Improving the usage of prevention of mother-to-child transmission of HIV services in rural Tanzania

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Declaration

I, Annabelle Gourlay, confirm that the work presented in this thesis is my own. Where information has been derived from other sources, I confirm that this has been indicated in the thesis.

Abstract

This thesis aims to investigate the use of prevention of mother-to-child transmission (PMTCT) of HIV services in rural Tanzania. Paper A, a systematic literature review of barriers and facilitating factors to the uptake of antiretroviral drugs for PMTCT in sub-Saharan Africa, identified many influencing factors at the level of individuals, their communities and health systems. Paper B discusses the challenges, including lack of unique identification numbers, associated with using routine clinic data for monitoring PMTCT programmes in Africa. Papers C and D use clinic data linked to community HIV cohort data to describe community-level access to PMTCT services among HIV-positive pregnant women. Paper C documented low, but increasing, coverage with PMTCT services in 2005-2012, with weaknesses throughout the PMTCT service continuum. Paper D identified women from remote areas, younger women, and unmarried women as less likely to access PMTCT services. Voluntary counselling and HIV testing before pregnancy, longer duration of HIV-infection, and more recent pregnancies were associated with improved PMTCT service use. Paper E critiques the use of a vignette within a qualitative investigation of barriers to PMTCT service uptake, suggesting that vignettes can be used successfully in rural Africa to draw out barriers to PMTCT service use. The qualitative analysis for paper F revealed a pivotal role for patient-provider interactions in PMTCT service use, through decision-making processes, trust, and features of care. The collective findings highlight the considerable barriers to uptake of PMTCT services that must be tackled in order to successfully eliminate new paediatric HIV infections. Potential positive impacts of 'Option B+' (initiating all HIV-positive pregnant women onto life-long antiretroviral therapy) may be limited by these barriers. Addressing health systems issues, particularly stock-outs of HIV test kits, drugs and delivery materials, and improving patient-provider relationships, may have the greatest immediate impact on PMTCT service use in this setting.

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List of acronyms

ANC	Antenatal Clinic
AIDS	Acquired Immune Deficiency Syndrome
ALPHA	Analysing Longitudinal Population-based HIV/AIDS data on Africa
ARV	Antiretroviral
ART	Antiretroviral Therapy
AZT	Azidothymidine
BMC	BioMed Central
CASP	Critical Appraisal Skills Programme
cART	Combination Antiretroviral Therapy
CI	Confidence Interval
CD4	Cluster of Differentiation 4 positive T cells
CTC	Care and Treatment Clinic
CVCT	Couples Voluntary Counselling and Testing
DMO	District Medical Officer
DNA	Deoxyribonucleic Acid
DSS	Demographic Surveillance System
ELISA	Enzyme-Linked Immunosorbent Assay
FGD	Focus Group Discussion
HBC	Home Based Care
HIV	Human Immunodeficiency Virus
HCT	HIV Counselling and Testing
HPTN	HIV Prevention Trials Network
ID	Identification (number)
IDI	In-Depth Interview
IeDEA	International Epidemiologic Databases to Evaluate AIDS
INDEPTH	International Network for the Demographic Evaluation of Populations and Their Health
IT	Information Technology
JAIDS	Journal of Acquired Immune Deficiency Syndrome
JIAS	Journal of the International AIDS Society
LSHTM	London School of Hygiene and Tropical Medicine
MCH	Maternal and Child Health
MDG	Millennium Development Goals
MOHSW	Ministry of Health and Social Welfare
MRCC	Medical Research Coordinating Committee

MTCT	Mother-to-Child Transmission
NACP	National AIDS Control Program
NGO	Non-Governmental Organisation
NIMR	National Institute of Medical Research
NVP	Nevirapine
OPD	Out Patient Department
OR	Odds ratio (aOR adjusted odds ratio)
PCR	Polymerase Chain Reaction
PDA	Personal Digital Assistant
PEPFAR	President's Emergency Plan for AIDS Relief
PITC	Provider-Initiated Testing and Counselling
PLA	Participatory Learning and Action
PLOS	Public Library of Science
PMTCT	Prevention of Mother-to-Child Transmission
PPV	Positive Predictive Value
RE	Remote
RD	Roadside
RNA	Ribonucleic Acid
sdNVP	Single-dose Nevirapine
SQL	Structured Query Language
STI	Sexually Transmitted Infection
STROBE	Strengthening Reporting of Observational studies in Epidemiology
TANESA	Tanzania-Netherlands Support programme on AIDS
TAZAMA	Tanzania AIDS Monitoring Activities
TB	Tuberculosis
TBA	Traditional Birth Attendant
TC	Trading Centre
TMIH	Tropical Medicine and International Health
UCC	University Computing Centre
UN	United Nations
UNAIDS	Joint United Nations Programme on HIV/AIDS
USA	United States of America
USD	United States Dollar
USAID	United States Agency for International Development
VCT	Voluntary Counselling and Testing
WHO	World Health Organisation

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1 Introduction

1.1 Background

While the rates of mother-to-child transmission (MTCT) of human immunodeficiency virus (HIV) in the developed world are now extremely low, owing to the success of programmes which provide antiretroviral (ARV) drugs to HIV-positive pregnant women and HIV-exposed infants, sub-Saharan Africa continues to experience a staggeringly high number of new paediatric infections. Two hundred and forty thousand new infections occurred in children globally in 2013 alone; 91% of children living with HIV are in sub-Saharan Africa (1).

Historic international commitments have been made to eliminate new HIV infections in children, with emphasis also placed on keeping mothers alive and reducing maternal mortality. The Global Plan, launched by the United Nations (UN) in 2011, set out ambitious targets for the elimination of new paediatric HIV infections by 2015, as well as improving linkages for women to long-term antiretroviral treatment (ART) (2). This followed from UN Millennium Development Goals (MDG) outlined in 2000, which included targets for improvements in child health (goal 4), maternal health (goal 5) and HIV/AIDS (goal 6), including to "have halted by 2015 and begun to reverse the spread of HIV/AIDS" (3). The World Health Organisation (WHO) specifically emphasised the importance of strengthening prevention of mother-to-child transmission (PMTCT) services to reach these MDGs in their PMTCT strategic vision for 2010-2015 (4).

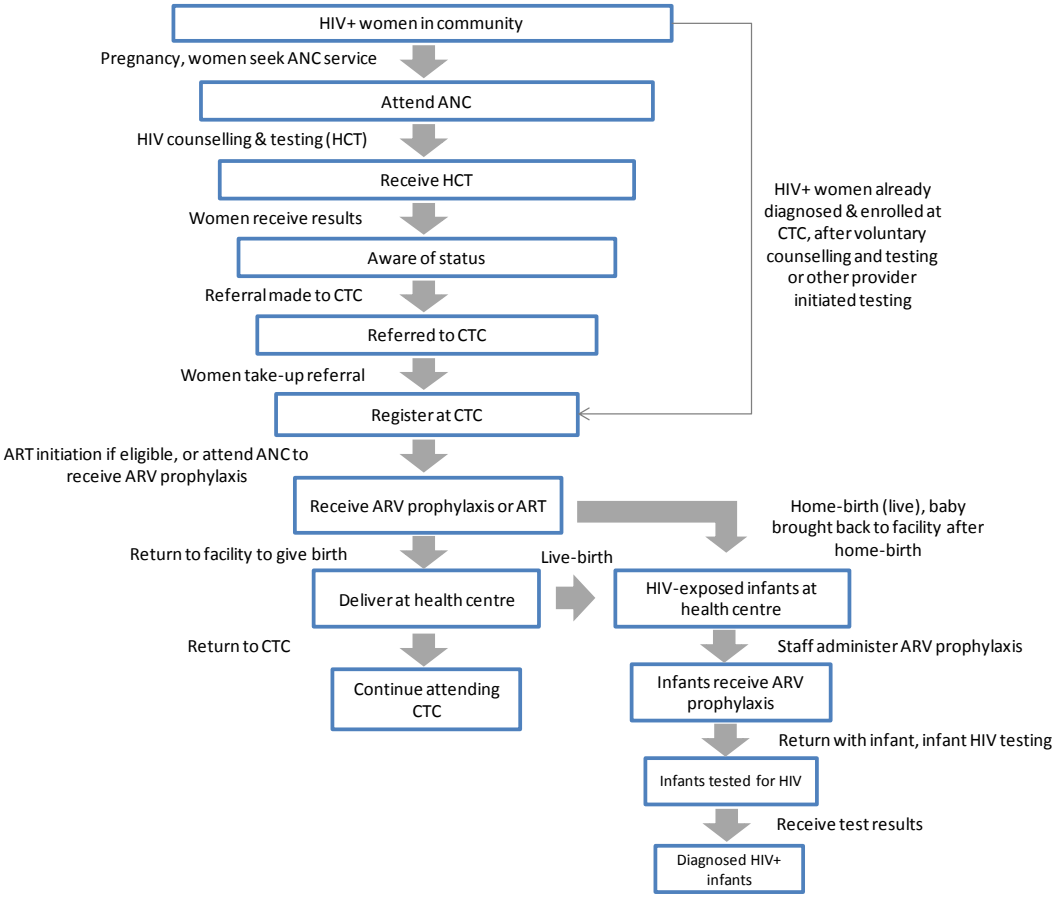
The scale-up and spotlight on PMTCT programmes in the region since these targets were set has resulted in some admirable achievements, reflected in significant declines in the reported numbers of new paediatric HIV infections worldwide: a 60% reduction between 2001 and 2013 (1). However, while giant strides have been made in some African countries, the situation in others remains less optimistic. Declines or stabilisation in the coverage of ARV drugs for PMTCT have been reported in some African countries, some falling short of 50% coverage, and with only half of 22 Global Plan priority countries appearing on track to meet their targets for 2015 (1, 5).

PMTCT programmes include a broad approach consisting of different stages: firstly focussing on prevention of HIV-infection among women of child-bearing age; secondly preventing unintended pregnancies among HIV-positive women; thirdly preventing MTCT of the virus among HIV-infected pregnant women; and fourthly the long-term care and treatment of HIV-positive women, their children and families (2).

The cornerstone of the third stage associated with PMTCT programmes for HIV-positive pregnant women is the provision of ARV drugs. By lowering the HIV viral load, ARVs can reduce the chance of MTCT of HIV during pregnancy, delivery and breastfeeding, from up to 45% to less than 5% (4). PMTCT programmes comprise a cascade of services beginning in pregnancy with the detection of HIV through provider-initiated testing and counselling (PITC) in the antenatal clinic (ANC) (Figure 1.1). Routine 'opt-out' HIV testing policies for pregnant women at ANC were first adopted in Africa around 2004, in a push to diagnose more HIV-infected pregnant women, and ultimately improve their own health and lower MTCT rates (6). Opt-out testing was envisioned to make HIV testing more routine and acceptable to pregnant women, when offered as part of routine ANC (pre-test counselling is generally offered in groups, followed by individual post-test counselling). This strategy has had notable successes in increasing the proportion of women testing in the ANC setting, although it has not necessarily translated into proportionate improvements in subsequent PMTCT or social outcomes (6, 7).

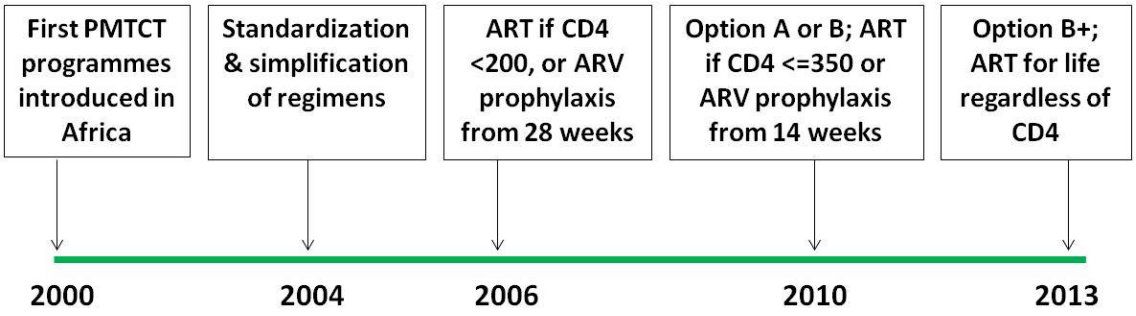
Subsequent services in the PMTCT cascade include the provision of antiretroviral drugs to women diagnosed with HIV (a short course of prophylaxis during pregnancy and breastfeeding, or life-long ART if medically eligible) and advice to deliver in a health centre. ARVs are also provided to the infant, with advice given about infant feeding options and returning for infant HIV-testing. Pregnant women who are diagnosed HIV-positive are referred to an HIV care and treatment centre (CTC) for long-term support, although some women may enter PMTCT services having been previously diagnosed and already attending HIV care services. Infants diagnosed with HIV are also enrolled into HIV care and treatment programmes. The PMTCT cascade thus includes services provided in the ANC and CTC setting, although sites differ in the extent of service integration; some ANCs referring patients to CTCs located in different health facilities, while others offer fully integrated services at the same-site.

Figure 1.1. Cascade of PMTCT services.



The composition, time of initiation and duration of ARV regimens taken for PMTCT have undergone substantial changes over time. Trials in the early 2000s which demonstrated the effectiveness of short course ARV prophylaxis, including single dose nevirapine (sdNVP) during labour and delivery, and nevirapine syrup for the infant, influenced the protocols implemented within many PMTCT programmes in sub-Saharan Africa at this time (8). However, as the evidence has mounted for improved outcomes when beginning more potent combination ARV regimens from an earlier gestational age and continuing ARVs longer during the breastfeeding period (9-12), guidelines have rapidly evolved to reflect this evidence (Figure 1.2).

Figure 1.2. Timeline for global PMTCT guideline changes.



The importance of providing ART to women for their own health was highlighted in 2006 (13), at which time women were recommended by the WHO to initiate full ART if their CD4 cell count was below 200 cells/mm^3, otherwise azidothymidine (AZT) prophylaxis was prescribed from 28 weeks gestation (sdNVP during labour and delivery, and infant prophylaxis for one week) (13). From 2010, 'Option A' and 'Option B' were recommended, bringing forward the time of initiation of ARV prophlyaxis during pregnancy to 14 weeks, and raising the CD4 count threshold for full ART initiation to 350 cells/mm^3, the options differing in terms of their specific drug regimens and duration of treatment (Table 1.1) (14).

Table 1.1. PMTCT guidelines in 2006, 2010 (Option A or B) and 2013 (Option B+).

	2006 guidelines	**Option A**	**Option B**	**Option B+**
ART eligibility criteria	CD4 **≤200** cells/mm^3 (or clinical stage 4, or stage 3 + CD4≤350)	CD4 **≤350** cells/mm^3 (or clinical stage 3 or stage 4)	CD4 **≤350** cells/mm^3 (or clinical stage 3 or stage 4)	None – all pregnant women
Mothers meeting eligibility criteria	Triple ARVs, starting from diagnosis and continued for life	Triple ARVs, starting from diagnosis and continued for life	Triple ARVs, starting from diagnosis and continued for life	Triple ARVs regardless of CD4 count, starting from diagnosis and continued for life
Mothers not meeting eligibility criteria	Prophylaxis: *Antepartum*: AZT from 28 weeks gestation *Intrapartum*: sdNVP at onset of labour and AZT/3TC *Postpartum*: AZT/3TC for 7 days	Prophylaxis: *Antepartum*: AZT from 14 weeks gestation *Intrapartum*: sdNVP at onset of labour and AZT/3TC *Postpartum*: AZT/3TC for 7 days	Prophylaxis: Triple ARVs from 14 weeks gestation until 1 week after exposure to breastmilk has ended	
Infants	NVP (daily) from birth continued for 1 week (or 4 weeks if mother had AZT for <4 weeks)	NVP (daily) from birth until 1 week after cessation of breastfeeding, or until age 4-6 weeks if replacement feeding	NVP or AZT (daily) from birth until age 4-6 weeks (regardless of infant feeding method)	NVP or AZT (daily) from birth until age 4-6 weeks (regardless of infant feeding method)

Adapted from Schouten et al. (15)
ARV= antiretroviral; AZT= azidothymidine; NVP= nevirapine; sd= single-dose

The latest guidelines launched by the WHO in 2013, known as 'Option B+', recommend that *all* pregnant women initiate life-long ART from the time of HIV diagnosis (16). The rationale for this change included simplified guidelines, eliminating the need for assessment of eligibility for ART through CD4 count testing, or the need to re-initiate HIV-positive women onto ARV drug regimens in subsequent pregnancies (17). Another benefit included preventing transmission to sero-discordant partners. Some countries such as Malawi have already launched Option B+ (2011, ahead of formal

global recommendations), with successes in raising uptake of ART in HIV-positive pregnant women and reducing the number of paediatric HIV infections (18). However, recent studies have also reported challenges with initiating and retaining pregnant women on ART (19, 20). Tanzania began to implement Option B+ more recently, with a phased roll out beginning towards the end of 2013 (21). Other countries are still in planning and piloting phases.

1.2 Rationale

The overall rationale for the investigation of PMTCT service usage follows from the global vision for elimination of MTCT of HIV, which will only be achieved if pregnant women living with HIV are able to access and adhere to PMTCT services. It is well known that antiretroviral drugs, delivered within a package of PMTCT services, have the ability to reduce or prevent MTCT of HIV (8, 22), but sub-optimal uptake of PMTCT services has blighted many countries across sub-Saharan Africa (5, 23), threatening the success of this intervention. While recent commendable improvements have been reported (5), operational research to improve the effectiveness of PMTCT interventions will remain an important area, in order to close the gaps and reach all pregnant women living with HIV, including the most marginalised and those from poor rural communities.

Understanding the propensity of asymptomatic HIV-positive individuals to use ARV drugs will also help in planning other "test and treat" initiatives: wide-scale provision of ART to all HIV-positive individuals, regardless of their immunological or clinical status, in order to reduce sexual transmission of HIV to sero-discordant partners (24). Interest in this approach has gathered momentum since the release of ground-breaking results of the Human Prevention Trials Network (HPTN) 052 clinical trial, demonstrating a 96% reduction in the transmission of HIV between sero-discordant couples among participants randomised to immediate ART compared to those in the delayed ART arm (initiation dependent on declining CD4 count or AIDS related illness) (25).

Tanzania has been earmarked as one of the UN Global Plan priority countries. It has one of the world's highest estimated numbers (~100,000) of HIV-positive pregnant women in need of ARV drugs for PMTCT, and the second highest number of new paediatric HIV infections among the 21 Global Plan priority countries, estimated at 16,000 in 2013 (1, 5). It is therefore vital to ensure effective and widespread delivery of PMTCT interventions to this population. UNAIDS figures for 2013 indicate that the proportion of these women receiving ARVs for PMTCT may have risen to approximately three quarters (1, 5), up from around a third in 2007 (23), indicating

progress, but with further work remaining to achieve universal coverage among this population.

Coverage may also be overestimated due to uncertainty in national estimates. The main sources of uncertainty arise from: 1) challenges of using routine PMTCT programme data to estimate the number of HIV-positive pregnant women; discussed further in paper B; 2) problems of finding out whether ARVs are dispensed but not ingested; and 3) difficulty of obtaining combined statistics for maternal *plus* infant ARV uptake. National figures may also mask regional variations, and the proportion of women accessing services in rural areas may be substantially lower. A study in a rural setting in Mwanza region in 2008 suggested that only one in three pregnant women diagnosed with HIV accessed any ARVs for PMTCT, and that only one in four accessed ARVs for themselves *and* their newborns (26). Although this is likely to have improved over time, there are no regional estimates of coverage with ARV drugs among all HIV-positive pregnant women. Such measures and robust monitoring systems are essential for tracking PMTCT service uptake relative to targets set, yet UNAIDS recently highlighted that such systems have lagged behind targets and aspirations, and called for improvements to collection and usage of routine data in order to inform programming and ultimately improve health outcomes for HIV-positive pregnant women and their infants (5). A further drawback is that most analyses of PMTCT outcomes are restricted to those already enrolled in antenatal clinics (ANC), and do not account for or characterise the women who do not seek care. This is important in order to design PMTCT interventions to reach this set of women and improve their access to these life-saving services.

The aim of the quantitative analyses presented in this thesis is to describe access to PMTCT services among HIV-positive pregnant women in a community cohort in rural Tanzania, by linking community-based research and routine clinic data, and thus attempt to understand the type of women who do not access services. Qualitative work is also important to explore in-depth the context-specific reasons why some women do not take up PMTCT services, or drop-out from services, and to understand the issues from health providers' perspective. This mixed-methods approach, allowing a synthesis of findings from different methodologies, will be essential to provide locally relevant recommendations for improving access to PMTCT services in this community, as well as in Tanzania and other rural African settings more widely.

1.3 Aims and objectives

The overall aim of this PhD research is to investigate uptake of PMTCT services in a rural community in Tanzania (Kisesa) and the reasons that hinder or facilitate service use, the ultimate goal being to recommend strategies for optimising access to and retention in the PMTCT programme.

The objectives are as follows:

1. To critique methods used to investigate uptake of PMTCT services and factors associated with service use.

2. To determine, at a community level, trends in the use of PMTCT services among HIV-positive pregnant women in Kisesa. More specifically, to calculate among Kisesa-resident HIV-positive women who were pregnant or gave birth since 2005, trends in the proportion that registered at ANC, were tested for HIV, registered for CTC services (before or after ANC) and accessed ARV drugs.

3. To investigate barriers and facilitating factors to the uptake of PMTCT services, including the following specific sub-objectives:
    a. To synthesise factors previously identified across sub-Saharan Africa.
    b. To explore factors influencing PMTCT service use in a rural community in Tanzania (Kisesa).

4. To identify and recommend strategies to improve access to and retention in PMTCT services, including long-term HIV care.

These objectives are summarised in Table 1.2, along with the methods used to address each objective.

Table 1.2. Research objectives with methods to address each objective.

RESEARCH OBJECTIVES	METHODS AND DATA SOURCES
To critique methods used to investigate uptake of PMTCT services and factors associated with service use	Systematic literature review (paper A) Report on challenges with use of routine clinic data sources for monitoring HIV-positive pregnant women and infants and their PMTCT outcomes, and for linkage with community data (paper B) Critical analysis of qualitative (vignette) methods used in research conducted in Kisesa (paper E)
To determine, at a community level, trends in the use of PMTCT services among HIV-positive pregnant women in Kisesa Specifically: To calculate trends in the proportion of Kisesa-resident HIV-positive women who accessed PMTCT service components in 2005-2012	Quantitative descriptive analysis (paper C) using community cohort (demographic surveillance & HIV sero-survey) data linked to clinic datasets
To investigate barriers and facilitating factors to the uptake of PMTCT services Synthesise factors identified previously across sub-Saharan Africa Explore factors influencing PMTCT service use in a rural community in Tanzania (Kisesa)	Systematic literature review (paper A) Quantitative statistical analysis using linked cohort-clinic Kisesa datasets (paper D) Qualitative study in Kisesa (paper F)
To identify and recommend strategies to improve access to and retention in PMTCT services, including long-term HIV care	Systematic literature review (paper A) Quantitative analyses of PMTCT service use in Kisesa (papers C and D) Qualitative study in Kisesa, including health provider perspectives and community views (paper F, chapter 10, appendix 12.1) Discussions with local scientists

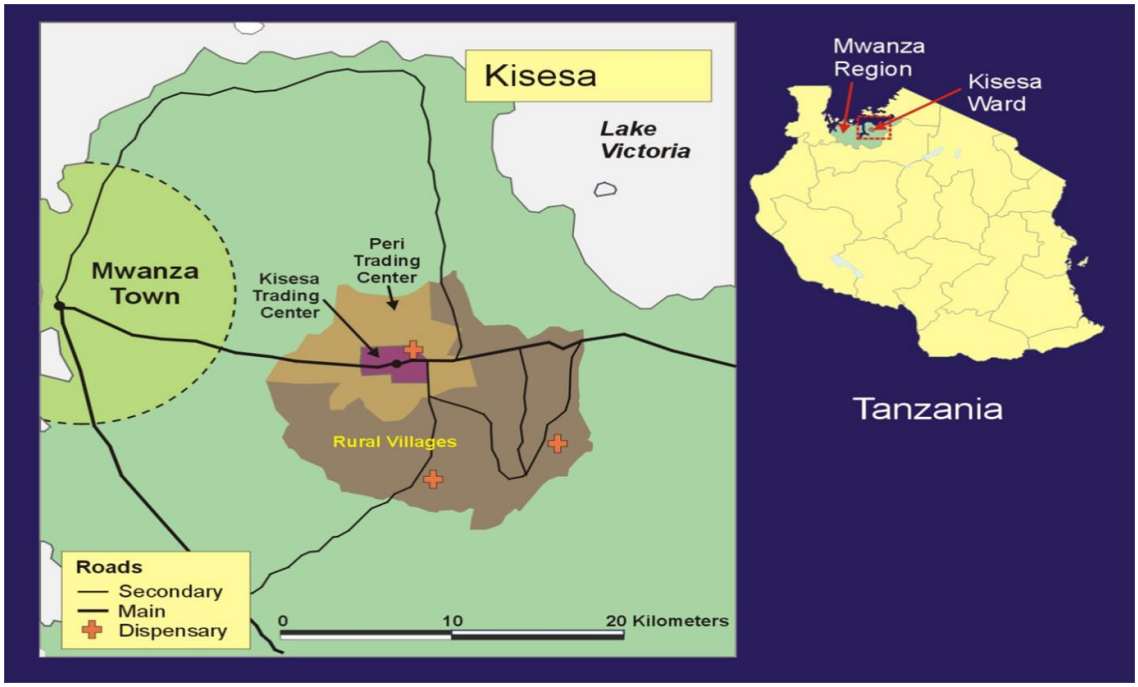
1.4 Project background and research setting

This PhD research took place in a rural area of north-west Tanzania known as Kisesa, located in Magu district of Mwanza region (Figure 1.3). This is the site of a long-term collaborative research project - 'TAZAMA' (Tanzania AIDS Monitoring Activities) - between the London School of Hygiene and Tropical Medicine (LSHTM) and the Tanzania National Institute of Medical Research (NIMR) in Mwanza city. TAZAMA, funded by the Global Fund for AIDS, Tuberculosis (TB) and Malaria, was initiated in order to monitor the ART programme since its implementation in this area in 2005. The primary research activity conducted by TAZAMA is the Kisesa HIV open cohort study, which has been monitoring trends in the HIV epidemic since 1994, initially funded by the Tanzania-Netherlands Support programme on AIDS (TANESA). This is the longest running HIV community cohort study in Tanzania, and one of the oldest in Africa.

In addition to community-based research activities, a partnership also exists between TAZAMA and government-run health facilities in the area, including the VCT clinic and CTC at Kisesa health centre (established in 2005 and 2008 respectively), and the CTC at Bugando Medical Centre, the national referral hospital in Mwanza city. Kisesa CTC is also part of a global research network of HIV clinics under the International Epidemiologic Databases to Evaluate AIDS (IeDEA) Consortium. Three rural dispensaries are also located in the study area, and first collaborated with TAZAMA during additional ANC surveillance activities. Recent goals of the TAZAMA project include the linkage of community cohort data to data from Kisesa-based health facilities in order to monitor, at a community level, the use and impact of HIV services.

Further details of the local geography and economy, health facilities, study population and TAZAMA research activities are provided in chapter 3. The following section briefly introduces the structure and nature of health services at a national level, including HIV services.

Figure 1.3. Map of the study area.



1.5 Tanzanian health services

The foundation of the health services structure in Tanzania constitutes primary care services, offered in small dispensaries and larger health centres, through public and private providers. District hospitals, then regional and national referral hospitals, comprise the higher tiers of the system. Following the socialist policies of President Nyerere in the 1970s, a great expansion of health infrastructure took place, with large increases in the number of health centres and dispensaries in rural areas (27). Dispensaries constitute the majority of health facilities in the country (88% in 2013), with health centres accounting for 9% and hospitals for 3% in 2013 (28). However, economic reforms and structural adjustment policies in the 1980s resulted in drastic shortages of staff and resources in health facilities, accompanied by poor service quality and user costs, due to a gross underinvestment in the health sector. This situation persists despite recent health sector reform programmes and international aid.

Government HIV treatment programmes introduced nationally in 2004 have benefitted from extra investments, largely through international donor support, with antiretroviral treatment provided free of charge to all HIV-positive patients (29). Maternal health services are also provided without cost, although in practice women sometimes pay for materials, such as delivery gloves, when supplies are limited. However, despite the programme of decentralisation, HIV services remain largely restricted to hospitals and larger health centres, with poorer access in rural dispensaries.

PMTCT services, implemented nationally in 2003 after an initial pilot phase, have undergone similar decentralisation, including the extension and scaling-up of HIV testing and provision of ARV prophylaxis to many health centres and rural dispensaries (30). Opt-out HIV testing policies at ANC were implemented in 2007. Over 90% of health facilities with reproductive and child health services were estimated to be providing PMTCT services in 2014 (31). However, services are often rendered inoperative through frequent stock outs of HIV testing kits and ARV drugs, and full PMTCT services, including long-term HIV care and treatment for HIV-positive pregnant women and infants, still remain fairly limited in remote areas of Tanzania. It was estimated that there were 1156 health facilities offering CTC services in Tanzania in 2013, representing three CTC sites per 100,000 population and approximately 17% of 6700 public health facilities nationally (28, 32).

1.6 Structure of the thesis

This thesis is presented in research paper style, including six published or submitted academic papers (A-F), and four additional chapters including this introductory chapter. A short introductory section is provided before papers B-F, briefly outlining the rationale for the paper, and linking it to the findings and material presented in preceding chapters. The specific objectives and data sources for each paper are summarised in Table 1.3, while Figure 1.4 provides a visual representation of how all the papers and datasets come together within the thesis.

Chapter 2 is the first research paper (paper A): a systematic literature review, published in the Journal of the International AIDS Society (JIAS) (33), which synthesises barriers and facilitating factors to the uptake of antiretroviral drugs for PMTCT in sub-Saharan Africa. This paper serves as a foundation for the investigations of PMTCT service use in Kisesa, Tanzania.

Chapter 3 provides details of the study setting, including the local health facilities and HIV programmes, as well as the Kisesa cohort activities that gave rise to some of the quantitative datasets used in this thesis. It also presents the methods used for the quantitative analyses, including fieldwork undertaken to prepare the datasets. This is followed by a technical section specifically focussing on data linkage. This includes an analysis of a gold standard dataset, the results of which were used to develop the algorithms to link the cohort data to the clinic data. The chapter concludes with full

details of the statistical analysis methods used to analyse the cohort-clinic linked datasets.

Chapter 4 is a short report (paper B), submitted to Tropical Medicine and International Health, discussing the merits of, and challenges with, using routine clinic data for the monitoring of PMTCT programmes, including the potential for linkage with community research data. This paper draws from my experience and lessons learned from working with the routinely collected data in Kisesa.

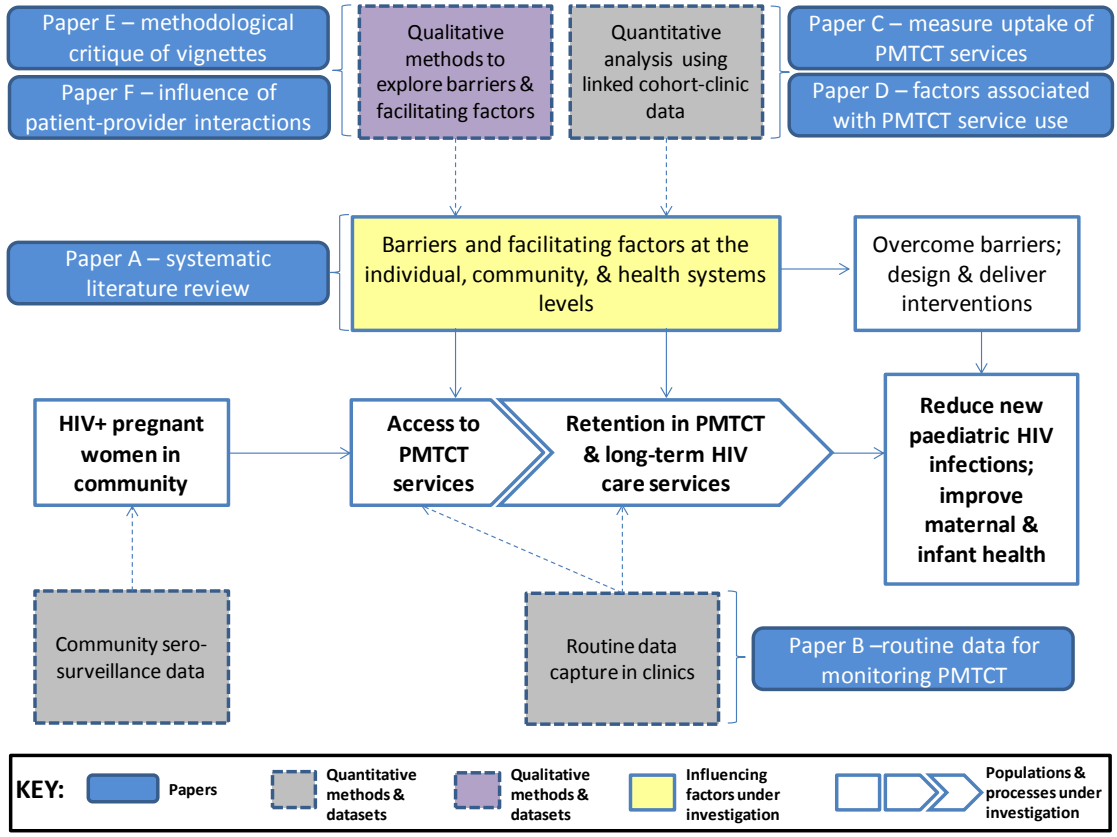
Chapters 5 and 6 present the results of quantitative analyses using linked cohort-clinic datasets. Chapter 5 is a research paper (paper C) submitted to the Journal of Acquired Immune Deficiency Syndromes (JAIDS) describing trends in coverage with PMTCT services at successive stages of the cascade among HIV-positive women in the community cohort in Kisesa. Chapter 6 (paper D) is a research paper submitted to Sexually Transmitted Infections (STI), investigating factors associated with access to PMTCT services in the Kisesa setting.

