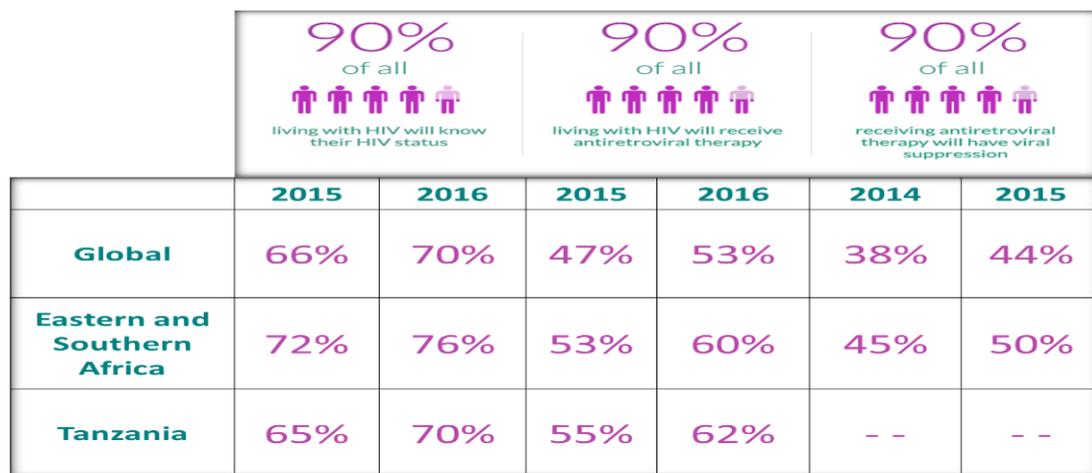
In December 2013, the UNAIDS added the 90-90-90 goals to increase HIV testing, treatment and viral suppression to 90% each throughout the world by the year 2020 with the hope of ending the AIDS pandemic by 2030(UNAIDS 2014a). The foundation of these goals is to increase the uptake of HIV treatment, which in turn can prevent further transmission of the virus. This model, known as ‘treatment as prevention’ (Cohen, McCauley, and Gamble 2012), was promoted after studies showed that HIV positive persons on ARVs who achieve viral suppression and therefore have no HIV detected in their blood, did not transmit the virus to onward to HIV negative partners(Cohen, McCauley, and Gamble 2012). Mathematical models consistently show that the rate of new infections reduces with treatment of those who are HIV positive. There is also a linear reduction in the new infections with increased coverage of ART and increased retention in care(Eaton et al. 2012).

### **1.1.3 Current statistics**

Globally, there have been tremendous gains towards achieving the 90-90-90 goals. The latest UNAIDS reports on HIV indicates an 11% reduction in the number of adults who were newly infected with HIV since 2010 and a 47% reduction in children less than 15 years globally. Access to ARVs for HIV infected persons increased by 171%

from 2010 to 2016. Available data on viral suppression shows an increase from 38% of all persons on ARVs virally suppressed in 2014 to 44% in 2015(UNAIDS 2017).

The eastern and southern regions of Africa had the highest number of new HIV infections globally at 43%, and 60% of the total number of people globally who are on ARVs. In the last 10 years, there has been a steady decline in new infections in these regions, with an increase in the proportion of people who know their HIV status, ARV coverage and viral suppression(UNAIDS 2017). In Tanzania, the overall HIV prevalence stands at 4.7% in 2016 according to the UNAIDS. This represents a decrease in the last 14 years, from 7% in 2004 and 5.3% in 2014. Although the overall picture demonstrates a decline, eight regions, including our study region of Kilimanjaro, saw a rise in the prevalence of HIV(UNAIDS 2017).



**Figure 1: Current overall HIV statistics as related to the 90-90-90 goals(UNAIDS 2017)**

(Top part of image from <https://www.avert.org/infographics/unaid-90-90-90-target>)

Considerable progress has been made toward the goal to eliminate mother to child transmission of HIV. At the end of 2015, the twenty-one priority countries in SSA had 60% reduction in new childhood HIV infections (Target 90%) and 43% reduction of maternal deaths due to HIV (Target 50%). Vertical transmission of HIV was down to 8.9% in these countries (Target <5%)(UNAIDS 2016). Despite the presence of a robust PMTCT program in Tanzania, it did not achieve any of these targets.

**Table 1: Statistics relating to prevention of mother-to-child transmission of HIV in Tanzania(UNAIDS 2015; Tanzania 2014)**

|   | 2010 | 2012 | 2015 |
|---|------|------|------|
| HIV testing for pregnant women                  | 86%  | >90% | >90% |
| ARV coverage for HIV positive mothers for PMTCT | 75%  | 95%  | 84%  |
| MTCT rate                                       |      | 23%  | 9%   |

## **1.2 Prevention of mother-to-child transmission (PMTCT) of HIV**

### **1.2.1 Mother-to-child transmission of HIV**

Transmission of HIV from the HIV positive mother to her child can occur during three key periods: during pregnancy, during childbirth, and during the breastfeeding period. The rate of transmission during these periods vary depending on when the mother acquired HIV, when diagnosis is done, the viral load, and the steps taken to minimize and prevent transmission. The rate of transmission from an HIV-infected

pregnant woman to her child without any interventions is estimated to be 15% to 45%(WHO 2018).

### 1.2.2 PMTCT evolution

The World Health Organization (WHO) first recommended ARVs for prophylaxis use during pregnancy in 2000. This was after clinical trials showed safety and efficacy of ARV use in pregnancy(WHO 2001). Over the years, as depicted in Table 1 below, the PMTCT guidelines have evolved, influenced by new evidence, availability and cost of ARVs, program efficiency, and human rights imperatives(Burton, Giddy, and Stinson 2015; Kellerman et al. 2013).

**Table 2: The evolution of PMTCT guidelines recommended by the WHO**

| Year           | For the mother   |                |             | For the child   |
|----------------|--|----------------|-------------|---|
| 2000(WHO 2001) | Intrapartum - Single 200 mg oral NVP tablet to be taken by the mother at the onset of labor  |                |             | Single oral dose of NVP in suspension (2 mg/kg) given within 72 hours of birth. |
| 2004(WHO 2004) | Treatment: as needed<br>Prophylaxis:<br>Antepartum – AZT daily from 28 weeks of pregnancy (or as soon as possible thereafter)<br>Intrapartum – AZT, 3TC plus single dose of NVP<br>Postpartum – AZT and 3TC for seven days |                |             | Single oral dose of NVP and AZT for seven days                                  |
| 2006(WHO 2006) | Treatment:<br>Lifelong with triple therapy first line of AZT+3TC+NVP   |                |             | AZT for seven days (or 28 days if mother received ART for <4 weeks antepartum   |
|                | WHO stage  | No CD4 testing | CD4 Testing |   |

|                |   |                          |                                     |   |
|----------------|---|--------------------------|-------------------------------------|---|
|                | 1   | ARV Prophylaxis          | Treat if <200 cells/mm <sup>3</sup> |   |
|                | 2   | ARV Prophylaxis          |                                     |   |
|                | 3   | Treat or ARV Prophylaxis | Treat if <350 cells/mm <sup>3</sup> |   |
|                | 4   | Treat                    | Treat with any CD4 levels           |   |
|                | Prophylaxis:<br>Antepartum – (AZT daily from 28 weeks of pregnancy (or as soon as possible thereafter)<br>Intrapartum –Single dose NVP at onset of labor plus AZT/3TC<br>Postpartum – AZT/3TC for seven days  |                          |                                     | Single oral dose of NVP and AZT for seven days  |
| 2010(WHO 2009) | Treatment:<br>Lifelong with triple therapy first line of AZT+3TC+NVP or AZT+3TC+EFV   |                          |                                     | Daily NVP or AZT for four to six weeks after birth (regardless of infant feeding choice)  |
|                | WHO stage   | No CD4 testing           | CD4 Testing                         |   |
|                | 1   | ARV Prophylaxis          | Treat if <350 cells/mm <sup>3</sup> |   |
|                | 2   | ARV Prophylaxis          |                                     |   |
|                | 3   | Treat                    | Treat with any                      |   |
|                | 4   | Treat                    | CD4 levels                          |   |
|                | Prophylaxis:<br>Option A:<br>Antepartum – AZT daily or triple therapy from 14 weeks of pregnancy (or as soon as possible thereafter)<br>Intrapartum –Single dose NVP at onset of labor plus AZT/3TC<br>Postpartum – AZT/3TC for seven days (No intra and postpartum ARVs needed of >4 weeks AZT given antepartum) |                          |                                     | If breastfeeding<br>Daily NVP until 1 week after cessation<br>If not breastfeeding,<br>daily NVP or AZT for four to six weeks after birth |
|                | Prophylaxis:<br>Option B:   |                          |                                     | Daily NVP or AZT for four to six weeks after  |

|   |  |   |                                     |  |
|---|--|---|-------------------------------------|--|
|   | Triple therapy (AZT+3TC + LPV/r or AZT+3TC+ABC or AZT+3TC+EFV or TDF+3TC [or FTC] +EFV) from 14 weeks of pregnancy (or as soon as possible thereafter) until one week after cessation of breastfeeding/ one week postpartum if not breastfeeding | birth (regardless of infant feeding choice)                               |                                     |  |
| 2013(WHO 2013)  | Treatment:<br>Lifelong with triple therapy first line of AZT+3TC+NVP or AZT+3TC+EFV  | Daily NVP for six weeks after birth (regardless of infant feeding choice) |                                     |  |
|   | WHO stage  | No CD4 testing  | CD4 Testing                         |  |
|   | 1  | ARV Prophylaxis   | Treat if <350 cells/mm <sup>3</sup> |  |
|   | 2  | ARV Prophylaxis   |                                     |  |
|   | 3  | Treat   | Treat with any CD4 levels           |  |
|   | 4  |   |                                     |  |
| Prophylaxis:<br>Option B:<br>Triple therapy (AZT+3TC + LPV/r or AZT+3TC+ABC or AZT+3TC+EFV or TDF+3TC [or FTC] +EFV) from 14 weeks of pregnancy (or as soon as possible thereafter) until one week after cessation of breastfeeding/ one week postpartum if not breastfeeding   | Daily NVP for six weeks after birth (regardless of infant feeding choice)  |   |                                     |  |
| Prophylaxis:<br>Option B+:<br>Initiation of triple therapy regardless of WHO stage or CD4 levels from 14 weeks of pregnancy (or as soon as possible thereafter) and continuation until all chances of MTCT are done/ continue for life for those who require lifelong treatment | Daily NVP for six weeks after birth (regardless of infant feeding choice)  |   |                                     |  |
| 2015(WHO 2015)  | Option B+:<br>Initiation of triple therapy regardless of WHO stage or CD4 levels during pregnancy or breastfeeding and continuation for life   | Daily NVP for six weeks after birth (regardless of infant feeding choice) |                                     |  |

AZT – Azidothymidine (Zidovudine)  
NVP – Nevirapine  
3TC – Lamivudine

LPV/r – Lopinavir/ritonavir  
TDF – Tenofovir  
EFV – Efavirenz

### **1.2.3 PMTCT Option B+**

In 2011, as a strategy to achieve the eMTCT goals(UNAIDS 2011), Malawi proposed a new option for treatment of all HIV positive pregnant women without consideration for CD4 levels or their WHO clinical stage(Schouten et al. 2011). This resulted from lack of CD4 testing across the country and inconsistent WHO clinical staging, paired with characteristics of Malawian women like late presentation to antenatal care and high fertility which rendered intermittent use of ARVs ineffective(WHO 2011; Schouten et al. 2011). After reviewing reports on the cost-effectiveness(WHO 2015) and efficacy of the Malawi trial(Fasawe et al. 2013), the WHO added Option B+ to the PMTCT guidelines. The rationale for this policy was to simplify PMTCT guidelines by eliminating triaging of pregnant women using CD4 test results and WHO clinical staging(WHO 2014). The prediction was that initiating lifelong ARVs during pregnancy would lead to improvement of the woman’s health while at the same time preventing the vertical transmission of HIV to their breastfeeding infants and forward transmission to their sexual partners(Doherty and Ciaranello 2013; WHO 2004).

### **1.2.4 Comprehensive PMTCT services**

As PMTCT evolved, other aspects of care were also outlined to ensure successful prevention of infection from the mother to the child as well as provision of timely and

quality treatment and support for the mother and the infected child to increase survival(WHO 2010). The scope of the PMTCT objectives were expanded to include preventing men and women of childbearing age from acquiring HIV in the first place, preventing unplanned pregnancies in those women who are infected, preventing transmission of HIV to the children for those who are infected and pregnant, and providing treatment, follow-up and support for men, women and children who are infected(WHO 2012).

Some of the specific services provided to ensure that these four objectives are met included: community HIV education and prevention advocacy; voluntary HIV counselling and testing; provider initiated counselling and testing; integration of PMTCT services into the healthcare delivery systems (e.g., antenatal clinic, labor ward, postnatal clinics, well child clinics, family planning clinics); opt out testing of pregnant women during ANC visit, labor and delivery and during breastfeeding; partner involvement and couple counselling and testing; initiation of ARVs for newly diagnosed pregnant or breastfeeding women; monthly follow-up visits from the antenatal period to 1.5-2 years after delivery; early infant diagnosis; follow-up of those lost in care; and community engagement and support(WHO 2015).

### **1.3 PMTCT Option B+ implementation**

There has been a steady increase in the adoption of PMTCT Option B+ guidelines globally. According to UNAIDS, 91% of all the pregnant and breastfeeding women who

are on ARVs for PMTCT were on lifetime treatment by 2015. Among the 21 priority countries in SSA, 20 have adopted Option B+ as their national PMTCT protocol. Nigeria has only piloted Option B+ in some regions of the country but has not adopted it nationally(UNAIDS 2016).

### **1.3.1 PMTCT Option B+ in Tanzania**

The scale up of PMTCT services in Tanzania has been ongoing since the inception of PMTCT in 2004. In 2010, 90% of the ANC clinics offered PMTCT services(Tanzania 2014). As one of the 22 countries targeted by the UNAIDS Global plan in 2011, Tanzania came up with a national PMTCT scale-up plan for 2011 to 2015(Kieffer et al. 2014a). In October 2013, soon after WHO urged countries to either move to PMTCT Option B or Option B+ protocols, Tanzania launched Option B+ and produced the “national guidelines for comprehensive care services for prevention of mother-to-child transmission of HIV and keeping mother alive” to guide implementation (Figure 2)(Tanzania Ministry of Health and Social Work 2013). The guidelines provided details on the implementation of Option B+ of the PMTCT intervention: HIV testing, use of ARV combinations, timing of ARV initiation and length of treatment, monitoring using CD4 tests and viral load tests, breastfeeding recommendations, and comprehensive approaches to optimize PMTCT services. At the time of implementation, nearly all facilities with reproductive and child health (RCH) services had integrated PMTCT into their services(EGPAF 2014). But not all were able to do the CD4 test needed to decide on

initiation of ARVs. The elimination of the preconditions of CD4 tests and WHO clinical staging before initiation of ARVs made it easier for patients receiving care from different facilities in Tanzania to have access to ARVs and increase the chances of preventing vertical transmission of HIV to their children. In early 2014, training of providers and roll-out of Option B+ was initiated, beginning with the larger referral hospitals, and then scaling up rapidly to other healthcare facilities(EGPAF 2014)

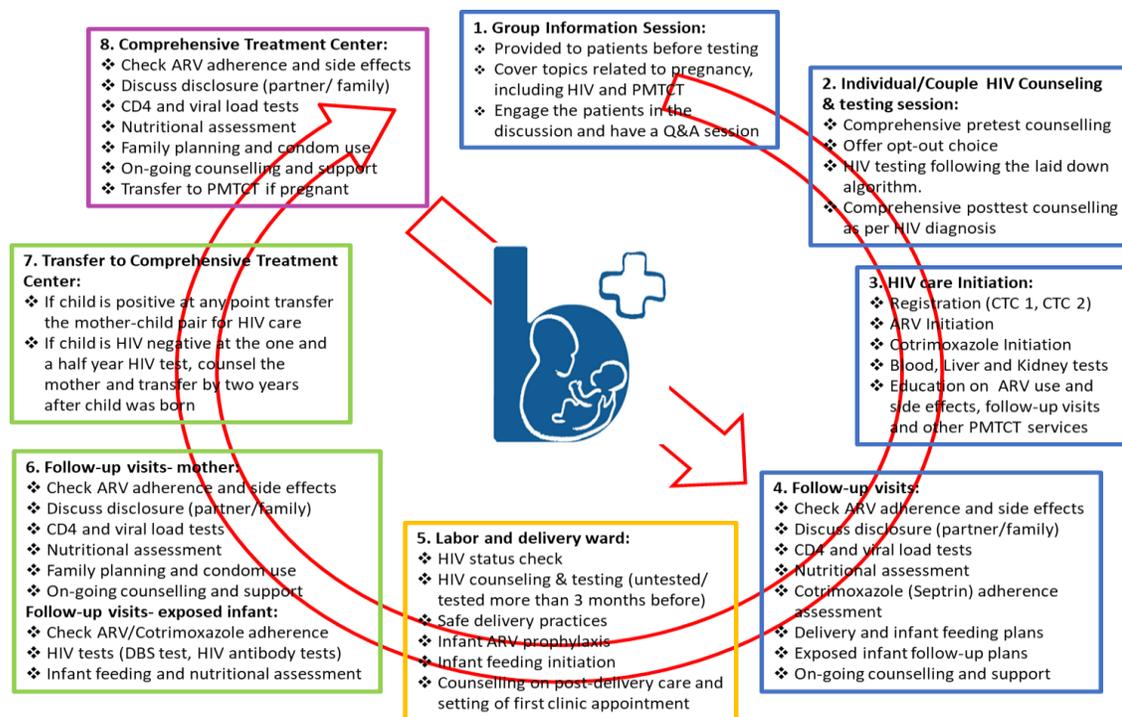


Figure 2: Summary of the Tanzanian national PMTCT Option B+ guidelines

## 1.4 Implementation research

Successful implementation of any intervention is key to the achievement of its purpose. In health, there have been many interventions that have been proven to work during research but have failed when implemented in the real world (Damschroder et

al. 2009). This is because there is an interaction between: 1) the intervention, 2) the process of implementation, and 3) the context where the intervention is implemented (Rycroft-Malone et al. 2002). This is implementation research, which involves focusing on the process of implementing an intervention to find out what is being done, as well as any deviations from the intended results and why (David Sanders and Andy Haines 2006). Implementation science is essential in assessing implementation of interventions for PMTCT of HIV, including the Option B+ mandate.

#### **1.4.1 PMTCT Option B+ implementation research**

As described in the evolution of PMTCT above, **interventions** to prevent transmission of HIV from mothers to their children have undergone several iterations based on emerging research findings and local capacity for delivery (see Table 2 and section 1.2.2). The iterations included new ARVs and ARV combinations, HIV testing and monitoring using CD4 tests and viral load tests, and coming up with a comprehensive approach to optimize PMTCT services (Table 2 above and section 1.2.2).

**Context** in PMTCT service provision is multilevel and includes patient factors, community factors, provider factors, facility-level factors and the overall health system (Mendel et al. 2008). Most research thus far on the implementation of Option B+ guidelines has focused on patient-level factors that facilitate or impede long-term care for pregnant women. Studies on acceptability of initiation of ARVs for life found that women were willing to initiate ARVs for their health and to prevent vertical

transmission (Katirayi et al. 2016; Chadambuka et al. 2017), but immediate initiation after a HIV positive diagnosis did not provide them time to accept their results leading to poor adherence and loss to follow-up (LTFU) (Landes et al. 2016; Cataldo et al. 2017; Elwell 2016; Matheson et al. 2015). The importance of male involvement in Option B+ was a conclusion of much research done with recommendations to increase and support partner and family involvement (Flax, Yourkavitch, et al. 2017; Chadambuka et al. 2017; Cataldo et al. 2017; Elwell 2016; Mitiku et al. 2016; Flax, Hamela, et al. 2017; Ebuy, Yebyo, and Alemayehu 2015). Studies done to assess issues around infant feeding in PMTCT Option B+ showed acceptance of recommended breastfeeding instructions but poor adherence to due to food insecurity and cultural practices (Marinda et al. 2017; Flax, Hamela, et al. 2017). Issues around retention in care and loss to follow-up (LTFU) have also been assessed finding that: lack of transport, ARV side effects, nondisclosure, stigma, bad experiences with providers, religious beliefs among others contributing negatively (Flax, Yourkavitch, et al. 2017; Landes et al. 2016; Cataldo et al. 2017; Elwell 2016; Mitiku et al. 2016; Flax, Hamela, et al. 2017; Martínez Pérez et al. 2014; Ebuy, Yebyo, and Alemayehu 2015; Tsegaye, Deribe, and Wodajo 2016; Naburi et al. 2016; Schnack et al. 2016; Atanga et al. 2017; Woelk et al. 2016; Chan et al. 2016).

Malawi was the first African country to roll-out the Option B+ guidelines and therefore provides an early case study for the **process** of implementation. Frank C. et al described that the process of implementation of Option B+ in Malawi involved

integration of HIV services into the RCH clinics, training of providers needed, and task-shifting of ARV initiation roles to clinical officers, nurses and medical assistants(Chimbwandira et al. 2013). The Elizabeth Glaser Pediatric AIDS Foundation (EGPAF) provided some insights into Option B+ adoption in 11 countries in Africa where the organization works. Their analysis focused mainly on the overall scale-up of the program and outcomes seen from the implementation (increased ART coverage). The report also highlighted patient-related issues (difficulties in accepting immediate initiation of lifelong ARVs, stigma, lack of disclosure, economic barriers, loss to care and poor adherence), facility related issues (stock-outs of drugs and test-kits), and poor documentation of patient information by providers(Kieffer et al. 2014b).

The process of initiation and roll-out of PMTCT Option B+ in Tanzania was described in an annual report by EGPAF on their work in Tanzania. The report described in general the launch of Option B+ in October 2013 and the training and technical assistance they provided to help the scale up of the program in Tanzania(EGPAF 2014). With the integration of PMTCT services in the health facilities, the intended increases in availability and accessibility of HIV care and reduction of stigma(An et al. 2015) were observed in a study done in Dar E Salam, Tanzania while a different study in the same city highlighted the negative outcomes of integration due to increased workload. Job dissatisfaction was high due to low compensation, longer working hours, poor feedback from supervisors among other factors(Naburi et al. 2017).

Thus far, no studies have been conducted to evaluate the day to day implementation of PMTCT Option B+, with a focus on expounding the facility level factors that affect the implementation. This gap in information on the implementation of Option B+, together with the goal of eliminating vertical transmission of HIV, are the drivers of this study.

## **1.5 Study goals and objectives**

The overall goal of the study is to examine the implementation of Option B+ in Tanzania, using the implementation science framework, the Consolidated Framework for Implementation Research (CFIR)(Damschroder et al. 2009). The objectives of the study are three-fold: 1) To evaluate the implementation of Option B+ in three sites in the Kilimanjaro Region of Tanzania; 2) To understand the facility-level factors that favor or undermine successful implementation; and 3) To identify opportunities to improve the implementation of Option B+.

## **2 Methods**

### **2.1 Overview**

This was a qualitative study that involved participant observation and key informant interviews (KII) with health service providers as the primary sources of data. An implementation science framework, the Consolidated Framework for Implementation Research (CFIR), provided a guiding framework for the research (Damschroder et al. 2009). All study procedures were approved by the ethical review boards at Kilimanjaro Christian Medical Center (KCMC), the Tanzanian National Institute for Medical Research (NIMR), and Duke University.

### **2.2 Conceptual Model**

The Consolidated Framework for Implementation Research (CFIR) was developed by Damschroder and colleagues as a way to synthesize the numerous theories, models and frameworks available for implementation science research for healthcare service delivery. The framework includes 5 overarching domains, which together encompass 26 constructs. The domains are: 1) intervention characteristics; 2) outer setting; 3) inner setting; 4) individuals involved; and 5) process of implementation. The five domains are constantly interacting in a complex way to determine success in the implementation of a health services intervention (Damschroder et al. 2009).

This study used the CFIR as a guiding framework to examine the implementation of Option B+ guidelines for PMTCT. Table 3 outlines how the five domains and related constructs were defined in the context of this research.

**Table 3: The Consolidated Framework for Implementation Research as applied to this research study**(Damschroder et al. 2009)

| <b>Domains</b>                      | <b>Constructs</b>            | <b>Definition</b>   |
|-------------------------------------|------------------------------|---|
| <b>Intervention Characteristics</b> | Intervention source          | Providers' perceptions of the source of the Option B+ protocol and other PMTCT protocol updates   |
|                                     | Evidence strength            | Providers' perception of the value of the Option B+ protocol in the prevention of HIV transmission from the HIV positive mother to the child  |
|                                     | Relative advantage           | Providers' perception on the advantage of implementing the Option B+ protocol versus previous protocols   |
|                                     | Adaptability                 | The ability of the Option B+ protocol to be adapted to the facility type, providers present and resources available. This includes evaluating the core components of the Option B+ protocol and the adaptable components. |
|                                     | Complexity                   | Perceived level of difficulty in implementation of the Option B+ protocol (e.g., time burden, steps, general workload) in comparison with previous PMTCT protocols  |
|                                     | Design quality and packaging | Not applicable  |
|                                     | Trialability                 | Not applicable  |
|                                     | Cost                         | Not applicable  |
| <b>Outer setting</b>                | Patient needs and resources  | The patient centeredness of the implementation of PMTCT Option B+,  |

|                      |                                  |  |
|----------------------|----------------------------------|--|
|                      |                                  | including the awareness of patient needs and steps taken to ensure that the patient needs are addressed  |
|                      | Cosmopolitanism                  | Communication and networking across healthcare facilities offering PMTCT services (e.g., shared goals, shared information)   |
|                      | Peer pressure                    | Presence of targets and ranking/recognition of individuals or facilities related to meeting PMTCT program targets  |
|                      | External policies and incentives | Overarching health system and policy environment and its effects on the implementation of PMTCT Option B+ protocol   |
| <b>Inner setting</b> | Structural characteristics       | Characteristics of the PMTCT clinical setting: facility type, departments involved, roles assigned to each department, leadership and supervision  |
|                      | Networks and communication       | Nature and quality of formal and informal communication and cohesiveness among individuals and departments involved in PMTCT care  |
|                      | Implementation climate           | Facility level of acceptance and prioritization PMTCT Option B+ service provision including setting of facility level goals and feedback and availability of facility level incentives/ rewards  |
|                      | Readiness for implementation     | Facility level engagement in the implementation of the PMTCT Option B+ protocol including availability of the required resources and training of providers, and engagement of the leadership department as well as overall facility leadership |
|                      | Culture                          | Not applied  |

|                                       |   |   |
|---------------------------------------|---|---|
| <b>Characteristics of individuals</b> | Knowledge and beliefs about the innovation  | Training, practice and feedback received on the PMTCT Option B+ protocol, as well as providers' attitudes towards the protocol  |
|                                       | Self-efficacy                               | How confident providers feel in implementing the PMTCT Option B+ protocol   |
|                                       | Individual identification with organization | Providers' perception of the facility, and their level of commitment to their role in PMTCT care delivery (e.g., willingness to put in extra effort, being proud to work there, valuing their job/impact)   |
|                                       | Other personal attributes                   | Personality traits of the providers (e.g., motivation to learn, motivation for quality work, empathy, presence of burn out)   |
|                                       | Individual stage of change                  | Not Applied   |
| <b>Process of implementation</b>      | Planning and Engaging                       | Planning and operationalization of the PMTCT Option B+ services including initiation and scale up, appointing and training of implementation leaders (PMTCT coordinators, PMTCT mentors) and engaging of key persons including local leaders and NGOs |
|                                       | Executing                                   | Fidelity of implementing PMTCT services according to the protocol   |
|                                       | Reflecting and evaluating                   | Presence of regular evaluation of the process of implementation and the giving of feedback and retraining needed to improve.  |

## 2.3 Setting

The study was conducted in three health care facilities in the Kilimanjaro Region of Tanzania that provided PMTCT services. These facilities were selected because they are some of the largest PMTCT-providing facilities in the region. Facility 1 was a tertiary referral hospital that serves more than 15 million people in the northern region of Tanzania. It is a teaching hospital that also has a robust research program. Facility 2 is an urban government health center that serves a population of about 9000 people. It also serves as a teaching facility. Facility 3 is also an urban government health center that serves a population of about 3000 people. It also serves as a teaching facility.

**Table 4: Summary of facilities involved in this study**

|                                  | <b>Facility 1</b>          | <b>Facility 2</b>                                  | <b>Facility 3</b>   |
|----------------------------------|----------------------------|--|---|
| <b>Population served</b>         | ~15 million                | ~9,000   | ~3,000  |
| <b>Inpatient capacity</b>        | 630 (multiple specialties) | 10 (Labor and delivery unit for normal deliveries) | 60 (General wards for men, women, and children separately, and a Labor and delivery unit for normal deliveries) |
| <b>Outpatient flow (per day)</b> | ~1,000                     | ~100   | ~120  |
| <b>Number of clinical staff</b>  | ~1,300                     | ~40  | ~55   |

The three sites follow the same national protocol for PMTCT. All the facilities house antenatal care clinics (ANC) where pregnant women are tested for HIV, and where ART is initiated and/or continued through pregnancy; a labor and delivery (L&D) unit; reproductive and child health (RCH) clinics where women come for exposed-infant

care as well as their ART continuation until the child reaches the age of two; and care and treatment center clinics (CTC) where women receive lifetime HIV care management. All HIV services, including PMTCT services, are provided at no cost to the patients. Some facilities may have a nominal fee for registration/opening a file (medical record).

The three facilities are embedded in the Tanzanian government health sector, which is under the Ministry of Health, Community Development, Gender, Elderly, and Children. The Tanzanian health sector has five levels of service delivery: national, regional, district, health center and dispensary. At the national, regional and district levels, there is a PMTCT coordinator who is part of the health management team (HMT) that is in-charge of PMTCT operations. The HMT is charged with operationalizing PMTCT services, including: capacity building; aiding local adoption; supply of HIV test kits, ARVs and Cotrimoxazole; workforce management; and processing PMTCT reports with provision of feedback(Tanzania Ministry of Health and Social Work 2013, 2012).

## **2.4 Procedures**

Data were collected over a period of ten weeks between May 22 and July 21, 2017. Data collection procedures happened concurrently across the three study sites. Participant observations in the first three weeks were used to finalize the semi-structured interview guides. During the following seven weeks, both KII and observations were conducted. All data collection was conducted by the lead author, a native Swahili speaker who is a medical doctor.

### **2.4.1 Observation procedures**

In each of the study sites, the implementation of the PMTCT Option B+ protocol was assessed using clinical observations along the PMTCT care continuum. The following sites were observed at each site: the ANC clinic where women receive pregnancy-related care, the Labor and Delivery ward, and the clinic where the mother and child pair are followed after delivery.

Targeted observations included shadowing patient-provider encounters and spending time in the clinic to observe the broader context and flow of care. Unstructured conversations with providers during the observation time provided additional information and clarified emerging questions. Record keeping procedures were reviewed and discussed with staff in the context of observations.

Before the observations began, meetings were held with the facility leadership and the providers involved in PMTCT service provision to inform them of the study and the specific procedures to be undertaken. When patient-provider encounters were observed, written consent was obtained from both the patient and the provider.