Chapter 7 provides full details of all the qualitative fieldwork and analyses conducted. This is followed by the first of two published papers using the qualitative data (chapter 8) (34). This paper (paper E), published in BMC Medical Research Methodology (34), critiques the use of vignettes for the investigation of barriers to PMTCT service use in Tanzania and similar settings in Africa. The second qualitative paper (paper F), using data from the same qualitative study but with a different analysis objective, is presented in chapter 9 and published in PLOS ONE (35). This results paper specifically explores the relationships between health service providers and HIV-positive pregnant women, and the ways in which their interactions impact on PMTCT service use.

This thesis concludes with a discussion (chapter 10) of the overall findings drawing from each of these results papers, policy recommendations and areas for future research, as well as the strengths and limitations of the PhD research.

The appendix includes all the study tools, and other disseminated work, including policy briefs, posters and slides presented at international conferences.

Figure 1.4. Schematic of elements covered in the thesis.



Each of the six papers are shown relative to the methods or data contributing to each paper.

Table 1.3. List of papers, with their objectives and data sources.

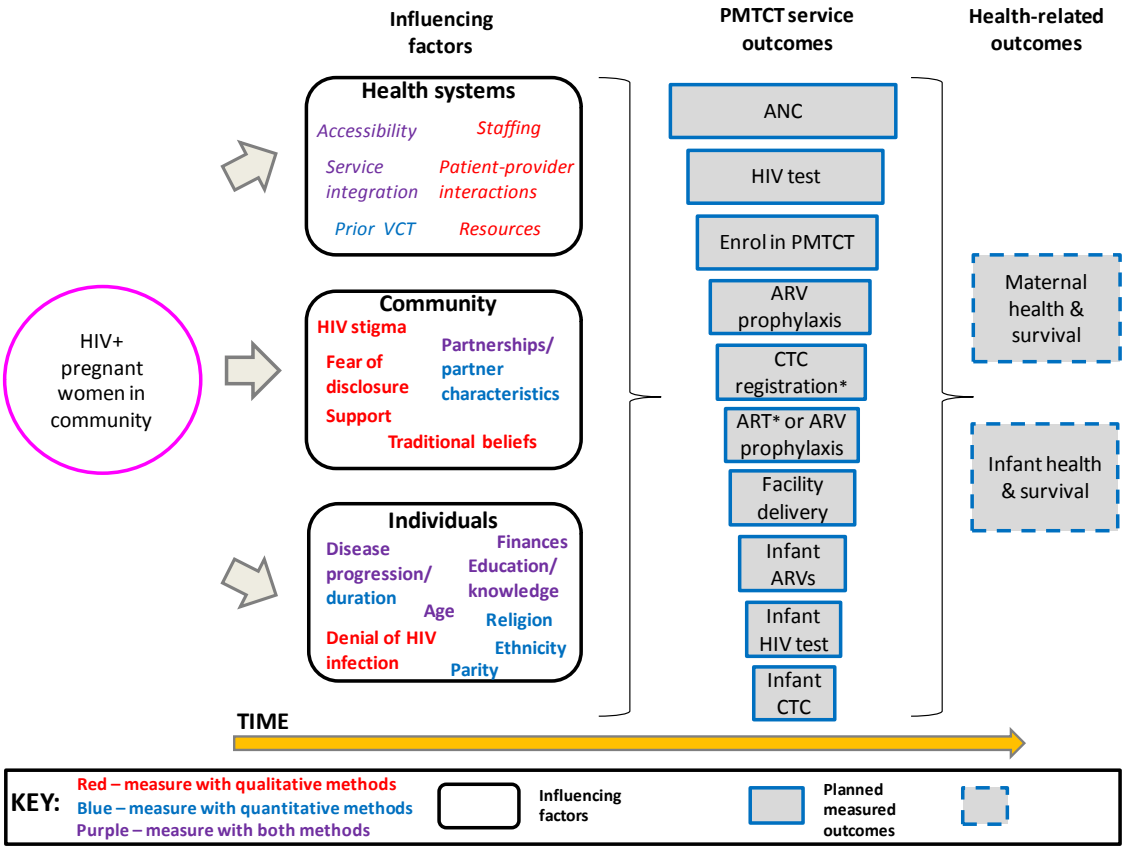
	PAPER TITLE	SPECIFIC OBJECTIVES OF THE PAPER	DATA SOURCES				
			a. Existing literature on qualitative & quantitative studies from sub-Saharan Africa	b. Qualitative (transcripts, fieldwork notes & photos generated during PLAs, IDIs, observations)	c. Kisesa cohort data (demographic surveillance & HIV sero-surveys)	d. Routine maternal & child health clinic data from four Kisesa clinics	e. Routine Kisesa health centre CTC clinic database
A	Systematic review of barriers and facilitating factors to the uptake of ARV drugs for prevention of mother-to-child transmission of HIV in sub-Saharan Africa	To investigate and synthesise reasons for low access, initiation and adherence to antiretroviral drugs by mothers and exposed babies for prevention of mother-to-child transmission (PMTCT) of HIV in sub-Saharan Africa	✓				
B	Optimising routine data sources for PMTCT programme monitoring in Africa: lessons learned from Tanzania	To describe the challenges with recording, linking and using routine PMTCT data from government health clinics in Tanzania				✓	✓
C	Uptake of services for prevention of mother-to-child transmission of HIV in a community cohort in rural Tanzania from 2005 to 2012	To describe and measure population-level uptake of PMTCT services among HIV-positive pregnant women in a community cohort in rural Tanzania			✓	✓	✓
D	Factors associated with access to prevention of mother-to-child transmission HIV services in a community cohort in rural Tanzania	To identify factors associated with access to PMTCT services among HIV-positive women in a community cohort in rural Tanzania			✓	✓	✓
E	Using vignettes in qualitative research to explore barriers and facilitating factors to the uptake of prevention of mother-to-child transmission services in rural Tanzania: a critical analysis	To describe the process, successes, and challenges of developing and applying a vignette to an investigation of barriers and facilitating factors to uptake of PMTCT services in rural Tanzania; to determine the feasibility and utility of using vignettes in sub-Saharan Africa		✓			
F	"It is like that, we didn't understand each other": exploring the influence of patient-provider interactions on prevention of mother-to-child transmission of HIV service use in rural Tanzania	To explore the nature of patient-provider interactions within PMTCT service provision, and how these interactions influence PMTCT service use; to provide recommendations for optimising patient-provider relations and PMTCT uptake		✓			

1.7 Overall conceptual framework for the thesis

Figure 1.5 illustrates the overall conceptual framework for this thesis which investigates uptake of PMTCT services in Kisesa. The flow from left to right shows the processes under investigation. Women living with HIV in the community (Kisesa) become pregnant and have the opportunity of accessing PMTCT services (column one). However, barriers at the level of individuals, their community, and health systems, can restrict women's ability to access and adhere to PMTCT services, while other factors may facilitate women's use of these services (column two). The third column depicts the PMTCT service cascade, including the outcomes measured within this thesis, with the narrowing of boxes representing the potential drop-out at each step of the programme. On entering the programme, women may be diagnosed for the first time, or they may already know their status from earlier testing at ANC, other PITC or VCT. Once diagnosed and enrolled into PMTCT services, women must be retained in the continuum of PMTCT services for the duration of their pregnancy, through delivery, and post-partum, including services for HIV-exposed infants. Emphasis is also now placed on life-long HIV care and treatment for HIV-positive women and infants diagnosed HIV-positive. Successes in access to and retention in PMTCT services can lead to the reduction of vertical HIV transmission and thus prevention of new paediatric HIV infections, as well as improved health outcomes and survival of mothers and their infants (column four).

Although health-related outcomes are not measured in the thesis, they are included in the framework as they represent the ultimate goal of PMTCT programmes, while the design of interventions to overcome barriers or capitalise on facilitating factors to PMTCT service use can improve PMTCT outcomes. The arrow at the bottom of the diagram represents the time element, with the extent of PMTCT service use and influencing factors expected to change over time. For example, factors may change in importance over time with the emergence of new factors, while PMTCT service use is likely to improve over time.

Figure 1.5. Conceptual framework for the thesis.



Bold text indicates factors expected to play a stronger role; non-bold italics font indicates factors expected to be relatively less important in Kisesa
*CTC registration followed by continued attendance at the CTC and sustained ART adherence

The barriers and facilitating factors expected to influence PMTCT service use in Kisesa are arranged within individual, community and health systems levels (drawing from a socio-ecological model which can be used to conceptualise barriers to HIV services (36)), and populated with factors that are hypothesised to play a role in this study setting (factors in bold are expected to play the greatest role). These hypotheses are based on previous work conducted locally, including a few studies investigating barriers to accessing other HIV testing and treatment services in Kisesa (none have focussed specifically on access to PMTCT services or pregnant women, but it is likely that the findings will be relevant and will provide important insights into the local context). These findings are outlined briefly below. The hypotheses also encapsulate some of the literature from other studies across sub-Saharan Africa, which were subsequently synthesised, analysed and discussed in detail in the systematic review presented in chapter 2.

Health systems barriers to attending the HIV clinic in Kisesa included the time and cost of travel plus long waiting times on arrival, although these studies were conducted at a time (before 2008) when HIV patients were referred for treatment to the referral

hospital in Mwanza city (37-39). Whether distance remains a barrier since the decentralisation of the HIV care and treatment programme is uncertain. It is possible that residents of remote rural villages still face this issue, although the introduction of the PMTCT programme in Kisesa would be expected to improve service access and lessen the importance of this factor. Service accessibility and integration of ANC and CTC services, as well as other health systems factors such as waiting times (numbers of staff) and availability of resources, may therefore be relatively less important than community and individual-level factors after decentralisation (conveyed in non-bold font in the diagram). Whether prior attendance at other HIV services including VCT is related to uptake of PMTCT services is not known, but may conceivably encourage PMTCT use if women are aware of their status before falling pregnant. Other health systems factors which have not emerged or have not been explored in research in Kisesa, but have been found to influence uptake of PMTCT services in similar African settings, include patient-provider interactions, and integration of reproductive health and HIV services (40-45).

Community-level factors are expected to play a prominent role in Kisesa. Qualitative research in this setting showed that stigma regarding HIV remains entrenched in this community, even since the introduction of ART and 'normalisation' of the disease (46, 47). Newer types of stigma, manifested as blaming of HIV-positive individuals, especially those on ART for engaging in risky sexual behaviour and spreading the disease, have also arisen (47). Scepticism about the ART programme was sometimes coupled with strong religious beliefs in the community, witchcraft, or provision of care by traditional healers (38, 39, 46, 47). Family support was an important factor in promoting attendance of clinic appointments and adherence to ART, though conversely family pressures also constrained and opposed women's own decisions (37-39). A quantitative study exploring factors associated with VCT uptake during a serological survey (2003-4) in Kisesa found that married women were less likely to complete VCT, possibly because they feared the negative consequences of subsequently disclosing their HIV status to their husband, but that women were more likely to complete VCT if their partner had also undergone VCT (48). This suggests that the extent of partner support is likely to play a role.

Individual level factors associated with VCT service use in Kisesa included ethnicity (non-Sukuma tribe associated with higher VCT uptake), religion (higher VCT use among Muslims compared to Christians) and education (those with less schooling still at risk for low VCT completion even two years after the availability of ART) (48, 49). Knowledge of HIV and ART was surprisingly low in Kisesa, in a community where HIV

research and education has been promoted for over 15 years, with less than 5% of women aged 15 or over aware of MTCT of HIV in 2006/7 (50). Poor knowledge of HIV/ART, particularly MTCT, might be an important factor in determining PMTCT service use in this setting based on associations reported with VCT attendance and the low levels of knowledge observed (48, 50). Denial of the disease and perceived disease severity were also associated with attendance of HIV clinic appointments and drop-out from the care and treatment programme at Kisesa health centre (38, 39, 46, 47). Individuals experiencing symptoms overcame barriers to attendance or expressed motivation to continue with treatment, while those who lacked physical signs of disease tended to ignore services or default from the programme. This may play a role in adherence to PMTCT services, given pregnant HIV-positive women may be fairly healthy (51), although it may be less problematic in the context of short-course ARV prophylaxis for PMTCT. Age did not appear to influence use of VCT services in Kisesa, although initial analyses of an ANC survey conducted in 2008 in Magu District indicated that lower uptake of PMTCT treatment was associated with younger maternal age, as well as parity (first birth) (26). This study found that only 33% of HIV-positive pregnant women attending ANCs across Magu District received ARV prophylaxis for PMTCT in 2008, and together with studies of VCT use in Kisesa showing that VCT completion was lower in women than in men (16% in women in 2006-7 versus 19% in men (49)), suggest that uptake of PMTCT and other HIV services by women in this area may be particularly low.

1.8 Role of the candidate

1.8.1 Overall design and planning

I contributed to the overall concept, framing of the research questions and design for this study, and was involved with writing the grant application which was successful in securing funding from IeDEA and the National Institutes for Health for the qualitative component and for ANC data entry (see section 1.10). As my PhD research was embedded within regular research activities of the TAZAMA project, TAZAMA colleagues at the LSHTM and NIMR were also involved in the ideas and design for the study. The LSHTM-based and Tanzanian principal investigators, Basia Zaba and Mark Urassa, provided technical support throughout the study and advice on the local setting and logistics. I prepared the ethical applications associated with my research project, including ethical clearance for the data linkage, which was part of a wider TAZAMA project objective to link the community cohort and Kisesa health facility data.

1.8.2 Literature review (paper A)

I conceived the idea for the systematic review (paper A), carried out the literature searches, appraised the quality of the literature, analysed the included studies and wrote the review. Since this was a collaborative paper (as were the other research papers included within this thesis), other co-authors provided contributions to the work. Isolde Birdthistle (IB) and Alison Wringe (AW), epidemiologists at the LSHTM, appraised the quality of a subset of the included articles, while IB contributed to the design of the quality appraisal tool. Colleagues from the International AIDS Alliance, Gitau Mburu and Kate Iorpenda, contributed to the discussion of programming and policy implications.

1.8.3 Quantitative data collection and analysis (papers B, C and D)

The quantitative work that forms this PhD thesis made use of some of the available secondary cohort datasets generated by TAZAMA. Although I was not responsible for the design or management of the sero-surveys, I gave feedback on the sero7 questionnaire, as well as observing the sero7 activities during one of my field trips to the study site and documenting my observations for feedback to the sero-survey manager and TAZAMA project principal investigator. I was heavily involved in DSS round 27, designing the processes and survey questions to capture information from women's ANC cards, organising and attending a pilot of the new questions, assisting with training of the enumerators and with the design of data cleaning checks.

Routinely collected clinic data from the government run health facilities was also used. The CTC data from Kisesa CTC and Bugando hospital is already routinely entered by government data entry clerks, although I was involved with designing edit specifications to clean the CTC data, pilot testing these edit checks and assisting in the training of data entry clerks to complete the data cleaning in Kisesa CTC.

Data from the antenatal clinics containing PMTCT outcomes is routinely collected in Kisesa health facilities, but had not previously been entered into a database. I planned, helped to design and supervised this data entry project during additional time (spread over approximately six months) based at NIMR. This included liaising with health centre staff and district officials with the help of Dr. Denna Michael (DM), the TAZAMA project clinician, consulting with NIMR-based data managers (Clemens Masesa and Richard Machemba) on development of the data entry screens, supporting training of the junior data manager and data entry clerks, and supervising data entry. I was involved in trips to Kisesa to collect clinic log books for data entry at NIMR, and in designing the paper work for this process. I assisted the data managers in

implementing data cleaning checks, supervised the data cleaning, and documented the data entry processes for future reference by TAZAMA project staff.

I carried out most of the work to link the community cohort data to the clinic datasets. The data linkage methods were first initiated by the TAZAMA project Information Technology (IT) consultant (Benjamin Clark), although I was also involved in the development process. I designed the ANC linkage algorithm and executed linkage of the ANC data to the cohort. Further details of my role in the data linkage project are provided in chapter 3.

I designed and carried out the statistical analyses, with guidance from LSHTM and NIMR statisticians, including Jim Todd. I attended an ALPHA (Analysing Longitudinal Population-based HIV/AIDS data on Africa) workshop which gave me initial training on the application of various statistical techniques to the Kisesa cohort datasets, and guidance on selection of variables.

1.8.4 Qualitative work (papers E and F)

For the qualitative component of this PhD, I designed the data collection tools, wrote the study protocols and constructed the sampling frame (making use of the secondary cohort datasets), working closely with qualitative advisors and local scientists at LSHTM and NIMR. I spent five months at NIMR spanning the period of the qualitative fieldwork. During this time I trained the fieldworkers with assistance from Gerry Mshana (GM), a senior Tanzanian social scientist, observed the group activities and held de-briefing discussions. I recruited health officials with assistance from DM, interviewed these participants and transcribed these interviews (transcription and translation for all other activities was done by local staff).

I conceived the ideas, together with GM and AW, for the two qualitative papers presented in this thesis. I carried out the analyses, with assistance from AW who double-coded a portion of the transcripts, and IB who gave guidance on qualitative analysis methods.

1.8.5 Dissemination

I wrote all the papers and additional chapters which are presented in this PhD, incorporating feedback from co-authors and peer-reviewers for the published collaborative papers. I have attended international conferences for poster and oral presentations of findings from my research, and will also disseminate the findings

locally (conference publications are included in appendix 12.1 and dissemination efforts are discussed further in chapter 10).

1.9 Ethical clearance

Ethical approval for the research included within this thesis was granted by the LSHTM ethics committee, the Lake Zone Institutional Review Board and the Medical Research Coordinating Committee (MRCC) of Tanzania (appendix 12.2).

1.10 Funding

I was awarded a four year graduate teaching assistantship by the LSHTM, which covered my research degree fees and an annual stipend, as well as the Dr. Gordon Smith travelling scholarship which covered most of my travel costs to Tanzania for data collection. The fieldwork costs for my PhD research were largely covered by a grant to NIMR, Mwanza from the East Africa IeDEA Consortium through the US National Institutes of Health - the Eunice Kennedy Shriver National Institute of Child Health and Human Development and the National Institute of Allergy and Infectious Diseases, grant award 3U01AI069911-06S2. The ongoing TAZAMA cohort activities were funded by the Global Fund to fight AIDS, TB and Malaria (Round 9; grant number TNZ-911-G14-S).

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COVER SHEET FOR EACH 'RESEARCH PAPER' INCLUDED IN A RESEARCH THESIS

Please be aware that one cover sheet must be completed for each 'Research Paper' included in a thesis.

1. For a 'research paper' already published

1.1. Where was the work published? Journal of the International AIDS Society

1.2. When was the work published? September 2014

1.2.1. If the work was published prior to registration for your research degree, give a brief rationale for its inclusion
N/A

1.3. Was the work subject to academic peer review? Yes

1.4. Have you retained the copyright for the work? **Yes** / **No**
If yes, please attach evidence of retention (OPEN ACCESS JOURNAL) (Appendix 12.7)
If no, or if the work is being included in its published format, please attach evidence of permission from copyright holder (publisher or other author) to include work

2. For a 'research paper' prepared for publication but not yet published

2.1. Where is the work intended to be published?

2.2. Please list the paper's authors in the intended authorship order

2.3. Stage of publication – Not yet submitted / Submitted / Undergoing revision from peer reviewers' comments / In press

3. For multi-authored work, give full details of your role in the research included in the paper and in the preparation of the paper. (Attach a further sheet if necessary)
I conceived the idea, carried out the review, designed quality appraisal checklists in collaboration with co-authors, conducted most of the quality appraisals of included papers, and wrote the manuscript.

NAME IN FULL (Block Capitals) ANNABELLE GOURLAY

STUDENT ID NO LSH201467

CANDIDATE'S SIGNATURE [redacted] Date 01/10/14

SUPERVISOR/SENIOR AUTHOR'S SIGNATURE (3 above) [redacted]

2 Paper A. Barriers and facilitating factors to the uptake of antiretroviral drugs for prevention of mother-to-child transmission of HIV in sub-Saharan Africa: a systematic review

2.1 Abstract

Objectives: To investigate and synthesise reasons for low access, initiation and adherence to antiretroviral drugs by mothers and exposed babies for prevention of mother-to-child transmission (PMTCT) of HIV in sub-Saharan Africa.

Methods: A systematic literature review was conducted. Four databases were searched (Medline, Embase, Global Health, Web of Science) for studies conducted in sub-Saharan Africa from January 2000 to September 2012. Quantitative and qualitative studies were included that met pre-defined criteria. Antiretroviral (ARV) prophylaxis (maternal/ infant) and combination antiretroviral therapy usage/ registration at HIV care and treatment during pregnancy were included as outcomes.

Results: Of 574 references identified, 40 met the inclusion criteria. Four references were added after searching reference lists of included articles. Twenty studies were quantitative, 16 were qualitative and 8 were mixed-methods. Forty-one studies were conducted in Southern and East Africa, two in West Africa, none in Central Africa, and one was multi-regional. The majority (n=25) were conducted before combination antiretroviral therapy for PMTCT was emphasised in 2006. At the individual-level, poor knowledge of HIV/ antiretroviral therapy/ vertical transmission, lower maternal educational level, and psychological issues following HIV diagnosis were the key barriers identified. Stigma and fear of status disclosure to partners, family or community members (community-level factors) were the most frequently cited barriers overall and across time. The extent of partner/community support was another major factor impeding or facilitating the uptake of PMTCT ARVs, while cultural traditions including preferences for traditional healers and birth attendants were also common. Key health systems issues included poor staff-client interactions, staff shortages, service accessibility and non-facility deliveries.

Conclusions: Long-standing health systems issues (such as staffing and service accessibility) and community-level factors (particularly stigma, fear of disclosure and lack of partner support) have not changed over time and continue to plague PMTCT programmes more than 10 years after their introduction. The potential of PMTCT programmes to virtually eliminate vertical transmission of HIV will remain elusive unless these barriers are tackled. The prominence of community-level factors in this review points to the importance of community-driven approaches to improve uptake of PMTCT interventions, although packages of solutions addressing barriers at different levels will be important.

2.2 Background

In 2008, 12 million women aged 15 years and over were estimated to be living with HIV in sub-Saharan Africa, and of the 330,000 new HIV infections among children (under 15) globally in 2011, over 90% were in sub-Saharan Africa (4, 52). The vast majority of new HIV infections among children occur through mother-to-child transmission (MTCT).

Antiretroviral therapy (ART) is the core intervention of the prevention of mother-to-child transmission (PMTCT) service package (programme 'prong 3', concerning interventions to reduce vertical transmission among HIV-positive pregnant women, alongside other 'prongs' covering HIV prevention in women of reproductive age, family planning, and long-term HIV care and treatment (4)). Antiretroviral (ARV) drugs can reduce the likelihood of HIV vertical transmission from as high as 45% in the absence of any intervention, to less than 5% (4). In 2010, the World Health Organisation (WHO) published guidelines advising that all HIV-positive pregnant women with CD4 counts below 350 cells/mm^3 should initiate combination antiretroviral therapy for their own health (herein referred to as 'cART') (53), although some countries in sub-Saharan Africa still use lower CD4 count thresholds (54). For those with higher CD4 counts, antiretroviral prophylaxis in pregnancy is advised, with variations in drug regimens and duration depending on the option (A, B or B+) adopted in each country (Table 2.1) (14, 15). PMTCT treatment guidelines have evolved considerably over time in sub-Saharan Africa, following the first recommendation for ARV drugs for PMTCT in 2000 (short-course prophylaxis starting late in pregnancy or during labour, including single-dose nevirapine (NVP) for mothers and infants) (55), and subsequent revisions in 2004 (standardisation and simplification of regimens) and 2006 which emphasised the importance of providing cART to pregnant women for their own health (cART for those with CD4 counts below 200 cells/mm^3, or azidothymidine (AZT) prophylaxis starting from 28 weeks of pregnancy, single-dose NVP during labour and delivery, and infant

prophylaxis for one week) (13, 56). The 2010 recommendations include an option (B) that unifies prophylaxis for PMTCT of HIV and treatment for an HIV-infected woman's own health. Option B+ (ARV therapy for all HIV-infected pregnant women continued for life) is expected to be formally recommended in 2013, with foreseen benefits including further simplification and operational simplicity, avoidance of stopping and starting ARV drugs, protection against vertical transmission in future pregnancies and protection against sexual transmission to sero-discordant partners (14).

Table 2.1. ARV treatment guidelines for prevention of mother-to-child transmission of HIV.

	Option A	**Option B**	**Option B+**
Mother (CD4 ≤350 cells/mm^3)	Triple ARVs, starting from diagnosis and continued for life	Triple ARVs, starting from diagnosis and continued for life	Triple ARVs regardless of CD4 count, starting from diagnosis and continued for life
Mother (CD4 >350 cells/mm^3)	Prophylaxis: *Antepartum*: AZT from 14 weeks gestation *Intrapartum*: sdNVP at onset of labour and AZT/3TC *Postpartum*: AZT/3TC for 7 days	Prophylaxis: Triple ARVs from 14 weeks gestation until 1 week after exposure to breastmilk has ended	
Infant	NVP (daily) from birth until 1 week after cessation of breastfeeding, or until age 4-6 weeks if replacement feeding	NVP or AZT (daily) from birth until age 4-6 weeks (regardless of infant feeding method)	NVP or AZT (daily) from birth until age 4-6 weeks (regardless of infant feeding method)

ARV Antiretroviral; AZT Azidothymidine; NVP Nevirapine; sd single-dose
(Adapted from the World Health Organisation 2012 update (14))

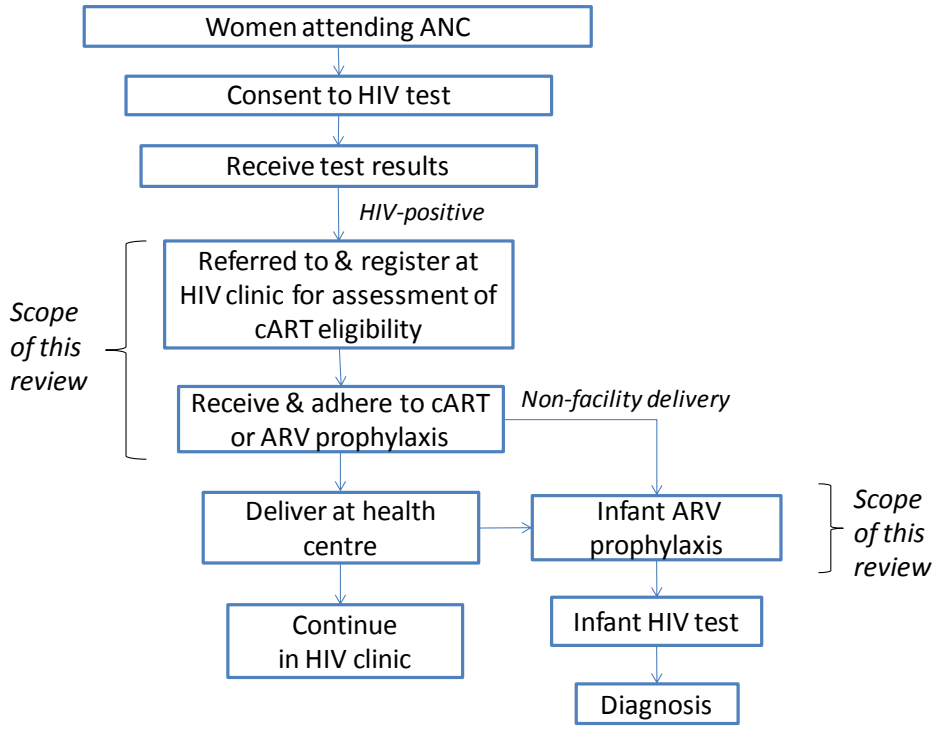
Although coverage of ARVs for PMTCT has increased, and some high-income regions have nearly achieved universal coverage, only 53% of pregnant women and 35% of infants in sub-Saharan Africa in need of ARVs for PMTCT received the treatment in 2009 (increased from 15% and 12% in 2005 respectively) (53).

While there is a greater understanding of barriers to ARV usage in the context of HIV treatment programmes in general (57, 58), less is known about the issues faced specifically by pregnant women. Reasons for low uptake (herein used to include access, initiation and adherence) of ARVs for PMTCT are emerging, but the results have not been comprehensively synthesised.

Two reviews, conducted between 2011 and 2012, focussed primarily on magnitude of uptake and levels of adherence to ARVs during and after pregnancy, rather than associated factors, and excluded qualitative studies which may offer important insights regarding reasons for poor uptake (59, 60). Other related reviews, conducted between 2009 and 2011, focussed more specifically on linkage and retention of HIV-positive pregnant women in care and treatment services (43), community-based interventions for PMTCT (61), and summarised achievements and failures of PMTCT services in specific regions (West Africa) (62). To our knowledge, no studies have systematically reviewed barriers to PMTCT ARV uptake (both prophylaxis and cART) in sub-Saharan Africa, from both a qualitative and quantitative perspective.

There is an urgent need to understand the reasons for low uptake of this intervention in order to prioritise strategies to enhance PMTCT programme uptake, and accelerate progress towards the United Nations Global Plan targets (eliminate new HIV infections in children and sustain lives of mothers) (2) and Millennium Development Goals 4 (child health), 5 (maternal health) and 6 (HIV/AIDS) (3). A systematic literature review was therefore conducted to inform HIV programming, by drawing together existing information on barriers and facilitating factors to the uptake of ARVs for PMTCT in sub-Saharan Africa (Figure 2.1 illustrates the focus of this review within the PMTCT continuum of care).

Figure 2.1. Scope of this review in relation to the PMTCT continuum of care for HIV-positive women and their infants.



ANC Antenatal Clinic; ARV Antiretroviral; cART Combination Antiretroviral Therapy for own health
The narrowing of boxes reflects the attrition in terms of numbers of women and infants through the steps. In different service delivery models, cART or ARV prophylaxis may be received either at the ANC or HIV clinic.

2.3 Methods

2.3.1 Search strategy

Four databases were searched (Medline, Embase, Global Health, Web of Science), combining terms related to HIV, PMTCT, ARVs and barriers/uptake (appendix 12.3.1). The search was limited to studies conducted in sub-Saharan Africa and published in English from January 2000 (when PMTCT/ART programmes were introduced in this region) to September 2012. Retrieved references were imported into EndNote X5 then duplicates were removed. Reference lists of included articles were searched.

2.3.2 Study selection

Titles and abstracts were screened by one researcher (AG) using pre-defined criteria (Table 2.2). Both qualitative and quantitative studies were eligible, as well as mixed-methods designs. Ten percent of titles and abstracts (randomly selected) were screened by a second researcher (AW) to verify inclusion decisions. Uncertainties were resolved through discussion between both reviewers. Authors of five studies were contacted to clarify methods and results.

Table 2.2. Inclusion and exclusion criteria for quantitative, qualitative and mixed-methods studies.