Observations were conducted with the assistance of a semi-structured observation guide. The guide was based on the national PMTCT guidelines (Tanzania Ministry of Health and Social Work 2013) (Table 5 below) mapped onto the domains of interest in the CFIR framework (Table 3 above). An additional guide (Table 6) was used to focus on the overarching factors that affect implementation as well as additional

components of implementation that are not captured in the flow of care. The guides were updated throughout the study period to accommodate for emerging areas of inquiry. The implementation of the PMTCT Option B+ protocol was assessed, from the pregnancy period, to labor and delivery, to the post-delivery period for the mother and HIV exposed child until 24 months post-delivery when the mother is transferred to the adult HIV clinic. A total of 35 hours of observation were completed. Short notes were taken during the observation sessions, followed by typing of detailed notes within 24 hours.

**Table 5: Observation of flow of care and implementation of the protocol**

| <b>Site</b>             | <b>Area of observation</b>                                    | <b>Content observed and noted</b>   |
|-------------------------|---|---|
| <b>Antenatal clinic</b> | <b>Group information sessions prior to HIV testing</b>        | When, where, by whom<br>Topic(s) covered<br>Teaching style (engaging vs lecture)  |
|                         | <b>Individual/couple HIV counselling and testing sessions</b> | Time spent<br>Pretest counselling: information covered, engagement<br>Testing procedures<br>Posttest counselling: information covered, engagement<br>Overall provider-patient interaction |
|                         | <b>Initiation of HIV care for those who test positive</b>     | Counselling on HIV care and follow-up<br>Registration into PMTCT care<br>Initiation of ARVs<br>Additional tests done  |
|                         | <b>Routine follow-up visits for HIV</b>                       | History and physical examination<br>Assessment of missed appointments   |

|                                |  |  |
|--------------------------------|--|--|
|                                | <b>infected pregnant women</b>                 | <p>Assessment of adherence to ARVs (direct questions, pill count)</p> <p>Monitoring of side effects</p> <p>Disclosure discussions: partner/family involvement</p> <p>Nutritional assessment</p> <p>TB screening</p> <p>Cotrimoxazole (Septrin) adherence assessment</p> <p>Laboratory tests (CD4 test, viral load test)</p> <p>Delivery and infant feeding plans</p> <p>Exposed infant follow-up plans</p> <p>Provision of counseling and support</p>  |
|                                | <b>Records</b>                                 | <p>Description of registers and records</p> <p>Completeness and accuracy of records</p>  |
| <b>Labor and delivery ward</b> | <b>Routine procedures</b>                      | <p>Registration of patients and establishment of HIV status</p> <p>Counselling and testing procedures</p> <p>Safe delivery practices</p> <p>Infant ARV prophylaxis</p>   |
|                                | <b>Records</b>                                 | <p>Description of registers and records</p> <p>Completeness and accuracy of records</p>  |
| <b>Postnatal clinic</b>        | <b>Routine follow-up visits for the mother</b> | <p>History and physical examination</p> <p>Assessment of missed appointments</p> <p>Assessment of adherence to ARVs (direct questions, pill count)</p> <p>Monitoring of side effects</p> <p>Disclosure discussions: partner/family involvement</p> <p>Nutritional assessment</p> <p>TB screening</p> <p>Laboratory tests (CD4 test, viral load test)</p> <p>Cotrimoxazole (Septrin) adherence assessment</p> <p>Breastfeeding discussions: Exclusive or mixed, weaning, monitoring of breast and infant mouth ulcers</p> |

|  |   |  |
|--|---|--|
|  |   | Provision of counseling and support<br>Transfer to CTC   |
|  | <b>Routine follow-up visits for the child</b> | History and physical examination<br>Assessment of adherence to medication<br>Nutritional assessment (growth monitoring)<br>Cotrimoxazole (Septrin) adherence assessment<br>HIV testing (HIV DNA PCR test (DBS) test, antibody tests) |
|  | <b>Records</b>                                | Description of registers and records<br>Completeness and accuracy of records   |

**Table 6: Implementation details**

| <b>Areas</b>                          | <b>Details</b>  |
|---------------------------------------|---|
| <b>Clinic Set Up</b>                  | Physical space<br>Privacy<br>Labeling of rooms<br>Information on walls<br>Waiting areas<br>Clinic schedule (special PMTCT days) |
| <b>Patient interactions</b>           | Social interaction in the waiting area  |
| <b>Provider-patient interactions</b>  | Attitude<br>Responsiveness/Engagement   |
| <b>Providers</b>                      | Characteristics/Attitude<br>Knowledge of the guidelines   |
| <b>Record keeping</b>                 | Types of records available and utility<br>Effect in the provider-patient interaction  |
| <b>Provider-provider interactions</b> | Team work<br>Mentorship and supervision   |
| <b>Interdepartmental interactions</b> | Communication<br>Team work  |

## 2.4.2 Interview procedures

Stakeholders to be interviewed for the key informant interviews were identified during the observations. Providers of any level (i.e., doctors, nurses, community health workers and facility managers) were eligible if they were involved with PMTCT service provision either directly or through leadership or community support. A total of 30 interviews were conducted, 10 from each of the three healthcare facilities (Table 7).

**Table 7: Summary of participants**

| <b>Provider type</b>     | <b>Facility 1</b> | <b>Facility 2</b> | <b>Facility 3</b> |
|--------------------------|-------------------|-------------------|-------------------|
| Doctor                   | 2                 |                   | 1                 |
| Nurse in-charge          | 2                 | 1                 | 1                 |
| RCH Nurse                | 3                 | 2                 | 3                 |
| HIV family clinic nurse  | 2                 |                   |                   |
| Labor & Delivery Nurse   |                   | 2                 | 2                 |
| CTC nurse                | 1                 | 2                 | 2                 |
| Home Based Care Provider |                   | 3                 | 1                 |

Interviews were conducted using a semi-structured guide that was tailored to the provider being interviewed and guides were updated often to include emerging themes from observations and from other interviews conducted. Interviews focused on: the provider's characteristics (e.g., training received, role in the implementation of Option B+ guidelines); review of the flow of care with attention to the standard practice; successes and barriers in the provision of PMTCT services as per guidelines; and then

suggestions for implementation improvement. Written informed consent was obtained before each interview. Interviews were conducted in Swahili and audio recorded with the participant's consent.

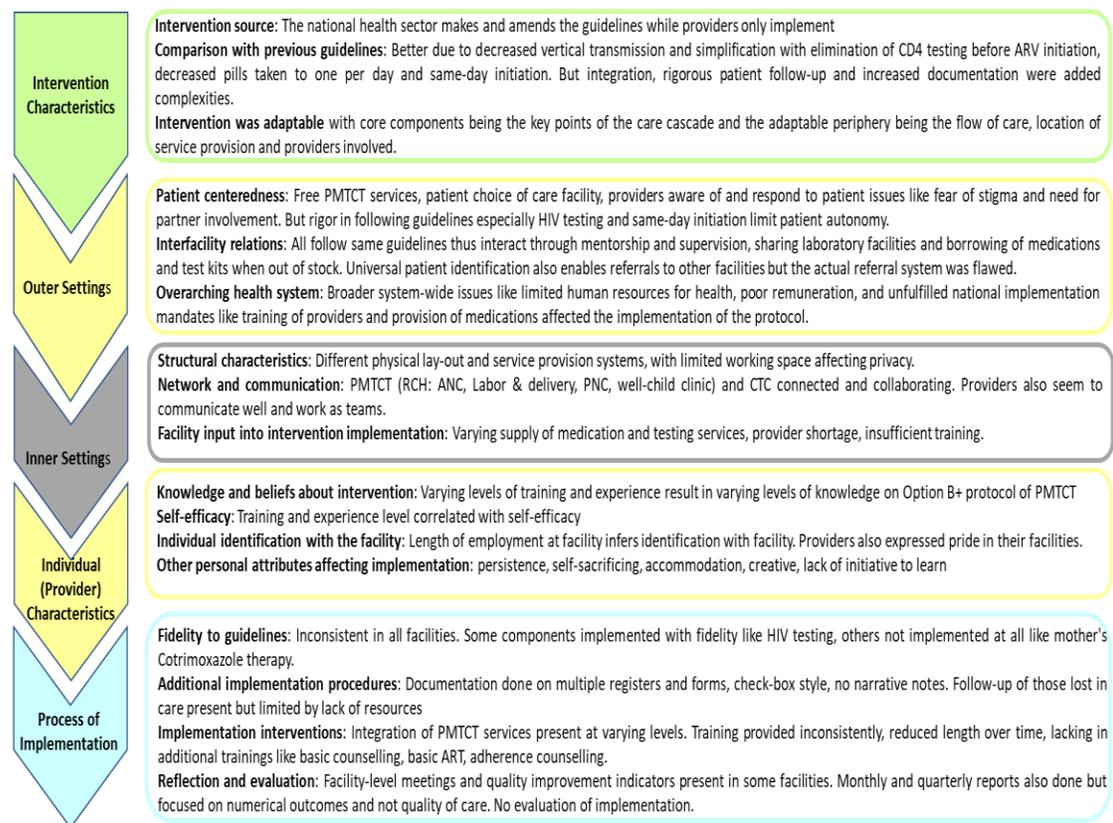
## **2.5 Data analysis**

Audio recordings of the interviews were simultaneously translated from Swahili and transcribed to English. Audio files, transcripts and typed observation notes were stored on an encrypted computer before being transferred to a protected server.

Throughout the data collection period, inductive analysis was used to describe emerging themes(Pope, Ziebland, and Mays 2000). During analysis, data from the interviews was coded on Nvivo 11.0(QSR 2016) software using a codebook that was mapped onto the CFIR domains and constructs. Through deductive analysis, coding was done under the domains and under specific constructs with double and triple coding of sections as seen fit(Pope, Ziebland, and Mays 2000). Queries were run to assess connections between nodes and sub-nodes. A second coding was done using codes derived from the flow of care and inductive analysis done to further expand the last domain on the process of implementation. Thematic analysis was then done in combination with data from the observation. Thick descriptions were written and then further synthesized according to facilities and across facilities, with discussions held with other authors to refine and agree on a common view of the results.

### 3 Results

The following results are presented under the five domains of the CFIR framework: intervention characteristics, outer setting, inner setting, individual (provider) characteristics and process of implementation. The different constructs described in Table 3 above are captured under themes that emerged from the data, as illustrated in Figure 3 below.



**Figure 3: Summary of results mapped onto the CFIR framework**

### **3.1 Intervention characteristics**

The CFIR domain intervention characteristics focuses on characteristics of the PMTCT Option B+ protocol: the source of the guidelines; available evidence to support it; superiority to the previous guidelines; comparison with previous guidelines; and adaptability to different facilities, with description of the core components and the adaptable components.

#### **3.1.1 Origin of the Option B+ protocol of the PMTCT guidelines**

Providers reported that the PMTCT guidelines were a directive from the ministry of health, with indicators and goals modified by the regional and local government authorities. A nurse at the PMTCT clinic said that “the guidelines are understandable and are followed. Providers are not involved in the updates. We [providers] just receive any new guidelines and work on them”. Providers were implementers and were neither involved in the development or updates of the guidelines, nor did they help set the goals and indicators.

#### **3.1.2 Superiority of the Option B+ protocol of the PMTCT guidelines**

With the Option B+ protocol having been in place since 2014, there was a consensus among all providers that Option B+ was superior to the previous protocols based on their observed outcomes. Providers overall echoed successes in the prevention

of HIV transmission from the mother to the child, which they regarded as the primary goal of PMTCT Option B+.

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“There are major successes, because the rate of infection for the children is reducing, there are quarters that pass with no infections. The main goal, the main outcome for PMTCT is no infection in the children, and we have been successful.”  
(PMTCT nurse in-charge)

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Providers reflected on elements of the protocol that they regarded as either being simplifications or additional complexities when compared to previous versions of PMTCT protocols. Simplifications mentioned were: the elimination of CD4 testing as a determinant of whether or not to start ARVs, the reduction of the number of pills taken to one per day, the use of a single ARV regimen, and the immediate initiation of ARVs. Providers found these simplifications as being “helpful” both to them and to the patients.

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“During that time (prior), they were using more than one drug and were taking them several times, but with Option B (+), the medication was reduced to one taken once a day, and this was helpful... It has really helped [patients], it is hard to forget.” (CTC/RCH Nurse)

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On the other hand, several providers mentioned intervention complexities relating to the delivery of PMTCT services under the new protocol. They noted that integrating PMTCT into RCH services increased the workload of the providers working in these departments. The counselling provided, from the initial HIV counselling and testing session, to the ongoing counselling required to ensure acceptance of the HIV status, commitment to lifelong therapy, and adherence to all elements of PMTCT care

consumed a lot of time and energy. Additionally, follow-up of those lost in care and detailed documentation in multiple registers were mentioned as being additional aspects of complexity.

### **3.1.3 Adaptability of the Option B+ protocol of the PMTCT guidelines**

Participant observations, supplemented by information from the interviews, revealed that there was some degree of adaptability of the PMTCT Option B+ protocol across the three facilities. The data suggested six core elements of the protocol which were delivered consistently across all clinics, and five adaptable elements of the protocol, which differed across the clinics, depending on the personnel, capacity and resources at the clinical sites. The description below does not imply that all the components described were provided with fidelity across the facilities, it is the way the PMTCT guidelines were set to be implemented in the facilities.

#### **Core components**

The following elements were identified as core components because they were delivered consistently (although not always with fidelity) across the clinics as the main service delivery points in the PMTCT cascade.

1. Group/General Health Information Sessions: All three facilities had planned general health information sessions for pregnant women. The sessions were conducted in the waiting area in the morning before clinic sessions began.

2. Individual/Couple HIV counselling and testing: All facilities were offering HIV counselling and testing to all pregnant mothers during the first ANC visit. Mothers were encouraged to come with their partners for couple counselling and testing. Testing was conducted by nurses in the RCH clinics of all three facilities.
3. Initiation of HIV care: All facilities offered same-day initiation of HIV care for those who were found to be HIV positive. This included: registration and assignment of a CTC number; counseling on ARV use and side effects; instructions for follow-up visits; and dispensing of ARVs.
4. Follow-up visits: All facilities offered follow-up visits to HIV positive pregnant women. In addition to routine pregnancy care, these visits included ARV refills and counselling on various aspects of PMTCT care (e.g. ARV adherence, partner involvement, infant feeding, care of HIV-exposed infant, future follow-up).
5. Labor and delivery care: All facilities had labor and delivery units that offered PMTCT services to women during childbirth. Providers checked for HIV status and offered counselling and testing for those who had not tested, those who had no written record of HIV status (e.g. lost or forgotten ANC card) and sometimes to those who had been tested in the first trimester of their pregnancy. Providers practiced safe labor and delivery practices, including delayed rupture of membranes and decreased vaginal examinations. Initiation of Nevirapine for the HIV-exposed infant was routinely provided after delivery in all three facilities.

6. Post-delivery care: All facilities offered follow-up visits to all HIV positive mothers and their HIV-exposed infants. In addition to routine postpartum and infant care, the visits included ARV refills and on-going counselling for the mother on relevant aspects of the PMTCT protocol (e.g., breastfeeding and adherence to ARVs for the mother and Nevirapine for the child). The HIV-exposed infant underwent HIV testing during the postpartum follow-up for early diagnosis of HIV. The first test was a HIV DNA PCR test (DBS) at four to six weeks after birth, the second test was a HIV antibody test or a DBS test 6 weeks after cessation of breastfeeding and the final test was a HIV antibody test offered at one and a half years. If the child was found to be HIV negative, he/she was said to have 'graduated' from care. The mother was then ready for transfer to the adult HIV care clinic.

### **Adaptable periphery**

The following elements were identified as the adaptable periphery because they varied across the clinics.

1. Content of the general health information sessions: Two of the facilities planned to discuss one topic per month and one facility had no monthly schedule; thus, providers were left to decide topics to cover in a session. In one of the sessions observed, the planned topic for the month was hemorrhage in pregnancy but the providers switched to PMTCT due to the observation. In another facility, the provider talked about different topics relating to pregnancy including nutrition, rest, importance of starting clinic early

in pregnancy, the tests that will be done including HIV tests, importance of partner involvement and the immunizations and medications given during pregnancy.

2. Location where different services are provided and the flow of care: Figure 4 below presents a summary of locations where PMTCT services were provided in each facility. Each facility had a unique flow of care due to the physical arrangements of the facilities and the providers involved.

3. Providers involved and their roles: Nursing staff were the foundation of the PMTCT workforce. In two facilities, no doctors were observed providing PMTCT care, but in the third facility doctors routinely saw patients. In that facility, doctors provided tailored physical examinations according to patient conditions and prescribed and monitored ARVs.

4. Clinical monitoring: The PMTCT guidelines recommend HIV treatment monitoring through CD4 testing every 6 months and viral load testing every 6 months for the mother, as well as HIV DNA PCR test (DBS) for the child (as explained in 'post-delivery care' above). All these tests were offered at each facility. One of the facilities had the laboratory services needed to do tests. The other two facilities took samples from patients and transported them to a designated laboratory for testing.

### **3.2 Outer setting**

The CFIR domain outer setting refers to the external context within which the facilities reside. The external context includes the target patient population, the

relationship among facilities, and the overarching Tanzanian health system, all of which influence the implementation of the protocol.

### **3.2.1 Patient centeredness of the implementation**

HIV services, including PMTCT, are offered free of charge in all government-affiliated facilities. Several providers expressed the freedom patients had when choosing their preferred facility. Given the network of national care centers, patients could request a referral letter when changing facilities to ensure continuity of care.

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“We tell them that the services they receive are free and their choice. When they need to move, I let them know that they can come for a referral letter to enable them to transfer care to a site of their choice.” (CTC Nurse)

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Beyond the choice of clinical sites, however, the implementation of the guidelines offered limited choice for tailoring to specific patient needs or preferences. Providers were required to follow the guidelines in a very strict sense. Patients could opt-out of HIV testing or treatment according to the guidelines, but the researcher did not observe this, nor did any of the providers suggest it to the patients. Providers put in extra effort in counselling to ensure that patients agree to the testing during the first ANC clinic visit and same-day initiation of ARVs. The RCH nurse below describes persistence in counselling, but the counselling also seems coercive.

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“It is true that we meet those that have the challenges of not wanting to start the medication on the first day because everyone has their own way of receiving information; there are those who can receive something and cope with them at that instant but there are those who find it difficult to cope. What is needed is that as you have been told that they should start the medicine regardless of the CD4 count or the gestation age, you have to use your wisdom and intelligence to do

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proper counselling until you reach the goal, even if they cry you just leave them to continue doing all other things that you can and then you come back and start again. What you are supposed to do is to focus on what the benefits are when one takes the medicine and at the end of the day you reach an agreement. If you see that it is becoming difficult then you know that you are not at work alone so you pass it on to another person given that each person has their own way of working so you tell the sister that it has become difficult dealing with that woman so they should go talk to them and see if they will listen. At the end of the day you will both reach a consensus and the mother will start the medication.” (RCH Nurse)

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But for patients who truly wanted to opt out, the extra counselling seemed not to change the patient’s decision and would even lead them to take the ARVs but not swallow them or disengage from care completely. An RCH nurse described a woman who refused to start ARVs due to religious reasons. The nurses provided on-going counseling, but the patient was adamant and later disengaged from care.

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“During my time here, I have only met one who belonged to these salvation-based religious groups and she told me that her God is good, and she will not take the medicine. So, when we meet such a case, we refer them to another counsellor and several others but still she refused. She still continued coming and we kept talking to her, but she still refused and told us that she delivered her other child who is just okay (HIV negative) while she never took any medication. When we asked her to bring that other child so that we could test them she also refused completely, and she refused to take the medicine. We continued with her but still with more counselling even from the doctor she still refused. Eventually we do not even know where she delivered, because she had come here from another hospital where all the efforts on counselling had fallen on deaf ears. She told us that she had come from another hospital where they had told her to do something she did not want and so she moved and when she saw that we were also hard on her she decided to move again.” (RCH Nurse)

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Providers were very aware of the needs of their patients. When asked about challenges in the implementation of Option B+, providers articulated, with examples, the patient-related issues that they have observed affecting PMTCT care engagement. The

two primary patient-level issues that arose were the pervasiveness of HIV stigma and the challenges of partner involvement.

Providers cited HIV-related stigma, including fear of stigma, self-stigmatization, and experienced stigma, as a primary and universal challenge that patients faced in their PMTCT programs. They discussed how stigma led to lack of HIV disclosure, poor adherence to ARVs, poor clinic attendance, and even failure to continue with care.

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“We are saying that the level of stigmatization has gone down but for the individual who is suffering, it has not gone down for all of them... The stigma and discrimination for self, is very bad. That is the first reason for lost to follow.” (RCH Nurse)

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Fear of stigma even led to patients resorting to deceit. Providers mentioned that patients lied to them about personal information, HIV positive diagnosis, and adherence to ARVs. During the observation sessions, the researcher did not perceive any stigmatizing attitudes or behaviors from the providers to their patients. The provider-patient interaction was often friendly, with providers using humor often to ease any tension and make patients comfortable.

Providers reported several strategies they used to either lessen the stigma patients felt or to mitigate the impact of stigma. These strategies included: on-going counselling; having a special clinic day for the PMTCT clients; cultivating friendship and trust; not turning patients back if they came outside of normal clinical hours; appointment rescheduling; and providing their personal cell phone numbers for communication and support.

Providers stated that involvement of partners from the beginning through couple counselling and testing was an important part of PMTCT. They expressed that partner involvement helped to support the mother's care engagement and ensure adherence to the exposed-infant's care, leading to prevention of HIV transmission to the child.

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"Partner involvement is very important for the sake of taking good care of the baby and for the mother to take the medicine at the correct time." (Labor & Delivery Nurse)

"It is true. Those who involve their partners, most of them do well in care. For example, there is this woman who was diagnosed with her partner back in 2009 before they were married. They accepted their status and lived well together. They even have 3 children who are HIV negative." (Facility Nurse in-charge)

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On the other hand, lack of partner involvement led to poor adherence to ARVs, as the woman had to swallow the ARVs secretly, and poor clinic attendance, as the woman would miss clinic on the days the husband is home.

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"...but those who came alone and got tested it becomes like...many are those who hesitate, and you find that on another day they come and say that 'the husband was home, so I was unable to leave and come to pick the medicine'..." (Labor ward nurse)

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Facilities encouraged partner involvement using strategies like invitation letters to the partners, giving priority to couple during service delivery, and requiring letter from village executive officers (VEO) for those who could not bring their partners. Providers were aware of the possibility of HIV status discordance with subsequent likelihood of abandonment and violence. Providers explained that they provided extra counselling and support to such discordant couples to mitigate any negative outcomes.

With PMTCT integration involving service provision at different points within the facility, there needed to be a process of transitioning between clinics within the same facility. Providers reported that patients were given guidance on the next step in their care continuum, the next appointments were set to be in the new clinic, and files transferred to the next clinic.

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“When they come for their appointment, we serve them as usual and then we tell them that they will go to the adult CTC for their next appointment. We then write on their card ‘to CTC Adult’. When they come to get their files the next time, the file will be taken to the adult CTC...” (Family HIV clinic nurse)

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However, some patients would be hesitant to move due being used the current clinic or fear of experiencing stigma in the new clinic. Providers counseled the patients as needed, oriented them to the next clinic, provided referral notes/letters, and sometimes physically accompanied the patients to hand them over to the next providers.

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“For those who are not ready, we do not force them to leave. We give them ongoing supportive counselling and until they are ready to go. We also orient them by taking them there to see how the place is, and then we tell that next time they can go on their own, bit by bit... we also request the providers there to support them and have them attended to first so that they don’t encounter any issues, things like that... you find that they understand.” (Family HIV clinic nurse)

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### **3.2.2 Inter-facility relations**

All facilities followed the same PMTCT guidelines and participated in similar trainings at the district or regional levels. Therefore, the facilities shared the same knowledge on the PMTCT guidelines. Additionally, providers who were trained as

mentors and supervisors would visit facilities for coaching, mentoring and on-the-job trainings as scheduled by the district health management team.

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“Sometimes the ministry calls on me to do supportive supervision, especially for the lower level facilities, where we do coaching and mentoring and on-the-job training. We then provide feedback, praising the strengths and talk about the areas of improvement to come up with an action plan for improvement.”  
(PMTCT nurse in-charge)

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Providers mentioned moments when they had sought assistance from nearby facilities. When they lacked ARVs for the mothers, ARV prophylaxis for the infants or HIV test kits, they borrowed from nearby facilities to ensure that the essential services were given for PMTCT. Some of the facilities did not have the means to process CD4 tests, viral load tests and HIV DNA PCR tests (DBS). They thereby utilized the laboratory in other facilities by sending samples there or sending patients there for testing.

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“It happened once that we did not have any (Nevirapine) and I called [Facility] and found that they had some, and I got the ambulance to go and get them so that the baby gets it.” (Nurse in-charge)

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The CTC numbers, the unique patient identification numbers given to each person who is HIV positive and to each HIV-exposed infant, is universal across the country. A provider can trace the original clinic of a patient and send them back or communicate with the clinic. The CTC numbers also make referral possible as patients are able to continue with care at any facility in the country.

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“When they come at some other time or you have tracked them, they will tell you that they are in a certain place or have gone to deliver while in the village so

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they will tell you that they are taking the medicine from that place so we do not have the assurance that they really are using the medicine, taking the medicine from there or not. But we have the follow up on them when maybe they come back and we check on the CTC 1 card if they were really using the medicine...if they truly were following up on the medicine or not.” (RCH Nurse)

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However, this system of universal identification does not work seamlessly as providers reported that patients can lie that they had not been tested before and get started into care anew or lie about their identification (no official identification card/form is used during registration). Also, providers did not have access to the national database and thus would not be able to trace a patient who has transferred or confirm where new patients came from.

Although not explicit, there appeared to be competition to be a high performing facility with the most impressive statistics in the region. Providers mentioned indicators that are monitored at facility, district, regional and national levels. They discussed reports and supervision visits by municipal health officials to check on their progress in HIV care provision and spoke of an aspiration to continually improve their performance compared with other sites.

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“This made us lead in Moshi municipal on the percentage of males involved. We even surpassed the target set by the municipal of 50% and were at 56-58%. But now, the target has been raised to 60% and we are still struggling to increase. We have not reached the target. But we not doing badly compared to other facilities in Moshi municipal, although there are other areas that are doing very well, like Mwanga, Same etc.” (PMTCT nurse in-charge)

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### 3.2.3 Overarching health system

Broader system-wide issues like human resources for the health workforce, remuneration, and national implementation mandates like training of providers and provision of medications affected the implementation of the protocol.

#### Health work force issues

Shortages of health care providers was very clearly articulated by providers and appreciated during the observations as an issue that impacted the implementation of the PMTCT protocol. During the study period, there was a government mandate that healthcare providers who could not produce the required legal education certificates be terminated. This led to loss of providers trained in the current PMTCT protocol, and transfer of providers to fill the gaps left in other facilities. During the period of observation, one facility lost its primary PMTCT nurse, leading to increased work load for the remaining provider. Additionally, frequent transfers of providers to different facilities was cited as a cause of loss of providers with Option B+ training and skills.

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“We also have a challenge with insufficient number of staff trained in Option B+ due to frequent transfers around the municipality. You find that those who had received training are transferred, leaving behind those who are not yet trained.”  
(Doctor in-charge)

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“The loss comes to us, the service providers. There is a lot of work, but the service providers are the same and it is not just the same, the number decreases every other day. At the moment the situation is so bad because the workers are very few, but you are the same person who must do all the work.... this is not something that you just go over very fast. Just think of it when you find someone

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who is positive, you have to do all these, but you have a long line out there of patients who you have to serve so it is a big challenge.” (RCH nurse)

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“The loss of providers is a challenge because, you had a team that was working, but they lose strength due to problems that are beyond our control. But as an in-charge, I work in all departments, including RCH. But I am not in the roster, but I can provide all the RCH services, including PMTCT.” (Facility nurse in-charge)

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### Incentives

Providers brought up concerns around poor pay and lack of incentives as reasons for reduced motivation to work. One of the facility leaders talked about the removal of overtime allowances by the government, even though providers had to work extra hours to provide care to patients because of under-staffing. Three other leaders talked about incentives for PMTCT providers that were provided during the initial stages of implementation but had been eliminated over time in some of the departments leading to demoralization of providers.

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“When we started PMTCT, [providers] were given some motivation (allowances), same for CTC. Then later on, they continued giving CTC but not PMTCT, yet in PMTCT they are doing CTC work; they have to diagnose, give medication, do EID, Early Infant Diagnosis, follow-up patients using their own phones... not just pregnancy care, if it was that one would check the pregnancy, give folic acid etc. and be done... This would cause people to be demoralized...” (Facility nurse in-charge)

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### Training

Training on PMTCT Option B+ was mentioned as being facilitated by the government and supported by NGOs like the Elizabeth Glaser Pediatric AIDS Foundation (EGPAF). Most of the providers who received training on the Option B+ protocol were trained during the initiation phase in 2013/2014, but many providers

mentioned that they had not received any refresher training, especially in Facility 2 and 3. Providers in the two facilities also mentioned that new changes and revisions on the protocol had been communicated in written form, without training for how to implement the changes. Facility three was different due to having a PMTCT Option B+ trainer on site, who ensured that training was provided to all new staff and that refresher training was offered frequently, supported by mentoring and coaching.

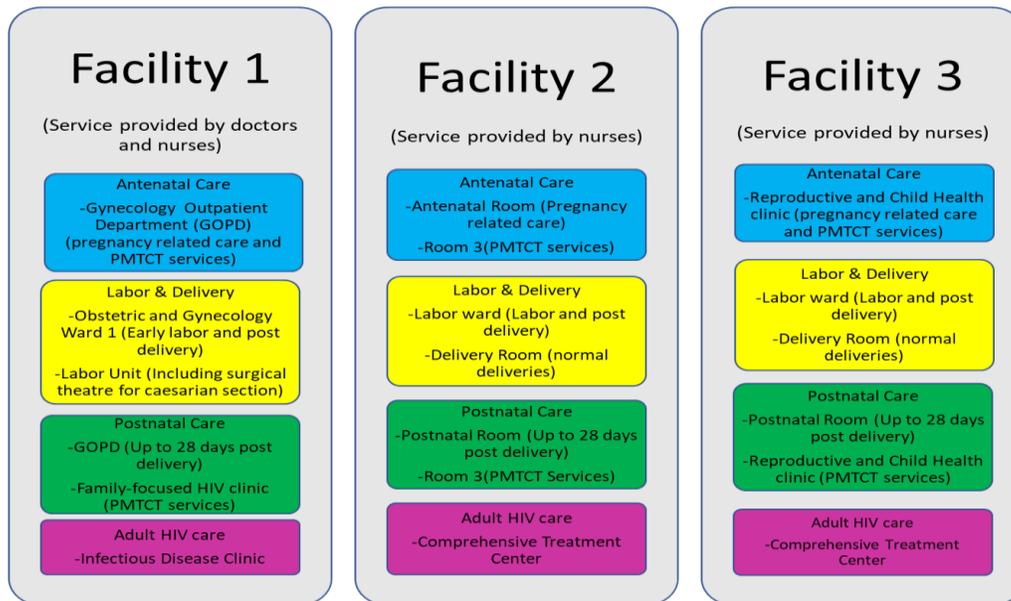
### **3.3 Inner setting**

The CFIR domain inner setting focuses on the facility environment in which the PMTCT protocol was implemented.

#### **3.3.1 Structural characteristics**

Each of the facilities had unique physical layouts and service provision systems. The physical features of the facilities give rise to compromises in efficient service delivery and patient privacy.

The figure below provides an overview of the PMTCT service delivery points and providers involved at the three facilities.



**Figure 4: PMTCT service delivery points at the three facilities**

The waiting area was very limited in one of the facilities, leading to overcrowding of patients, breach of privacy, and fear of increased risk for acquisition and spread of Tuberculosis due to poor ventilation. Another waiting area had no roof; thus, when it rained patients had to be moved e.g. a health information session was cut short due to rain during observation.