All study designs	
Excluded:	Location: Not conducted in sub-Saharan Africa Publication type: Reviews, commentaries and editorials
Quantitative studies	
Included:	Analysis of factors associated with any of the following outcomes: • maternal and/or infant receipt or use of ARV prophylaxis • maternal combination antiretroviral treatment (cART) initiation (or adherence), or maternal registration at the ART clinic, during pregnancy Participants: HIV-positive women (pregnant or with previous experience of the PMTCT programme) and their infants
Excluded:	•cART initiation among HIV-positive children (outcome) •Referral to HIV care and treatment after exit from the PMTCT programme (outcome) •Uptake of ARVs for PMTCT over time (time period as the explanatory variable) •Studies that did not report a multivariate analysis (did not adequately control for confounding), or gave insufficient information on statistical methods to reach a decision
Qualitative studies	
Included	Specifically explores barriers or facilitating factors related to any of the following: •receipt or use of maternal or infant ARV prophylaxis •cART during pregnancy , or referral to HIV care and treatment during pregnancy •challenges to delivering the components (above) of the PMTCT programme Participants: Any with experience or perceptions of the PMTCT programme
Mixed methods studies	
Included:	Either qualitative or quantitative component meets inclusion criteria above

Hierarchy applied to exclusions: (1) Location (2) Included outcomes not reported, or publication type (3) Included outcomes reported but no associated factors, or excluded factor (time period) (4) Included outcomes/ explanatory variables but no multivariate analysis/ brief methods

2.3.3 Quality appraisal

Quantitative studies were excluded if they did not control for confounding through multivariable analysis. Those meeting inclusion criteria were further appraised for quality and a sensitivity analysis was conducted.

Qualitative studies were not excluded on the basis of quality as there are no objective methods or evidence base for guiding such decisions, so a quality appraisal and sensitivity analysis was performed, using the approach of Thomas and Harden (63). A qualitative appraisal checklist and scoring scheme was adapted from the Critical Appraisal Skills Programme (CASP) tool (64) by two reviewers (AG and IB), after reviewing relevant tools and literature (57, 63-68). The adaptation aimed to: cover the core evaluative criteria/main quality issues identified by Cohen et al. and Thomas and Harden (63, 65), and include objective and specific questions that could be answered 'yes' or 'no' (appendix 12.3.2). One point was awarded for each 'yes', for a total of 16 points. A quantitative appraisal checklist, based on CASP and 'Strengthening Reporting of Observational studies in Epidemiology' (STROBE) tools and using a similar (17 point) scoring system, was also developed (by AG, IB, AW) to cover multiple quantitative designs (appendix 12.3.3) (64, 69).

One researcher (AG) applied the checklists to all the included qualitative or quantitative literature (including applicable components of mixed-methods designs). For quality control, 25% of the qualitative studies and 30% of the quantitative studies were double-marked (by AW and IB). There was agreement on 5/6 double-marked qualitative studies and 6/7 quantitative studies, in terms of their inclusion/exclusion during sensitivity analyses; after discussion the qualitative study was retained while the quantitative study was excluded.

Studies (quantitative or qualitative) with scores below 10 were considered *a priori* to be of lower quality. In the sensitivity analyses, results and conclusions were re-considered after removing findings of lower quality studies.

2.3.4 Data extraction and analysis

Data were extracted from qualitative studies using thematic synthesis (63). Quotations and descriptions of findings in results sections and abstracts were potential 'data'. Factors were only recorded if they were specifically related to PMTCT ARV uptake: barriers to other PMTCT cascade steps were not recorded. Codes were then categorised to build descriptive themes. Quantitative results were categorised using the same broad headings. Any factors analysed with regards to PMTCT ARV use (as defined in Table 2.2) were listed, and the results of statistical tests for association were noted. Data were only extracted from components of mixed-methods studies that satisfied inclusion criteria. Findings from data collected prior to and after 2007 were compared to gauge whether barriers and facilitating factors changed over time, following updates in WHO recommendations in 2006.

2.4 Results

2.4.1 Characteristics of included studies

A total of 574 references were identified, of which 44 articles met the inclusion criteria. Four were added after searching reference lists (Figure 2.2). There was agreement on 56/58 of the double-screened references. Twenty studies were quantitative (primarily cross-sectional or cohort), 16 were qualitative and eight used mixed-methods. Overall, the studies were conducted in 12 different countries, with most in Southern (n=13) and East Africa (n=28), few in West Africa (n=2), none in Central Africa and one mixed-region study. More studies were conducted in urban (n=21) than rural (n=10) settings (11 in both rural and urban settings, 2 settings unclear). The majority of studies were conducted during early phases of PMTCT programmes, before the introduction of cART for PMTCT, although an increasing amount of literature has emerged recently (approximately 1/3 included studies were published since January 2011). Table 2.3 to Table 2.5 summarise the included studies.

Figure 2.2. Flow diagram of systematic search results.

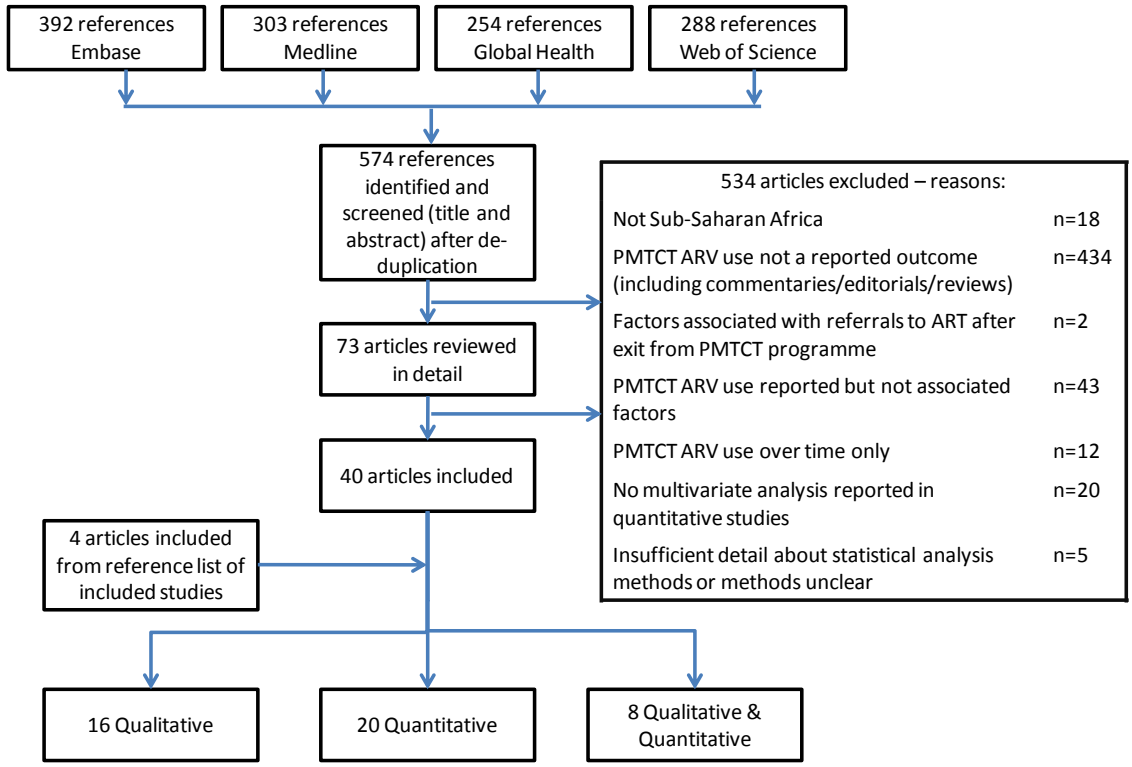


Table 2.3. Characteristics of qualitative studies included.

#	Author, year	Setting	Study design	Participants	Sample size
1	Awiti, 2011	Kenya, Urban & rural	Narratives	HIV+ pregnant women on cART	28; 16 rural & 12 urban
2	Burke, 2004	Tanzania, Urban & rural	IDIs and FGDs	Health workers, pregnant women, HIV+ individuals, other men & women	12 interviews; 5 FGDs
3	Chinkonde, 2009	Malawi, Urban & rural	IDIs and FGDs	HIV+ women (sub-sample of cohort at PMTCT sites); husbands	28 IDIs; 4 FGDs of 6-9 per group (28 total); 12 IDIs with men
4	Delva, 2006	South Africa, Urban	IDIs	Key informants	14
5	Duff, 2010	Uganda, Urban & rural	IDIs and FGD	HIV+ mothers (registered in PMTCT programme)	45 interviews, 1 FGD (8 women)
6	Duff, 2012	Uganda, Urban & rural	FGDs	Men (married/ with female partners)	40 participants in 4 groups
7	Kasenga, 2010	Malawi, Rural	IDIs	HIV+ women (registered in PMTCT programme)	24
8	Levy, 2009	Malawi, Urban	IDIs, FGDs, observations	HIV+ women (participating in PMTCT programme), key informants	IDIs: 34 women, 21 key informants; FGDs: 21 women (4-6 per group)
9	Nkonki, 2007	South Africa, Urban & rural	IDIs	HIV+ women (sub-sample of cohort study on PMTCT)	58
10	O'Gorman, 2010	Malawi, Rural	IDIs and FGDs	Ante/post-natal women, fathers, grandmothers, TBAs, health workers, community leaders	44 in FGDs in total, 26 interviews
11	Painter, 2004	Cote d'Ivoire, Urban	IDIs	HIV+ women (discontinued/ refused PMTCT follow up visits)	27
12	Sprague, 2011	South Africa, Urban	IDIs (and patient file review)	HIV+ women, female carers of HIV+ children, key informants	83 women, 32 carers, 38 key informants.
13	Stinson, 2012	South Africa, Urban	IDIs (structured)	Pregnant/postnatal HIV+ women (on cART or eligible for cART)	28 women; 21 health workers
14	Theilgaard, 2011	Tanzania, Urban	IDIs, FGDs, and observations	HIV+ women; health care providers	FGDs: 12 women; 6 HWs. IDIs: 18 women
15	Towle, 2008	Lesotho, Urban & rural	IDIs and participant observation	Health workers; HIV programme staff; women/ men (reproductive age); grandmothers	29 (total)
16	Winestone, 2012	Kenya, Rural	IDIs	Health care providers	36

Study number (sequential order; differs from bibliographic reference number); IDI In-Depth Interview; FGD Focus Group Discussion; NVP Nevirapine; TBA Traditional Birth Attendant; ANC Antenatal Clinic; cART Combination Antiretroviral Therapy; PMTCT Prevention of Mother-to-Child Transmission

Table 2.4. Characteristics of quantitative studies included.

#	Author, year	Country, Setting	Study design	Participants	Sample size*	Outcome**
17	Albrecht 2006	Zambia, Urban	Clinical trial; sub-analysis	HIV+ women enrolled into the trial at 2 ANC clinics	760	Maternal/ infant non-adherence (no ingestion of NVP)
18	Barigye, 2010	Uganda, Rural	Prospective cohort study	HIV+ women enrolled in PMTCT programme at 4 clinics	102	Receipt of maternal NVP; maternal/ infant NVP ingestion
19	Delva, 2010	Kenya, Urban and rural	Prospective cohort study	Pregnant women attending ANC at 5 health centres	Not clear	Provision of NVP (defined as receipt of NVP).
20	Delvaux, 2009	Rwanda, Urban and rural	Case-control study	HIV+ women who did not adhere (cases)/ adhered (controls) to PMTCT prophylaxis	236	Receipt of NVP; NVP adherence (ingestion in recommended time) in mothers and/or infants
21	Ekouevi, 2004	Cote d'Ivoire, Urban	Analysis within cohort study	Subset of HIV+ pregnant women within cohort study	1023	Women who started the prophylaxis regimen.
22	Farquhar 2004	Kenya, Urban	Prospective cohort study	Pregnant women attending 1 clinic; male partners	314	Maternal receipt of NVP; maternal/ infant dose administered
23	Karcher, 2006	Tanzania/ Uganda, Rural	Prospective cohort study	Subset of HIV+ pregnant women attending 4 PMTCT sites	619	Infant nevirapine intake (administration)
24	Killam, 2010	Zambia, Urban	Intervention study; stepped-wedge design	HIV+ pregnant women at 8 ANC clinics, eligible for cART	1566	Enrollment & initiation onto cART within 60 days of HIV diagnosis
25	Kinuthia, 2011	Kenya, Urban	Cross-sectional study	Subset of HIV+ women and their infants attending 6 MCH clinics	336	Mother and/or infant receipt of, or adherence to PMTCT ARVs
26	Kirsten, 2011	Tanzania, Rural	Prospective cohort study	HIV+ pregnant women enrolled in PMTCT programme at 1 site	122	Non-acceptance of, or adherence to prophylaxis
27	Kuonza, 2010	Zimbabwe Urban	Cross-sectional study	HIV+ pregnant women and their infants enrolled in PMTCT programme in 4 facilities	212	Maternal/ infant non-adherence to NVP (no ingestion; ingestion >72hrs post-birth or <2 hrs pre- delivery)
28	Megazzini 2009	Zambia, Urban	Clinical trial; sub-analysis	Pregnant women in the trial intervention arm who had HCT	71	Ingestion of NVP or calcium tablet >2 / >1 hour before delivery
29	Mirkuzie, 2011	Ethiopia, Urban	Prospective cohort study	HIV+ women attending 15 facilities and their infants	219	Mother and/or infant receipt or ingestion of drugs
30	Msuya, 2008	Tanzania, Urban	Prospective cohort study	HIV+ pregnant women attending ANC at 2 public clinics	184	Maternal ingestion of NVP
31	Peltzer, 2008	South Africa, Unclear	Cross-sectional study	HIV+ pregnant women in a PMTCT cohort from 5 clinics	116	Maternal/ infant adherence to NVP (consumption).
32	Peltzer, 2010	South Africa, Rural	Cross-sectional study	Postnatal HIV+ women and their infants at 47 clinics	815	Mother and/or infant not ingesting NVP, or not at recommended time
33	Peltzer, 2011	South Africa, Rural	Cross-sectional study	HIV+ pregnant / postnatal women and their infants at 48 clinics	746	Maternal/ infant adherence to ARV prophylaxis (NVP- ingestion; AZT- never missed dose)
34	Stinson, 2010	South Africa, Urban	Retrospective cohort study	HIV+ women eligible for cART attending 4 ANCs	516	Initiating cART during pregnancy; on cART at delivery
35	Stringer, 2003	Zambia, Urban	Cluster randomized trial	HIV+ pregnant women attending the 2 health facilities in the trial	201	Maternal ingestion of NVP
36	Stringer, 2010	4 countries, Unclear	Cross-sectional study	HIV+ women and their infants attending 43 delivery sites	3196	Maternal/ infant NVP ingestion

*Sample size for analysis associated with uptake of ARVs **Some studies also analysed other outcomes that are not shown

Study number (sequential order; differs from bibliographic reference number); VCT Voluntary Counselling & Testing; cART Combination Antiretroviral Therapy; NVP Nevirapine; AZT Azidothymidine; ANC Antenatal Clinic; MCH Maternal and Child Health; PMTCT Prevention of Mother-to-Child Transmission; HCT HIV Counselling and Testing

Table 2.5. Characteristics of mixed-methods studies included.

#	Author, year	Setting	Study design	Participants	Sample size*	Outcomes** (quantitative)
37	Balcha, 2011	Ethiopia, Urban & rural	IDIs / descriptive analysis of aggregated programme data	IDIs with key informants	3 IDIs	Uptake of PMTCT indicators only
38	Doherty 2009	South Africa, Rural	Operational research: FGDs, observations, structured interviews, descriptive analysis of routine PMTCT data	Facility managers, counsellors, primary health care supervisors, district coordinators	15 interviews with managers/ 35 with counsellors; 1 FGD	Uptake of PMTCT indicators only
39	Kiarie, 2003	Kenya, Urban	FGDs / randomized clinical trial	HIV+ postpartum/ pregnant women	124 (quantitative analysis); 7 FGDs	Compliance: took maternal & infant NVP / >=80% of AZT doses
40	Laher, 2012	South Africa, Urban	Cross-sectional survey / structured interviews and FGD	Women attending a paediatric clinic with HIV-infected infants	Survey: 45; 2 FGDs: 10 women in total; Interviews: 35	Uptake of PMTCT indicators only
41	Mepham, 2011	South Africa, Rural	IDIs / quantitative sub-study within clinical trial	Subset of HIV+ women enrolled into the trial	94 (quantitative analysis); 43 IDI	No statistical analysis of factors associated with PMTCT ARV uptake
42	Muchedzi, 2010	Zimbabwe Urban	FGDs / cross-sectional study	HIV+ women from 4 ANCs referred for cART & key informants (from ANC)	Survey: 147; 2 FGDs (of 10-12)	Registration at the HIV clinic
43	Varga, 2008	South Africa, Urban & rural	Participatory group workshops (role plays), FGDs and cross-sectional survey	RCH clinic/programme staff and adolescent mothers	10-15 per workshop (x2); 10-12 per FGD (x2); 100 for survey	No statistical analysis of factors associated with PMTCT ARV uptake
44	Watson-Jones, 2012	Tanzania, Urban	Cohort study / structured interviews and observations	HIV+ women at 2 delivery wards / health workers	Cohort analysis: 175; Observations: 9; IDI sample unclear	Attendance at the HIV clinic up to 4 months post-delivery

*Sample size for qualitative work and/or quantitative analysis associated with uptake of ARVs
**Some studies also analysed other quantitative outcomes that are not shown; quantitative analyses for study numbers 37,38,40,41 and 43 were excluded (only qualitative component met inclusion criteria)
Study number (sequential order; differs from bibliographic reference number); cART Combination Antiretroviral Therapy; NVP Nevirapine; AZT Azidothymidine; ANC Antenatal Clinic; MCH Maternal and Child Health; PMTCT Prevention of Mother-to-Child Transmission; IDI In-Depth Interview; FGD Focus Group Discussion

2.4.2 Quality appraisal results

Most qualitative studies (15/16) were appraised as good quality (scored ≥10 on the checklist) (appendix 12.3.2). Six qualitative components of mixed-methods designs (out of eight) scored below 10, where methods were brief or the research was operational. Authors rarely (2/24 studies) acknowledged their own role in influencing the research. Analysis by ≥2 assessors was infrequently mentioned (7/24 studies). The sensitivity analysis did not reveal any major changes in results or interpretation: the main themes remained the same, in broadly the same relative order of importance.

Twenty quantitative studies were excluded from this review because they did not report a multivariate analysis, or had unclear statistical methods (n=5). Included quantitative research was mostly good quality (scored ≥10) (appendix 12.3.3), with only one paper excluded in the sensitivity analysis; this did not result in changes in conclusions. Small

sample sizes (for example sub-analyses) and potential lack of power was a common issue, but not often discussed by authors. Residual confounding was possible in at least 1/3 of the studies.

2.4.3 Barriers and facilitating factors to uptake of ARVs for PMTCT

Barriers and facilitating factors fell into 3 broad categories relating to individuals, their partners and community, and health systems. This hierarchy, described as a socio-ecological model, has previously been applied to PMTCT and HIV health-services research (61, 70). Findings are summarised in Table 2.6 and Table 2.7.

Individuals

Socio-demographic factors

Maternal education and age were the most frequently investigated factors in quantitative analyses. Seven studies reported an association between lower maternal educational level/literacy and not receiving/taking ARV prophylaxis (71-77). Nine quantitative studies investigated maternal education but found no association (78-86), and were conducted more recently (7/9 since 2008) than the studies reporting associations (5/7 prior to 2007).

The majority of studies (11/15) exploring maternal age found no association with uptake of PMTCT ARVs (71, 73, 77, 78, 80-82, 84-87), although four found that younger mothers (<20-25 years) were less likely to receive/adhere to prophylaxis (79, 88), or to receive NVP for their infants (cross-regional, Tanzanian and Ugandan studies) (72, 75). Mixed-methods research in South Africa also highlighted difficulties and discrimination faced by adolescents participating in PMTCT services (42).

Knowledge and individual beliefs

Poor knowledge of HIV transmission and ARV drugs emerged frequently as a reason for dropping out of PMTCT programmes and failing to access/ingest ARVs in qualitative research (82, 85, 89-96). Doubts about the efficacy of ARVs for MTCT (85, 92, 94, 95) and beliefs that ARVs could cause HIV (93) or harm the unborn child (97) were raised. In quantitative research in rural South Africa, women with higher PMTCT knowledge scores were more likely to adhere to NVP (82), though there was no/weak evidence for an association between knowledge scores and adherence to prophylaxis in other Southern and East African studies (73, 81, 83, 85, 86).

Psychological factors

Qualitative work revealed psychological barriers to initiating and adhering to PMTCT interventions following an HIV diagnosis. Women described shock, depression and denial on learning their status at antenatal clinics (ANC) (41, 85, 94, 97-101), as well as fears about their condition and death (90, 101), or handling side effects and lifelong treatment (97).

Regaining health in response to cART, and a mother's desire to protect her own/ unborn baby's health and to care for her family, were facilitating factors for initiating or continuing with combination treatment (41, 97).

Obstetric and pregnancy-history factors

Qualitative studies highlighted the difficulties rural women faced in reaching the clinic following sudden onset of labour, particularly at night (40, 85, 100, 101). In quantitative studies, greater cervical dilation on admission (reflecting late admission to the delivery ward or rapid labour) (102) and pre-term deliveries/low infant birth weight were associated with lower odds of ingesting treatment (71, 82, 88). Ill-health following home-delivery prevented or delayed women from taking their baby to the facility for prophylaxis (40). Poor infant health was also associated with the infant not receiving NVP (71). Maternal adherence to PMTCT ARVs influenced subsequent adherence to prophylaxis by the newborn (73) and linkage to HIV care and treatment (84).

Disease progression

Three qualitative studies revealed that HIV-positive pregnant women lacking symptoms did not feel they needed ARVs for PMTCT (41, 91, 95). However, immunological status (CD4 count) was not significantly associated with adherence to NVP in quantitative analyses (71, 77, 79, 80).

Personal management and supply of treatment

Losing or selling tablets, forgetting to take them, running out, or finding them stolen affected ARV adherence in qualitative research (40, 85, 89, 96, 101), as well as difficulties administering infant prophylaxis due to tolerability issues (eg. vomiting) (103).

Partners and community

Stigma, disclosure of HIV status and community support

Stigma regarding HIV status and fear of disclosure to partners or family members (particularly grandmothers or mothers-in-law) were major barriers to uptake of PMTCT

ARV interventions in almost all the qualitative research (40-42, 44, 85, 89-92, 94, 96-98, 100, 103-106). Two quantitative studies reported associations between stigma measures and PMTCT ARV use (78, 82), including self-stigma (also mentioned in qualitative research (94, 97, 100, 105)). Discrimination directed specifically at pregnant HIV-positive women (blame for potentially dying and leaving an orphaned baby) was described in one qualitative study in Kenya (105).

In quantitative studies, non-disclosure of HIV status to partners, or not telling them about NVP, was associated with not attending the HIV clinic in Tanzania (84), and not ingesting maternal or infant prophylaxis in South Africa (81, 82), Zimbabwe (76), and Zambia (among home-births (71)). Similarly, married women or those living with a male partner were less likely to use prophylaxis or access cART in 3 studies (73, 74, 86), although there was no evidence for an association in other analyses (72, 77-79, 82-85).

Qualitative research confirmed that fear of disclosure could deter HIV-positive women from attending HIV clinics and initiating treatment (41, 42, 44, 92, 94, 97, 98), from ingesting or storing ARVs (40, 89, 91, 100, 103), or from seeking/administering infant prophylaxis (96, 100, 105). Some women faced or feared negative reactions from their partners including refusals to test for HIV, abandonment or violence (40, 41, 91, 92, 97, 107). Conversely, women who did not disclose their status were more likely to take their medication in one qualitative study (these women were better accepted by their community and life could continue as normal, while those whose positive status was known faced stigmatisation) (105).

Lack of partner or family support was frequently mentioned (40, 41, 90, 91, 96-98, 100, 106), while support was also a facilitating factor (40, 41, 86, 100, 105). Partner/ couples voluntary counselling and testing (CVCT) were related to elevated adherence to/ receipt of prophylaxis in 3 quantitative studies (73, 82, 107), although 5 studies found no/weak evidence for an association (71, 72, 84, 85, 108).

Cultural traditions

General scepticism towards facilities or modern medicine among community or family members, and strong roles of elders and their beliefs, could influence decisions to use traditional healers and medicines alongside/ in place of ARVs (41, 89, 97, 105), as well as place of delivery (preferences for traditional birth attendants (TBAs) and home-births) (40, 90, 93, 100, 105).

Health systems

Resources and infrastructure

Shortage of (trained) clinic staff was a major barrier to PMTCT ARV uptake (41, 44, 91, 94-96, 98, 101, 104, 106, 109). As a result, health-workers were overwhelmed with high patient volume, contributing to long waiting-times (41, 44, 84, 91, 94, 95, 98), brief or poor quality counselling sessions (95), staff stress (42, 95), staff failings and misunderstandings by staff (84, 101).

Shortages of resources (including ARVs) (95, 101, 104, 106, 109), poor record keeping (104), and poor integration of services, referral links or tracking systems (44, 84, 90, 95), also contributed to low uptake of ARVs. Integrated ANC and ARV services (ARV drugs provided within the ANC building) was related to improved uptake of cART or prophylaxis in quantitative (110) and qualitative research (44, 90), although uptake was comparable if cART services were offered one day per week at ANC or in separate buildings/sites in another quantitative study (87).

Staff-client interactions

Experience of negative staff attitudes was a frequently cited barrier to returning to facilities (40, 42, 44, 85, 90, 91, 94, 98, 101, 104), limiting the opportunity to receive prophylaxis or cART (91). For example, women experienced or feared scolding from staff for home-deliveries when returning with their baby for NVP administration (40), or were stigmatised (42, 91). Confidentiality breaches were reported in one study (42), and sub-optimal layout of clinics contributed to lack of privacy (41, 85, 96, 98, 109). However, some women described how counsellors helped them to persevere with PMTCT interventions or HIV clinic attendance, and deal with stigma, disclosure and relationship issues (41, 104).

Access to services

Another key issue affecting access to PMTCT treatment for mothers and infants was the distance to facilities and frequency of visits required (40, 41, 85, 90, 91, 94, 95, 98, 100, 106), particularly in rural areas (40, 100, 106). Perceived or real costs of maternity services and treatment were sometimes concerns (90, 94, 95, 100).

Home-births resulted in barriers to mothers and infants receiving PMTCT ARVs in quantitative (76, 78, 80, 85) and qualitative studies (40, 90, 93, 100) conducted in rural and urban settings. For example, distance or fear of inadvertent disclosure hindered women from returning to facilities for infant prophylaxis (40, 100). In some settings, women were provided with nevirapine (to take during labour, and/or give to their infant)

during ANC appointments, resulting in improved PMTCT ARV ingestion in mother-baby pairs in one quantitative study (76) and no association between place of delivery and uptake of prophylaxis in three other quantitative studies (72, 73, 81).

Late presentation at ANC was a barrier to accessing ARVs in two qualitative studies (97, 103). Similarly, one quantitative study suggested earlier enrolment at ANC was associated with better uptake of cART during pregnancy (87). However, other quantitative research found women presenting earlier in pregnancy were less likely to take NVP (72) or collect AZT prescriptions (79).

Type of ARV regimen taken during pregnancy influenced maternal adherence: women taking twice-daily AZT were less likely to adhere than women taking NVP (85), while Stringer et al. found that women on cART were more likely to adhere than those taking NVP alone (88).

2.4.3.1 Changing factors over time

Dividing the studies into those conducted pre- and post-2007 revealed no major difference in community and health systems factors over time (Table 2.8 and Table 2.9). Psychological factors (denial/shock/depression), knowledge, and maternal education were less frequently reported in recent studies (compared to earlier studies). It would have been preferable to take into account the number of studies that had *investigated* each factor within each time period, however details of the topic guides were not often provided in the manuscripts of qualitative studies, and not all quantitative study manuscripts clearly listed all the variables that were collected and analysed.

Table 2.6. Factors associated with PMTCT ARV uptake in the included qualitative research.

	Study number																						
Factors	1	2	3	4*	5	6	7	8	9	10	11	12	13	14	15	16	37*	38*	39*	40	41*	43	44*	**Total**
Individual																								
Psychological		✓	✓	✓			✓		✓		✓		✓	✓					✓	✓				10
Denial /shock (following results)/ depression		✓	✓	✓			✓		✓		✓		✓	✓					✓					9
Fear (of being HIV positive/ death / ARVs)		✓							✓				✓							✓				4
Desire to protect baby/ self / family (facilitating)													✓	✓										2
Feeling better, well after taking cART (facilitating)														✓										1
Knowledge and beliefs		✓		✓	✓	✓		✓			✓		✓		✓				✓		✓			10
Poor knowledge of HIV / MTCT / ARVs		✓		✓	✓	✓		✓			✓		✓		✓				✓		✓			10
Scepticism about ARVs						✓		✓			✓		✓		✓				✓					6
Obstetric factors and pregnancy-history							✓		✓	✓		✓							✓					5
Sudden/ unclear/ early/ night-time onset of labour							✓		✓	✓		✓							✓					5
Post delivery ill-health										✓														1
Disease progression					✓			✓						✓										3
Lack of symptoms - (perceived) disease severity					✓			✓						✓										3
Personal management & supply of treatment				✓					✓	✓			✓						✓	✓	✓			7
Lost/ sold/ stolen/ forgetting/ ran out of tablets				✓					✓	✓									✓		✓			5
Difficulties administering infant treatment													✓							✓				2
Partner and Community																								
Stigma	✓	✓	✓	✓	✓	✓	✓			✓	✓	✓	✓	✓		✓	✓		✓	✓	✓	✓		18
Disclosure issues/ fear of disclosure	✓		✓	✓	✓	✓	✓			✓	✓	✓	✓	✓		✓	✓		✓	✓	✓	✓		17
Relationship strains / violence	✓					✓				✓			✓	✓							✓			6
Fear of someone finding/seeing pills	✓					✓						✓									✓			4
Partners controlling finances					✓									✓										2
(Lack of) community/ relative/ partner support	✓	✓	✓	✓	✓		✓			✓			✓	✓			✓							10
Unwillingness of partners to test					✓									✓										2
Partner support (facilitating)	✓													✓										2
Cultural traditions and beliefs	✓	✓					✓			✓			✓	✓	✓		✓				✓			9
Preference for TBAs/ home-births	✓	✓					✓			✓					✓									5
Traditional medicines/ healers	✓												✓	✓							✓			4
Strong role of grandparents, associated beliefs	✓									✓														2
Scepticism regarding facilities in general															✓		✓							2
Health-systems																								
Client - staff interactions		✓	✓		✓			✓	✓	✓	✓	✓		✓		✓			✓			✓		12
Staff attitudes / fear of negative attitudes		✓	✓		✓				✓	✓	✓	✓		✓		✓			✓			✓		11
Trust in staff/ helpful advice/ support (facilitating)			✓							✓		✓		✓										4
Fear of lack of confidentiality																						✓		1
Health-worker - client power imbalance								✓														✓		2
Resources and infrastructure		✓	✓	✓	✓			✓	✓		✓	✓		✓		✓	✓	✓	✓			✓	✓	15
Staff shortages			✓	✓	✓			✓	✓		✓	✓		✓		✓	✓	✓					✓	12
Long waiting times			✓		✓			✓			✓			✓		✓								6
Staff too busy/ workload high /stressed			✓	✓				✓			✓							✓				✓	✓	7
Lack of training/ trained staff				✓																				1
Counselling sessions too short/ too few								✓																1
Staff failings									✓									✓					✓	3
Failure to give NVP/ poor instructions									✓															1
Late bookings for delivery																		✓						1
Misunderstanding of client services required																							✓	1
Drug or supplies shortages								✓	✓			✓					✓	✓						5
Delays (HIV tests, results, CD4 counts)									✓			✓					✓							3
Privacy issues (layout)			✓	✓										✓		✓		✓	✓					6
Integration of services		✓						✓								✓							✓	4
Poor referral links/no/delayed referral to cART								✓															✓	2
Integration as a facilitating factor		✓														✓								2
Poor coordination between regional/ local levels		✓															✓							2
Poor record keeping												✓												1
Access to facilities/ services		✓	✓		✓		✓	✓		✓	✓			✓			✓		✓					10
Transport issues/ time and cost		✓	✓		✓		✓	✓		✓	✓			✓			✓		✓					10
Costs /perceived costs of services/ treatment		✓					✓	✓			✓													4
Late first presentation to ANC													✓							✓				2

ANC antenatal clinic; ARV antiretroviral; cART combination antiretroviral therapy; MTCT mother-to-child transmission; NVP nevirapine; PMTCT prevention of mother-to-child transmission; TBA traditional birth attendant

✓ indicates the factor was related to PMTCT ARV uptake *Studies removed during sensitivity analysis of qualitative results

Table 2.7. Factors associated with PMTCT ARV uptake in the included quantitative research and cases where these factors were explored but no statistical evidence for an association with PMTCT ARV uptake was reported.