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“There is no waiting area. Someone is next to the wall, and you are on the other side of the wall doing counselling... if the person faints, wouldn't they know? (laugh) There is no privacy... there is only visual privacy, no audio privacy, when one is there they... no, there is privacy, but no confidentiality, you can be accused of disclosing, and yet people may have heard while outside.” (Facility nurse in-charge)

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Providers reported issues relating to the physical work environment that affected service provision. In one clinic, limited work space led to having two providers sharing a table while each is attending to a patient. This arrangement helped to serve patients

faster and could provide a chance for on-the-job training to new providers but compromised patient privacy. Providers reported shifting services to rooms elsewhere in the facility for privacy. Examples given included providing counselling and testing sessions in a different clinic or moving patients to a different room in the middle of the counselling and testing session. These shifts were an inconvenience to the providers and patients and disrupted care.

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“After doing the (HIV) test, given that our area is small we cannot do counselling when you find that both the mother and father are positive, or you find discordant results, but you have to move from one place to the other for the sake of privacy and confidentiality of the results.” (RCH nurse)

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The labeling of rooms in the facilities generated different reactions from patients. One facility had a room labeled PMTCT, but this did not come up as being an issue. On the other hand, a different facility had the PMTCT room labeled “Room 3,” and providers reported that some patients were afraid to enter Room 3 because of the perception that Room 3 was for HIV positive patients.

### **3.3.2 Network and communication**

Providers from all three facilities highlighted the connection and collaboration among the different departments involved in PMTCT service provision. The same patient file was used in the different points of service delivery. The pregnant woman also had an ANC card with information on her HIV diagnosis and ARVs which she presented during ANC visits and when presenting for delivery.

Providers appeared to communicate well as team members in the department and across different departments. There were meetings held at different frequencies (from 3 times a week to weekly or monthly) for providers involved in PMTCT services (RCH, CTC, L&D). The two smaller facilities included the labor and delivery providers in the regular meetings. In the larger facility, there was communication with the labor and delivery team leadership through facility leadership meetings. The PMTCT nurse in-charge in the larger facility also planned the PMTCT training and refresher trainings for providers throughout the facility.

The network among the different departments was further seen in the procurement of HIV antibody testing kits and medicines (e.g., ARVs, Nevirapine and Cotrimoxazole) that was done centrally under CTC. This ensured that the medication and supplies needed were available. Also, when there was a shortage, providers commented that priority was given to PMTCT services to ensure that testing and treatment was carried on.

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“PMTCT and CTC are under the same department... when a mother is tested there [RCH] and found to be positive, they are counselled by the nurses there. But when it comes to the CTC number, they have to obtain it from the CTC clinic. If they find partners who are both HIV positive, the male partner has to be brought here together with the woman for additional counselling and the man is counselled on initiation of ARVs. So, we have to work in tandem with them. Even the medications for PMTCT, I am the one who orders for them through the CTC order. They do not order for them separately, we do the ordering here at CTC and when the medication comes we distribute to them.”  
(CTC nurse)

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Providers across the care continuum also described moments where they requested for help or offered help during PMTCT service provision. This included providing additional counselling when needed, and stepping in to provide care when a department did not have adequate staff. A provider at the CTC in Facility 2 described that during PMTCT clinic days, CTC does not schedule appointments to ensure that CTC providers are available to help in the PMTCT clinic when need arises. This teamwork, which the researcher also observed, ensured that patients received the care and support that they needed, especially when additional counselling was required.

### **3.3.3 Facility commitment and input into implementation**

#### Engagement of the leadership

Engagement of leadership was present in all three facilities. All the nurses in-charge mentioned helping where they are needed to provide PMTCT services and making sure all supplies needed are present. During observation, two of the leaders were present in the clinic, ensuring that all service stations were staffed and that operations were running smoothly. One of the CTC in-charge nurses talked about her pre-planning of procurement to ensure that the facility did not run out of ARVs and HIV test kits. Another nurse in-charge talked about passing by the labor ward every Friday to ensure that there was enough Nevirapine present.

#### Availability of resources

Each facility experienced limitations of resources to support implementation of the protocol. In addition to the physical space limitations noted above, supplies, including medications and testing equipment, were available in varying degrees across the facilities. Table 8 summarizes the resources across the facilities.

**Table 8: Resource availability**

|   | <b>Facility 1</b>                  | <b>Facility 2</b>  | <b>Facility 3</b>  |
|---|------------------------------------|--|--|
| <b>ARVS (TLE)</b>   | Present                            | Present  | Present  |
| <b>Nevirapine syrup</b>                                     | Present                            | Present (history of stock outs)                          | Present (history of stock-outs)                          |
| <b>Cotrimoxazole Tablets</b>                                | Absent                             | Absent   | Absent   |
| <b>Cotrimoxazole syrup</b>                                  | Present but supply is not steady   | Absent but is present sometimes                          | Present but supply is not steady                         |
| <b>HIV Antibody test kits</b>                               | Present                            | Present  | Present  |
| <b>Infant HIV test (Dry Blood Spot for DNA PCR testing)</b> | Sample collection and testing done | Sample collected and sent to larger facility for testing | Sample collected and sent to larger facility for testing |
| <b>Viral load test</b>                                      | Sample collection and testing done | Sample collected and sent to larger facility for testing | Sample collected and sent to larger facility for testing |
| <b>CD4 test</b>   | Sample collection and testing done | Absent but was previously present                        | Sample collection and testing done                       |
| <b>Full Blood Count</b>                                     | Present                            | Absent; only Hemoglobin level test present               | Absent only Hemoglobin level test present                |
| <b>Kidney function tests</b>                                | Present                            | Absent   | Absent but was previously present                        |
| <b>Livery function tests</b>                                | Present                            | Absent   | Absent but was previously present                        |

As mentioned previously, provider shortage was experienced across all three facilities. Provider shortage spills over to different department as providers are pulled from their station to assist other departments, leading to strain in their assigned department. In facility 3 the CTC provider explained, “Providers are few. You will find that sometimes, for example here [CTC] we are two. But there [RCH], you find sometimes they are limited, maybe at immunization, you find that you are called to help them out. We go. One is left here [CTC]. You find that having that one person dealing with medication refills and testing becomes a problem”. Providers also commented that those who fill in are sometimes not trained and/or not experienced in providing PMTCT services, leading to poor documentation and lack of provision of complete services.

#### Training and experience

Facility one was among the first facilities to pilot the PMTCT Option B+ protocol. Overall, all the providers from Facility 1 who were interviewed had received PMTCT Option B+ training and additional refresher trainings as additions and changes to the protocol occurred. Providers interviewed also reported that most, except for fairly new employees, had received the Option B+ training. In facility 2, providers reported that most of the providers directly involved with PMTCT service provision had received Option B+ training. Of the providers interviewed, 6 of the 7 nurses interviewed had PMTCT or Option B+ training. In facility 3, the nurse in-charge reported that only a

handful of providers had Option B+ training. Of those interviewed, 6 of the 8 nurses had Option B+ training and only one nurse had received additional refresher training.

### **3.4 Individual (provider) characteristics**

The CFIR domain individual characteristics focuses on the providers' knowledge, beliefs and attitudes towards the PMTCT Option B+ protocol as well as their confidence in their ability to provide PMTCT services. Additionally, personal attributes that contributed to service provision are explored.

#### **3.4.1 Knowledge and beliefs about the Option B+ protocol of PMTCT guidelines**

Knowledge on PMTCT Option B+ was present among all providers interviewed, but varying levels of training and experience led to varying depth of knowledge on the protocol. In the interviews, providers were asked to explain the components of PMTCT services in their respective facilities and comment on the successes. Most providers were confident in their explanations and were mostly accurate, missing only some of the adaptable components. There were two providers who were unsure of the exact explanations and one requested an overview of Option B+ at the conclusion of the interview. As explained in section 3.1.2 above, providers believed in Option B+ for prevention of vertical transmission, with some providing scientific evidence supporting specific components of the protocol. One provider clarified their support for initiation of

lifelong ARVs for all HIV positive pregnant women as the previous short-term ARV use was more likely to lead to drug resistance.

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“And, the other thing on the issue of medicine, at the beginning they used to use the medicine only when one was pregnant and then they stopped. So that one was not good because the mother used to get the medicine and they build a resistance to the medicine. At the moment they just continue, and I think it is much better.” (RCH Nurse)

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### **3.4.2 Self-Efficacy**

Providers who had more training and experience on PMTCT Option B+ were very comfortable when providing information on PMTCT services during interviews and observations, as well as during actual service provision. Providers with limited training expressed hesitation when providing information on PMTCT Option B+ during the interview. These providers also expressed hesitation in provision of PMTCT services and would seek someone else with more training and/or experience to provide the services. A nurse in the labor ward gave the following example:

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“There was one woman who came here and had not been tested, when I was new, so I asked the nurse who was there to counsel her as I did not know the current guidelines. She told me even she had not gone for Option B (training). So, we just used our own experience, me with the PMTCT that I had learnt previously, we counselled her... and then we gave her the results and she received them.” (Labor ward nurse)

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There were providers who expressed reservation in their ability to counsel the patients properly. Some of the hesitation was attributed to lack of training and experience with the PMTCT Option B+ guidelines, and some of it was attributed to lack of adequate training on counselling. The providers would compare themselves to fellow

providers who either had more training and experience working in PMTCT or more comprehensive training on counselling.

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“I see counselling as something which is wide because I have also attended counselling on ‘how to counsel’ but when I sit with a patient... (Laughing) I cannot sit with a patient and compare...for example sister [NAME], I cannot compare myself with her on counselling, because there are people I can’t...I cannot say that I know 100% how to counsel because there are people who know how to counsel so that the patient will not get any problem. Some of us do not know how to counsel well.” (Labor and delivery nurse in-charge)

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### **3.4.3 Individual identification with the facility**

Providers’ identification with the facility was inferred from the number of years of employment at the facility. Most providers in Facility 1 have worked there for some time. Of those interviewed, the longest period was 32 years, followed by one who had been there for 20 years. In facility 2 and 3, most of the providers interviewed had been in the facility for less than 10 years, with some being less than one year in the facility. Although there were no obvious effects of provision of care, providers staying in a facility for long ensured continuity of care and retention of the knowledge and skills gained over time in the facility.

Pride in the facility came up in several interviews. Providers would speak of their facility when explaining the successes of PMTCT Option B+ and also praise the efforts put in at the facility when explaining the challenges faced.

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“I am in the labor ward, but I get a chance to go and sit in the clinic to help with drawing samples for the DBS test and do follow up for the children, and I see that most of them are happy, I mean most of them like coming for care here. I also see that the service providers are also people who have given themselves

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wholly and have placed themselves on the shoes of those people (they serve) and they become good friends with them. Honestly, attendance (at out facility) is good.” (Labor and delivery nurse)

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Providers in facility 1 described a reporting system that differentiated patients who received PMTCT services in their facility from those who were referred from other facilities. ‘Their children (those followed up at the facility) were usually born safe’ unlike the referrals who were likely to acquire HIV from their mother. This statement seemed to signify that PMTCT services provided at facility 1 was superior to services provided in the facility the referrals were from.

#### **3.4.4 Other personal attributes that affect implementation of the Option B+ of the PMTCT guidelines**

Other personal attributes that affected implementation of the Option B+ protocol emerged during the observations, both from providers’ expressions of their behaviors and values, and from providers’ commentaries about their colleagues.

##### Persistence

Many providers talked about ongoing counselling and ‘insisting’ (emphasizing) different aspects of PMTCT Option B+ to the patients multiple times to ensure that they understood and followed through. For example, for patients who were struggling with acceptance of their HIV diagnosis and initiation of ARVs, providers talked about taking their time counseling the patient and even referring to their colleagues whenever needed to ensure that the patient got sufficient counselling and started ARVs.

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“It is true, doctor, we educate them. But when they go, do they really implement the teachings? (laughter) Do they bring the condoms to show you that they have used them? But we don’t tire in providing education” (CTC nurse)

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### Self-sacrificing

Several providers described a colleague as being unselfish, hardworking and self-driven. The issue for working extra hours and with little help due to provider shortage also came up in several interviews. Providers noted their colleagues were self-sacrificing for the sake of the patients. The nurse in-charge below explains the self-sacrifice nature of a nurse which seems to be shaped by her religious beliefs.

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“But I thank God because my providers who work at PMTCT, RCH, 95% of the time, I leave the 5% due to being human, 95% of the time, they work from their heart. I can even mention one who, when I am home and know that she is working, I am at peace... [NAME]. She is a provider who is faithful, hardworking and loves her work. Not just at antenatal, even if you take her to the labor ward, or to immunization, or to the children’s clinic, she does her work from her heart. I am not saying she is the only one, but even if it is late, she keeps on going. She has helped me so much in PMTCT, especially with the shortage present, someone is doing the job of three people, and it reaches 4pm, she has not eaten or drank any water, but because if she does not serve the client, she knows that no one else will, and she knows that it is a sin to God, this ensures that all my clients are served.” (Facility nurse in-charge)

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### Accommodating

During transition of patients from one service point to another (e.g. PMTCT to CTC, Labor ward to RCH or Family HIV clinic, CTC to PMTCT), providers explained that they often worked to ensure that the mothers understood why and when they would be moving, and to prepare them psychologically. During the actual transition,

some providers described personally accompanying the patients to the new clinic to introduce them to the providers and hand them over. A provider from CTC stated that, “[she] assured her [patient] that if she [patient] has any questions, she [patient] is welcome here [CTC] to ask and seek any guidance as we [CTC and PMTCT] all work together.” Some providers described providing support to transferred patients and counseling them to alleviate any fears and doubts. Providers mentioned special accommodations like letting them go first in line, having them choose their preferred clinic day, getting their medication for them from the pharmacy, etc.

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“We also orient them by taking them there to see how the place is, and then we tell that, next time they can go on their own, bit by bit... we also request the providers there to support them and have them attended to first so that they don’t encounter any issues, things like that... you find that they understand.”

(Family HIV clinic nurse)

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“Here, during the first couple of visits, we give them priority, and we ask them the day they prefer to come for clinic, Monday or Wednesday, and we give them that day, and they continue coming to us for care.” (CTC nurse)

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### Creative

Providers explained different strategies they used to get the job done. When talking about encouraging partner involvement, providers described coming up with creative ways like using invitation letters, reaching out to village executive officers (VEOs) to involve them in writing letters for those who cannot come with their partners, serving couples first, and using support staff to spot and link partners with providers for counseling and testing. With some patients having a habit of providing the wrong contact information, one provider explained that she would dial the patient’s phone

number when given in the name of providing her phone number to the patient, yet she really was checking to see if the phone number is true.

#### Lack of initiative to learn

One of the providers talked about other providers who did not take the initiative to learn skills that their colleagues have. These providers would take the back seat when the person who has official training was present instead of learning from them.

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“...and you will find that there are those who do like on-the-job training... you know we are not the same, there are some who will not try to learn because the person who was trained is there. So, when the trained one is gone, the work will not be done well.” (Facility nurse in-charge)

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### **3.5 Process of implementation**

The CFIR domain process of implementation focuses on the process of implementing the PMTCT guidelines in a clinical setting, specifically: fidelity of implementation, factors that affect fidelity, activities undertaken to improve implementation, and suggestions for future improvements.

#### **3.5.1 Fidelity of implementing the Option B+ protocol of the PMTCT guidelines**

From the observations done, together with information from the interviews, implementation of PMTCT Option B+ was not consistent in all three facilities. The table below provides a summary of the report on fidelity of implementation of the PMTCT guidelines.

**Table 9: Summary of the report on fidelity of implementing the PMTCT guidelines**

| <b>PMTCT service</b>  | <b>Summary of implementation</b>   |
|---|--|
| <b>Group information session</b>                              | <p>-Only two facilities were providing the sessions in practice. Providers in the third facility reported that they were unable to provide the sessions due provider shortage.</p> <p>-Additional topics provided/scheduled due to the clinic needing to cover topics related to pregnancy.</p> <p>-For additional sources of information, education, and communication (IEC) materials, there are some posters on partner testing and importance of PMTCT testing but there are no</p>  |
| <b>Individual/ Couple HIV counselling and testing session</b> | <p>-Testing was done in all three facilities.</p> <p>-Time spent counselling patients prior to testing varied. During observation, some counselling sessions lasted less than 5 minutes while the longest lasted 45 minutes (provider was deliberate as researcher was observing).</p> <p>-No sessions with HIV positive diagnosis observed. Providers reported that they supported the patient to accept their diagnosis and accept initiation of care and also provide counselling on ARV use and future care.</p> <p>-Observed sessions where patients were found to be negative thus not able to comment on fidelity to the HIV testing algorithm. Providers in one of the facilities draw blood from the vein in a syringe (unlike finger prick) "in-case they need to repeat the test"</p> |
| <b>HIV care initiation</b>                                    | <p>-No session observed but providers reported that they initiate ARVs on the same day for most patients.</p> <p>-Providers mentioned reasons why same-day initiation didn't happen to be: some patients to initiate due to religious reasons or due to being forbidden by the husband; some patients just needed more time to be ready and were therefore allowed to go and come back for more counselling and initiation.</p> <p>-Providers reported that they do provide counselling on ARV use, side effects and follow-up visits</p>  |
| <b>Antenatal Follow-up visits</b>                             | <p>-All facilities offered follow-up visits to all HIV positive pregnant women.</p> <p>-Most of the visits were monthly, but some patients were given longer intervals as an accommodation for personal issues like employment and distance to clinic.</p> <p>-ARV refills, according to the guidelines should include confirmation of adherence through pill counts. Only one of the facilities inquired about remaining pills and provided refills of pills enough to last until</p>   |

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|---|---|
|   | <p>the next appointment date (they would take pill from a bottle or add more from another bottle to match the number of days). The other facilities dispensed per bottle.</p> <p>-On-going counselling was done very inconsistently. Most patient encounters observed lasted less than 10 minutes and included heavy documentation by the provider throughout the visit. This distracted from focusing on the patient, listening attentively and offering comprehensive counselling. When some counselling was offered, it usually entailed the provider giving advice and not discussing with the patient.</p>   |
| <b>Labor and delivery</b>                         | <p>-No PMTCT care services were observed in labor and delivery during the observation sessions there.</p> <p>-Providers reported that they usually checked for antenatal HIV diagnosis and tested those who had not been tested before. For safe labor and delivery practices, providers were aware of the practice of reduced vaginal examinations, delaying rupture of membranes and avoiding prolonged labor. Providers interviewed in two of the facilities mentioned an additional practice where they ensured that they had two separate pairs of scissors for the mother and for the baby to avoid exposing the baby to the mother's blood. The providers interviewed in the third facility did not mention this as part of their routine care. Initiation of Nevirapine for the exposed infant was reported to be done after delivery in all three facilities but the exact time of initiation after delivery varied.</p> |
| <b>Postpartum follow-up for mother-child pair</b> | <p>-All facilities offer follow-up visits to all HIV positive mothers and their HIV exposed infants.</p> <p>-As in antenatal visits, there were similar variations in visit intervals, ARV refill style and on-going counselling.</p> <p>-CD4 and viral load testing done inconsistently. DBS tests done but test results delay.</p>  |
| <b>Transfer to CTC</b>                            | <p>-After confirmation of the child's HIV status as being negative, mothers are to be informed of the upcoming transfer and any necessary counselling and support done. This was not done consistently.</p> <p>-During observation, there were mothers who were told they would start attending clinic at CTC during the next appointment; there seemed to have been no prior preparation and no discussion about the patient's options.</p> <p>-The actual time after the child's final HIV test when the mother transferred varied across facilities and across patients. There were</p>  |

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|  | mothers in the clinic whose children were more than two years and providers did not address the issue of transfer of care during the observed visit. |
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### 3.5.2 Other implementation procedures

In addition to the specific components of the PMTCT guidelines, clinical documentation and tracking of patients who are lost to follow-up are essential components of program success.

#### Documentation

Documentation of patient information was done manually in registers and patient files. Table 9 summarizes the multiple registers that providers completed.

**Table 9: Registers present for documentation during a routine PMTCT clinic visit**

| Type                        | Content  |
|-----------------------------|--|
| Appointment Register        | A counter book used to record patient appointments. Contains patient names and CTC number. Also used at the beginning of each clinic day to arrange files and stock ARVs and Cotrimoxazole needed for the day.   |
| ARV Register                | Contains the patient details and the amount of medication given. ARVs are registered in terms of number of pills given and Cotrimoxazole is registered in terms of number of pills (or bottles of syrup) given. Both the provider and the mother initialize after ARVs are dispensed |
| Register for pregnant women | Contains information on all pregnant women. Includes information on the current pregnancy, including visits, tests done, medications and immunizations given.  |
| DNA PCR test (DBS) Register | This contains mother and child information, date sample was collected, date results were received, and date results were returned to the mother.   |

|                                   |  |
|-----------------------------------|--|
| Register for HIV-exposed children | This register contains information on the child including birth information, ARV prophylaxis and Cotrimoxazole given and monthly visits. It also contains information on HIV tests done including DBS test(s) and HIV antibody test(s) |
| Lost to follow-up Register        | Contains patient names, CTC number, HIV treatment information, last appointment attended, steps taken to find patient, reasons given for lack of attendance and date patient returns to clinic.  |
| PITC Register                     | Contains all HIV tests done including DBS test for exposed infants and all HIV antibody tests.<br>Does not contain any patient names, only patient numbers and test results.   |

The individual patient file contained CD4 and viral load test results when done, and three main forms/cards. The first form was a Tuberculosis (TB) screening form with questions to ask the patient and boxes to check, followed by instructions on the next steps to take depending on the screening results. The next card was a CTC 2 card. This card was initiated on the day of HIV diagnosis and was filled out at each clinic visit. The CTC2 card contained detailed information on the patient including contact information (phone number, physical address and contact information for a next-of-kin), clinic visits and tests done. The back of the card had a list of topics to cover during on-going counselling with boxes to check when a topic was covered. The third card was the HIV-exposed infant card. The card was initiated at the labor and delivery ward when the child was born or at the clinic during the first contact with the child and was filled out at each child visit until the child was confirmed to be HIV negative at one and a half years or was found to be HIV positive and initiated on ARVs. It contained the mother's information as well as the child's follow-up information. It had the child's birth date,

weight, if Nevirapine was given/refilled, if Cotrimoxazole was started/refilled, HIV DNA PCR test (DBS) test and results.

The patient carried with her three cards: the CTC 1 card documenting patient's personal and HIV information and clinic visits including the next appointment date; the ANC card documenting information on routine pregnancy and delivery services including PMTCT services (HIV diagnosis, ARVs initiated, adherence to ARVs and check box for counselling on infant feeding); and the child's wellness clinic card documenting the child's immunization and growth monitoring information. All three cards are filled during clinic visits.

All documentation on the clinical forms (both registers and individual patient records) was done via checking boxes and writing short statements (names, addresses, phone numbers, short comments). The forms did not include any space or instructions for narrative notes; there were no details of the social circumstances of the patient or the content of the counselling and support provided.

Documentation inconsistencies were observed in all facilities, which limited the quality and consistency of information. The researcher observed that the presence of multiple registers and forms/cards distracted the provider-patient interaction during routine patient care.

When asked about documentation, some providers commented that "the books for documentation are so many" and that "[providers] may work to the level where

[they] get confused" (RCH nurse). Other providers highlighted that although documentation was time consuming, it was important for facilitating patient care and follow-up and for compilation of monthly reports.

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"The registers are many but when you look at it, every register has its importance. So, when you miss to find, for example if I fail to find the appointment book, there will be problems and also if you fail to find the register for children it becomes a very big problem because this register guides me well to do my work since I may look for the child's card and I don't get it. Then on the other side you may find that the mother came with the card and I had written the number for the child when we got the DBS test, so I check the child's card and confirm the number in the register and I find the child, so it becomes easy. So it gives me ease when doing my work unlike when you do the work and, maybe if the books were few, truly you can see the time that you write here and there and there becomes a lot but sometimes if you think that it is making your work easier, though there is some difficulty but it gives you a lot of ease when maybe you want to look for your documents as it becomes easy...even when at the moment of reporting, I am writing a report, it becomes easy to look for the books unlike when I will have to look for the files one by one. It becomes easy when I look at the books and check; how many are they this month, and if there are positive, how many are they, so I check in the book instead of starting to check in files one after the other." (Facility nurse in-charge)

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Providers suggested combining registers and installing electronic medical records to improve documentation. A facility in-charge even talked of a plan by the government to initiate the electronic medical record system.

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"To be honest, on documentation, the registers have become so many, more than the working area. And this is a challenge as we are still using paper system of data collection and storage. But there is a plan to move to electronic data storage, it is a government plan, and there is a plan in place to install the system and eliminate manual data collection and storage. Even with that, the government needs to come up with a data collection system that is central, so that the information available is comprehensive. There should not be separate registers for follow up of the child, a different one for the pregnant women. We need to

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find a way of combining the registers to help collect all the information at once.”  
(Facility doctor in-charge)

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#### Follow-up of those lost to care

The Tanzanian PMTCT guidelines require providers to follow-up closely with their patients and reach out to those who do not come for appointments. All three facilities had procedures in place for follow-up, with varying timing and processes involved. Providers described that they would use information from the appointment book and/or the no-show files from the clinic day to identify patients who did not come to the clinic. One facility waited for three days before adding the patient to the loss-to-follow-up (LTFU) register; another facility waited for four days and others talked of waiting for three months. Some providers even talked of calling patients at the end of the clinic day to find out why they did not come on their appointment day. Providers in all three facilities talked about calling patients using their personal cell phones. Funds for the calling card were usually not available and providers noted that they used their own funds to follow-up with patients.

All three facilities talked about the use of home-based care (HBC) providers for patient follow-up. HBCs are volunteer providers trained in community-based health services (CBHS) by different organizations. They are not part of the official Tanzanian national health workforce but trained and supported by different organizations to provide community-based health services. One HBC provider interviewed reported that she was trained by the Ministry of Health to provide services to people with chronic

diseases (diabetes, hypertension, HIV) while the others were trained by EGPAF and/or Red Cross to provide HIV support. HBCs are sometimes provided with allowances for travel and calling patients depending on availability of donor support. HBCs are then scheduled to be at CTC (and at the TB clinic and PMTCT clinic in some facilities) to provide patient education, link with HIV-positive patients and create a relationship to facilitate social support and HIV care support and follow-up.

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“And there are home based care providers who help too to come to the clinic, at CTC they come. And since they are from the community, if there is someone who is lost to follow up, we give them the names to look for them. Sometimes when we have the patient’s contact information, we call them so as to solve the issue of being lost to follow up.” (CTC nurse)

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Some of the HBC providers interviewed expressed willingness to be involved in PMTCT patient support more but faced lack of cooperation from some PMTCT providers, uncondusive clinic space, and lack of appreciation by some providers in the facilities.

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“I was recently talking with the nurse here... for example, on a date like this... RCH, it was 11th when I was supposed to be in the women’s clinic but here there are some issues. You will come... having been planned for to go this clinic, but you will find that all the women will have gathered; those who are of a special group, who know their status and have given birth while infected and those who were not infected. So, at that point you will know that, according to the doctrines, it is not good to.... you will see that if you educate them in that gathering you will have troubled them in some way, and the others will understand that their fellow mothers are on a certain regimen.” (HBC)

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“The other thing is the providers at that clinic. I usually use force to get there. Sometimes the providers are not very cooperative, it even came up in a meeting recently that the providers at that clinic are not incorporating us well... The first thing, we need cooperation from providers in the facility. If I come to the clinic, on a day that I am not scheduled, to pick up medication for one of my clients, I

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should be valued as a fellow provider. Sometimes you find that I have to queue like all the other patients” (HBC)

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Follow-up was not consistently done. During the observations, some of the files indicated that patients had missed appointments for more than 5 months and yet no follow-up had been made. Providers reported that lack of resources to contact the patients, including money and time, wrong contact information, few HBCs with no allowances and lack of funds for home visits, all hindered effective follow-up.

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“It is that issue of the service providers and the follow up where at times you may find that the one to do follow-up does not have a voucher and they decide to say that, maybe let me leave it first and when I have a voucher I will do follow-up.” (CTC/RCH nurse)

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### **3.5.3 Implementation interventions**

Interventions done to facilitate the implementation of the PMTCT guidelines in the different facilities included: varying levels of integration of PMTCT services into the reproductive and child health (RCH) care continuum and educational interventions.

#### Varied levels of integration

WHO recommends integration of PMTCT services into the RCH care continuum to increase uptake of the PMTCT services and reduce stigma. Only one facility had full integration of PMTCT services into the RCH services where a mother received both routine pregnancy services and PMTCT services in the same room. There was also a ‘one-stop clinic’ as they dispensed medication at their area of service provision (ARVs and Cotrimoxazole for RCH clinic and ARVs and Nevirapine syrup in the labor ward). The second facility also had full integration of PMTCT services and a ‘one-stop clinic’

with an additional PMTCT room separate from the ANC room. The third facility had partial integration as during the postpartum period, the mother-baby pair, as well as their family members, received services together at a stand-alone family-centered HIV clinic. This third facility did not have a 'one-stop clinic' as their medications were dispensed at the pharmacy.

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"At the family HIV clinic, the mother is enrolled as a mother of exposed infant and is followed up monthly on Wednesdays. If they have not tested their family, we ask them to bring them for testing, especially their partners and children, and even the extended family. Because our clinic is for the family. If the father is infected, they are also followed up on the same day in the same clinic." (PMTCT Nurse in-charge)

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Integration of PMTCT services into the RCH services and the addition of the Option B+ protocol increased the work load as described in section 3.1.2 above. Yet, no changes were made to increase the number of providers needed and this worsened their workload and reduced the efficacy in implementation of Option B+.

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"When we started working, when we were employed, documentation was very minimal, MTUHA (Mfumo wa Taarifa ya Uendeshaji wa Huduma za Afya, a Register for pregnant women) was very small, just a few pages. Now, there are MTUHAs that are very long, and there are many, and the provider is the same one... you find at the municipal, if it says that a facility is supposed to have a certain number of nurses and a certain number of clinicians. And they forget that then all you did was inject a patient and that's it, now you have to fill the MTUHA registers, the immunization register has places to fill the name, circle the number... documentation has increased especially with the new services like PMTCT, but they have not increased the number of providers." (Facility nurse in-charge)

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Two of the facilities had designated one day in the week to be a PMTCT clinic day for both antenatal and postpartum care. For the third facility, there was no special

clinic day for antenatal care, but there was a special clinic day for postpartum care. This facility nurse in-charge explained the rationale for special PMTCT clinic days:

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“So, we see them all on the same day. This also helps us as when you are concentrating with one thing, it is hard to get mixed up. Earlier on, we used to serve them all together, but when we separated, it helped us, it is easy to tell who came and who didn’t. There is also an appointment book that shows how many people are supposed to come that day, and we check them off as they come. Therefore, we are able to know who did not come at the end of the day and follow-up on them.” (Facility nurse in-charge)

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The special clinic days helped to provide peer support among mothers as during observations, mothers were seen talking among one another and the researcher listened to mothers offer words of encouragement and orient a newly-diagnosed mother who had come to the clinic for the first time with her 6-weeks-old child. But on the other hand, one provider described patients who would not come for PMTCT services on the designated day for fear of unintended disclosure as others present at the clinic would say “so she is one of us”.

#### Educational (training) intervention

As the national PMTCT guidelines got updated, including during the inclusion of Option B+ into the guidelines, comprehensive training was not done consistently. Providers who received training earlier on during the scale up of PMTCT services described the PMTCT training as being 4 weeks long. Providers who received Option B+ training during the pilot stages (2013/2014) received 6 weeks of training. Some of the providers, especially those who had been providing HIV care for longer had received

additional training on HIV testing and counseling and basic ART delivery. But providers who went for training in the past year mentioned the training being only three to five days. One provider highlighted this insufficiency of training as follows.