	Study number																						
Factors	17	18	19	20	21	22	23*	24	25	26	27	28	29	30	31	32	33	34	35	36	39	42	44	**Total**
Individual																								
Socio-demographic																								
Education (or literacy)	✓	✓		✓	✓		✓		x	x	✓		x		x	x	x(u)		✓		x	x	x	16
Age of mother	x	✓		x			✓		x	✓			x		x	x		x	x	✓	x	x	x	15
Religion				x			✓				x(u)												x	4
Ethnicity																							✓	1
Socio-economic																								
Income activities/ occupation	x				x		x		x	✓	x								x			x	x	9
Knowledge and beliefs																								
HIV/MTCT knowledge				x											x	✓	x(u)				x(u)	x		6
Lived in villages exposed to HIV research		✓																						1
Obstetric and pregnancy-history																								
Mother took PMTCT prophylaxis				✓																			✓	2
PMTCT in previous pregnancy											✓													1
Parity	x						x		x		✓								x(u)					5
Cervical dilation												✓												1
Term/ premature delivery																✓								1
Caesarian / vaginal delivery																x				✓				2
Infant factors/ charateristics																								
Birth weight of infant	✓																			✓				2
Knowledge of infant HIV status																✓								1
At risk for neonatal death	✓																							1
Partners and community																								
Stigma																								
Internalized stigma									✓								x(u)							2
Experience of HIV/AIDS discrimination																x(u)	✓					x		3
Disclosure																								
Disclosure of HIV/ARVs to partner	✓			x(u)					x		✓		x		✓	✓			x		x(u)			9
Disclosure to anyone		x		x						x(u)					x(u)	x(u)	✓						✓	7
Disclosure to other (not partner)				✓																				1
Married or living with partner		x		✓	✓				x	x						x	x(u)		x		x	✓	x	11
Support																								
Partner VCT		x		✓										x(u)		✓					x(u)		x	6
Couples VCT	x					✓																		2
Male involvement																x	✓							2
Attendance at support group																x(u)	x(u)					✓		3
Health-systems																								
ARV services integrated into ANC								✓										x						2
Client understood referral process																						✓		1
HIV status kept confidential at clinic																✓								1
Site of PMTCT counselling							✓																	1
Place of delivery	✓	x		x(u)					✓		✓		✓		x	x(u)					✓			9
Urban/ rural facility			✓																					1
Number of ANC visits				✓							x(u)	✓			x	x(u)				✓			x(u)	7
Gestational age at first ANC visit		✓		x(u)						✓			x					✓							5
HIV test after/at first ANC visit				✓																				1
Mother given NVP to take home											✓													1
Regimen type													x							✓	✓			3
Universal NVP without HIV testing																			✓					1

✓ indicates statistical evidence for an association (p<0.05 or 95% CI excludes the null value of 1) was reported with at least one relevant outcome (adherence/receipt of PMTCT ARVs/cART/attendance at ART clinic)

x Indicates no statistical evidence for an association; x(u) Statistical evidence for an association in univariate analysis only

ANC antenatal clinic; ARV antiretrovirals; MTCT mother-to-child transmission; NVP nevirapine; PMTCT Prevention of mother-to-child transmission; VCT voluntary counselling & testing

*Study removed during sensitivity analysis of quantitative results

Table 2.8. Changes over time in the number and % of studies that reported factors associated with PMTCT ARV uptake in qualitative research.

	Number of studies (%)			
Factors	**Fieldwork before 2007* (N=12)**		**Fieldwork in/ after 2007** (N=11)**	
Individual				
Psychological	7	58%	3	27%
Denial /shock (following results)/depression	7	58%	2	18%
Fear (of being HIV positive/ death / ARVs)	2	17%	2	18%
Desire to protect baby/ self / family (facilitating)	0	0%	2	18%
Feeling better, well after taking cART (facilitating)	0	0%	1	9%
Knowledge and beliefs	8	67%	2	18%
Poor knowledge of HIV / MTCT / ARVs	8	67%	2	18%
Scepticism about ARVs	5	42%	1	9%
Obstetric factors and pregnancy-history	3	25%	2	18%
Sudden/ unclear/ early/ night-time onset of labour	3	25%	2	18%
Post delivery ill-health	0	0%	1	9%
Disease progression	2	17%	1	9%
Lack of symptoms - (perceived) disease severity	2	17%	1	9%
Personal management & supply of treatment	3	25%	4	36%
Lost/ sold/ stolen/ forgetting/ ran out of tablets	3	25%	2	18%
Difficulties administering infant treatment	0	0%	2	18%
Partner and Community				
Stigma	9	75%	9	82%
Disclosure issues/ fear of disclosure	8	67%	9	82%
Relationship strains / violence	1	8%	5	45%
Fear of someone finding/seeing pills	1	8%	3	27%
Partners controlling finances	1	8%	1	9%
(Lack of) community/ relative/ partner support	5	42%	5	45%
Unwillingness of partners to test	1	8%	1	9%
Partner support (facilitating)	0	0%	2	18%
Cultural traditions and beliefs	3	25%	6	55%
Preference for TBAs / home-births	3	25%	2	18%
Traditional medicines/ healers	0	0%	4	36%
Strong role of grandparents, associated beliefs	0	0%	2	18%
Scepticism regarding facilities in general	1	8%	1	9%
Health-systems				
Client - staff interactions	8	67%	4	36%
Staff attitudes / fear of negative attitudes	7	58%	4	36%
Trust in staff/ helpful advice/ support (facilitating)	1	8%	3	27%
Fear of lack of confidentiality	1	8%	0	0%
Health-worker - client power imbalance	2	17%	0	0%
Resources and infrastructure	9	75%	6	55%
Staff shortages	6	50%	6	55%
Long waiting times	4	33%	2	18%
Staff too busy/ workload high /stressed	5	42%	2	18%
Lack of training/ trained staff	1	8%	0	0%
Counselling sessions too short/ too few	1	8%	0	0%
Staff failings	1	8%	2	18%
Failure to give NVP/ poor instructions	1	8%	0	0%
Late bookings for delivery	0	0%	1	9%
Misunderstanding of client services required	0	0%	1	9%
Drug or supplies shortages	2	17%	3	27%
Delays (HIV tests, results, CD4 counts)	1	8%	2	18%
Privacy issues (layout)	3	25%	3	27%
Integration of services	2	17%	2	18%
Poor referral links/no/delayed referral to cART	1	8%	1	9%
Integration as a facilitating factor	0	0%	1	9%
Poor coordination between regional/ local levels	1	8%	1	9%
Poor record keeping	0	0%	1	9%
Access to facilities/ services	7	58%	5	45%
Transport issues/ time and cost	7	58%	3	27%
Costs /perceived costs of services/ treatment	3	25%	0	0%
Late first presentation to ANC	0	0%	2	18%

*Study numbers & fieldwork dates: 2 (2001), 3 (2005), 4 (2003), 5 (2006), 6 (2006), 7 (2006), 8 (2009), 9 (2005), 11 (1998-99), 15 (2006), 39 (1999-2001), 43 (2002-3)

**Study numbers & fieldwork dates: 1 (2010- imputed 1 year before year of publication), 10 (2008), 12 (2008-9), 13 (2007-8), 14 (2009-10), 38 (2007), 37 (2007-8), 40 (2009), 41 (2008), 44 (2008-9)

Table 2.9. Changes over time in the number and % of studies that reported factors associated with PMTCT ARV uptake in quantitative research.

	Number of studies (%)			
Factors	**Fieldwork before 2007 (N=13)**		**Fieldwork in/ after 2007 (N=10)**	
Individual				
Socio-demographic				
Education (or literacy)	6	46%	1	10%
Age of mother	2	15%	2	20%
Religion	1	8%	0	0%
Ethnicity	0	0%	1	10%
Socio-economic				
No income generating activity	0	0%	1	10%
Knowledge and beliefs				
HIV/MTCT knowledge	0	0%	1	10%
Lived in villages exposed to HIV research	1	8%	0	0%
Obstetric and pregnancy-history				
Mother took PMTCT prophylaxis	1	8%	1	10%
PMTCT in previous pregnancy	0	0%	1	10%
Parity	0	0%	1	10%
Cervical dilation	1	8%	0	0%
Term / premature delivery	0	0%	1	10%
Caesarian / vaginal delivery	0	0%	1	10%
Infant factors/ charateristics				
Birth weight of infant	1	8%	1	10%
Knowledge of infant HIV status	0	0%	1	10%
At risk for neonatal death	1	8%	0	0%
Partners and community				
Stigma	0	0%	0	0%
Internalized stigma	0	0%	1	10%
Experience of HIV discrimination	0	0%	1	10%
Disclosure				
Disclosure of HIV/ARVs to partner	2	15%	2	20%
Disclosure to anyone	0	0%	2	20%
Disclosure to other (not partner)	1	8%	0	0%
Married or living with partner	2	15%	1	10%
Support				
Partner VCT	1	8%	1	10%
Couples VCT	1	8%	0	0%
Male involvement	0	0%	1	10%
Attendance at support group	0	0%	1	10%
Health-systems				
ARV services integrated into ANC	0	0%	1	10%
Client understood referral process	0	0%	1	10%
HIV status kept confidential at clinic	0	0%	1	10%
Site of PMTCT counselling	1	8%	0	0%
Place of delivery	2	15%	3	30%
Urban/ rural facility	1	8%	0	0%
Number of ANC visits	2	15%	1	10%
Gestational age at first ANC visit	2	15%	1	10%
HIV test after/at first ANC visit	1	8%	0	0%
Mother given NVP to take home	0	0%	1	10%
Regimen type	1	8%	1	10%
Universal NVP without HIV testing	1	8%	0	0%

*Study numbers & fieldwork dates: 17 (2001-3), 18 (2002-7), 19 (2004-6), 20 (2006), 21 (2000-2), 22 (2001-2), 23 (2002-4), 28 (2005-6), 30 (2002-4), 34 (2005), 35 (2000-1), 39 (1999-2001)
**Study numbers & fieldwork dates: 24 (2007-8), 25 (2008-9), 26 (2008-9), 27 (2008), 29 (2009), 31 (2005-6), 32 (2008-9), 33 (2010- imputed 1 year before year of publication), 36 (2007-8), 42 (2008), 44 (2008-9)

2.5 Discussion

2.5.1 Main findings

This is the first study, to our knowledge, to systematically review barriers and facilitating factors to uptake of antiretrovirals (both prophylaxis and cART) for PMTCT in sub-Saharan Africa, from both a qualitative and quantitative perspective, thus allowing an analysis of the relative importance of different factors and changes over time. The identified factors fell broadly into individual, community and health systems levels.

At the individual-level, poor knowledge of HIV/MTCT/ARVs, lower maternal educational level (potentially manifested through poor knowledge, or differences in socio-economic status), and psychological factors following diagnosis of HIV were the key barriers that emerged from the review. Stigma and fear of disclosure to partners/ others were the most frequently cited barriers overall, with stigmatisation occurring at all levels (self-stigma, discrimination by partners, community members and health-workers). The extent of community/partner support was another major factor affecting uptake of PMTCT ARVs, while cultural traditions including preferences for traditional healers and TBAs were also common. Key health systems barriers were staff shortages, (fear of) scolding from staff, facility accessibility issues and non-facility deliveries.

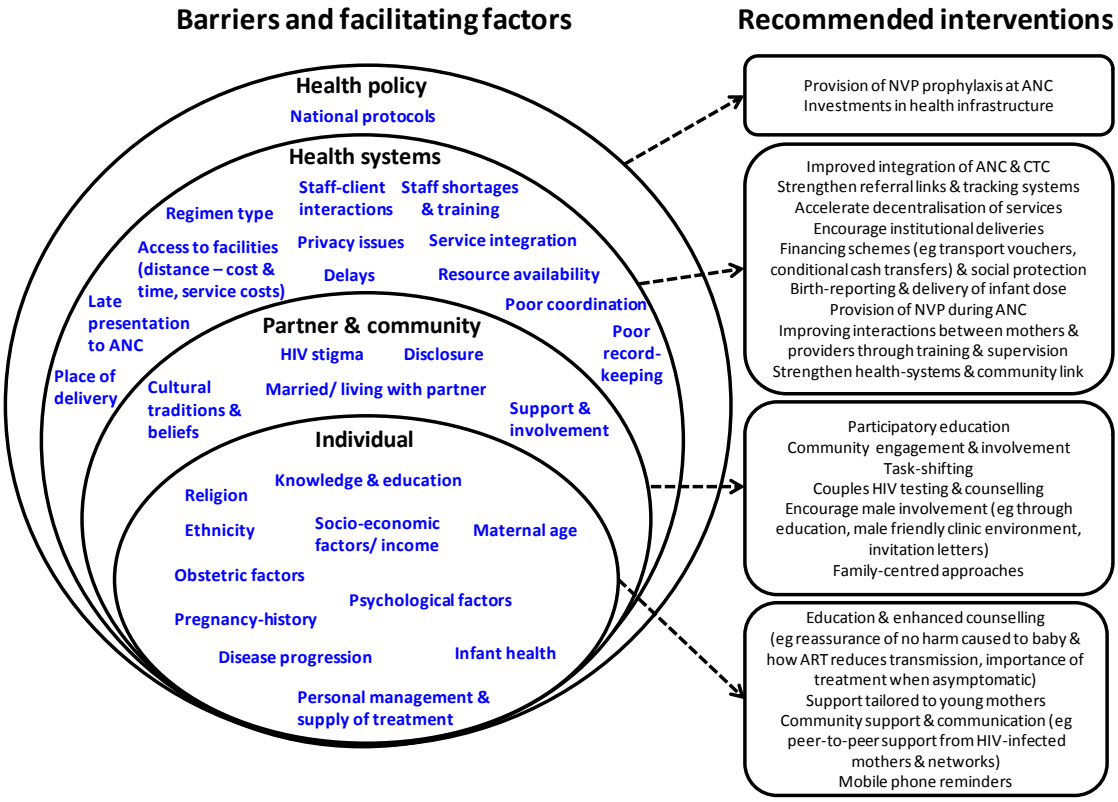
Qualitative results provided arguably the most useful insights, for example describing barriers and facilitating factors from the perspective of the patient or provider and *how* they affected ARV uptake. However, few qualitative studies ranked barriers in terms of relative importance, which would facilitate interpretation and help to prioritise intervention strategies. Quantitative results were less conclusive due to heterogeneity and the diversity of factors investigated. Some important factors that are difficult to measure, such as stigma, were not often investigated in quantitative work, while socio-demographic factors that are more easily measured were frequently analysed. Therefore the frequency of citations for a particular factor does not necessarily reflect its importance, but the number of times it has been investigated.

2.5.2 Programmatic implications

Addressing barriers at each social/structural level is essential in order to realise the full potential of PMTCT programmes. Mitigating these barriers may also have benefits beyond improved uptake of PMTCT programmes, in reducing the risk of transmission

to sero-discordant partners of HIV-infected mothers (111). Figure 2.3 illustrates recommended interventions to address barriers at different levels.

Figure 2.3. Factors affecting uptake of ARVs for PMTCT identified in the literature review.



ART Antiretroviral Therapy; ANC Antenatal Clinic; CTC (HIV) Care and Treatment Clinic; NVP Nevirapine
Factors are populated within a hierarchy of individuals (pregnant women or infants), their community, and health systems around them, which are in turn part of the wider health-policy environment. A complex interplay of factors from each level ultimately impacts on PMTCT ARV uptake. This hierarchy is adapted from a socio-ecological model (36). Possible interventions and policy recommendations addressing barriers at each level are illustrated to the right-hand side. Some interventions may address more than one barrier within a level, or barriers at multiple levels, and may be packaged together.

At the individual-level, poor knowledge could be addressed through counselling and educational strategies. However, authors occasionally noted educational efforts had made little impact on service use. Delva et al. suggested transport fares or experience from previous pregnancies may have been a greater barrier to accessing services (99). Careful distribution of information will also be needed, as attempts to educate women using pamphlets have occasionally failed due to illiteracy or fear of disclosure (being seen with the documents) (91). Further counselling by health-providers (for example providing reassurance that ARV treatment will not harm the unborn baby and explaining in simple terms how the drugs can reduce transmission) could encourage women to take their treatments, as well as community-driven participatory communication strategies (112), or new technologies (such as mobile phone reminders) (113).

The frequency of citations of psychological barriers (denial, depression, and fears about being HIV-positive, treatment and death) in the qualitative research, also suggests the need for strengthened supportive counselling. Careful management and advice for women initiating ARVs early in pregnancy will be needed, to ensure they do not discontinue treatment if symptoms decrease. Peer-support from other HIV-infected individuals, for example Mothers2mothers and 'networks' programmes may also offer psychological support (112, 114, 115 , 116). Support tailored for pregnant adolescents could also help address their fears and other social and legal challenges faced by this particularly vulnerable group. Barriers to PMTCT ARV uptake were not explored among any other specific populations (such as sex-workers or refugees), representing an area for further research.

The prominence of community-level barriers, particularly stigma and fear of disclosure, suggests the need for approaches that engage communities and create an enabling environment for PMTCT. Further education about PMTCT and sensitisation to HIV, particularly focussing on HIV infection during pregnancy, is needed to reduce stigma and improve disclosure. Approaches might include participatory educational group activities (34, 37, 117), and involvement of HIV-infected individuals in tackling stigma, offering peer-support and counselling (114).

The effect of disclosure may be context/culture-specific (possibly explaining heterogeneity in findings for this factor). Although qualitative findings suggested overwhelmingly that fear/lack of disclosure hindered uptake of PMTCT ARVs, women living in rural Kenya who concealed their HIV status in order to preserve family stability, follow traditions and please elders were more likely to adhere to PMTCT services (105). This suggests community-level approaches including elders and community leaders, and solutions tailored to the setting, are needed. Such approaches might also address preferences for traditional healers and TBAs.

Tackling disclosure issues may benefit uptake of infant prophylaxis, as non-disclosure appeared to be an important factor limiting receipt of NVP among infants in qualitative and quantitative research, particularly in the case of home-births (73, 76, 81, 82, 96, 100, 105). However, a minority of studies specifically reported barriers to receiving the infant dose (quantitative studies often combined maternal and infant outcomes), suggesting a need for further research.

Lack of support (emotional, financial or physical) was another frequently cited barrier to PMTCT ARV uptake, and good support was occasionally noted to improve uptake in qualitative and quantitative research. Support and disclosure are likely to become increasingly important in the context of 'Option B+'.

Several authors suggested engaging men in the PMTCT programme to improve communication, disclosure and support (90-92, 96, 98, 99, 107). A review of family-centred approaches to PMTCT also described positive outcomes of partner participation at different points of the PMTCT cascade (118). However, other studies did not support this finding (71, 72, 84, 85) and a Cochrane review (2012) concluded there was insufficient rigorous evidence for the effectiveness of male involvement on PMTCT services, highlighting that further evaluation is required. While partner VCT is advised in many national PMTCT guidelines, levels of male involvement were often very low, and few studies reported male perspectives on involvement in pregnancy/ delivery. Research is emerging on how to implement CVCT/male involvement in the context of ANC and other settings, for example, through invitations given to partners and 'male friendly' clinics including flexible opening hours and priority for couples (61, 107, 108, 119-121). However, evidence for the effectiveness of these interventions remains limited. It is clear that while male involvement holds promise for improving uptake of PMTCT interventions, further rigorous evaluation and implementation research is needed.

Expanding PMTCT services to include other family-members (for example in counselling) has also shown promise (118), and may be particularly important for single women or those with unsupportive partners.

At the health systems level, staff shortages, (fear of) scolding from staff, and facility accessibility issues emerged frequently during qualitative investigations. Addressing these issues should be a priority. Community-based approaches may help to overcome the shortfalls in health-workers through task-shifting (41, 120, 122, 123), although evaluation of these strategies in the context of PMTCT is limited and concepts are mostly inferred from HIV or maternal health programmes more broadly (reviewed by Buzsa et al. (61)).

Accelerating service decentralisation, particularly to rural areas, financing schemes such as provision of transport and service vouchers (124), conditional cash-transfers (125), or transport services provided by community-members (124, 126) may alleviate access issues. Provision of the NVP dose during ANC appointments, or birth-reporting

strategies, have the potential to improve NVP uptake in mothers and/or infants and could be implemented more widely, particularly where a high proportion of women have home-births.

Improving interactions between mothers and health-providers, for example through toolkits, training and supervision should be promoted to allay fears of negative staff reactions and to capitalise on facilitating effects of trust in staff. Confidentiality and privacy issues could be addressed by optimising facility layout. Participatory improvement approaches involving staff might also address poor behaviour, low morale and record-keeping (109), while attention should also be given to underlying systemic issues such as sufficient and regular staff payments.

While supply shortages (of HIV test kits and drugs) were mentioned to a lesser extent than staff and accessibility issues, they were mostly noted by health-providers, so the relatively smaller number of citations may reflect that fewer studies included such participants. As the availability of working tools is a pre-requisite for a fully functioning PMTCT programme, this should be considered a critical issue.

Integration of ANC and cART services appeared to facilitate linkage of HIV-infected pregnant women to care and treatment (110), although partial integration seemed less effective (88) (reviewed by Ferguson et al. (43)), and a Cochrane review (2011) called for further research on the effect of integration of PMTCT with other health services due to paucity of data meeting inclusion criteria (127). Retention after successful transition to an HIV clinic also requires further exploration.

2.5.3 Changes over time

The majority of studies reviewed were conducted in early stages of PMTCT programmes prior to cART provision, so further research is needed to understand the implications of PMTCT policy and changing protocols, particularly Option B+. As more pregnant women are encouraged to initiate cART or ARV prophylaxis earlier in pregnancy and continue during breastfeeding (53), some of the factors associated with adherence to PMTCT treatment may change or become more pronounced. It was not clear whether pill burden of prophylaxis or cART earlier in pregnancy presents a growing barrier to ARV use during this period, as the 2 studies investigating this issue found conflicting results. Health-workers may struggle to keep up with changing protocols, although health-worker knowledge was rarely assessed and should be investigated further. This review suggests that early adoption of Option B+ may help to overcome some barriers to the uptake of ARVs for PMTCT, for example delayed

ANC attendance. However other barriers identified, such as stigma, fear of disclosure of HIV status and lack of support (which may be more problematic with the need to store and take ARV treatments more regularly) as well as health systems issues (eg. the need for repeated trips to the clinic to collect drugs, and already strained infrastructure and resources), suggest the need for cautious implementation, reflecting recent debates in the literature (128).

Our assessment of changing barriers over time revealed that stigma, alongside fear of disclosure, remains entrenched across sub-Saharan Africa, while long-standing health systems issues such as staffing and accessibility continue to hamper uptake of PMTCT ARVs. The lack of progress in addressing these fundamental issues over ten years since the implementation of PMTCT programmes is disappointing, and points to a lack of commitment by international donors to invest in health infrastructure, while giving preference to funding more readily audited inputs such as drugs. However, it was interesting that knowledge/education and some psychological barriers appeared less often in recent studies, which may suggest that educational efforts and counselling messages could be beginning to have an effect, or that familiarity with the programme is growing (although these results should be interpreted with caution given the small sample size, and frequency that factors were potentially *investigated* could not be determined for all studies).

2.5.4 Strengths and limitations

Inclusion of both qualitative and quantitative research and triangulation of results were strengths of this review. The quality appraisal, a weak area of existing systematic reviews incorporating qualitative literature, allowed us to consider study quality when reporting the strength of evidence, and to assess the overall quality of work in this area. The quality assessment tools provide a methodological contribution. Interpretation is limited by the fact that included studies were almost exclusively observational designs, with possible (residual) confounding resulting in over- or under-estimation of some of the reported associations. The diversity of factors explored in quantitative studies and range of designs impeded a quantitative synthesis of evidence; instead we aimed to describe the results in detailed narrative and tables, and synthesise findings through thematic analysis. Reasons for heterogeneity in quantitative results may include lack of power (sub-analyses), factors varying in importance in different settings, differences in local PMTCT guidelines, different outcome definitions or explanatory factor categories, or spurious results (small p-values) generated by chance when many risk factors were analysed. Some of the quantitative outcome measurements were based on self-report by the mother or health worker, suggesting the possibility for recall bias.

Only English language publications were searched and studies that found no evidence for/negative associations may not have been published (publication bias). Selection bias is also possible as one reviewer screened the majority of references, but there was a high level of agreement on the double-screened random sample.

This review is limited in its scope, as it does not cover barriers to the whole PMTCT 'cascade' or other programme 'prongs'. However, many of the identified barriers are cross-cutting and could have implications for other PMTCT 'prongs' or cascade steps, or other HIV/maternal and child health (MCH) services more broadly.

2.6 Conclusions

This review revealed many factors that contribute to the low uptake of ARVs for PMTCT in sub-Saharan Africa, at the level of individuals, their community and health systems. Fundamental health systems issues such as staffing and service accessibility, along with community-level factors of stigma, fear of disclosure and lack of partner support, emerged consistently across a range of settings in sub-Saharan Africa, and continue to plague PMTCT programmes over ten years since their introduction. The potential of PMTCT programmes to virtually eliminate vertical transmission of HIV will remain elusive unless these barriers are tackled, and coverage is extended to (as yet) unreached vulnerable populations; an under-researched area. Solutions must involve local communities given the prominence of community-level factors in this analysis. Health systems strengthening, enhanced counselling, community/partner support, male involvement and educational strategies also have the potential to improve uptake. Packages of solutions to address barriers at different levels are likely to be the most effective.

3 Quantitative research methods

This chapter begins by introducing the context for this PhD research, including an overview of the study setting, details of the health services offered and the TAZAMA project activities. Methods for the collection of quantitative data and specifics of the datasets are outlined. Procedures to link together different datasets are then described in detail. The final section of this chapter documents the statistical analysis methods.

3.1 Context

3.1.1 Overview of the study setting

The research for this PhD took place in Kisesa and Bukandwe wards, located in Magu District of Mwanza Region, in north-west Tanzania. The study population is the Kisesa open HIV cohort, which numbered approximately 30,000 individuals when residents were enumerated in 2010. The study area, herein referred to as 'Kisesa', is situated 20 kilometres east of Mwanza city along the main road leading to the Kenyan border (Figure 1.3 section 1.4). It comprises six villages which include a roadside trading centre, and other villages that stretch from the roadside to more remote rural areas.

The primary economic activities of the area are subsistence farming and trade of agricultural and other produce such as rice, maize, tomatoes and fish. The vast majority of Kisesa cohort inhabitants are from the Sukuma tribe. The dominant religion is Christianity (88% in 2010 in the sixth sero-survey – see section 3.1.7), with a smaller proportion belonging to traditional religions (10%) and Islam (2%). GDP per capita in Mwanza Region increased from less than $200 US in 2000 to around $500 in 2010 (129), but is likely to be lower in Kisesa. There are 14 primary schools and 3 secondary schools in the study area.

3.1.2 Health services overview

Kisesa includes four government-run health facilities. A health centre is located in the trading centre, offering ANC services, delivery and under-five child clinic services, clinics for sexually transmitted infections (STI) and tuberculosis, as well as VCT, PMTCT and HIV care and treatment services for HIV-infected individuals (Figure 3.1). Approximately three clinical officers and five nurses/ midwives or nursing assistants are employed in the health centre, although they typically work in rotation. There is also a laboratory worker and a VCT counsellor, and trainee nurses are often present. The TAZAMA project has been collaborating with the health centre since 2005 when the

VCT clinic was opened, although a relationship was first established when the centre was included as a site in the ANC surveillance studies (see section 3.1.8). Three dispensaries are located in the more remote rural villages of Kisesa (Igekemaja, Welamasonga, Ihayabuyaga), and provide a more rudimentary ANC, PMTCT, delivery, and child clinic service (Figure 3.2). Ihayabuyaga and Kisesa health centre are very close to the roadside, while Welamasonga and Igekemaja clinics are >8km from the main road (Figure 3.3 and Figure 3.4). These dispensaries include one or two clinical officers, a nurse or midwife (one dispensary lacks a qualified midwife) and in some cases a few nursing assistants, although there are usually no more than two or three staff present at one time. Uncomplicated deliveries are sometimes carried out at the dispensaries, although basic emergency obstetric care as defined by the United Nations Population Fund (130) is not usually available at the dispensary level. The latter is theoretically available in the health centre but is subject to the stock of equipment, and, in reality, complicated cases and emergency caesarean sections are usually dealt with at the hospitals in Mwanza city or Magu District hospital. The dispensaries were included in the ANC surveillance, although more regular contact with TAZAMA was initiated in 2012 for this PhD research. Three private facilities are also available in the study area offering simple out-patient (OPD) services (PMTCT services were not offered prior to 2013). The nearest government hospitals are at least 20km away from the study site, and include Bugando Medical Centre (national referral hospital) and Sekou-toure (regional referral hospital) to the east in Mwanza town, and Magu District Hospital roughly 40km to the west along the main road to the Kenyan border.

Figure 3.1. Images of Kisesa health centre.

Top left: the health centre site (VCT building in the front left, the labour and delivery ward behind the VCT building, and on the far right hand side the CTC building). Top right: the CTC building. Middle left: the labour and delivery ward building. Middle right: labour room. Bottom left: delivery room. Bottom right: ANC post-test counselling and pregnancy examination room.

Figure 3.2. Images of Kisesa dispensaries.

Top left: Welamasonga dispensary exterior. Top right: Welamasonga examination and delivery room. Middle left: Ihayabuyaga dispensary exterior. Middle right: Ihayabuyaga examination and delivery room. Bottom left: Igekemaja dispensary exterior. Bottom right: Igekemaja dispensary examination and delivery room.

Figure 3.3. Locations of Kisesa health facilities.

Kanyama and Kitumba clinics are only temporarily constructed during sero-surveys (see section 3.1.7), while the remainder represent permanent facilities. (Image reproduced with permission from Jocelyn Poppinchalk).

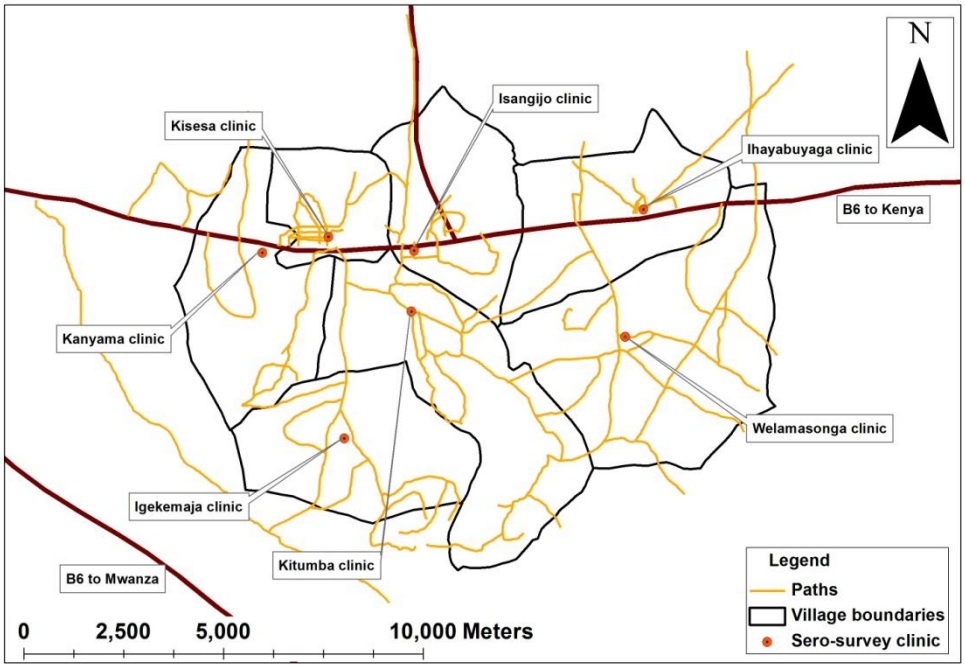
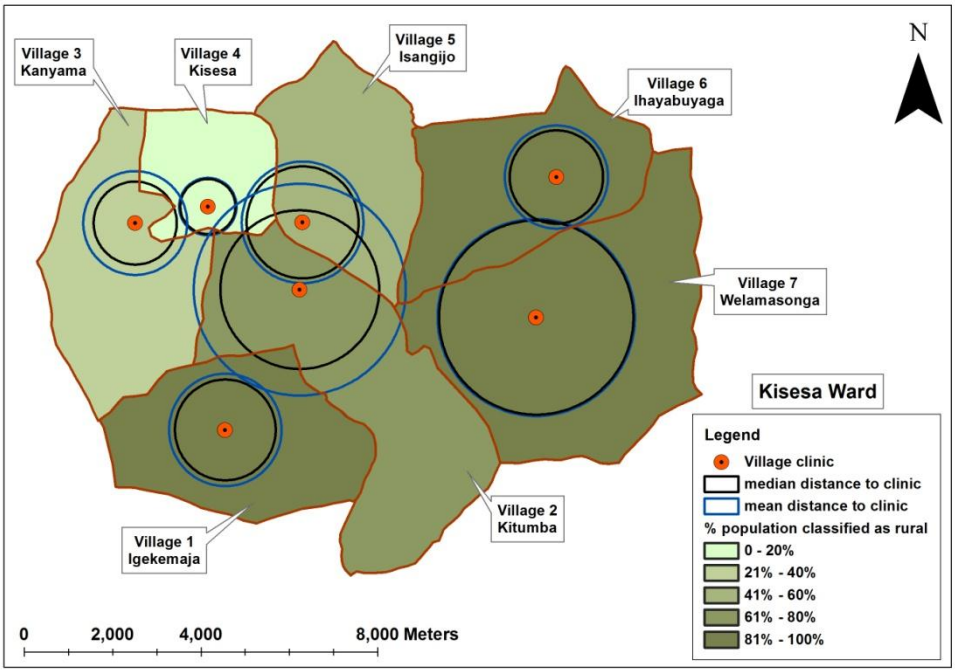


Figure 3.4. Mean distances to travel to Kisesa clinics, and proportion of each village or clinic catchment area classified as rural.