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“But there have been updates, and those who are in those departments do not have the updates, that all mothers found to be HIV positive are to be started on ARVs right away. Therefore, the providers have counselling training for HIV testing but not ART counselling or adherence counselling. You can find that a patient has been given medication but there is no follow up to ensure that they are taking the medication due to lack of knowledge on adherence counselling.”  
(Facility doctor in-charge)

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As mentioned in section 3.4.1 above, some providers had not received official training on the Option B+ protocol of PMTCT. Some providers mentioned learning about the PMTCT services through on-the-job training and “feedback” from the providers who went to trainings during regular meetings at the facility. One nurse in-charge mentioned that on-the-job training was necessary, as not all providers could go for all trainings due to limited funding and need for continuation of care provision at the facility. Another nurse in-charge raised concerns around on-the-job training as she was expected to train new providers, yet she had not been trained officially herself. This provider also added that there was limited time available for on-the-job training due to other commitments. A different provider cited insufficiency, as one was forced to two weeks of training into half an hour.

Even when trainings were available, providers reported that the choice of providers to participate in the trainings was biased. Some providers mentioned that

those who were likely to go for training were nurses in-charge or friends of those in leadership (some of whom were not actively providing PMTCT services) because of the monetary allowances given during the training and the certificate, which boosted one's resume.

### 3.5.4 Reflecting and evaluation

At the facility level there were meetings, reports and follow-ups done with indicators and goals that were tracked and adjusted. The purpose of the meetings ranged from discussing daily challenges at the clinics and preparing for the day ahead, to having continuous medical education and discussing progress and challenges overall. Providers would also use the meetings for quality control and improvement. During one of the meetings observed, the data management team commented on the issue of incomplete records and encouraged providers to fill the records completely.

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**“Yes, we (CTC) meet every month, together with those from PMTCT. I: And, in those meetings, what are some of the things that you discuss?** Most of the time, it is about those who are lost to follow-up, inability to find them, teachings... on how to insist in couple counselling and testing at PMTCT. These are some of the things we talk about.” (CTC nurse)

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“We have indicators that we track in our QI, Quality Improvement team, where I am a member... We stated this QI last year September to set goals for improvement, and one of the indicators is the HIV status of children born of HIV positive mothers, others are number of mothers who come with their partners, number of those who start clinic before 12 weeks of pregnancy, plus other indicators with goals set. After next September, we will set new goals. But for this one on PMTCT, we have been successful 100%, there is no positive [child]. So, there has been success.” (Facility nurse in-charge)

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Providers talked about preparing monthly and quarterly reports, but they seemed to mainly focus on the number of HIV-exposed infants/children who were identified as HIV negative and positive. During clinic day at one of the facilities, some officials from the DHMT were present to collect information on PMTCT services. Their focus was entirely on the registers, without any focus on the quality of the service provision at the clinic. In another facility, during a supportive supervision visit by the DHMT, the nurse in-charge seemed irritated, commenting on the disruption caused by the visit that involved lengthy meetings and reviewing of registers with no significant changes occurring after the visit.

### **3.5.5 Suggestions for improvement**

During the interviews, providers were asked to provide their suggestions for improvement of PMTCT care delivery, particularly including the mandate of Option B+.

The most common suggestions offered, from most mentioned to least, were:

1. *Training*: More training on the latest PMTCT guidelines, refresher trainings targeting providers directly involved in PMTCT care and not just leaders, additional training on ART adherence counselling and standalone training on counselling
2. *Workforce*: Address the provider shortage by reducing transfers, replacing the providers lost and adding more providers
3. *Physical space*: Address the physical space constraints in the different facilities

4. *Supply chain*: Ensure constant supply of medication and tests needed
5. *Community outreach*: Continuous community health education and awareness campaigns to address early access to ANC clinic, partner involvement, stigma elimination and PMTCT. Suggestions included using community champions like local leaders, religious leaders and government officials.
6. *Referral system*: Improve inter-facility referral system to enhance continuity of care.
7. *Incentives*: Provide monetary allowances to providers to motivate them.
8. *Electronic medical records*
9. *Home-based care*: Increase the number of trained HBC providers
10. *Support groups*: Form support groups for the HIV positive mothers based on their clinic appointment days
11. *Nutrition*: Provide food to the HIV positive mothers to improve their health and enable them to breastfeed their infants well.
12. *Economic*: Provide grants/loans for economic development
13. *Information*: Print and video media information for mothers to read/watch while waiting for care

## 4 Discussion

The Option B+ protocol for prevention of mother-to-child transmission of HIV has great potential to eliminate the vertical transmission of HIV and to improve the wellbeing and longevity of the mothers. First-hand reports from providers actively involved in the implementation of Option B+ PMTCT guidelines in Tanzania show an overall acceptance of the guidelines, but reveal challenges and inconsistencies in the delivery of PMTCT services throughout the care cascade. The use of the CFIR framework afforded a broad view of the multi-level factors that impact implementation of the PMTCT guidelines based on Option B+.

Implementation challenges were noted at the levels of the patient, provider, institution, and health systems. There were several patient factors that affected care engagement, with the main ones being stigma and partner involvement. At the provider level, the quality of counselling was varied depending on the provider and the time available. At the facility level, HIV antibody test kits were available and almost all mothers got tested. Physical space affected delivery of services due to privacy issues. Provider shortage also greatly affected delivery of services. The main ARVs needed, TLE and Nevirapine syrup, were available and provided to the patients, but there was a shortage of Cotrimoxazole which is an essential medication for the PMTCT program. Testing delays and inconsistencies for CD4 tests, viral load tests and DNA PCR test (DBS) occurred due to lack of testing capacity in the facility, use of referral laboratories

and breakdowns of machines. Documentation of patient information was perceived as burdensome and often redundant, without contributing to continuity of on-going counselling or the improvement of PMTCT services.

The following discussion explores the primary over-arching themes that emerged as affecting optimal implementation of the PMTCT guidelines and the implications of the study to future implementation, research and policy.

#### **4.1 Focus on prevention of vertical transmission while sidelining maternal long-term care engagement**

The Tanzanian national PMTCT guidelines are titled “Elimination of new HIV infections among children by 2015 and keeping their mothers alive,” (Tanzania Ministry of Health and Social Work 2013) which highlights the dual goal of initiation of ARVs for prevention of vertical transmission as well as improving the mother’s health. Despite this dual goal, providers tended to judge the success of the PMTCT services exclusively on the outcome of the numbers of HIV-exposed infants who turn out to be HIV negative, which indicates that they are under-prioritizing the goal of women’s long-term care engagement. The focus on vertical transmission seems to drive the rigidity of the same-day initiation of ARVs, as providers tried to convince the hesitant mothers to start ARVs in order to protect their unborn child from HIV. This focus on prevention of vertical transmission seems to be carried over from the initiation of ARVs, throughout pregnancy, delivery and the postpartum period. Providers reported drop-outs from care

in the postpartum period from after delivery, after the first infant HIV test (DBS) is negative, after cessation of breastfeeding or at the time of transition to CTC, all of which are associated with a period of reduced/eliminated chances of infant HIV infection from the mother.

In 2014, UNAIDS issued a brief highlighting the importance of focusing on women as a fundamental strategy to prevent vertical transmission of HIV to the child. The issue takes a rights-based approach to highlight the struggles that women are facing around the pregnancy period, including lack of empowerment, financial constraints, abandonment and violence. In a rights-based framework, women need support to initiate into care and continue for life in order to achieve their own rights for full health(UNAIDS 2014b). Tweya et. Al. (2014) highlighted that the woman is usually dealing with difficult decisions having received a HIV diagnosis and needing to start lifelong treatment (Tweya et al. 2014). Same-day initiation of ARVs has clinical importance, as it ensures timely initiation of ARVs and prevents loss of mothers from care prior to ARV initiation. However, a rigid approach of same-day initiation may not be the best fit for all patients. A systematic review on retention in care in PMTCT programs (Knettel et al. 2017) highlighted a loss of 3%-48% patients after the initial clinic visit. Some women may need more time to decide to start and providers should work to ensure that they recognize such patients and provide them the space and support needed to get ready for initiation. Additionally, providers need to also emphasize on the

importance of lifelong ARV use for the mother's health and longevity to ensure long-term care engagement and achievement of elimination of vertical transmission of HIV.

## **4.2 Stigma**

HIV stigma has been widely researched and concerted efforts have been put in place to mitigate and even eliminate HIV-related stigma (Turan and Nyblade 2013). Not surprisingly, providers in our study universally presented the issue of stigma as a barrier to the successful implementation of the PMTCT guidelines. The types of stigma (Earnshaw et al. 2013) that were widely described by providers was internal/self-stigma and anticipated stigma or fear of stigma. Experienced stigma was mentioned, although very infrequently. Additionally, no indications of stigmatizing attitudes or behaviors by providers were observed during the study. The findings on stigma differ from the systematic review by Gourlay et al (2015), where patient stigma was reported at the personal, partner, community and health facility levels. Nevertheless, the internal and anticipated stigma by patients in the study clinics were attributed were attributed to lack of HIV disclosure, poor adherence to ARVs, poor clinic attendance, and even failure to continue with care. Interventions targeting this fear need to be developed and implemented to increase PMTCT care engagement (Gourlay et al. 2015).

## **4.3 Counselling**

Systematic reviews on uptake of ARVs for PMTCT (Gourlay et al. 2015) and retention in care in PMTCT programs (Knettel et al. 2017) have highlighted factors that

affect care engagement, ranging from personal (lack of acceptance, self-stigma), partner/family (lack of disclosure, fear of stigma, lack of support), community (stigma, lack of support), facility (poor counselling, privacy issues) and logistical issues (finances, time, travel). These factors impact women's capacity to adhere to medication, come for follow-up visits, and follow other specific procedures like exclusive breastfeeding and prevention of secondary HIV infection. The intersecting and complex factors portray the fundamental importance of quality counselling of PMTCT patients.

Providers often noted that they and their colleagues were not well equipped to provide quality counselling to the patients. Providers described gaps in initial training and refresher training, as well as on-going mentoring and coaching on the current PMTCT guidelines. Providers often mentioned that they were learning "on the job," but they were concerned about whether they were adequately following the protocol, considering the large amount of information that it included. Additionally, providers noted that they were busy and therefore were unable to take time and teach comprehensively during on-the-job training. Some providers also mentioned colleagues who lacked the initiative to acquire new knowledge and skills from their colleagues, an attribute that would hinder quality on-the-job training.

Providers raised concerns about the lack of training on basic counselling skills, as PMTCT training only offered very surface-level training on counselling. Providers who had received additional training in areas like adherence, basic ART management, and

voluntary counselling and testing indicated that these additional trainings were essential to PMTCT service provision and should be provided routinely to all providers.

Physical space constrains, demotivated providers due to poor remuneration, and lack of additional incentives all hindered provision of quality counseling. Lack of descriptive documentation due to the documentation forms not including space for narrative notes hindered continuity of counseling care and support.

Interventions needed to improve counselling services span multiple levels of service delivery, including: individual provider knowledge and attributes; creating safe private spaces in the facility environment; training and mentorship by master counselors; and improvement in medical record format and documentation practices.

#### **4.4 Health workforce**

Comprehensive PMTCT care encompasses patient support through delivery of quality clinical services, on-going counselling, partner/family engagement, and follow-up of those lost to care to ensure consistent care engagement and thus achieve elimination of vertical transmission and keeping mother alive. However, comprehensive care also comes with increased workload and detailed documentation in multiple registers. Despite the increase in requirements, clinic staff note that the number of providers has stayed level or, in some cases, decreased, making it impossible to offer optimal comprehensive PMTCT services as per the guidelines.

Nursing staff were on the frontline of implementation of the PMTCT guidelines. Two of the facilities in the study only had nurses providing PMTCT services throughout the care continuum. Task-shifting of ART initiation and monitoring services to nurses was key to the success of Option B+ implementation in Malawi(Schouten et al. 2011) and this is also being seen in Kilimanjaro, Tanzania. This key role played by the nurses needs to be highlighted especially when looking at ways to address the health workforce crisis Tanzania and many other countries worldwide. A report by Toure et. al (2013) on the scaling up human resources for health in Africa highlights key guiding principles to achieve effective scale-up. These principles include country-level commitment, equitable distribution, and results-oriented focus (Bokar Touré et. al 2013). Knowing that nurses are the frontline workers in PMTCT service delivery should prompt efforts to increase training and retention of nurses in Tanzania.

Another cadre of healthcare providers that have been shown to have a key role on enhancing healthcare services are the community health workers (HBCs in Tanzania). A systematic review on the role and outcomes of CHWs in HIV care in SSA concluded that CHWs improved HIV service delivery and boosted the health workforce(Mwai et al. 2013). Yet, a systematic review on the interventions to improve PMTCT services and promotion of retention in care only highlighted four studies involving use of CHWs(Ambia and Mandala 2016). In the three facilities involved in this study, HBCs are not utilized maximally in PMTCT service support. Tanzania should work on expanding

their CBHS by training more HBCs and incorporating them in PMTCT care support especially in providing social support and enhancing long-term care engagement.

#### **4.5 Feedback and quality improvement**

The top-down origin of the PMTCT Option B+ guidelines was clearly articulated in our data. This is consistent with a study done by Mwangome et. al (2016) focusing on the PMTCT guidelines in Tanzania. The authors found that guidelines and updates usually followed WHO guideline recommendations and were passed down from the national level to the facilities(Mwangome et al. 2017). Additionally, there is a discord between the updates/changes and the implementation process. New updates arrive regardless of the status of the implementation of the present guidelines. For example, there is a recent update on viral load testing that require testing to be done on a three-month interval for PMTCT mothers instead of a six-monthly interval(Tanzania National AIDS Control Program 2015). With the current viral load testing being inconsistently done due to lack of testing capabilities in the facilities and equipment failures in the designated laboratories, facilities are set to fail in the implementation of the new guidelines.

The Tanzanian PMTCT guidelines highlight the registers in Table 10 above as monitoring and evaluation tools. Facilities generate reports based on the registers and send the reports to the DHMT. The DHMT is in turn expected to provide feedback and coordinate and perform supervision visits. From the results, the supervisory visits are

mainly output/outcome-based involving review of registers and meetings with providers and are not focused on the process of implementation(Tanzania Ministry of Health and Social Work 2013).

At the facility level, meetings are conducted, and one facility had a QI team with indicators. This can be duplicated across facilities to enhance feedback and improvement, and the content of the meeting discussions and indicators should include measures of implementation fidelity and quality to improve PMTCT services.

#### **4.6 Implications for policy and practice**

There is clear evidence that there are many gaps in implementation and many factors affecting optimal implementation at the facility level in this setting. Providers themselves suggested several steps that can be taken to improve current practices. The most common suggestions were around better implementation support including more providers, more training and better supervision. There were also suggestions for improvement of supply chain management, HIV monitoring tests especially viral load testing to monitor suppression and improved documentation content and procedures.

Policy makers need to address the health system level factors that affect implementation, from health workforce issues to feedback and updates on the guidelines. CHWs need to be incorporated into the health work force and utilized to provide support of care engagement for PMTCT and other RCH services in general.

## **4.7 Implications for further research**

With the fidelity of implementation being very inconsistent, the process of implementation of the PMTCT guidelines needs to be revised. Further research is needed on implementation interventions that can be applicable to improve implementation in this setting. Some examples of interventions that can be explored are: feasibility of electronic medical records; use of IECs like print/media to replace info sessions and cover all topics related to RCH with emphasis on PMTCT; behavioral therapy to combat fear of stigma and education/training interventions for providers to improve the quality of delivery of PMTCT services.

## **4.8 Study strengths and limitations**

The strengths of the present study include the approach and the data collection. The use of a robust implementation science framework (CFIR) helped to present a systematic view of the implementation of PMTCT guidelines as it highlighted multiple levels of factors that impact implementation of the guidelines at the facility level. Using both observation and interviews enable triangulation of information and provided richer data. Also, the ability of the researcher to blend into the context being a native Swahili speaker and a healthcare provider further enhanced the depth of the data collected.