(Image reproduced with permission from Jocelyn Poppinchalk).



3.1.3 HIV services: HIV testing and counselling

Kisesa health centre VCT clinic opened in March 2005 (initially a 2 day service in the neighbouring Red Cross building, before a 5 day service began at the health centre later in 2005) and is staffed by 1 full-time trained VCT counsellor. This permanent clinic is located on the same site as other clinical services at the health centre, but housed in a separate building (Figure 3.1). HIV rapid tests are used to provide same-day results to walk-in clients. Prior to 2006, venous blood was collected for HIV testing. VCT services have also been available temporarily in the study area since 1996, during rounds of HIV serological surveillance as detailed below (section 3.1.7); offered in temporary huts constructed at the field sites that move from village to village. PITC has also been initiated by the OPD in Kisesa health centre since 2010, including STI and tuberculosis services, and ANC since 2009. In practice, PITC is sometimes done in the VCT building, particularly in the case of the small number of out-patients, or during shortages of HIV test kits. When HIV test kits are available, PITC for pregnant women takes place in the ANC building.

3.1.4 HIV services: Antiretroviral treatment (ART)

Bugando and Sekou-toure hospitals have been offering ART services since late 2004 through the Tanzanian national ART programme. Between 2005 and 2008, prior to the provision of ART in the study area, individuals diagnosed HIV-positive at Kisesa VCT services were referred to Bugando (mostly, or Sekou-toure if the client preferred) for HIV care and treatment. Kisesa health centre CTC opened in August 2008, and from this time patients diagnosed with HIV could initiate ART on-site. Most Kisesa residents who had commenced their HIV care at Bugando opted to be transferred back to Kisesa CTC, while some chose or were requested (e.g. complicated cases failing treatment or enrolled in clinical studies) to continue attending Bugando CTC. By the end of 2012, approximately 1700 patients had registered at Kisesa CTC (including patients from areas outside of Kisesa, and patients who died, transferred elsewhere or were lost to follow-up), around 250 of whom had started their care at another clinic (including Bugando). Around 450 Kisesa-based clients are continuing to receive care and treatment at Bugando hospital.

Referrals from HIV testing and counselling services in Kisesa to ART services within Kisesa health centre, as well as Bugando and Sekou-toure hospitals, are made by completing referral slips – in the case of VCT, the referral slip comprises a two-part form specially designed and implemented by the TAZAMA project (one part retained by the counsellor and the other part taken by the client to the CTC), while other PITC services use national government PITC transfer forms.

Protocols for initiating ART in Kisesa CTC for all adults and adolescents initially followed national ART guidelines recommending that patients in clinical stage 4 (regardless of CD4 count), those with CD4 counts below 200 cells/mm^3 (regardless of clinical stage), and those with CD4 counts <350 cells/mm^3 and in clinical stage 3 initiate treatment (131). In 2012, eligibility criteria were widened to all patients in clinical stage 3 and 4 regardless of CD4, or all patients with CD4 <350 cells/mm^3 regardless of clinical symptoms (132). Tanzania has recently implemented Option B+ (ART for life for all pregnant women) which came into effect in 2013 after the time-frame of this PhD research (21), although the latest global guidelines for starting all adults and adolescents on ART at CD4 <500 cells/mm^3 (133) has not yet come into effect.

3.1.5 HIV services: PMTCT

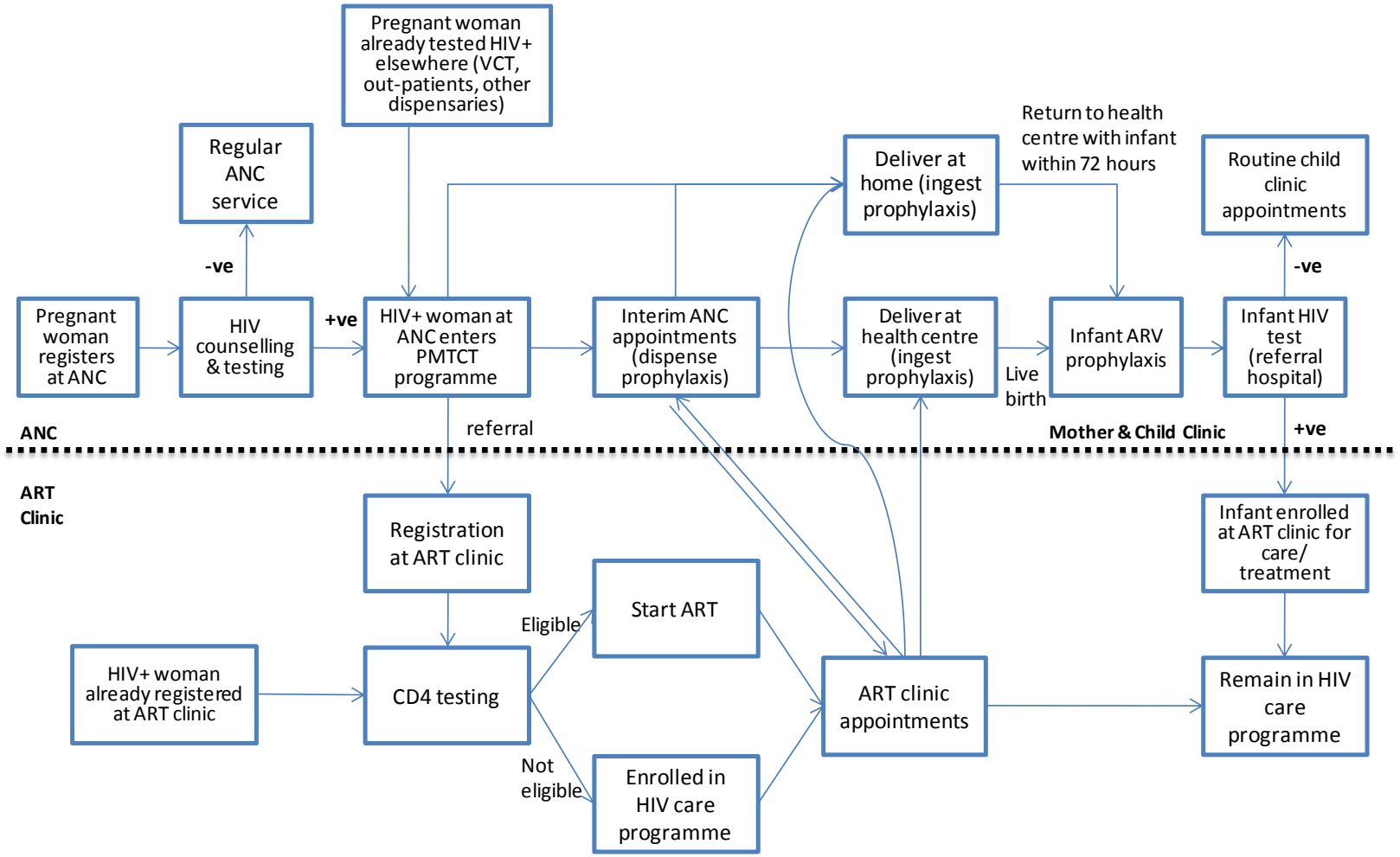
Between 2005 and 2008, pregnant women who were diagnosed HIV-positive at Kisesa health centre VCT clinic were referred to Bugando or Sekou-toure hospitals for PMTCT services. PMTCT services were introduced to health facilities in Kisesa in 2009, with comprehensive services offered in Kisesa Health Centre including ANC (>95% of women in Kisesa attend ANC at least once according to data from sero6), HIV-testing, ARV prophylaxis, HIV care and treatment, labour and skilled delivery services. A more basic service is offered in the dispensaries including HIV-testing (when stocks of HIV test kits and drugs are available), ARV prophylaxis provision and limited delivery services (skilled attendance at delivery in some but not all the dispensaries). PMTCT services at the dispensary level do not include long-term HIV care and treatment, so patients testing HIV-positive are referred to the CTC at Kisesa health centre. PMTCT services across all the facilities are intermittent due to frequent HIV test kit and drug stock-outs. Figure 3.5 illustrates the flow of PMTCT services in Kisesa.

Kisesa facilities operate routine PITC for pregnant women at the ANC following national guidelines that were outlined in 2007 (30). Women diagnosed with HIV are referred to the CTC at Kisesa health centre where they receive long-term HIV care, CD4 count testing, and if eligible, initiate ART for their own health. Treatment eligibility criteria and ARV prophylaxis provision protocols have evolved since the start of the PMTCT programme in Kisesa, reflecting changing global and national guidelines. Initially, following the 2007 Tanzanian PMTCT guidelines (30), pregnant women (and all HIV-infected adults) with CD4 counts <200 cells/mm^3, 200-350 cells/mm^3 and clinical stage 3, or clinical stage 4 regardless of CD4 count, were eligible for ART. At this time, pregnant women who were not eligible for ART received ARV prophylaxis (AZT from

28 weeks gestation and combinations of AZT, lamivudine, nevirapine as indicated during labour, delivery and 7 days postpartum (30). HIV-exposed infants received nevirapine immediately after birth, and AZT for 1 or 4 weeks (duration depending on how long AZT was taken by the mother at ANC). In 2012 'Option A' was adopted (summarised in Table 1.1 in the introduction (chapter 1)), with treatment eligibility criteria for HIV-positive pregnant women widened to CD4≤350 or clinical stage 3-4, and ARV prophylaxis from an earlier gestational age (14 weeks) for women not eligible for ART (134). Under Option A, infant prophylaxis was also lengthened to 1 week after cessation of breastfeeding, or 4-6 weeks if replacement feeding. Option B+ was implemented in late 2013 (21).

HIV-infected women are advised to bring their infants within 4-6 weeks for HIV testing (polymerase chain reaction (PCR), which can be used to detect viral DNA or RNA while maternal HIV antibodies are still present) and 6 weeks after cessation of breastfeeding. Dried blood spot samples are sent from Kisesa to Bugando hospital for PCR. A further HIV antibody test at 9 months is recommended to detect infant antibodies to HIV, followed by a confirmatory PCR. Re-testing HIV-negative pregnant women in their third trimester has also been advised since 2011, as well as HIV-testing of women of unknown status in the labour ward, when feasible.

Figure 3.5. Diagram of the PMTCT programme and referral routes at Kisesa facilities.



ART clinic located at Kisesa health centre.

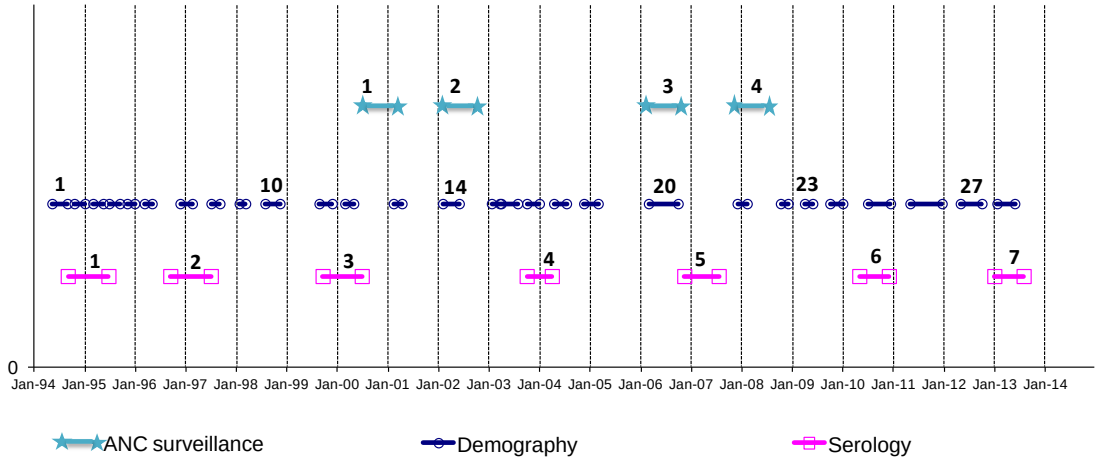
3.1.6 HIV services: Ancillary HIV services

Other HIV services established in Kisesa and the wider district since the early 1990s include a village AIDS committee, community groups for individuals diagnosed HIV-positive, and home-based care services (HBC). HBC includes health and social services, physical and psychosocial support, and is provided by formal or informal caregivers in the home (135). HBC services were introduced in Kisesa in 2002 by a programme called TUMAINI, and from 2007 by the TUNAJALI programme, both funded by the US Presidents Emergency Plan for AIDS Relief (PEPFAR) and implemented by different Non-Governmental Organisations (Care International and Family Health International) as part of a national effort to scale up support services, including HBC, for HIV patients (135). The programme has been run since 2012 by the Christian Social Services Commission, supported through USAID and PEPFAR. Kisesa HBC services include encouraging use of VCT and use of modern health facilities, identifying and referring sick individuals to health facilities, escorting patients to CTC services (at the time these services were only available outside Kisesa), and counselling and nursing for people living with HIV in their homes. HBC workers have also been involved with following up clients who do not return for CTC appointments. Under TUMAINI, drugs for opportunistic infections and food were also provided. In 2009, HBC services were being offered to over 270 clients in Kisesa, by a team of 11 (15 by 2014) volunteer HBC workers with a presence in each village, although funding for this programme at the time of writing is limited.

3.1.7 Kisesa cohort activities: Demographic and HIV sero-surveillance

The Kisesa open HIV cohort study was initiated in 1994 and is the longest running HIV community cohort study in Tanzania (Ifakara demographic surveillance system (DSS) in the south of Tanzania has also recently implemented HIV sero-surveillance). A summary of the cohort activities over time is shown in Figure 3.6.

Figure 3.6. Timeline of Kisesa demographic, HIV sero-surveillance and ANC surveillance.



The cohort study incorporates twice-yearly rounds (28 to-date) of demographic surveillance and 7 rounds of HIV serological surveillance (1994-1995 (sero1), 1996-1997 (sero2), 1999-2000 (sero3), 2003-2004 (sero4), 2006-2007 (sero5), 2010 (sero6) and 2012-2013 (sero7)). Four rounds of ANC surveillance were also conducted across Magu District, including in Kisesa, as described in section 3.1.8.

Kisesa DSS collects information on pregnancies, births, spousal and parent-child relationships, in- and out-migration and deaths from the entire population of Kisesa (appendix 12.4.1). Trained fieldworkers visit individuals in their homes, with information now recorded using hand-held personal digital assistant (PDA) devices (since DSS round 27; previously paper-based questionnaires were used). Verbal autopsies are also conducted for all deaths reported through the DSS. Relatives of the deceased are interviewed by a specially trained fieldworker who is also clinical officer, with the data used to ascertain cause of death.

All Kisesa residents (based on the last round of demographic surveillance) aged 15 and above were eligible and invited to participate in the sero-surveys. Participation has ranged from 60-86% in sero1 to 5 with higher participation among women than men (136) (provisional estimates are 50-60% for sero6 and sero7). During each sero-survey participants were interviewed in Kiswahili or Kisukuma (the local language) by trained fieldworkers, using a structured questionnaire. The questionnaire captured detailed information on sexual behaviour and partnerships, family planning, HIV-related knowledge and attitudes, and use of health services including ANC and HIV testing (appendix 12.4.2). Core questions have remained fairly consistent across the rounds,

while new questions have been added over time, for example questions about ART knowledge were added from sero5 onwards.

HIV status was determined in each round using a research testing protocol (informed consent without disclosure of results). Blood was collected by finger prick (with the exception of sero1 when venous blood was collected), then transported and tested anonymously in laboratories at NIMR. Two ELISA assays were used to confirm HIV status (Uniform 2, BioMerieux, Boxtel, the Netherlands; Enzygnost HIV1/HIV2, Dade Behring Marburg GmbH, Germany). Discordant results were resolved using Western blot (sero1) or by repeat testing with two ELISAs (subsequent sero-surveys). These results are used to estimate HIV incidence (0.9 per hundred person years in women and in men in 2008-2012), and prevalence (7.0% in women and 5.1% in men in 2008-2012 (unpublished, earlier results are published in Wambura et al. (136)).

Voluntary counselling and testing (VCT) was also offered for those who want to know their HIV status. Twenty-six percent of participants at sero6 opted for VCT; an increase from 1% in sero3, 9% in sero4 and 17% in sero5 (137). Up to sero4, clients accepting VCT received pre-test counselling, had venous blood collected for HIV testing at NIMR, and were then asked to return a week later for post-test counselling at the same site. After sero4, HIV testing was done using venous blood collection and rapid tests, with same day results (usually within 45 minutes). The most recent protocol (sero7) used Determine for the initial screening test, followed by a confirmatory Unigold test for all samples with an initial HIV-positive test result. Sero5 and sero6 used Capillus as the preliminary test. Discrepant results after the first two tests were resolved by ELISA.

Ethical considerations for sero-surveys

The cohort activities were granted ethical approval by the LSHTM (approval number 7191 for the latest round - sero7) and the Tanzanian MRCC (approval number NIMR/HQ/R.8a/ Vol_IX/ 1489 for sero7). Verbal consent (due to low literacy levels) was taken up to sero4, thereafter written consent was obtained, with thumbprints and witnesses for those who are illiterate. During each sero-survey, temporary field sites were constructed at a central location within each village, with purpose-built huts or private rooms ensuring confidentiality for individual interviews, drawing blood and medical consultations. All participants and their families were offered free treatment for common medical conditions other than HIV. Participants opting for VCT received this service from a trained counsellor at a confidential site near to, but separate from, the main sero-survey site. Individuals testing HIV-positive in sero5 were referred for ART to CTCs at hospitals in Mwanza city, and after 2008 (sero6 and sero7) to Kisesa

CTC. Those testing HIV-positive in sero4 were told that ART would soon be available in the study area, and if they agreed, were traced by VCT counsellors and subsequently referred to city-based CTCs once ART was available.

3.1.8 Kisesa cohort activities: ANC surveillance

Four rounds of ANC surveillance were also conducted by NIMR and the LSHTM between 2000 and 2008. Health workers were trained to administer surveys with pregnant clients attending ANCs in Mwanza city and across Magu district, covering topics including sexual and reproductive behaviour, HIV, and family planning. Blood samples routinely collected for syphilis screening were also used, with the consent of participants, for HIV testing. HIV prevalence in women attending ANCs was estimated as 10.7% in the first round and 8.9% in round four (138, 139).

In 2009, after the final survey round, over 2000 women (of the 5284 participants in the 2007-8 survey) were followed up and interviewed after they had given birth. This follow-up survey revealed that only 24% of HIV-positive mothers (n=168) and their infants had received ARV drugs for the prevention of mother-to-child transmission (PMTCT) of HIV, despite the increasing availability of PMTCT services across the district - available in all clinics in Mwanza city and almost half of rural facilities at the time (26).

3.2 Quantitative data collection

3.2.1 DSS 27

In order to facilitate linkage of clinic log books to the DSS (described in detail in section 3.3 on data linkage), women's ANC card numbers were collected during DSS round 27. Personal ANC cards (appendix 12.4.3) are given to pregnant women when they register at the ANC, holding information such as the ANC number, date of registration, expected delivery dates, and clinical details. A new ANC card, with a new ANC number, is assigned by the clinic for each pregnancy (women may have multiple cards over time). The ANC number consists of the year of registration and a serial number.

A pilot was undertaken in order to assess the feasibility of capturing this information during the DSS. I attended home-visits with enumerators during the pilot, assisting in training them to collect this information. The pilot revealed that the clinic name, registration dates and expected date of delivery would be important in verifying and matching the ANC card numbers collected during the DSS to the clinic information, as ANC numbers were sometimes incomplete or unclear.

Based on the pilot results, a series of questions was then integrated into the main DSS questionnaire for round 27. These questions are listed in full in appendix 12.4.1. The extra questions were asked to women aged 15-49. In brief, women were asked if they had ever had a pregnancy, and if so, if they had any ANC cards. After explaining to them about the purpose of obtaining the extra information from ANC cards, women were asked if they were willing to find their cards and show them to the enumerator. The enumerator then recorded details from up to 3 of their most recent ANC cards: the ANC number, clinic name, registration date at ANC, and expected dates of delivery.

I applied cleaning checks to the raw DSS 27 dataset received from DSS data manager, including standardisation of the ANC number format recorded on clinic cards, and cross-referencing the ANC number with the date of registration at ANC and the expected delivery date. Incomplete ANC numbers were identified: missing year components were imputed using the ANC registration date if known, or otherwise the expected delivery date.

3.2.2 ANC data

Design and preparations

Before commencing the data entry, the officers in charge from each of the four facilities in Kisesa, and the District Medical Officer (DMO) were visited to explain the study purpose and procedures.

All the registers related to ANC, PMTCT, delivery, and mother and child clinics were photographed and reviewed in order to identify which books captured information relevant to PMTCT, and ultimately, those that would be selected for data entry. The potential for linkage to the DSS and between different registers was also assessed. Four registers were identified that captured information on PMTCT related outcomes (an example is shown in appendix 12.4.4), as well as one general name-based ANC register (no data on PMTCT, appendix 12.4.5) that could be used for linkage to the DSS, and to the other PMTCT-specific registers via the ANC number (Table 3.1).

Table 3.1. Details of registers selected for data entry.

Book	Population of women included	PMTCT outcomes data available or other purpose	Linkage	Years of books entered
General ANC Register 'Mtuha6'	Women who attend ANC (HIV-positive and HIV-negative, but without distinguishing the HIV status)	Name-matching to the DSS. Contains ANC ID which can be used to link the whole PMTCT dataset to the DSS	Mother name, age, & village enables link to DSS; ANC ID links to PMTCT registers	2005-2012
PMTCT ANC Register	Women who attend ANC (HIV-positive and HIV-negative)	HIV test results	ANC ID links to other PMTCT registers	From first book available (2008/9)
PMTCT Care Register	HIV-positive women who registered for PMTCT care at ANC during pregnancy	ARVs dispensed during ANC; referrals to CTC	ANC ID links to other PMTCT registers CTC ID for those referred links to CTC dataset	From first book available (2008/9)
PMTCT Labour & Delivery Register	All women who deliver in the health centre (HIV-positive and HIV-negative)	ARVs dispensed during labour and delivery & receipt of ARV infant dose	ANC ID links to other PMTCT registers	From first book available (2008/9)
PMTCT Mother and Child Follow-up Register	All HIV-positive women and HIV exposed infants registered in under 5 clinics.	ARVs taken by the mother during labour and delivery; infant HIV testing dates and infant HIV test results	Cannot be directly linked to other PMTCT registers pre-2012 From 2012 onwards: register has ANC ID which links to other PMTCT registers, and child ID	From first book available (2008/9)

Registers were selected that included data from the start of the PMTCT programme in 2009 until the end of 2012. During this time frame, in 2012, a new format was introduced for all PMTCT registers, with new information captured or changes to the layout, and all instructions printed in Swahili (formerly in English). As a result, there were two versions of the book for each PMTCT register series (with the exception of the general ANC register). Data were captured from 2005 for the general ANC register, prior to the start of the full PMTCT programme in Kisesa, but during the time when VCT was operating in Kisesa health centre, with referrals for pregnant women testing HIV-positive to the CTC at Bugando hospital.

Nine data entry screens were designed using CSPro; one for each register, with the pre-2012 and post-2012 versions of the PMTCT registers each requiring a separate data entry screen. I provided advice to the project data managers on the design of all data entry screens.

Data collection

The majority of the data were entered on-site at NIMR. Registers containing retrospective data and no longer in regular use were collected from the clinics by data managers, the project clinician, or myself, and transported to NIMR. The collection of registers from each clinic was documented using a sign-out sheet, with signatures of the health worker authorising permission to release the book, and of the data manager or researcher collecting the book. The same sheet was also used, again obtaining signatures, when returning the logbooks after data entry was completed. Registers containing the most recent data from 2012 that were still in regular use were photographed, with the permission of clinic staff, and then uploaded to the secure NIMR server, catalogued, and printed in NIMR.

Data entry and management processes

Data entry began in October 2012 and was completed in December 2013. All registers were double entered by two or more trained data entry clerks using the CSPro interface, then compared for inconsistencies. Inconsistencies were resolved by reviewing the registers, and corrections were applied by the data entry clerks. Spot checks were also made by the data managers after all inconsistencies had been resolved. Logs were kept in Microsoft Excel of the data entry processes, detailing batch numbers, dates of first and second entry and completion for each batch.

I applied edit checks in Stata 12 on the cleaned data received from data managers. These included checks for missing data, integrity of ID numbers (e.g. ANC numbers),

duplicate ID numbers or records, validity of dates, and completeness of village information (where batches corresponding to logbook pages with missing village information were identified, these were imputed where possible by referring back to the books, observing the book structure and page sequencing, by cross-referencing with notes recorded in the data management log, and checking with the clinic staff where uncertainty remained). Records potentially missing from the general ANC register and PMTCT ANC register datasets were identified by sorting the data according to ANC number and registration dates, and checking for missing stretches of sequential ANC numbers and dates of registration. Missing records were listed and discussed with staff on follow up visits to each clinic. At least three attempts were made to retrieve missing books or pages from each clinic. When missing records were identified, they were collected and entered using the same data entry screens, and added to the existing datasets.

Once the ANC numbers had been cleaned and standardised for each dataset, these identifiers were used to link the information from each different register series (PMTCT ANC, PMTCT Care and general ANC register, see section 3.3.1). Datasets corresponding to the first and second version of each register were also appended.

3.2.3 CTC data

Information about HIV-positive patients registered at Kisesa health centre CTC and details of their appointments, including drugs prescribed and CD4 count test results, are routinely recorded on clients' personal CTC1 appointment cards (not held in a database), and a CTC2 form (appendix 12.4.6). Each patient is assigned a unique CTC ID number which is maintained if they subsequently change clinics. CTC2 forms are filed and stored in an office in the CTC in Kisesa health centre. A government-employed CTC data entry clerk routinely enters the data recorded on the CTC2 form into the clinic CTC2 database on-site at the CTC. The CTC2 database contains names and identifiers and is only accessible by authorised clinic staff. The CTC data are then extracted without names and identifiers (except the unique CTC number) into the CTC3 database, which is the nationally implemented database system, managed by National AIDS Control Programme (NACP) with technical assistance from University Computer Centre (UCC) in Dar es Salaam. The extracted CTC3 data can be made available to a wider set of researchers within the clinic, or (with suitable data sharing agreement) by the NACP. Data for HIV-positive clients from Kisesa who opted to continue attending the CTC at Bugando hospital are held in the equivalent database system at Bugando. The CTC3 data are periodically extracted by the TAZAMA project data manager

through a special agreement with Bugando. CTC3 data for the analyses contained within this thesis were abstracted up to the end of 2012.

3.2.4 Ethical considerations for ANC and CTC data

Permissions were obtained from district health authorities to collect and process the ANC data. The DMO prepared and sent a letter to the clinics to authorise the data entry. Ethical approval was obtained from the LSHTM and Tanzanian MRCC ethical review boards for the collection and use of these quantitative datasets (see section 3.3.2 for details of ethical permissions for linkage of clinic and cohort datasets; existing TAZAMA project ethical approvals already cover the cohort activities).

Data entry clerks who entered the ANC clinic data were trained in the importance of confidentiality, while data managers also took part in ethical training courses. I completed an ethics certificate (Collaborative Institutional Training Initiative: Human Research – Biomedical Researcher), assisted with training, and participated in discussions about ethical issues relating to data collection and storage.

The name-based ANC register does not contain any sensitive information about HIV status or receipt of drugs for PMTCT, while the PMTCT registers containing details of HIV test results only record sequential ID numbers (ANC number) without names. Nonetheless, these final datasets were stored in independent files on the secure NIMR server, with password restricted access. Raw CTC datasets are held on the same restricted server with the names in encrypted format. All photographs of log-book pages were subsequently deleted from the NIMR server, while registers on loan from the clinics and print-outs of photographs were retained securely in a locked office at NIMR.

3.3 Data linkage methods

This section firstly outlines the methods used to link together the data from different clinic registers (e.g. from PMTCT registers to general ANC registers or the CTC dataset). The procedures used to link the clinic datasets to the Kisesa cohort data are then described in detail, incorporating the results of a statistical analysis which informed the development of the linkage algorithms. A background to record linkage work and discussion of the strengths and limitations of the approach is also provided. The datasets and fieldwork methods referred to in this section have been described in detail in sections 3.1 and 3.2.

3.3.1 Linkage between clinic datasets

Records from different clinic registers were linked to each other (deterministically) using clinic registration numbers. The ANC registration number was used to link records held in the general ANC register to the PMTCT registers (PMTCT Care and PMTCT ANC registers), and to link between PMTCT registers. A prefix for the clinic number (from which the register was derived) was added to the ANC number, to attempt to overcome issues with duplicate ANC numbers that arise in different clinics. During the data management phase and pilot DSS work I had discovered that duplicates of ANC numbers can arise across facilities, with each clinic using the same ANC numbering system (year of registration plus serial number of the client attending in that year). A smaller number of duplicates can also arise within the same facility, when women reside in a village outside the immediate catchment of that facility. These visits were typically recorded on a separate page of the log books but the same ANC numbering system was used. For example, within Welamasonga dispensary's pregnancy register, clients who reside in a village other than Welamasonga (e.g. Isangijo, or outside Kisesa) would usually be entered in a separate labelled section of the log books from the Welamasonga residents. Their ANC number could thus be a duplicate of the ANC number of a woman from Welamasonga. Therefore, where village of residence was recorded in both of the clinic datasets that were being linked, this information was cross-compared. For each link, additional checks were also made for compatible dates of registration between the services, and age.

Unique CTC ID numbers recorded in the PMTCT registers were used, where available (CTC numbers were sometimes written unclearly in the PMTCT registers, or were incomplete or missing), to link the PMTCT Care register to the CTC dataset (nurses in the ANC use the client's personal CTC card to record their CTC number in the PMTCT registers). The CTC database includes a space to record a pregnant woman's ANC

number, although this is rarely filled in, so additional measures were also taken to link the CTC dataset to the ANC dataset. This included a manual search through paper-based patient files in Kisesa CTC of ~200 female patients with a pregnancy documented in the CTC database, to check for any PMTCT transfer forms which should be stored alongside the CTC card and other medical notes. This search yielded very few ANC numbers (n=10), as PMTCT transfer forms were rarely found. Links made from the PMTCT Care register to the CTC dataset using the CTC ID were validated manually, where possible, by comparing the names of individuals in the ANC (where the record in the PMTCT Care register was also linked to the name-based ANC register) and CTC datasets, as well as age, village, dates of registration, and pregnancy information within the CTC database. Other links between the PMTCT and CTC datasets were made indirectly, by linking the CTC data to the DSS through name-matching, and merging the CTC-DSS linked records to the ANC-DSS matched dataset via the DSS identifier (see section 3.3.2).

Thirty records (9%) from the PMTCT Care book were not linked to the ANC register or the CTC dataset (PMTCT record missing ANC ID and CTC ID (n=6), or PMTCT record contained an ANC ID but it did not merge with the ANC dataset, and the CTC ID was missing (n=24)). There were no differences between the linked (to ANC or CTC records) and unlinked PMTCT Care records in terms of age, gestational age or clinic, although a higher proportion were from earlier years (21% of unlinked records from 2009 versus 13% of the linked records, p=0.01). Approximately 25% of the name-based ANC register records (for 2009 onwards) were not linked to the 'PMTCT ANC' registers containing HIV test results (either because the ANC numbers did not match or the link was ruled out after subsequent checks for compatible dates of registration and village, although village information was weakly recorded in this dataset).

Linkage of the PMTCT delivery registers to the other PMTCT or ANC registers was not attempted for the analyses described in this thesis, as the proportion of records with missing ANC numbers in the PMTCT delivery register was found to be large (20%) and PMTCT delivery registers containing over two years of data, including for Kisesa health centre where most deliveries take place, could not be located. The PMTCT mother and child follow-up register could not be linked directly to the other PMTCT and ANC registers before 2012, as this register did not contain a field for the mother's ANC number until the register was re-designed. As such it was not used in the analyses for this thesis, given the time needed to develop other methods to link in the earlier data. Ways in which these datasets may eventually be linked and used in the future are outlined in the thesis discussion (chapter 10).

3.3.2 Linkage of cohort data to clinic datasets

Background

The cohort dataset had previously been linked crudely to the CTC dataset (using referrals from VCT up to 2010). However records for some cohort members attending the CTC were not linked, for example because patients lost their referral forms, were tested elsewhere, decided to go directly to the CTC or because of issues in the implementation phase of the referral system. A more complete CTC-cohort linked dataset, updated to 2012, therefore needed to be constructed using alternative methods. No prior work on linkage between the cohort and the ANC data had been undertaken.

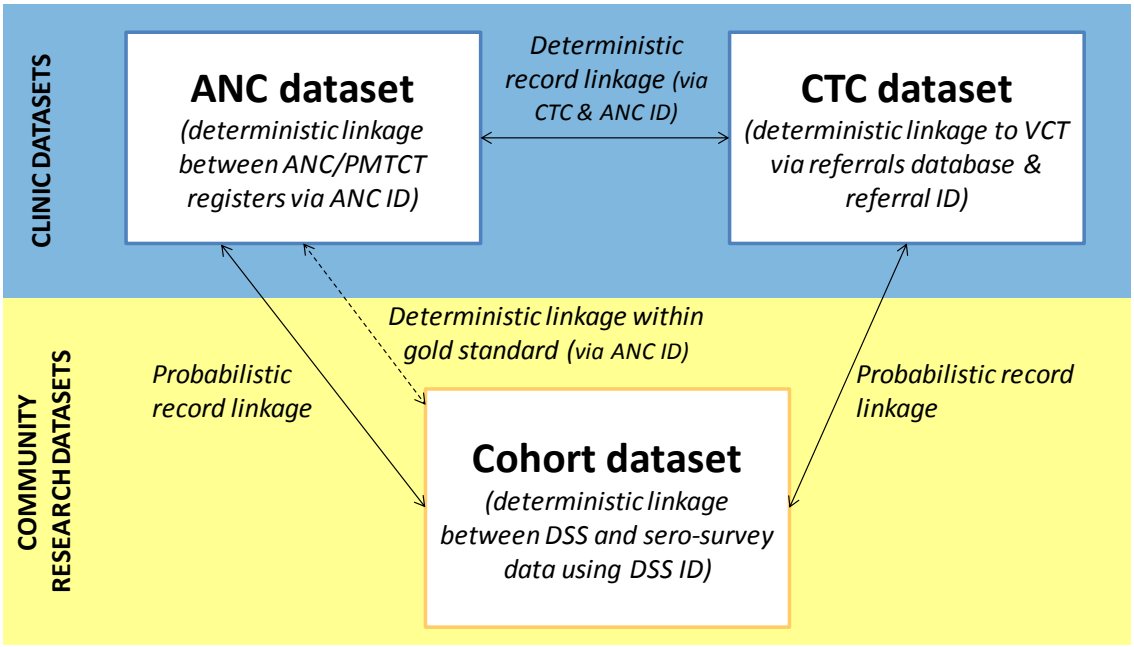
Relatively few research sites in East Africa have implemented systems to link population-level data from DSS with data from local health facilities. A few DSS sites (e.g. Rakai and Masaka in Uganda, and Hlabisa in South Africa) have implemented systems based on linkage via unique identification (ID) numbers, recorded in the clinics and in the DSS. For example, in Masaka, HIV-positive individuals and a sample of HIV-negative individuals are referred directly from the DSS to the study clinic maintaining the same DSS ID number, while in Rakai the study clinic records the DSS ID number of attending patients, and in Hlabisa government ID numbers are used in the DSS and the clinic. However, in many research sites, there are no ID numbers that uniquely link clinic patients to the DSS. Alternative methods for retrospective record linkage (after the time point of clinic access) are still in development, and are largely based on matching records on personal attribute data that are common to both datasets (e.g. name, date of birth, sex, residence) (140). However, records corresponding to the same individual rarely match exactly on these identifiers, due to spelling errors, using nicknames, masking of real names, change in last name after marriage, interchanging middle and last names, poor recall of date of birth, or change in place of residence. The procedure for matching records must therefore employ a probabilistic approach whereby the likelihood of the match is calculated based on these (non-unique) identifiers (140, 141) (the alternative deterministic approach relies on an exact match on a unique identifier, or on personal attributes). There is a trade off between finding a combination of identifiers that is permissive enough to retrieve the record for the correct person (high sensitivity), but not so imprecise that mis-matches are made for people who happen to have similar names and demographic details (high positive predictive value (PPV)).

In probabilistic record linkage strategies, some identifiers selected for use in the matching exercise (i.e. common to both datasets) will be more reliable than others for determining whether records can positively identify the same person. For example, declaring a match based solely on matching gender would be less reliable than if a match was declared on the basis of a cell phone number. Weights are therefore applied, representing the 'importance' or probability of a match on each identifier. Weights are calculated based on the observed agreement on each identifier for matched record pairs (known, or 'true' matches, which theoretically should agree perfectly on each identifier, but may differ due to reporting or recording errors in either dataset), and for non-matched record pairs (known non-matches, which may have identifiers that agree by chance). An overall linkage score for each record pair is then calculated by summing the weighted scores for each variable.

The outputs from automated probabilistic matching procedures can be supplemented by a component of clerical review in the area of overlap between the two theoretical distributions of non-matches and matches, or practically, between two thresholds of the linkage score (matches above the upper threshold are considered definite matches; those below the lower threshold are considered definite non-matches) (140, 141). This additional manual review, where logistically feasible, can help to reduce the number of false-positive linkages (declared a match, but in reality not a match) and false-negative linkages (real matches that were incorrectly assigned as non-matches) (140).

This was the premise for work undertaken to link ANC and CTC clinic records to the cohort dataset. The aim was to automate the matching procedure, given the large volume of records (in the order of 30,000 current DSS records, 16,000 antenatal clinic records, and 2,000 CTC records), and to make the process as reproducible and objective as possible. Figure 3.7 summarises the different clinic and cohort datasets and ways of linking between these datasets.

Figure 3.7. Overview of linkage between datasets.



The process of linking the data comprised several stages: 1) Creating gold standard datasets and designing scoring schemes and weights; 2) Writing matching algorithms ('auto-matcher') to link the clinic and DSS records and compute the scores for each link; 3) Testing the algorithms developed to ensure they were running correctly, viewing the results, then refining the algorithms and re-processing the matches (numerous iterations); 4) Validating the match set produced by the 'auto-matcher', including resolving cases of multiple matches (≥1 DSS record matched to 1 clinic record; this match set is described in further detail below).

I undertook the entire process (steps 1-4) for the ANC linkage work using Stata software, building on advice from the TAZAMA IT consultant and other researchers. For the CTC linkage work, the TAZAMA IT consultant and senior data manager primarily carried out steps 1-3, implementing the auto-matcher algorithm in a Structured Query Language (SQL) server database at NIMR. However, I was involved with these preliminary steps to some degree, for example reviewing and checking the output datasets (described briefly in later sections), and discussing these with the data managers. Decisions made by the data managers about the parameters and weights for the CTC algorithm (technical details included in appendix 12.5) were guided by these discussions. I subsequently carried out the final step (4) for the CTC linkage. All stages of the linkage process for the ANC and CTC datasets are described in further detail below; different algorithms were developed for each, although the processes were similar.

Gold standard dataset preparation and analysis (step 1)

Preparatory work was conducted to develop the algorithms for ANC and CTC clinic linkage using gold standard datasets. The aim was to develop gold standard datasets, one for each clinic environment, comprising 'true' matches (e.g. deterministic record linkage on a unique ID number, so the match is certain). Attributes of true matches were compared to those of non-matches (unique ID numbers do not match), in order to develop an optimised scoring scheme capable of predicting a true match (i.e. by probabilistic record linkage).

ANC gold standard: preparation

The gold standard for the ANC clinic linkage was constructed using the name-based general ANC pregnancy register and data from DSS round 27: ANC cards collected during this round were joined with the ANC register dataset using the ANC number (recorded in the clinic registers, and on personal ANC cards) and the clinic ID (since the same ANC number, based on calendar year and serial number, may occur in a different clinic). This gave a gold standard dataset in which a true match was defined by a match on ANC number and clinic.

Given the potential for duplicates of ANC numbers that can arise within the same facility, as described previously in section 3.3.1, I applied checks to identify and verify any records that were linked between the clinic and DSS based on matching ANC number and clinic ID (and assigned as 'true matches'), but did not match on village. In such cases, dates of registration recorded on the ANC card collected in DSS 27, and in the ANC register, were compared. Where these were not similar (n=740), the linkage was dropped from the gold standard dataset, as it was no longer certain the records were a 'true' match. All gold standard links were also subjected to clerical review, given the limitations of the ANC numbering system: record pairs (n=146) that had no resemblance on any attributes (e.g. names, year of birth) or dates of registration, and had obviously been mis-matched, possibly due to recording errors in the field or clinic, were dropped. A few duplicate cases (n=5 pairs), where the same DSS record (same ANC card number) was linked to more than one ANC clinic record (for different women), were also resolved using the dates of registration and clerical review.

The final number of ANC gold standard links (true matches) for analysis was 788. Non-matches (no match on ANC number and clinic) were also added to this dataset: each of the 788 ANC records within the gold standard, were joined to all the other DSS records linked to a clinic record in the gold standard, thus creating certain non-matches. This process produced a total of 620,156 non-matches (788*(788-1)).

ANC gold standard: preparation of variables for probabilistic record linkage

The resulting dataset containing true matches (n=788) and non-matches (n=620,156) was analysed to develop an optimised scoring scheme which could be used for probabilistic record linkage of ANC and DSS records.

First name, last name, year of birth (age), village of residence, number of pregnancies, dates of pregnancies or births, and dates of residency in Kisesa (compared with clinic visit dates), were identified as candidate fields for the matching of records from the ANC to the DSS. A crude scoring scheme was developed (without weights) for each of these potential matching variables, yielding a score for each variable ranging from 0 to 1, and the separate scores then summed to give a total score for each ANC-DSS record link. The raw scores are summarised in Table 3.2.

Levenstein distances were used to compare the similarity of names between the DSS and ANC records (142, 143). This string metric, or 'edit-distance' function, compares two string variables by measuring the changes, such as insertions, substitutions or deletions of characters, necessary to convert one word into the other; the smaller the value, the more similar the words, with zero indicating identical words. String edit-distance functions are considered to be less dependent on the language than other string comparison functions such as soundex or double metaphone, although the performance of different string metrics for record matching in a similar setting in South Africa did not differ greatly (140). A variable accounting for both names matching (Levenstein scores ≥0.7 on first and on second name) was also included as this was expected to predict a correct match *a priori*.

The contents of variables were standardised across the clinic and the DSS dataset, and within each dataset, for example changing all names to upper case, or consistently assigning codes to represent the different villages. Missing values for each variable were imputed where possible. For example, a small number of missing values for the number of pregnancies recorded in the ANC register was identified and imputed by taking the average number of pregnancies (3) per woman in this dataset. Where dates of ANC registration were missing from clinic books (used in the calculation of year of birth), the year of registration was imputed from the ANC number (which includes a component corresponding to the year). All remaining missing values resulted in a component score of zero for each matching variable with missing data.

A few alternative versions of the scores shown in Table 3.2 were also investigated. Categorical versions of each of the numeric variables were explored, and a categorical pregnancy count score distinguishing between primigravida and higher order pregnancy (this distinction often being used for clinical management during pregnancy). The three variables drawing from different sources of information regarding deliveries (using child records with their dates of birth and links to mothers; and mothers' DSS records in which births are reported) and pregnancies were also assessed as a combined variable using all sources.

Table 3.2. Details of component scores used for matching of ANC clinic records to DSS records.

Variable	Description/ formula	Score range
First name	Levenstein distance used to compare ANC first name to DSS first name, accounting for string length: 1 – (Levenstein distance/ max(length name1, length name2)) ANC first name also compared to DSS last name using the same formula; the highest score is used	0-1 (identical name=1)
Last name	Levenstein distance used to compare ANC last name to DSS last name, accounting for string length: 1 – (Levenstein distance/ max(length name1, length name2)) ANC last name also compared to DSS first name using the same formula; the highest score is used	0-1 (identical name=1)
Both names match	First name score ≥0.7 and last name score ≥0.7	0 or 1 (1=both names over the threshold)
Year of birth (age)	ANC year of birth calculated from age recorded in ANC register and date of registration; DSS year of birth recorded directly in the DSS. 1-(absolute difference in DSS and ANC year of birth/ 10) Where the difference >10, a minimum score of zero is used	0-1 (identical age=1, or 0.9 (allowing for year of birth to be out by 1 year dependent on whether individual had already had their birthday or not in that year))
Village	Village of residence recorded in ANC compared to DSS village	0 or 1 (1=same village)
Pregnancy count	Number of pregnancies recorded in ANC register compared to number of children per woman in DSS (accounting for births to the same woman in another household). If these are not equal, DSS child count is divided by number of pregnancies in ANC register, or vice versa if DSS child count>ANC pregnancy count	0-1 (DSS child count=ANC pregnancy count gives a score of 1)
Delivery date (child date of birth)	Birth dates of children born to women in DSS (birth date in child's DSS record, with link to mother ID) compared to ANC registration date; Match if date of ANC registration ≤42 weeks before birth date of child	0 or 1 (1=matching date range)
Delivery period (mother report)	Recent births reported by women in DSS (did she give birth since last DSS) compared to ANC registration date; Match if date of ANC registration falls between the interview date in DSS round X and DSS round X-1)	0 or 1 (1=matching date range)
Pregnancy reports (mother report)	Report of current pregnancy by the woman at the time of DSS visit compared to ANC registration date; Match if absolute difference (interview date – ANC registration date) ≤42 weeks	0 or 1 (1=matching date range)
Residence	Periods of residence within a household (dates of entry, leaving, or returning to a household) are compared to the date of ANC registration; exact overlap is defined as the clinic visit falling within a residence episode for that DSS record, otherwise the number of days between the clinic visit and start or end of the residence episode is calculated	0 or 1 (1=exact overlap, or residence dates within 1 year of clinic visit)

ANC gold standard: statistical analysis

A descriptive analysis was conducted to investigate, by match status (true versus non-match), the distributions of the raw scores for each potential matching variable, using cross-tabulations for categorical variables (Table 3.3), and histograms and box plots for quantitative variables (box plots are illustrated in Figure 3.8 to Figure 3.11). Proportions were compared using chi square tests, while differences in distributions for quantitative variables were compared using Wilcoxon rank sum tests.

Crude and multivariate logistic regression models were then used to further investigate predictors of a true match (match status as the outcome). Quantitative versions of score variables (scores ranging 0-1) were re-scaled (multiplied by ten) for use in the models, to aid the interpretation of resulting odds ratios. Differences in distributions by match status and the relative magnitude of crude and adjusted odds ratios were used to assess the strength of associations, and the utility of each variable as a potential predictor of match status.

Table 3.3. Distribution of true and non-matches within each category of the variables.

Variable (raw score)	Category	Distribution of scores				p value**
		Non match		True match		
		n	%	n	%	
First name	<0.5	588,934	95%	100	13%	<0.001
	0.50-0.69	23,556	4%	86	11%	
	0.70-1	7,666	1%	602	76%	
	Median (IQR)	0.2 (0.1-0.3)		1 (0.7-1)		
Second name	<0.5	598,378	96%	125	16%	<0.001
	0.50-0.69	15,160	2%	50	6%	
	0.70-1	6,618	1%	613	78%	
	Median (IQR)	0.2 (0.1-0.3)		1 (0.7-1)		
Both names	≥1 name <0.7	620,077	100%	314	40%	<0.001
	≥0.7	79	0%	474	60%	
Year of birth	<0.5	352,840	57%	77	10%	<0.001
	0.5-0.8	189,949	31%	238	30%	
	0.9-1	77,367	12%	473	60%	
	Median (IQR)	0.3 (0-0.7)		0.9 (0.7-1)		
Village	Different village	497,150	80%	113	14%	<0.001
	Identical village	123,006	20%	675	86%	
Delivery dates (child DOB)	No match	485,915	78%	224	28%	<0.001
	Matching	134,241	22%	564	72%	
Delivery period (mother report)	No match	520,977	84%	605	77%	<0.001
	Matching	99,179	16%	183	23%	
Pregnancy report	No match	502,479	81%	526	67%	<0.001
	Matching	117,677	19%	262	33%	
Pregnancy count	<0.3	145,002	23%	19	2%	<0.001
	0.3-0.59	227,053	37%	133	17%	
	0.6-1	248,101	40%	636	81%	
	Median (IQR)	0.5 (0.3-0.8)		0.9 (0.7-1)		
Residency overlap with clinic visit	No (>1 year gap)	106,916	17%	110	14%	0.02
	Overlap <1 year	513,240	83%	678	86%	

*name scores, age and pregnancy count analysed as quantitative explanatory variables
**Chi square test

Figure 3.8. Box plot of first name score by match status.

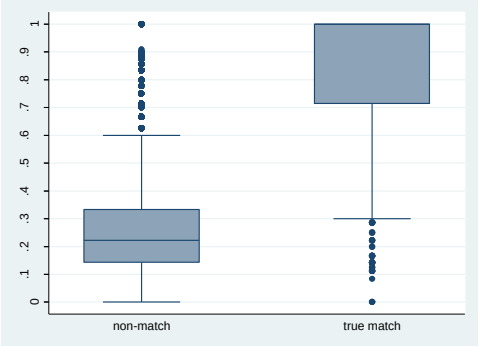


Figure 3.9. Box plot of second name score by match status.

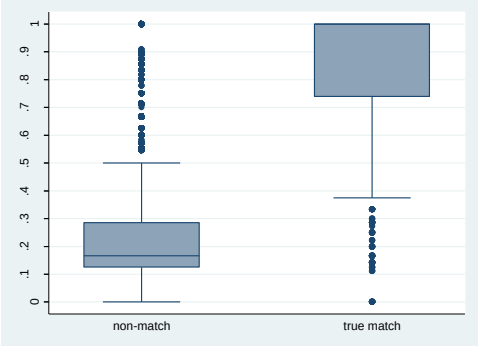


Figure 3.10. Box plot of age score by match status.

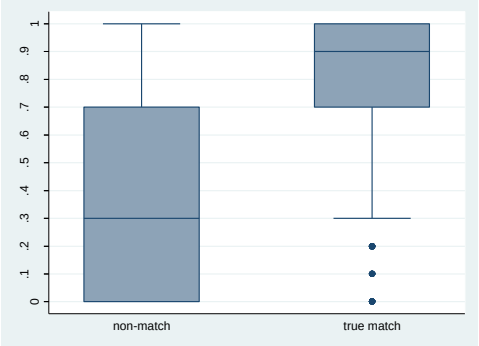
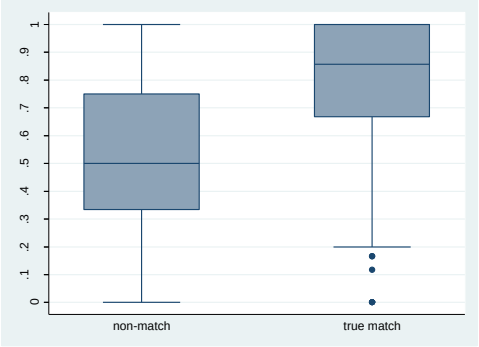


Figure 3.11. Box plot of pregnancy count score by match status.



There were statistical differences in the distributions of true and non-matches observed for all variables (Table 3.3). Name scores appeared to separate these distributions to the greatest extent, with the majority of true matches (≥60%), but very few non-matches (≤1%), having a first and/or second name score ≥0.7. Very few true matches scored below 0.2 on first and/or second name (Figure 3.8 and Figure 3.9). All true matches scoring zero on first name had a second name score >0.5, and all but two of those with a second name score of zero had a first name score >0.5 (data not shown). Although significant, the distributions of true and non-matches based on residence episodes relative to the date of clinic visit appeared less discriminatory, with a high proportion of non-matches also having residence episodes close to the date of clinic visit.

All the matching variables assessed were associated with match status in the crude analysis, and evidence remained for most of the associations in the multivariate analysis (Table 3.4). The strongest predictors of match status were first name (adjusted OR (aOR) 2.1 [95%CI 2.0-2.2] for each increase of 1 unit in the score), and second name (aOR 2.0 [95%CI 1.9-2.1]), with an independent association remaining for both first and second names matched (aOR 3.5 [95%CI 2.1-5.8])[1]. There was also good statistical evidence for associations with match status for the following: year of birth, village, delivery dates (based on child's date of birth), pregnancy reports, and pregnancy count. Residence episodes relative to dates of clinic visit were only weakly associated in the adjusted analysis, and there was little evidence remaining for an association with delivery dates based on the mother's report. Alternative categorical versions of the variables (e.g. for names and pregnancy counts) investigated produced similar results (data not presented).

[1] The adjusted OR for the variable 'both names match' is reduced substantially in the multi-variate analysis after adjusting for first name and second name, which partially explain the effect seen for 'both names match'. These three name variables nonetheless had independent effects and there was no evidence for collinearity, as some individuals with matching first names do not necessarily have matching second names and vice versa.

Table 3.4. Crude and multi-variate analysis of potential predictors of true match status.

Variable (raw score)	Category	Crude OR* (95% CI)	p value**	Adjusted OR* (95% CI)	p value**
First name	(Quantitative)	2.3 (2.2-2.3)	<0.001	2.1 (2.0-2.2)	<0.001
Second name	(Quantitative)	2.2 (2.1-2.2)	<0.001	2.0 (1.9-2.1)	<0.001
Both names	No match (<0.7) Matching (>=0.7)	1 11849 (9112-15407)		1 3.5 (2.1-5.8)	<0.001
Year of birth	(Quantitative)	1.6 (1.5-1.6)	<0.001	1.4 (1.3-1.5)	<0.001
Village	Different village Identical village	1 24.1 (19.8-29.5)	<0.001	1 23.7 (17.3-32.4)	<0.001
Delivery dates (child DOB)	No match Matching	1 9.1 (7.8-10.6)	<0.001	1 8.0 (6.1-10.4)	<0.001
Delivery period (mother report)	No match Matching	1 1.6 (1.3-1.9)	<0.001	1 1.2 (0.8-1.6)	0.4
Pregnancy report	No match Matching	1 2.1 (1.8-2.5)	<0.001	1 1.7 (1.3-2.2)	<0.001
Pregnancy count	(Quantitative)	1.5 (1.4-1.5)	<0.001	1.4 (1.3-1.5)	<0.001
Residency	No overlap Overlap	1 1.3 (1.0-1.6)	0.01	1 1.5 (1.0-2.1)	0.04

*name scores, age and pregnancy count analysed as quantitative explanatory variables where ORs can be interepreted as the OR for a unit increase in score of 1
**Likelihood ratio test
DOB, date of birth; OR, odds ratio; CI, confidence interval

These results were used to guide the choice of variables for inclusion in a total score, and weightings for each variable. Where two different scoring schemes for the same variable were investigated, for example quantitative versus categorical versions of the variable, the choice was also guided by the range of scores produced, as a greater diversity in scores would reduce the number of linkages with tied scores in the final linked dataset and resulting difficulties in choosing between DSS records for each clinic ID with tied scores.

Different combinations of variables (all those with statistical evidence for an association with match status in the adjusted models) and weights were investigated, using summary statistics (e.g. percentiles, histograms, box plots, or cross-tabulations by match status) to evaluate and compare the total scores, aiming to separate the distribution of scores for true matches and non-matches. A stepwise approach was used, adding or removing variables, or adjusting weights, one at a time, beginning with the routine identifiers.

Different cut-offs that could potentially be applied to the full linked dataset were also explored for the total scores, by calculating sensitivity (the proportion of true matches that are correctly identified by the model), PPV (the proportion of all matches declared by the model that are true matches) and specificity (the proportion of 'true' non-matches that are correctly identified by the model). Sensitivity and PPV are considered the most informative metrics for record linkage, as the number of true non-matches is usually very large, rendering the specificity (and negative predictive value – the proportion of non-matches declared by the model that are true non-matches) less useful (140). Nonetheless specificity was still found to be useful in relative terms when comparing different cut-offs and scores to one another.

These metrics were also used to compare the total scores, for example by fixing the sensitivity and calculating specificity or PPV at this cut-off, or fixing the specificity and calculating the sensitivity (see Table 3.5). The aim was to maximise sensitivity and PPV, although the priority was to limit the quantity of false positive matches, thus ensuring the quality of the eventual dataset for analysis. The initial goal was to identify a cut-off that could be applied within the matching routine, to eliminate as many false matches as possible, but without losing too many true matches (further validation steps would subsequently be taken on the resulting linked dataset, for example to select the top scoring match where multiple matches were made for one record, and de-duplication of records – see step 4).

First name score, second name score, both names matched, age score, village, delivery dates (based on child's date of birth) and pregnancy count featured in the best performing total score (final row in Table 3.5 which illustrates some of the total scores investigated). Quantitative versions of the name, age and pregnancy count scores were selected based on their greater spread of scores compared to the categorical versions. Pregnancy date reports, or an alternative summary variable including pregnancy and delivery dates, and residence dates were excluded from the total score, as they lowered its performance in terms of sensitivity and/or PPV. Different values for weights and different combinations of weights for different variables were investigated. A weight of 3 was applied to first name score and to second name score, and a weight of 1 given to the remainder. The magnitude of these weights (e.g. raising them above 3) made relatively little difference, and varying the weights applied to the other variables (e.g. village score; age; both names; delivery dates) did not improve the total score.

Table 3.5. Comparison of different total scores at fixed cut-offs.

Variables included	Specificity at a cut-off that gives 99% sensitivity	Sensitivity at a cut-off that gives 99% specificity	PPV at a cut-off that gives 80% sensitivity
Un-weighted			
First name + Second name + Age + Village	87.0%	88.7%	29.8%
First name + Second name + Age + Village + Both names	87.0%	90.4%	52.5%
First name + Second name + Age + Village + Both names + residency	69.0%	87.8%	44.1%
First name + Second name + Age + Village + Both names + Delivery dates (DOB)	82.2%	88.3%	43.4%
First name + Second name + Both names + Age + Village + pregnancy date reports	79.6%	80.0%	9.2%
First name + Second name + Both names + Age + Village + pregnancy count	82.4%	90.5%	58.3%
With weightings			
First name(x3) + Second name(x3) + Age + Village + Both names	93.1%	94.0%	45.3%
First name(x3) + Second name(x3) + Both names + Age + Village + residency	91.8%	93.3%	46.0%
First name(x3) + Second name(x3) + Both names + Age + Village + Delivery dates (DOB)	89.7%	94.8%	62.7%
First name(x3) + Second name(x3) + Both names + Age + Village + Delivery dates (DOB) + pregnancy date reports	84.4%	92.8%	52.9%
First name(x3) + Second name(x3) + Both names + Age + Village + Delivery dates (DOB) + pregnancy count	89.7%	95.2%	68.8%

Weighted scores were summed to create the final total score which ranged from 0 to 11. The distributions of the final selected total score (final row in Table 3.5) by match status are illustrated in Figure 3.12, and are compared to the distributions for the raw total score (which includes only routine personal identifiers - names, age and village) (Figure 3.13), before optimisation of the scoring scheme to include further variables or applying weights. The graphs illustrate how the optimised final total score further separated the distribution of scores for true matches and non-matches (median 2.6 [IQR 1.9-3.3] for non-matches, compared to 9.1 [IQR 7.4-10.0] for true matches), with the lower quartile for true matches (3/4 of true match record pairs) above the 99th percentile for non-matches.

Figure 3.12. Histogram of final weighted total score, by match status.

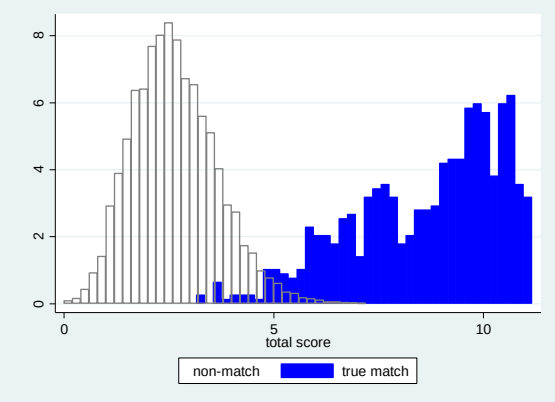


Figure 3.13. Histogram of raw total score including routine identifiers only, by match status.

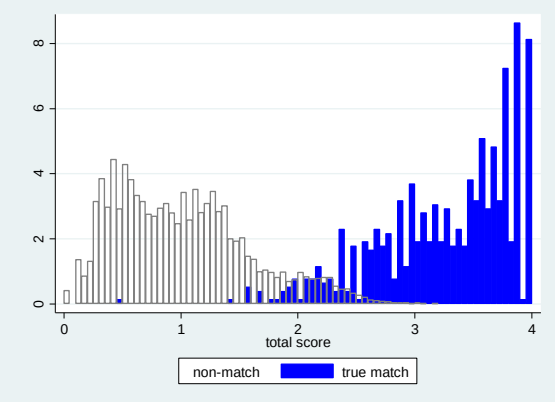


Figure 3.14. Sensitivity, specificity and PPV at different cut-offs of final weighted score.

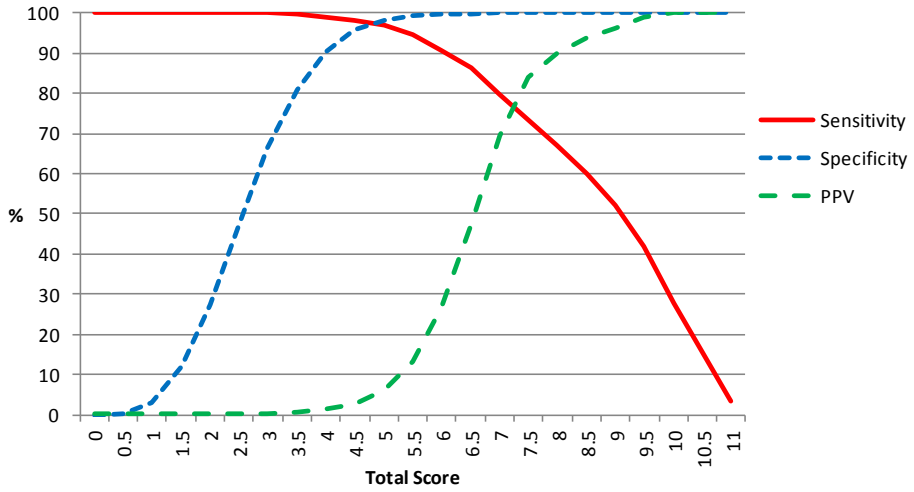


Figure 3.14 illustrates the sensitivity and specificity at different values of the final weighted total score. A cut-off at a total score of 5.4 was selected for use in the auto-matcher algorithm, giving a specificity of 99% with a sensitivity of 95%, allowing the elimination of most false matches (useful given the expected large number of potential matches for each clinic ID, and thus in reducing the size of the output dataset from the auto-matcher), whilst only losing 5% of true matches. At this cut-off, PPV was low (11%), suggesting that the output dataset would still include a sizeable volume of false matches, including a large number of possible matches found for each clinic ID. Further validation steps would therefore be required (step 4). The threshold was not raised further at this stage (to give a higher PPV), owing to the loss in sensitivity.