Several limitations are present in the study which might have affected the data used in the study. Logistically, time and financial constrains limited the number of hours

of observation done. In the study time period, it was not possible to observe all PMTCT services e.g. no counselling and testing with a HIV positive diagnosis and/or initiation of care was observed. As is expected of observation studies, it was impossible to remove the observer effect, especially during the initial hours of observation at each facility. However, with increasing presence at the facility, providers tended to revert back to routine activities. Convenience sampling was used for the interviews, and some participants were limited in the time they had available for interviews. To account for this, the researcher focused on questions that related to the provider's role in PMTCT service provision capturing the necessary information and point of view of the particular provider.

## **5 Conclusion**

By applying the CFIR conceptual framework, this study furthers the use of implementation science approaches to evaluate HIV services in general, with a specific focus on PMTCT services. Prevention of mother-to-child transmission of HIV is a complex intervention with multi-level factors involved. Just as described in implementation science, all these factors interact in varying ways to affect implementation. Therefore, implementation of PMTCT interventions need to move from the present top-down approach with focus on outputs and outcomes, to a more inclusive feedback loop with a focus on the process to enhance implementation and sustainability.

## Appendix A: Data collection tools

### Interview guide

#### Assessing the implementation of Option B+ in the Kilimanjaro Region of Tanzania and identifying facilitators and barriers to implementation

##### Interview Guide

1. Can you tell me about profession and your role in the PMTCT program

-When did you start

-Trainings received before starting and ongoing CMEs on Option B+

2. I would like to know more about PMTCT services. Can you guide me through the process a woman goes through to access PMTCT services at this facility from the time she comes to the antenatal clinic for the first time to the time she gives birth and then continues HIV care after birth.

-Counselling

-HIV Diagnosis

-Laboratory tests: CD4, Viral load, CBC, UECs, LFTs

-ARVs

-Monthly Visits: Adherence, side effects, disclosure, social and psychological support

-Labor and Delivery

-Breastfeeding and family planning

-Postpartum care and transfer to CTC

**Note:** Use flow of care format to go through

-content

-current practices

-Facilitators

-Barriers

-What can be done

Consider sketching a flow of care during above exercise

3. On specific components of Option B+, what are your comments on and any successes and improvement points of:

-Counselling: Pre and post-test, adherence, disclosure, psychological, infant feeding, family planning

-Follow-up: Missed appointments, drop-outs, poor adherence

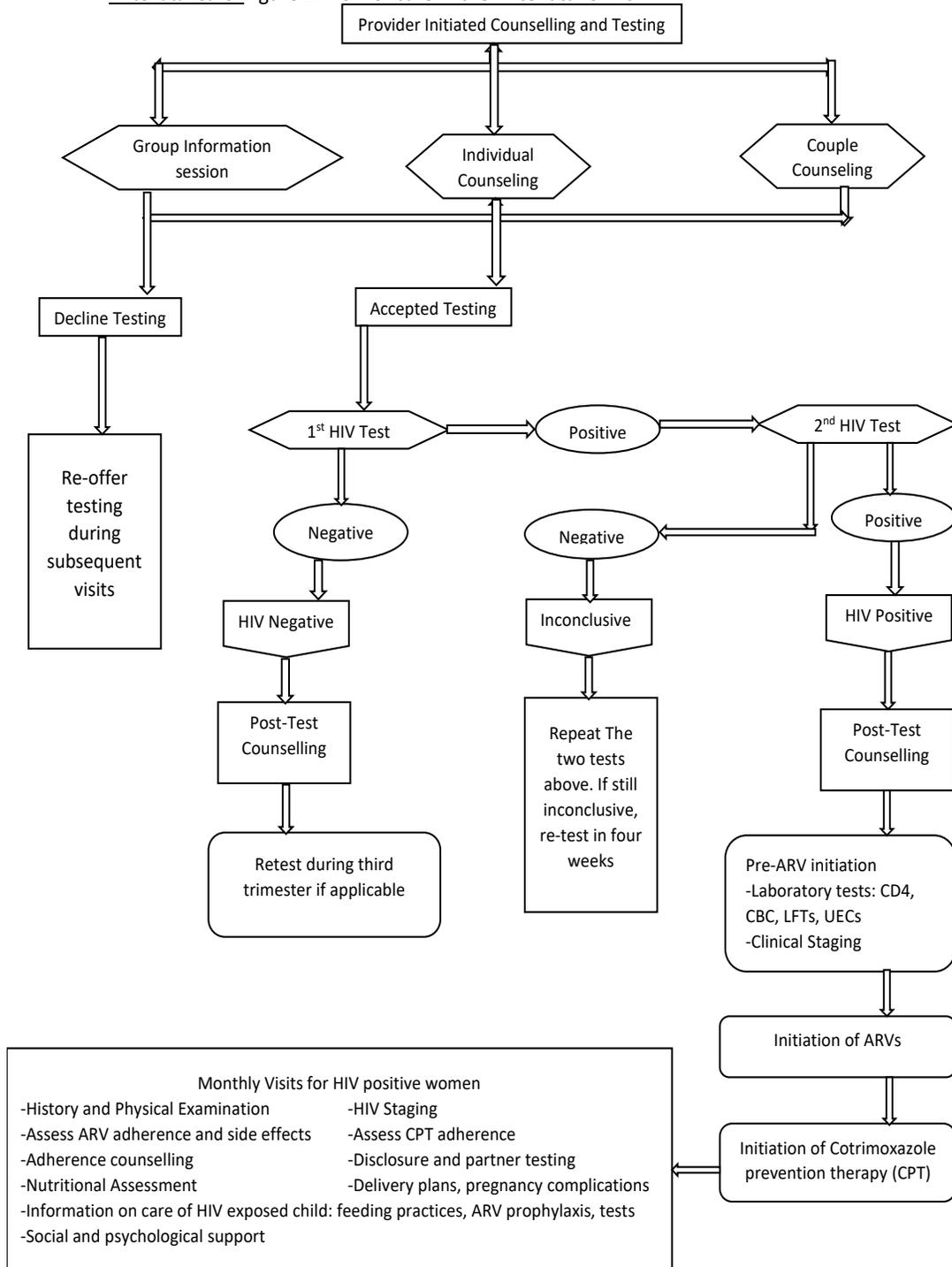
-Support: Partner involvement, family and friends, support groups

-Lab tests: HIV tests, CD4, viral load, infant HIV testing

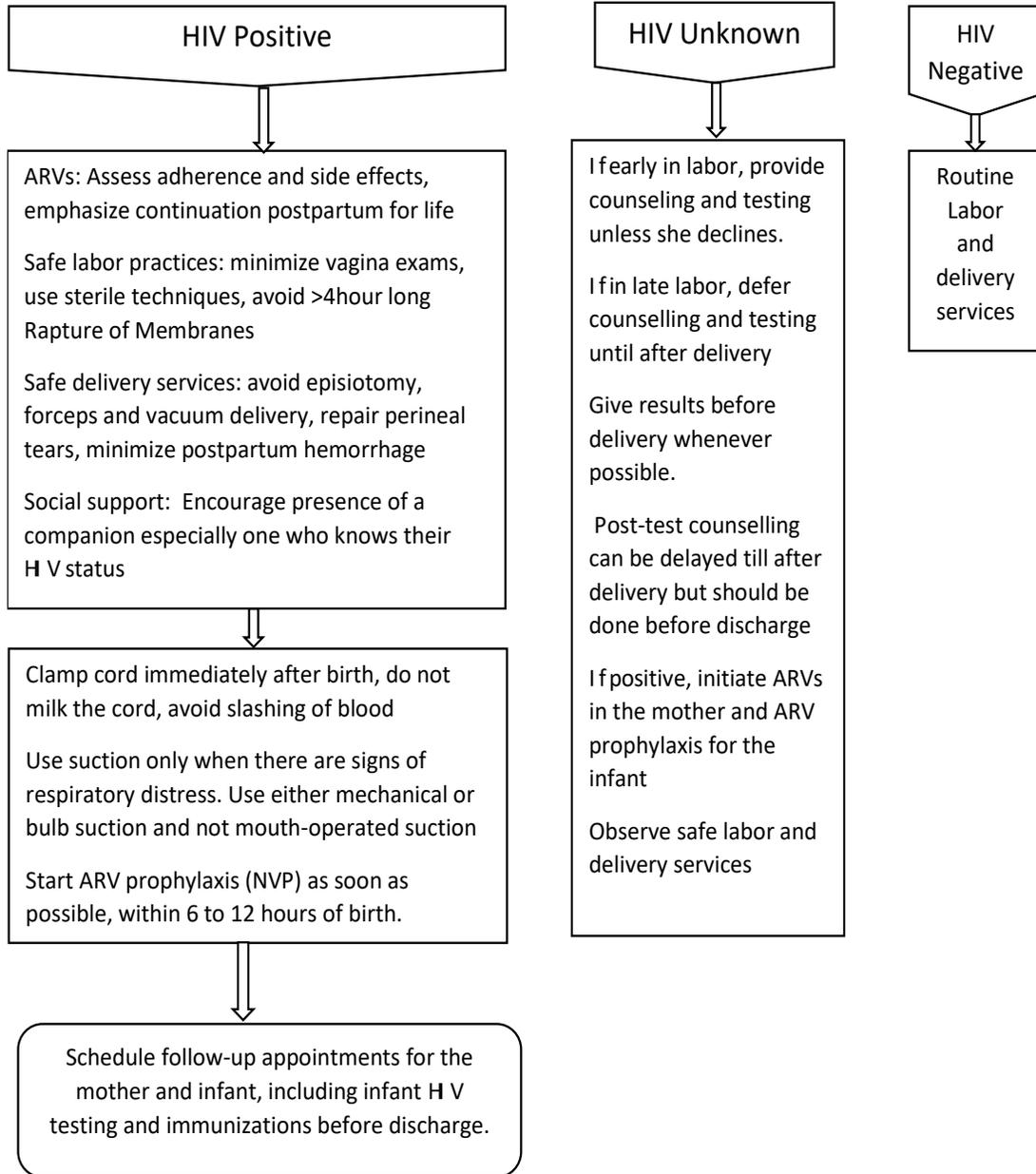
- ARVs: Availability, adherence, side effects and their management
  - Safe delivery practices
  - Stigma reduction
  - Documentation: Registries, Patient files, effect on care provision
4. What are your personal views on the addition of new protocol called Option B+ where HIV positive mothers are started on ARVs for life with elimination of clinical and lab triaging?
- content, implementation, feasibility
- Were there any other changes that occurred with the new guidelines?  
What do you think about them?
5. What specific facility level factors do you think work well to support the implementation of PMTCT?
- personnel
  - Medication and test kit availability/supply issues
  - Integration of PMTCT into routine care
6. How about facility level factors that slow down successful implementation?
- Personnel
  - Clinic set-up
  - Stigma
  - Training and Support
  - Documentation issues
  - Availability of medication and lab tests
7. Do you have any suggestions on what can be done to improve the implementation of Option B+ in your facility and in Tanzania as a whole?
- Knowledge and understanding of Option B+: initial training, refresher training, educational materials like posters, videos, brochures, campaigns
  - Provider-patient relationship
  - Support patients in terms of adherence, disclosure, continuing of care
  - Clinic set-up changes
  - Support to personnel
  - Support from and communication with local, district, regional and national PMTCT offices
  - Health system level changes
  - Policy level changes

Summary of the flow of care and observation points

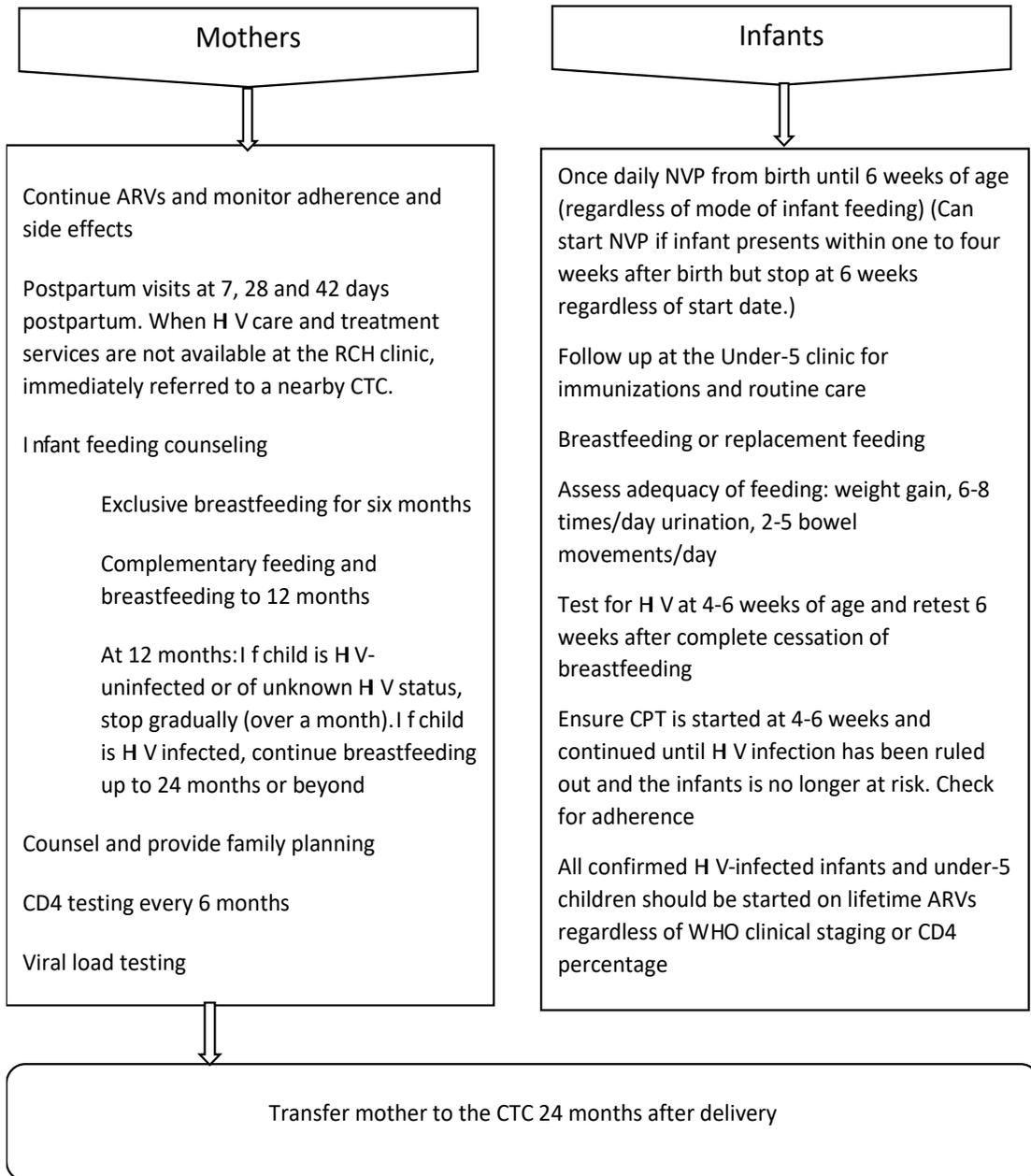
**Antenatal Care:** Figure 2: Flow of care in the Antenatal Clinic



**Labor and delivery**



**Postpartum care**



In all facilities, the following are the areas of interest with regards to PMTCT Option B plus implementation.

- Examine the physical layout of the clinic and its effect of privacy and overall patient care

- Examine order, overcrowding, waiting time and effect on quality of care

- Examine provider-patient interactions

- Examine the specific roles played by the different providers in the PMTCT cascade

- Examine data-collection and record-keeping methods

- Map out the flow of care

- Assess information delivery to providers and patients: availability of posters, brochures, actual PMTCT guide, trainings, meetings

- Examine any strategies for retaining any women in care and finding those who are lost to follow up

- Examine internal and external stigma

- Comment on the facility's culture

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