CTC gold standard

The gold standard data used to train the algorithms for the CTC matching exercise was based on records from VCT conducted during sero-survey 6, in which true matches (n=338) were linked deterministically via unique sero-survey ID numbers. In the absence of any data sources with definite links to the CTC, and ethical issues that would be raised by collecting information from HIV-positive individuals' personal CTC cards in the field, this was the most appropriate gold standard data available for the CTC work.

The gold standard data for the CTC was analysed using a similar theoretical approach to that used for the ANC gold standard analysis: attributes of true matches were compared to those of non-matching records (in this case name, sex, age, village and sub-village were identified as candidate matching variables), and a scoring scheme developed for probabilistic linkage of CTC clinic records to DSS records. The gold standard data and associated analysis was implemented in Microsoft Excel, using the 'solver' function to refine the weights and optimise the sensitivity, specificity and PPV of the matching tool.

I reviewed the gold standard data and helped to refine the scoring scheme by checking the plausibility of true matches, and examining false positive (declared a match by the algorithm, but without matching ID) and false negative (not assigned a match by the algorithm, but with matching ID) record pairs. This process identified errors in the code requiring correction, for example issues with missing values, and led to adjustments to the threshold score above which a match is declared by the model.

Creation of the matching algorithms (step 2)

Based on the optimised scoring schemes developed using the gold standard data, matching algorithms were written for automated probabilistic record linkage of the clinic records to the DSS.

The algorithms were used to compare the clinic dataset to the DSS data, searching for possible matches for each clinic record. In order to constrain the overall volume of DSS records searched (which would be huge - equal to the product of the total number of records in both datasets) and reduce the computing time, a technique called 'blocking' was used: rather than searching the entire DSS dataset, the search was restricted to portions of the DSS data with an exact match on a specified blocking variable (e.g only records with matching sex are compared).

Within this restricted set of DSS data, the algorithms compared each clinic record to every DSS record, calculating component scores for each pair of variables, and summing these to produce a total score for each record pair (based on the matching variables, scoring schemes and weightings selected in the preparatory gold standard analysis). A cut-off at a specified value of the total score was applied (again based on the preparatory work), below which records were dropped and above which records were declared a match and retained in the output linked dataset.

ANC matching algorithm

The ANC auto-matcher was implemented in Stata. For each ANC clinic record in the general pregnancy register (dataset from 2005 to 2012), DSS records were searched, blocking on females of reproductive age (aged 15-49 at some point between 2005 and 2012). Record pairs with an age (year of birth) difference of more than 20 years were also excluded, as were record pairs with very low name scores (both first and second name scores <0.2; zero for first name score with second name score <0.5, or vice versa).

Total scores were calculated for the remaining comparisons using the optimised total score developed in the ANC gold standard analysis, retaining record pairs with a total score above the identified threshold of 5.4, as described in step 1 above.

CTC matching algorithm

The matching algorithms were implemented in SQL for the CTC data. Each CTC clinic record (dataset from 2005 up to 2012) was compared to all DSS records, with sex used as a blocking variable. Constraints were also placed on the names scores (>0.6 on

both first and second name) and age difference (≤10 years) between the clinic and DSS record pairs. The total score included name, sex, age, village and sub-village; further details of the optimised total score, including the component scoring schemes, weights, and the threshold value are provided in appendix 12.5.

Running the matching algorithms (step 3)

The matching algorithms were run, checking for errors in the code, and the time taken to process the matches. The limited computing capacity to cope with the large volume of records, and consequent length of time taken to run the algorithms, partly influenced the decisions to block on certain variables (as outlined in step 2). Although data managers were responsible for running the CTC matching algorithm, I helped scrutinise the performance of the algorithms, including the total number of linkages made and linkage rate (proportion of clinic records linked to any DSS record), and gave feedback regarding any possible errors in the code that were preventing the algorithms from running correctly.

The algorithms generated linked datasets that were characterised by multiple DSS records linked to most clinic records; in some cases hundreds of DSS records were matched per clinic record. Details of the output linked datasets for each matching algorithm were as follows:

ANC matching algorithm output

The initial linked dataset generated using the ANC auto-matcher contained 16,494 ANC records (visits) that were linked to at least one DSS record (out of a total of 16,601 ANC clinic records entered). Two hundred and thirty ANC records (1%) were linked to only one DSS record, and approximately half were linked to ≤30 DSS records, with a maximum of 742 potential matches per ANC record among the remainder.

CTC matching algorithm output

The linked dataset resulting from the CTC matching algorithm contained 1003 CTC records matched to ≥1 DSS record (linkage rate of 79% out of 1269 CTC records from Kisesa in the database up to December 2012). Two percent of linked CTC records were only matched to 1 DSS record, approximately half were linked to ≤100 records, and a maximum of 1108 potential DSS matches per CTC record.

Linkage validation (step 4)

The primary goal of the validation steps, applied to the output datasets generated by the auto-matchers, was to reduce the number of potential matches for each clinic

record and to select the best match. Validation steps for the ANC and CTC datasets made use of reported deaths and residency information from the DSS, the rationale being that many of the multiple matches would likely reflect the same individual who had moved and been assigned a different DSS identifier in the new household. All record pairs with a death recorded in the DSS prior to the date of clinic registration were eliminated, as well as any record pairs for which the person had left the study area prior to 2005 (start of the clinic datasets). Additional validation steps included de-duplication of cases of the same DSS record (or records with different DSS numbers but the same sero-survey identification number, representing individuals who had moved household but were known to be the same person as they had attended a sero-survey in each household) being matched to more than one clinic record, where appropriate (where this could not be the same person). Some elements of the approach for the ANC and CTC linkage validation differed, due to the difference in information available and size of the linked datasets: a component of clerical review was undertaken for the CTC matches, which was not possible for the ANC matches given the large volume of ANC clinic records (over 10,000). Details of each approach are outlined below.

ANC linkage validation

For each ANC clinic ID, the top scoring match was selected. Where the same DSS record was linked to more than one ANC clinic record (ANC visit), these were examined to see if they represented the same woman attending the clinic in different pregnancies, and de-duplicated if they were not compatible: dates of registration at ANC within 9 months of each other were considered incompatible with distinct pregnancies. In these cases, records with the highest total score were prioritised, dropping the lower scoring matches with another ANC record. Ties on the top rank (n=473 ANC records each linked to 2-4 DSS records with identical scores) were resolved by selecting the record with a residence episode closest to the date of clinic visit, otherwise by random selection.

The dataset containing the gold standard links was used to calculate the PPV and sensitivity of the entire procedure (auto-matching algorithm plus subsequent validation steps) for linking the ANC records to the DSS: PPV was calculated as 98% (10 false positive matches made) and the sensitivity to detect true matches was 70%. The final linked dataset contained DSS links for 12,396 ANC records (a linkage rate of 75% out of the initial 16,601 ANC records entered including women from villages inside and outside of Kisesa).

CTC linkage validation

An additional step was added to the CTC linkage validation procedure. HIV test results (from research testing in sero) were merged into the linked dataset using the DSS ID, and record pairs with two negative HIV test results documented either side of the date of registration at CTC were flagged and dropped. Those who had only one negative test result after the CTC registration date were flagged but not dropped immediately, due to a lower certainty based on one test result (possible error in the result). This information was used to discriminate between record pairs with tied scores; dropping the record pair with a negative test result post-CTC registration when the other tied record pair did not have a negative test result. Records with negative results prior to the CTC registration were not flagged as the individual may have sero-converted since the last test date.

In contrast to the ANC linkage scenario, the same DSS ID could not theoretically be linked to more than one CTC ID, as the CTC ID represents one unique ID maintained over time for all future visits to that clinic (the chance of a person being reassigned a different CTC ID is very small, although theoretically possible due to a combination of office error and the person not bringing their CTC card). De-duplication of these cases arising within the linked dataset was similarly done by selecting the record pair with the highest score and eliminating the other lower scoring duplicate record pair.

CTC records for women of reproductive age (15-49) in the linked dataset were subjected to clerical review. This process was initiated by sorting the record pairs on total score, then browsing the matches and determining a threshold above which record pairs appeared to be certain matches, and a threshold below which record pairs appeared to be mis-matched. Those below the threshold were dropped, while record-pairs between the upper and lower threshold were reviewed. In addition to the personal identifiers used in the matching routine, other variables were inspected including HIV status (e.g. flag for a negative HIV test result recorded after the CTC registration date), and residence episodes relative to the date of CTC registration. The most likely match was selected for each CTC record, or in cases where none of the links for a particular CTC record appeared viable, all links were dropped.

The final CTC linked dataset contained DSS links for 760 women of reproductive age (679 (51%) were a subset of the 1324 women of reproductive age in the CTC from within or outside Kisesa, according to dates of birth recorded in the CTC dataset; a further 81 links were made between women of reproductive age between 2005 and 2012 according to their dates of birth on file in the DSS).

Ethical considerations for linkage procedures

Development of the matching routines necessitated viewing of names and other personal demographic identifiers in the gold standard and interim (draft) linked datasets by the data managers and researchers. Ethical clearance to cover these aspects of the linkage process and the analysis of resulting linked datasets was obtained from the LSHTM and the Tanzanian MRCC review boards (appendix 12.2.2). Only a restricted team of researchers and data managers who have completed ethics training (including myself) had access to interim linked datasets with names and other personal demographic identifiers. The gold standard and interim linked datasets containing names were stored on secure servers at NIMR (primarily), LSHTM, and on my personal laptop, all with password restricted access. Prior to using the linked results for statistical analyses, all personal identifying information, including names, were stripped from the datasets, leaving only numerical scores and ID numbers. No data in this thesis has been reported below the village or grouped area level (e.g. trading centre, roadside or remote villages).

Strengths and limitations

The key strength of the data linkage was the robust automated approach using algorithms developed with gold standard datasets, whereas data linkage has often relied solely on more manual and subjective approaches that are generally not feasible with very large datasets. The PPV of the ANC algorithm (98%) was very high, and the CTC algorithm, using a similar approach, was subjected to an additional step of clerical review.

The primary limitations reflect constraints of the input datasets. Firstly, the number of matching variables was limited, while other record linkage studies have suggested that increasing the number of matching variables, for example to include the first name of another household member, can substantially improve the sensitivity and PPV of the algorithm (140). Ideally, the gold standard links would not have been subjected to any clerical review, because some of the same information (e.g. names) was used subsequently in the probabilistic record linkage procedure. However, the potential for error, as a result of duplicates arising from the ANC numbering system, meant that this step was necessary to ensure the accuracy of the gold standard. The proportion of records with missing values for the matching variables was not large (e.g. <1% with missing pregnancy number in the ANC dataset), but may also have introduced errors (less likely to positively identify the match). While imputing the information may have increased the chances of identifying the match, it may also have increased the chances

of mismatches (although in the case of the pregnancy number, the decision was taken to impute the number because by definition a woman attending the ANC must have at least one pregnancy).

3.4 Statistical analysis methods

All statistical analyses were conducted in Stata 12 (StataCorp LP, Texas, USA). Analyses for both quantitative results papers included in the denominator HIV-positive women who were resident in the DSS area during the period 2005-2012 (corresponding to the time of clinic data abstraction) and were pregnant (while HIV-positive) during the same interval. HIV-positivity was defined based on a positive HIV test result at any sero-survey, and for the analysis of coverage with PMTCT services (paper C) also included women whose DSS record was linked to an HIV-positive clinic record (for women with no HIV test results from sero-surveys, or who had sero-converted since last testing HIV-negative). The analysis of predictors of PMTCT service use (paper D) was restricted to women who had attended and tested HIV-positive at the sero-surveys, to ensure that a like for like comparison was possible in terms of the characteristics of service users and non-users, comparing the group with the outcome to the group who could potentially have had the outcome. Dates of HIV sero-conversion were estimated by taking the mid-point between the date of the first positive and last negative test result. For cases with no prior HIV-negative test date available, the date of sero-conversion was assumed to be three years prior to the first HIV-positive test date (based on data for the average duration of infection for sero-incident cases by sex and age group). Sources of pregnancy information included children's dates of birth with links to mothers, self-reports by mothers in the DSS and sero-surveys of recent pregnancies and births, and pregnancies recorded in clinic records. Analyses were carried out at a pregnancy level, with all pregnancies since the estimated date of HIV sero-conversion (within the time period 2005-2012) included in the denominator.

A descriptive analysis of uptake of PMTCT services was conducted for paper C. The proportion of women accessing PMTCT service components (ANC, HIV testing, enrolment in PMTCT care, access to ARV prophylaxis or ART, registration at the CTC), per pregnancy, was calculated overall and by year of pregnancy. Access to PMTCT services was ascertained based on linkage of a woman's DSS record to health facility records. To determine service access during a particular pregnancy, dates of pregnancies and clinic attendance were aligned. Diagnosis of HIV for women who did not access the clinic was based on attendance at VCT during sero-surveys, or self-reported usage of VCT services in the sero-survey interview. Diagnosis at ANC incorporated test results derived from linkage to PMTCT testing registers, or diagnosis at earlier VCT. It was assumed that women who attended ANC (found in the general ANC registers) but who could not be linked to the PMTCT ANC (test) registers had not

tested. Women who were linked to the test books but had a negative test result were assumed to be undiagnosed at ANC, unless they had also been found in the PMTCT registers or CTC database. Access to ARVs during pregnancy was defined using entries in the PMTCT registers (if the relevant field was left blank, and the date for dispensing ARVs was also left blank, it was assumed that no ARVs had been dispensed), or recorded initiation or continuation of ART (before the recorded or estimated delivery date; delivery dates are sometimes recorded in the CTC database, and were otherwise estimated based on the gestational age of the woman at ANC registration and the ANC registration date) in the CTC database.

To account for matches (cases of clinic attendance) that may have been missed by the linkage algorithms, raw coverage estimates for attended ANC, enrolment in HIV care (PMTCT or CTC) and access to ARV drugs during pregnancy were adjusted by dividing by the proportion of Kisesa-resident clinic records that were not linked to the DSS in each calendar year (of pregnancy) or alternatively by the sensitivity of the linkage algorithm. Access to HIV care and ARVs were focussed on as these outcomes represent access to the minimum intervention to prevent MTCT of HIV. Some women who were linked (via automated record linkage) to the CTC were not found in the ANC registers. Adjusted estimates of coverage with ANC services excluded such cases and were based on linkage to ANC records. The overall proportions of Kisesa-resident ANC records and CTC records that were not linked to any DSS record were similar (79% versus 78% respectively), so the proportion for the ANC was used in the coverage adjustments. The proportion of CTC records linked to the DSS by year of pregnancy was not available, as dates of pregnancy were not often recorded in the CTC dataset, so again the proportions of ANC records linked in each year of registration were applied. Further adjustments were made by dividing estimates by the proportion of women who may have accessed HIV services outside of Kisesa. Although this proportion is not known, among the women who participated in sero7 and had attended ANC in their last pregnancy (n=2045), 12% had attended ANC outside Kisesa (in Magu district hospital (0.5%), clinics in Mwanza city (3%), or elsewhere).

To further explore the performance of the PMTCT programme in terms of linkage to HIV care and treatment services, Kaplan Meier analysis was used to examine time to CTC registration following pregnancy for HIV-positive women. Time was calculated from the date of ANC registration (or the reported pregnancy date if the ANC registration date was unknown) until the date of CTC registration (or the date of the next CTC visit if the individual was already registered at the CTC), or the DSS exit date (out-migration, death or enumerated in the most recent DSS round), or the end of the

study period (31st December 2012, with no CTC data available subsequently) if this came before the DSS exit date. Differences in time to CTC registration by calendar year of pregnancy were explored visually with survival plots and statistical differences were assessed using log-rank tests.

Factors associated with uptake of PMTCT services in the cohort (paper D) were analysed using the denominator of HIV-positive pregnancies restricted to sero-survey attendees, and restricted to pregnancy records within 5 years of a sero-survey interview date (to exclude data from sero-survey interviews many years previously in sero1-3 which were likely to be out of date by the time of pregnancy, for example knowledge of HIV). Data were analysed firstly by cross-tabulating each explanatory factor, described below, with PMTCT service outcomes.

Explanatory variables were prepared using questions from the sero-surveys and information from the DSS, using the data point closest to the date of pregnancy. Factors for investigation were chosen according to *a priori* hypotheses, for example based on factors that were identified in the systematic literature review, or predictors of access to other HIV services in Kisesa, or drawing from findings emanating from the qualitative component of this thesis. The choice of factors was also limited by the consistency of questions across sero-survey rounds. Knowledge of HIV transmission was based on asking participants to name any modes of HIV transmission they were aware of, without prompting by the interviewer but probing for more than one answer. Knowledge of ART drew from 5 true or false statements about ART in the sero-survey: 1) “Drugs can only slow down HIV illness, not stop it”; 2) “ART drugs are very dangerous and can kill people”; 3) “ART drugs have to be used for life”; 4) “ART drugs are available free of charge in Tanzania”; and 5) “Everyone who is infected with HIV needs drugs”. The total number of correct statements given by the participant was used. Given the potential for reverse causality, as knowledge was hypothesised to change as a result of attending HIV services, responses in sero-survey interviews preceding the pregnancy date were distinguished (separate category) from answers recorded after the pregnancy date. Death of any children was defined using mothers’ self-reports during sero-survey interviews of any miscarriages, still births, or child deaths. Use of VCT services before pregnancy was defined based on recorded attendance at VCT offered at the sero-surveys, or self-reported use of any VCT services based on a sero-survey interview question. HIV status of male partners was ascertained using spousal links in the DSS, and sero-survey HIV test results of the spouse. Duration of HIV infection used the time period between the estimated HIV sero-conversion date and the date of pregnancy. Quantitative variables were

categorised using pre-defined categories, with the exception of age (at the time of pregnancy) which was modelled as a continuous variable (one way of dealing with the fact that there were no women with the outcome in the lowest pre-defined age category, and to exclude the potential for residual confounding when using a categorised version of the variable).

PMTCT service outcomes assessed for the risk factor analysis presented in paper D were: 1) registered in the PMTCT programme and/or at the CTC during or prior to pregnancy ('HIV care'); and 2) accessed ARV drugs during pregnancy, based on entries in PMTCT registers or the CTC database, as described above for the analysis of uptake.

Logistic regression models were built to identify independent predictors of access to PMTCT services. Logistic regression methods were chosen in favour of a time to event analysis given the short and relatively homogeneous follow-up time per pregnancy, and difficulties with assigning dates for all time changing covariates for a longitudinal multiple event analysis. To account for clustering of multiple pregnancies per woman, random effects logistic regression was used. The reliability of estimates was assessed for each model by checking the quadrature approximation (e.g. checking for stability, with a relative change in coefficients <0.01%, when varying the number of quadrature points) and increasing the number of quadrature points if necessary to improve the approximation.

Crude odds ratios were calculated for the association between each explanatory variable and each outcome. All factors with statistical evidence for an association ($p \leq 0.1$) were investigated in the multi-variate analyses. A forwards stepwise approach was used to add each explanatory factor into the model, using likelihood ratio tests to determine if the variable significantly improved the model fit ($p \leq 0.1$). Variables which improved the fit were retained. Interactions with year of pregnancy and age were assessed *a priori*. Departure from linearity assumptions were assessed for age (modelled as a continuous variable) using likelihood ratio tests.

4 Paper B. Optimising routine data sources for PMTCT programme monitoring in Africa: lessons learned from Tanzania

Introduction to the paper

The following paper is a short commentary that discusses the value of routinely collected clinic data for monitoring PMTCT programmes in sub-Saharan Africa. The possibility of linkage to community research datasets for population-level estimates of coverage with PMTCT services is proposed, while some of the challenges that need to be overcome in order to make the most out of this potentially rich data source are outlined. The idea for this paper was conceived while collecting the quantitative data for this thesis, based on observations of the clinic log books, procedures relating to data capture in the clinics, conversations with health providers, and preparing the datasets for linkage and analysis. Some of the difficulties with using the data, such as duplicate identification numbers and lack of linkage between maternal and infant records, were described in further detail in the previous chapter. The examples within the paper are drawn primarily from these observations and experiences in Tanzania, while the scope of the paper was widened by making comparisons to the data collection systems in other countries in sub-Saharan Africa.

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   I managed the process for collection of routine clinic data, and wrote the manuscript.

   .....

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Submitted manuscript

Prevention of mother-to-child transmission (PMTCT) HIV services have recently come under the spotlight, with the United Nations (UN) Global Plan and Millennium Development Goals outlining ambitious targets for the elimination of new paediatric HIV infections, and for improvements in maternal and child health by 2015 (2, 3). Despite considerable progress - a reduction of 60% in new HIV infections in children globally between 2001 and 2013 - an alarming number of infections continue to take place: 240,000 estimated in 2013 (1). Africa bears the brunt of the epidemic with over 90% of paediatric infections occurring in the region (1).

PMTCT programmes comprise a cascade of services including provider-initiated HIV testing at antenatal clinics (ANC) and labour wards, provision of antiretroviral (ARV) drugs (prophylaxis or life-long antiretroviral treatment (ART)) to HIV-positive pregnant women and their infants, delivery in a health facility, infant HIV testing, and long-term HIV care. Collection of high quality routine data on these services and outcomes for HIV-positive mothers and HIV-exposed infants is not only essential for monitoring and evaluation of PMTCT programmes relative to local, national and international targets, but is also paramount in the clinical management of patients and in managing stocks of HIV test kits and drugs. Recording and using data from each service component is important, as one component may suggest high coverage and impact, but may mask drop-outs further along the cascade (144).

Linkage of PMTCT clinic data to community-level research data such as demographic surveillance systems (10 sites in Africa with HIV sero-surveillance (145)), could provide direct estimates of coverage with PMTCT services; currently a problematic statistic. Recent UNAIDS estimates for several African countries are unrealistic, with coverage reaching over 95% (1). This suggests over-reporting of the number of pregnant women receiving ARVs (the numerator, based on aggregate statistics using routine clinic records), or inaccuracies in estimating the number of pregnant HIV-positive women (the denominator). Inaccuracies in calculating this core indicator can have profound implications, including for negotiating donor funding for PMTCT programmes, monitoring progress towards internationally agreed targets, identifying weaknesses in PMTCT programmes and subsequently implementing necessary interventions to bring about improvements in coverage. As such, improvements in the accuracy of routine data and additional methods for direct measures of PMTCT coverage are urgently needed.

PMTCT data are routinely collected in maternal and child health (MCH) clinics in Africa, reflecting integration of the PMTCT programme into these services. The degree of integration between MCH and HIV care and treatment services varies, with some MCH and HIV clinics located on the same site, and other stand-alone ANCs referring HIV-positive patients to HIV clinics elsewhere. Infant blood samples are usually collected on-site, but are often tested for HIV at larger hospitals that house the necessary laboratory equipment. The spectrum of PMTCT services may thus encompass several physical locations within one facility, or incorporate different facilities, adding to the complexity of data capture and linkage throughout the service continuum.

The collection of routine PMTCT data in many African clinics takes place using various paper-based registers, each covering a different service step. Taking Tanzania and Malawi as examples, HIV test results, ARV drugs dispensed during pregnancy, ARVs during delivery, and infant HIV test results are recorded across three or four different registers. In some contexts, including Tanzania, these registers are used alongside the standard suite of MCH registers (e.g. general pregnancy register that records patient names without HIV test results). This constitutes a large volume of paperwork, with duplicated information, and a consequent burden on staff workload.

The ability to track outcomes of women and infants through the entire PMTCT cascade is contingent on linking records held in each PMTCT register, and on linking maternal and infant records. This necessitates a unique identification (ID) number for each woman and infant. However, current systems for assigning IDs can give rise to duplicates, presenting considerable challenges when attempting to link records and monitor programme adherence and retention, and reducing the accuracy of reported statistics (e.g. the numbers of women accessing ARVs). The lack of unique identifiers within MCH/PMTCT services is not an issue confined to Tanzania, having been noted in Kenya and Malawi (146).

In Tanzania and Malawi, ANC numbers are assigned to pregnant women on their first ANC visit, but each facility uses the same numbering system, giving rise to duplicate ID numbers between clinics. Switching facilities is fairly common, particularly for delivery, and it is then difficult to distinguish between patients from different facilities assigned the same ANC number (duplicate IDs). Equally problematic is the identification of women who are assigned a new ANC number when they change clinics, and thus appear on two distinct registers with different IDs (multiple IDs). The ANC numbering system is used to identify patients within the PMTCT programme, with no specific PMTCT identifiers assigned. Tanzanian PMTCT registers do not contain patient

names for confidentiality reasons, so the ANC number is the only means of linking patient records held in different PMTCT registers within the same facility. The ability to monitor patients' clinical progress and attendance at each PMTCT service is therefore compromised by the lack of unique ID, with the potential for mis-matching records. Duplicate and multiple IDs also complicate the linkage of ANC and HIV clinic records, or maternal and infant PMTCT records (historically a weakness of PMTCT data, although commendable improvements have been made in Tanzania to capture both the infant and mother's identifier in one register), and the aggregation of data at a national level.

General data quality issues, such as missing data (ANC numbers, follow-up visits, and loss of log-books) and duplicate records, also limit the accuracy of results based on routinely collected data. It is likely that health workers' limited engagement with the data for their own planning, monitoring or research purposes is the primary explanation for poorly completed and stored records.

Ideally, pregnant women and their infants should each be assigned a unique ID number on enrolment into the PMTCT programme. Tanzanian HIV care and treatment clinics (CTC) have already implemented a unique numbering system for patients, based on area and facility codes where the person first registers for care, plus serial number. This unique identifier is maintained when patients change facility; documented on transfer forms and patient-held cards. A similar system is currently being implemented in Tanzanian MCH services for HIV-infected pregnant or breastfeeding women as new guidelines are rolled out (Option B+, lifelong ART for all pregnant women (16)), although it might theoretically be used for all pregnant women. Ideally, each clinic would be issued a list of unique numbers by a central office, to be allocated to patients upon registration.

While investments in establishing electronic medical records in MCH services would clearly facilitate data storage and usage, the costs and infrastructure required would be prohibitive in many African countries. Useful enhancements can be made to paper-based systems: the patient's unique ANC/PMTCT number would be recorded in each register by each clinic, as well as on the woman's ANC card with the dates of attendance at each PMTCT service, and on the infant's under-5 card. Issuing a booklet to women documenting multiple pregnancies, similar to the 'health passport' used in Malawi, and maintaining the same ANC number, would avoid double-counting women in programme coverage statistics and aid clinical management by making patients' pregnancy history more accessible to health workers. Use of filing systems

with patient records filed by the number of the health passport, with clinical information updated at each visit would also facilitate cross-service links for each patient, and could aid the production of summary reports.

Health workers should be trained about the importance of recording the ANC number, or tracing it from earlier ANC records with the aid of the registration date if the woman returns without her ANC card (a common reason for missing identifiers), and motivated to take ownership of the data for their own monitoring purposes. The importance of bringing ANC cards to all follow-up visits, including delivery and child clinics, should be emphasized to pregnant women and their relatives. Streamlining PMTCT registers into fewer books, where services take place in close proximity, would facilitate follow-up and reduce paperwork for health workers. In facilities where statistics are compiled manually for reporting to higher levels, distinguishing *first* receipt of each service (e.g. first ANC visit per pregnancy, or first positive HIV test), would avoid double counting (e.g. when patients switch clinics) without the need to search on ID number.

To further strengthen the linkage between ANC and HIV clinic records, CTC IDs must be accurately recorded by nurses in all PMTCT registers, while CTC clinicians and data entry clerks should be trained to record the ANC number of pregnant HIV-positive patients in HIV clinic records (rarely documented in the available field in Tanzania). It is also important to capture HIV-exposed infant ID numbers alongside mother IDs, as well as infant prophylaxis and HIV testing results: useful additions that have recently been made to the Tanzanian CTC database.

Strengthening the indexing and recording of routine PMTCT data would not only capitalize on this rich data source for service monitoring and patient management at a facility level, but would facilitate more accurate estimates of PMTCT programme coverage at a national level, and reduce the burden for health workers. We must ensure that data monitoring systems keep pace with rapidly evolving guidelines and advances in PMTCT service delivery.

5 Paper C. Uptake of services for prevention of mother-to-child transmission of HIV in a community cohort in rural Tanzania from 2005 to 2012

Introduction to the paper

Paper B discussed the potential for extending the usage of routine clinic data to providing estimates of coverage with PMTCT services, through linkage of the clinic data to community cohort records. The following paper (C) presents an analysis of the linked clinic-cohort datasets, created through the processes described in chapter 3, providing coverage estimates for PMTCT service use among HIV-positive pregnant women in the community of Kisesa, Tanzania.

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   I managed the collection and entry of routine clinic data, I linked the clinic data to the Kisesa cohort data and designed the antenatal clinic data matching algorithm, I analysed the data and wrote the manuscript.

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Submitted manuscript

5.1 Abstract

Background: Estimates of population-level coverage with prevention of mother-to-child transmission (PMTCT) services are vital for monitoring programmes but are rarely undertaken. This study describes uptake of PMTCT services among HIV-positive pregnant women in a community cohort in rural Tanzania before the implementation of Option B+.

Methods: Kisesa cohort incorporates demographic and HIV sero-surveillance rounds since 1994. Cohort data were linked retrospectively to records from four Kisesa clinics with PMTCT services from 2009 (HIV care and treatment clinic (CTC) available in one facility from 2008; referrals to city hospitals for PMTCT and antiretroviral treatment (ART) from 2005). The proportion of HIV-positive pregnant women residing in Kisesa in 2005-2012 who accessed PMTCT service components (based on linkage to facility records) was calculated per HIV-positive pregnancy and by year.

Results: Out of 1497 HIV-positive pregnancies overall (849 women), 26% were not linked to any facility records, 35% registered for ANC but not HIV services (29% were not tested at ANC or diagnosed previously), 8% enrolled in PMTCT but not CTC services (6% received antiretroviral prophylaxis), and 32% registered for CTC (14% received ART or prophylaxis) (raw estimates). Adjusted estimates for coverage with ANC were 92%, 57% with HIV care, and 29% with antiretroviral drugs in 2005-2012, trending upwards over time.

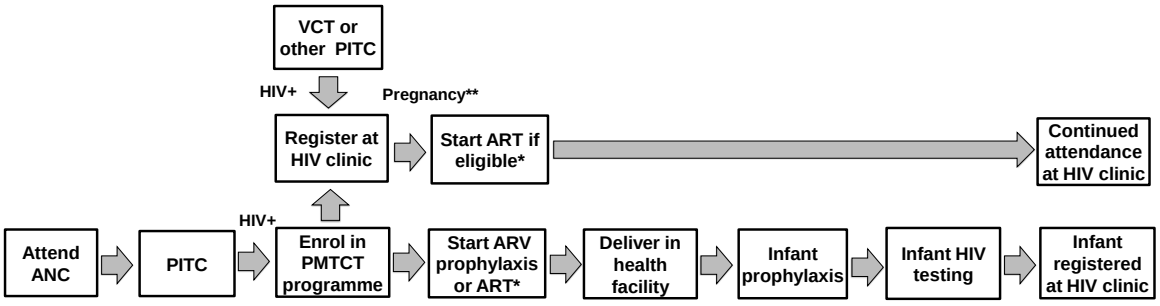
Conclusions: Population-level coverage with PMTCT services was low overall, with weaknesses throughout the service continuum, but increased over time. Option B+ should improve coverage with antiretrovirals for PMTCT through simplified decisions for initiating ART, but will rely on strengthening access to CTC services.

5.2 Background

In 2011, the United Nations Global Plan set out ambitious targets to eliminate mother-to-child transmission of HIV by 2015 (2). Scale-up of prevention of mother-to-child transmission (PMTCT) programmes has contributed to an estimated reduction of 60% in new paediatric HIV infections since 2001, although 240,000 infections still occurred globally in 2013 (1). Most infections via mother-to-child transmission occur in sub-Saharan Africa (1), with 21 of the 22 Global Plan priority countries, including Tanzania, located in the region (2). Estimates suggest 65% of HIV-infected pregnant women living in these countries received antiretroviral drugs for PMTCT in 2012, falling short of targets for universal coverage (5).

PMTCT programmes include a 'cascade' of services beginning with antenatal clinic (ANC) attendance and provider-initiated HIV testing and counselling (PITC) (Figure 5.1). Pregnant women diagnosed with HIV are referred to HIV clinics for long-term care and treatment, are provided antiretroviral drugs, are advised to deliver in a health centre, and are counselled about infant feeding. HIV-exposed infants receive ARV prophylaxis, are tested for HIV, and if diagnosed HIV-positive are enrolled in HIV programmes. Global PMTCT guidelines have evolved from short-course ARV prophylaxis for mothers and infants to prevent HIV transmission, towards longer and more potent ARV regimens with the potential to improve maternal health (16, 55). The latest guidelines ('Option B+') recommend all HIV-positive pregnant women initiate ART for life (16). Several African countries have adopted this approach, including Tanzania which began implementing Option B+ in 2013 (21).

Figure 5.1. PMTCT cascade of services for mothers and infants.



ANC Antenatal Clinic; ARV Antiretroviral; ART Antiretroviral Therapy; PITC Provider-Initiated Testing and Counselling; VCT Voluntary Counselling and Testing
*ARV prophylaxis for PMTCT, or ART for the woman's own health if she meets eligibility criteria
**Woman was pregnant at the time of VCT or other PITC, or became pregnant after registration at the HIV clinic, before or after starting ART.

Estimates of coverage with PMTCT services among all HIV-infected pregnant women are vital to monitor progress relative to targets, and to secure donor funding for PMTCT programmes (147). Measuring coverage for each component of the cascade can highlight programme weaknesses where a disproportionately high number of women fail to receive PMTCT services. However, national-level PMTCT coverage may be over-estimated due to problems with the quality of aggregated programme data (numerator) and estimating or modelling the number of pregnant HIV-positive women (denominator) (147). Furthermore, national-level estimates may mask substantial regional differences in coverage, but regional-level estimates are rarely available. Most research investigating uptake of PMTCT components starts from the point of programme entry, missing HIV-infected women who are undiagnosed, or diagnosed but do not seek services (60).

Linkage of community research data to routinely collected clinic data provides an important opportunity to calculate direct estimates of coverage with PMTCT services, yet very few studies have used this approach (147). A recent study from a demographic surveillance site (DSS) in Malawi determined uptake of PMTCT services by linking records of DSS residents to health service data, reporting sub-optimal uptake of ART (67% on ART during pregnancy or delivery) in the context of Option B+ (19). High coverage (96%) of ANC services but only 64% coverage with HIV testing during pregnancy was documented within a population cohort study in Uganda (148). No studies have provided direct estimates of PMTCT service coverage over time since the implementation of PMTCT programmes at a local level, nor the coverage at successive steps of the cascade, despite the value of such data for service monitoring. We therefore use data from a community cohort study in north-west Tanzania to describe and measure uptake of PMTCT services among HIV-positive pregnant women, including trends over time since the introduction of HIV and PMTCT services to the area.

5.3 Methods

5.3.1 Setting

This study took place in Kisesa, a rural community of approximately 30,000 in north-west Tanzania, 20km to the east of Mwanza city in Magu District. Population HIV prevalence was 6% in women in 2011 (149) and 8% among pregnant women during ANC surveillance across Magu district in 2006 (150).

Four government-run health facilities in Kisesa offer PMTCT services (since 2009). The health centre in the trading centre includes an ANC, voluntary counselling and testing (VCT) clinic (opened 2005), and HIV care and treatment clinic (CTC) (opened 2008). Between 2005 and 2008, pregnant women diagnosed HIV-positive at the VCT clinic were referred to Bugando hospital in Mwanza city for PMTCT services. Three dispensaries, located 5-10 kilometres from the health centre in more rural villages, offer basic PMTCT services including HIV testing at ANC, provision of ARV prophylaxis when stocks are available, and referral to Kisesa health centre CTC.

Until 2011, national guidelines recommended ARV prophylaxis for HIV-positive pregnant women from 28 weeks gestation, during delivery and post-partum for 7 days, with infant ARV prophylaxis recommended for ≤4 weeks after birth (30). Women with CD4 counts <200 cells/mm^3, clinical stage 4, or clinical stage 3 with CD4 <350 were eligible to initiate ART (30). In 2012, the threshold for ART eligibility was raised to CD4<350, and prophylaxis was prescribed from 14 weeks gestation until 7 days post-partum to mothers and until cessation of breastfeeding for infants ('Option A', (134)).

5.3.2 Demographic and HIV sero-surveillance

An open cohort study has been ongoing in Kisesa since 1994, including a demographic surveillance system (DSS) with rounds (28 to-date) of household enumeration every 4-12 months recording pregnancies, births, deaths, migrations, and 7 rounds of HIV sero-surveillance at approximately 3 year intervals (sero7 in 2013). Adults aged ≥15 are eligible to participate in the sero-surveys. Participants who give their consent are tested for HIV without disclosure of results, are offered VCT (since 2004), and are interviewed about their use of health services. Detailed methods for the cohort were described previously (137, 151).

5.3.3 Clinic data

ANC pregnancy registers for 2005-2012 and PMTCT programme registers for 2009-2012 were collected retrospectively from all four Kisesa-based facilities. Less than 10% of records were missing[2]. Data were double-entered into a custom-built database by trained data entry clerks at the National Institute of Medical Research in Mwanza, and stored on a password-restricted computer network (PMTCT programme registers contain registration numbers: names of HIV-positive patients are not visible). CTC data are entered into a national database by government data entry clerks. Data were

[2] Approximately 1-18 months out of 96 months of ANC register data were missing from each dispensary; approximately 7/96 months of data were missing from the health centre

abstracted from 2005-2012 (names are stored in encrypted format), including data for Kisesa-resident patients who initially enrolled at Bugando CTC.

5.3.4 Record linkage

Clinic records were linked to community cohort data with an automated matching procedure using personal attributes such as name, sex, age, and pregnancy dates. The algorithm was developed using a gold standard based on anonymous identification numbers collected from women's ANC cards during DSS round 27. Approximately 80% of ANC and CTC clinic records for women from Kisesa were linked to a DSS record. Positive predictive value of the algorithm was 98%, with a sensitivity of 70%. CTC records for women of child-bearing age were matched using a similar algorithm. Clinic records for the same woman in ANC, PMTCT or CTC registers were linked using ANC registration numbers and/or CTC numbers. Linked datasets were stored on a secure computer network, and analytical datasets were stripped of identifying information.

5.3.5 Statistical analysis

The denominator included pregnancies to HIV-positive women in Kisesa, resident in 2005-2012. HIV-positivity was determined from research testing during HIV sero-surveys, or linkage of a DSS record to an HIV-positive clinic record (for women whose HIV status was not known from sero-survey testing, or who had sero-converted since last testing HIV-negative). Sero-conversion dates were estimated, taking the mid-point between last HIV-negative and first HIV-positive test results for sero-incident cases. For prevalent cases, sero-conversion dates were estimated as three years prior to first testing HIV-positive at a sero-survey (based on data for sero-incident cases by sex and age). Pregnancies to HIV-positive women were identified using children's dates of birth with links to mothers, mother's self-reports of recent births and pregnancies in the DSS and sero-surveys, or pregnancies recorded in the clinic. Women who were pregnant in 2005-2012, whilst HIV-positive, were eligible for inclusion.

The proportion of women accessing each service, per pregnancy, was calculated overall and by year of pregnancy. Service use was based on linkage of a woman's DSS record to a clinic (ANC or CTC) record. Dates of pregnancy and clinic attendance were aligned to determine service access during a particular pregnancy. Receipt of ARV drugs during pregnancy was defined using PMTCT registers which capture ARVs dispensed during ANC, or CTC records (continuation of ART at the time of pregnancy, or initiation of ART before the recorded or estimated delivery date). Diagnosis of HIV before pregnancy or CTC registration was determined using attendance at VCT

services in sero-surveys, or self-reported VCT use in sero-survey interviews. Diagnosis at ANC was based on linkage to HIV test results in PMTCT testing registers, or prior VCT. The proportions of women enrolling in HIV care by facility type were calculated among individuals who registered at ANC services and compared using chi square tests.

Estimates of service coverage (enrolment in ANC, HIV care, and receipt of ARVs during pregnancy) were adjusted for cases of clinic attendance that were missed by the linkage algorithm: raw proportions were divided by the proportion of clinic records that were linked to the DSS, or by the algorithm sensitivity. Estimates were also adjusted by the proportion of women who may have accessed ANC services outside Kisesa (measured in sero7 as 12%).

Kaplan-Meier survival plots were used to analyse time to CTC registration. Time was calculated from the ANC registration date (or reported pregnancy date if ANC registration date was unknown) to the CTC registration date (or date of next visit to the CTC if already registered), or date of exit from the DSS (out-migration, death or enumerated in the latest round), or end of the study period (December 31 2012) if this preceded the DSS exit date. Log-rank tests were used to compare differences in time to registration by year of pregnancy.

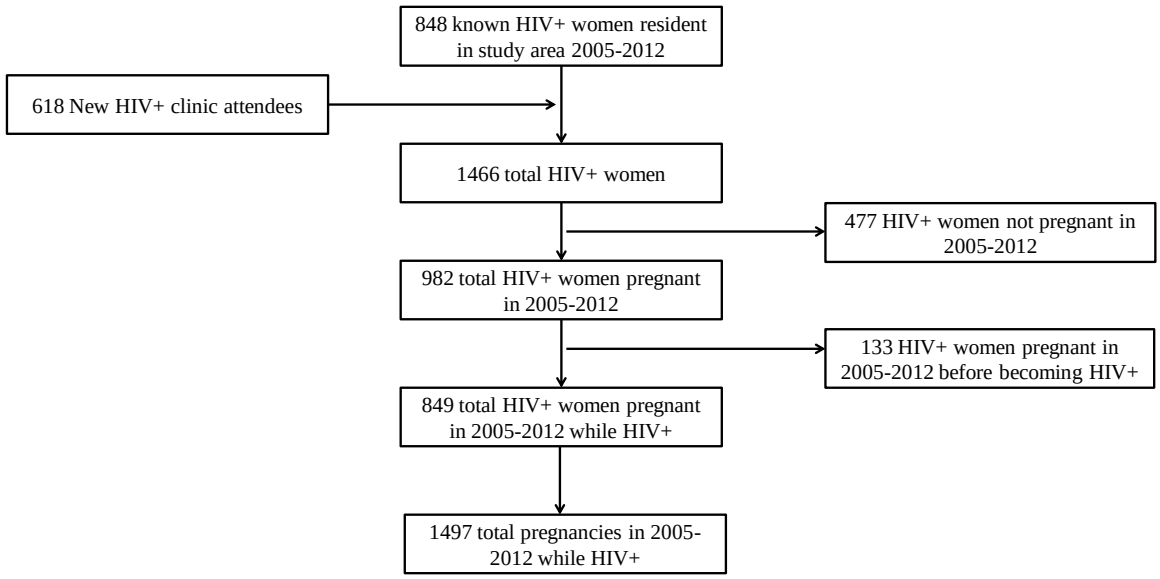
5.3.6 Ethical approval

This study was granted ethical approval by the London School of Hygiene and Tropical Medicine, and the Tanzanian Medical Research Coordinating Committee.

5.4 Results

Eight hundred and forty eight Kisesa-resident women had ever tested HIV-positive during sero-surveillance. Another 618 DSS records were newly identified as HIV-positive based on their linkage to a record in PMTCT registers or the CTC. Of these women, 849 had been pregnant in 2005-2012 since they were infected, giving a denominator of 1497 pregnancies while HIV-positive (49% out of 849 women had ≥2 pregnancies) (Figure 5.2).

Figure 5.2. Flow chart of participants eligible for inclusion in the analysis.



5.4.1 Characteristics of the study population

Table 5.1 presents characteristics of included women around the time of pregnancy. Half the women were aged between 20 and 29 while pregnant, 72% were married, 40% were residing in remote rural villages (31% in the trading centre, 29% in roadside villages), and 67% were in their third or later pregnancy (median 3rd pregnancy). The number of pregnancies to HIV-positive women in each calendar year increased over time, although this is most likely to reflect the greater availability of linked antenatal clinic records in later years which provided an additional means of identifying pregnancies.

Table 5.1. Characteristics of HIV-positive women in Kisesa at the time of or closest to each pregnancy.

(N=1497 pregnancies)

Factor	Category	number of pregnancies	% of pregnancies
Age	<20	88	5.9
	20-29	749	50.0
	30-39	576	38.5
	40+	84	5.6
Year of pregnancy	2005	74	4.9
	2006	135	9.0
	2007	159	10.6
	2008	199	13.3
	2009	192	12.8
	2010	220	14.7
	2011	249	16.6
	2012	269	18.0
Residence area	Remote rural	600	40.1
	Roadside	434	29.0
	Trading Centre	463	30.9
Marital status	Currently married	1,079	72.1
	Never married	150	10.0
	Previously married	267	17.9
Gravidity	1	217	14.5
	2	275	18.4
	3	305	20.4
	4	238	15.9
	5+	462	30.9

5.4.2 Uptake of PMTCT services

Figure 5.3 illustrates raw estimates for uptake of PMTCT service components overall, and by year of pregnancy. Of the 1497 pregnancies to HIV-positive women overall, 387 (26%) were not linked to ANC or HIV services during pregnancy, of whom 82 (21% out of 387) were already diagnosed. Thirty-five percent (n=519/1497) registered at ANC but did not enrol in HIV services, of whom 434 (84% out of 519; 29% overall) had not had an HIV test at ANC or earlier VCT. A small proportion (8%, n=119/1497) enrolled in the PMTCT programme at ANC but not at the CTC: most (80% out of 119; 6% overall) had received ARV prophylaxis. Thirty-two percent (n=472/1497) had registered at the CTC, of whom 204 (43% out of 472; 14% overall) had received ART

or ARV prophylaxis during pregnancy. Overall, 20% out of 1497 accessed ARV drugs during pregnancy at ANC or CTC. Ninety-seven (21% out of 472, or 6% overall) had already started ART (none had documented treatment interruptions, although 3 had not been seen for over 12 months, and 12 transferred to another clinic). Among 268 who registered at the CTC but did not acquire ARVs, 45 (17% out of 268) had not attended CTC appointments for >12 months. Among those who had not started ART (n=319), 48% had no CD4 recorded, while 11% were eligible for ART.

Prior to 2008, few individuals were enrolled in HIV services during pregnancy. Uptake of PMTCT services increased over time, with the largest increases occurring between 2007 and 2008 (opening of Kisesa CTC) and between 2008 and 2009 (implementation of the PMTCT programme in Kisesa). In 2009, 44% (n=85/192) had enrolled in the CTC or ANC-based PMTCT services, and 17% (n=32/192) had been prescribed ARV prophylaxis or ART. These proportions increased to 68% (n=184/269) in care and 44% (n=117/269) accessing ARVs in 2012 (raw estimates). Among those registered at the CTC in 2012 (n=134), 39 (29%, or 14% out of 269) had already started ART. Median CD4 count trended upwards among those already on ART (median 327 in 2005-8 (n=8), 391 in 2009-10 (n=13) and 413 in 2011-12 (n=28)). Eighteen women eligible for ART in 2012 had not started (23% out of 78 CTC patients not on ART, versus 9% in 2009).

Women who attended ANC at dispensaries (n=389 pregnancies) were less likely to be in care (n=148, 38%) than women who attended ANC at the health centre (51% out of 569 pregnancies) ($p<0.001$), with the differential remaining over time (Figure 5.4).

Figure 5.3. Raw proportions of pregnancies to HIV-positive women in Kisesa in which PMTCT service components were accessed, over time.

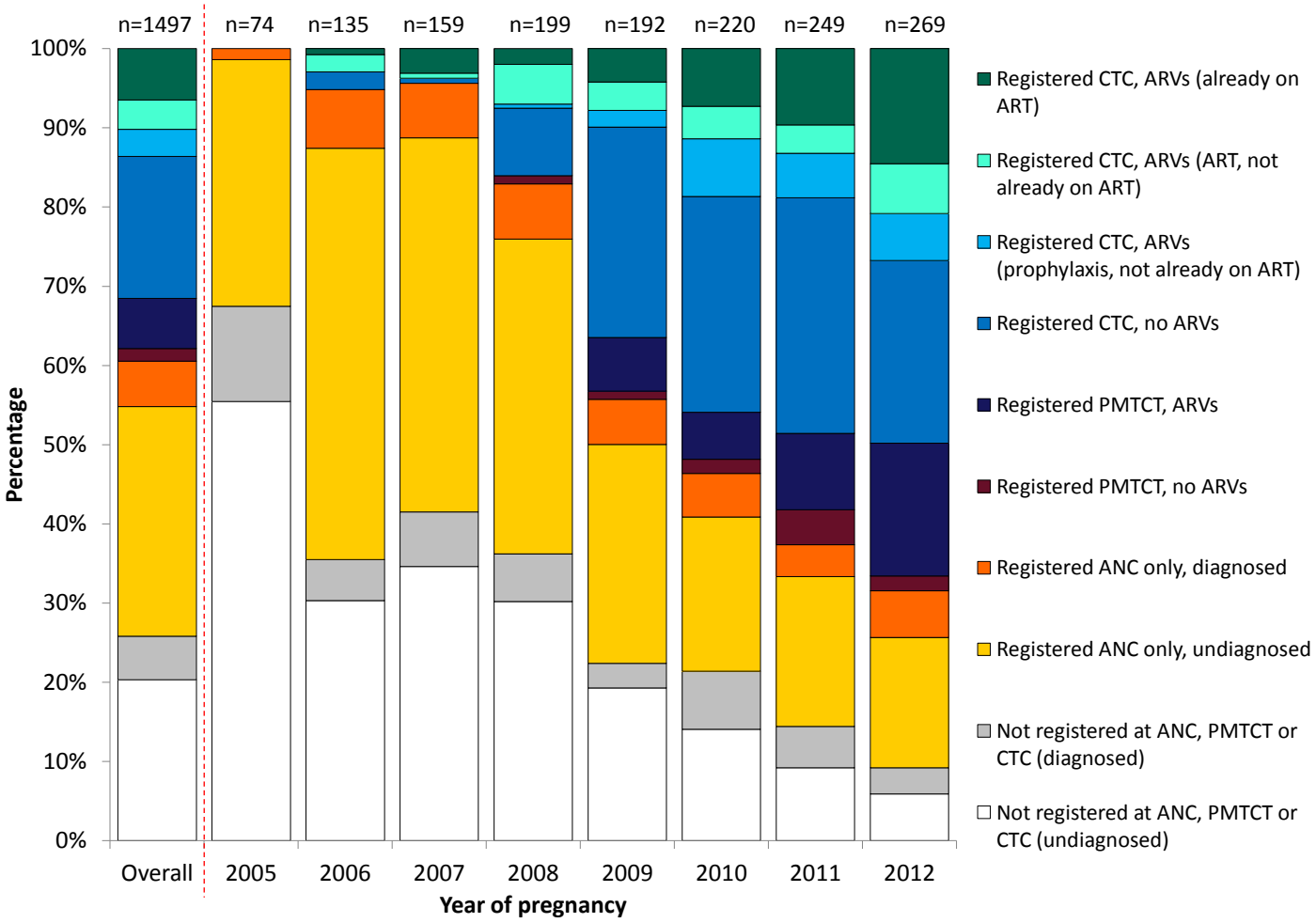
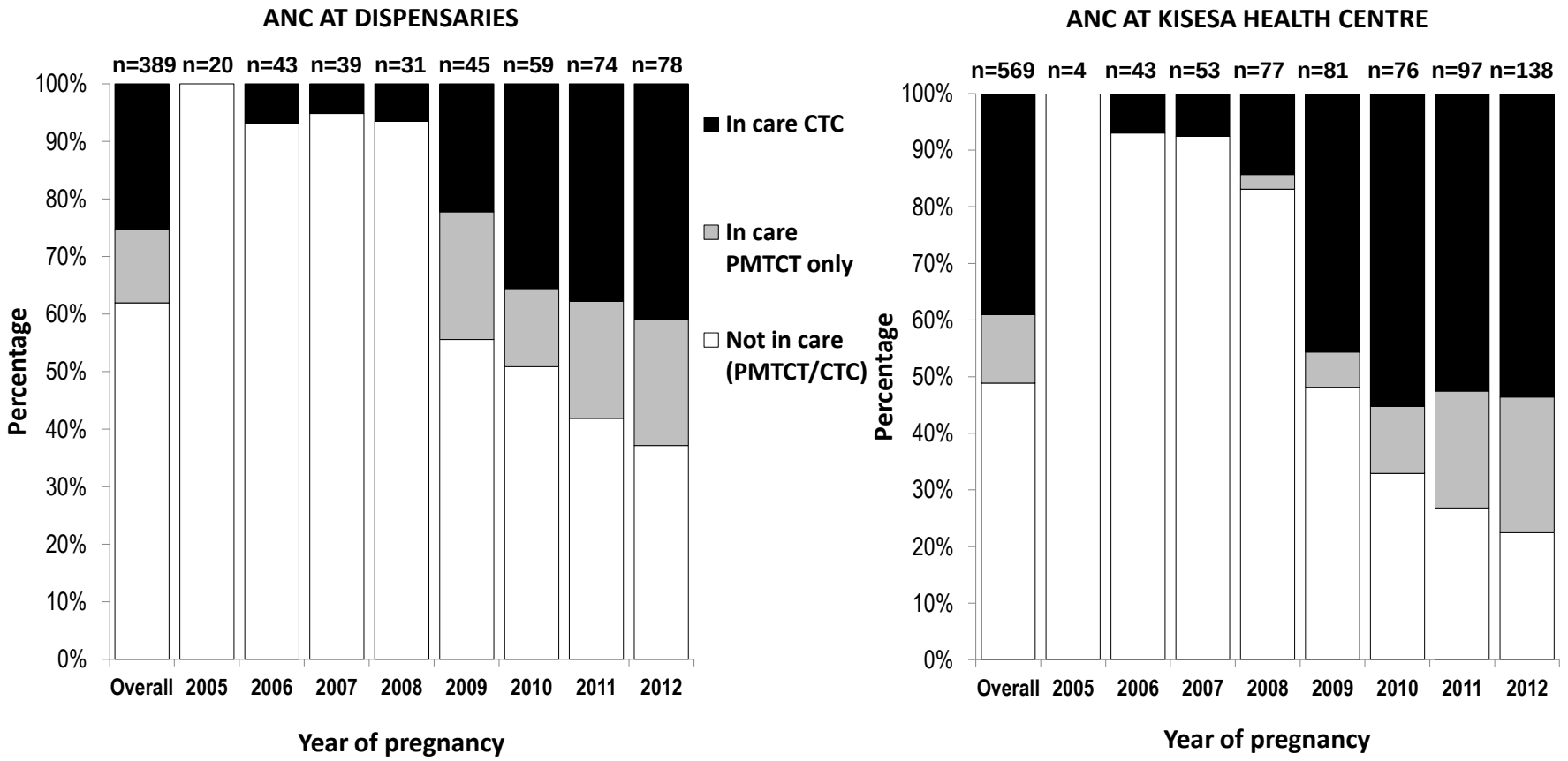


Figure 5.4. Raw proportion of pregnancies to HIV-positive women enrolled in Kisesa ANC services from Jan2005-Dec2012 in which HIV care was accessed.



5.4.3 Coverage estimates

Adjusted coverage estimates for the proportion of HIV-positive women who accessed ANC, PMTCT/CTC (HIV care), and ARVs per pregnancy in 2005-2012 are summarised in Table 5.2. The (adjusted) proportion of HIV-positive women accessing ANC was estimated to be as high as 92%, 57% for access to HIV care, and 29% for coverage with ARV drugs. By 2012, coverage with HIV care was estimated to reach over 90% while coverage with ARVs reached 62% (calculations in Table 5.3 to Table 5.5)

Table 5.2. Raw and adjusted coverage estimates for the proportion of HIV-positive women who accessed service components during each pregnancy in 2005-2012.

Service	Raw estimate (95% CI)	Estimate adjusted by % ANC records linked to DSS*	Estimate adjusted by % ANC records linked to DSS & local ANC attendance**	Estimate adjusted by algorithm sensitivity***
ANC	64.0%[a] [61.6%-66.4%]	80.6%	91.6%	91.4%
In HIV care (PMTCT/ CTC)	39.5% [37.0%-42.0%]	49.7%	56.5%	56.4%
ARV drugs	20.0% [17.9%-22.0%]	25.2%	28.6%	28.6%

*raw estimate divided by 79% (% of ANC records linked to the DSS)
**previous estimate (column three) divided by 88% (accounting for 12% of women that reported accessing ANC services outside Kisesa ward in sero7)
***divided by 70% (sensitivity of the algorithm)
[a] raw estimate for the proportion who attended ANC, excluding women who attended CTC in Kisesa but were not linked to Kisesa ANC services (e.g. may have attended ANC outside the area)

Table 5.3. Adjusted coverage estimates for the proportion of HIV-positive pregnant women who accessed ANC in each pregnancy by year.

A	B	C	D	E	F
Year of pregnancy	% Kisesa-resident ANC records (pregnancies) linked to a DSS record	Raw % of pregnancies to HIV+ women that attended ANC	Adjusted coverage estimate 1* (attended ANC)	Adjusted coverage estimate 2** (attended ANC)	Adjusted coverage estimate 3*** (attended ANC)
2005	84.0%	32.4%	38.6%	43.8%	46.3%
2006	77.1%	63.7%	82.6%	93.9%	91.0%
2007	80.4%	57.9%	72.0%	81.8%	82.7%
2008	79.0%	54.3%	68.8%	78.1%	77.6%
2009	78.3%	65.6%	83.8%	95.2%	93.7%
2010	77.5%	61.4%	79.3%	90.1%	87.7%
2011	75.4%	68.7%	91.1%	103.5%	98.1%
2012	84.8%	80.3%	94.7%	107.6%	114.7%
Overall	79.4%	64.0%	80.6%	91.6%	91.4%

*column C divided by column B
**column D divided by 88% (accounting for 12% of women that reported accessing ANC services outside Kisesa ward in sero7)
***column C divided by 70% (sensitivity of the algorithm)
Estimates may range over 100% in some years due to the assumptions of the same sensitivity across all years, inaccuracies in the recording (by nurses) or reporting (by women) of women's village of residence in the ANC registers, or because a smaller proportion of women attended ANC out of area than assumed, as this information would be expected to vary by year

Table 5.4. Adjusted coverage estimates for the proportion of HIV-positive pregnant women in care at PMTCT/CTC in each pregnancy by year.

A	B	C	D	E	F
Year of pregnancy	% Kisesa-resident ANC records (pregnancies) linked to a DSS record	Raw % of pregnancies to HIV+ women that enrolled in PMTCT/CTC	Adjusted coverage estimate 1* (enrolled in PMTCT/CTC)	Adjusted coverage estimate 2** (enrolled in PMTCT/CTC)	Adjusted coverage estimate 3*** (enrolled in PMTCT/CTC)
2005	84.0%	0.0%	0.0%	0.0%	0.0%
2006	77.1%	5.2%	6.7%	7.6%	7.4%
2007	80.4%	4.4%	5.5%	6.2%	6.3%
2008	79.0%	17.1%	21.6%	24.6%	24.4%
2009	78.3%	44.3%	56.6%	64.3%	63.2%
2010	77.5%	53.6%	69.3%	78.7%	76.6%
2011	75.4%	62.7%	83.1%	94.4%	89.5%
2012	84.8%	68.4%	80.6%	91.6%	97.7%
Overall	79.4%	39.5%	49.7%	56.5%	56.4%

*column C divided by column B
**column D divided by 88% (accounting for 12% of women that reported accessing ANC services outside Kisesa ward in sero7)
***column C divided by 70% (sensitivity of the algorithm)

Table 5.5. Adjusted coverage estimates for the proportion of HIV-positive pregnant women who accessed ARVs in each pregnancy by year.

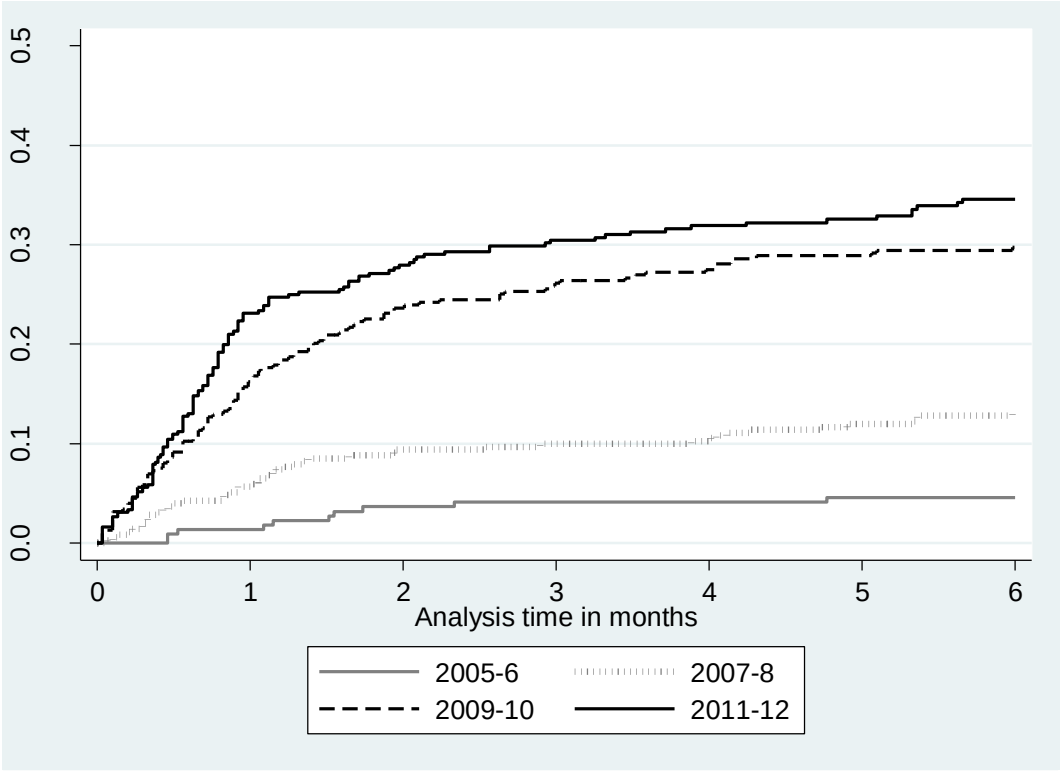
A	B	C	D	E	F
Year of pregnancy	% Kisesa-resident ANC records (pregnancies) linked to a DSS record	Raw % of pregnancies to HIV+ women that accessed ARVs	Adjusted coverage estimate 1* (accessed ARVs)	Adjusted coverage estimate 2** (accessed ARVs)	Adjusted coverage estimate 3*** (accessed ARVs)
2005	84.0%	0.0%	0.0%	0.0%	0.0%
2006	77.1%	3.0%	3.8%	4.4%	4.2%
2007	80.4%	3.8%	4.7%	5.3%	5.4%
2008	79.0%	7.5%	9.5%	10.8%	10.8%
2009	78.3%	16.7%	21.3%	24.2%	23.8%
2010	77.5%	24.5%	31.7%	36.0%	35.1%
2011	75.4%	28.5%	37.8%	43.0%	40.7%
2012	84.8%	43.5%	51.3%	58.3%	62.1%
Overall	79.4%	20.0%	25.2%	28.6%	28.6%

*column C divided by column B
**column D divided by 88% (accounting for 12% of women that reported accessing ANC services outside Kisesa ward in sero7)
***column C divided by 70% (sensitivity of the algorithm)

5.4.4 Time to CTC visit

Figure 5.5 illustrates the time to CTC visit by calendar year of pregnancy over the first six months of follow-up. Time to CTC visit decreased with increasing year of pregnancy (p<0.001). For pregnancies since 2009 a steeper increase was noticeable within the first month compared to earlier years, corresponding to a greater proportion of women visiting the CTC within this time window.

Figure 5.5. Kaplan Meier plot of time to CTC visit by year of pregnancy.



5.4.5 Characteristics of clinic attendees by linkage to the DSS

Compared to ANC records that were linked the DSS (n=9842), unlinked (Kisesa-resident) ANC records (n=2579) were more often from a dispensary (44% versus 39%, p<0.001) (data not shown), but there was no difference in age or year of registration. A greater proportion of unlinked CTC records (n=174) were registrations prior to 2008 (25%, compared to 3% of linked CTC records (n=661), p<0.001), but there was no difference in age, village of residence, clinical stage or CD4 count at registration.

5.5 Discussion

This study documented fairly low population-level uptake of PMTCT services in rural Tanzania in 2005-2012 before the implementation of Option B+. However, there was an encouraging upward trend over time following implementation of ART and PMTCT services within the study area in 2008-9; coverage with HIV care during pregnancy rising to 68% (raw) or as high as >90% (adjusted) in 2012, and coverage with ARV drugs reaching between 44% (raw) and 62% (adjusted). These estimates are lower than national-level estimates of coverage with ARVs for HIV-positive pregnant women in Tanzania (73% in 2013 (1)), potentially reflecting over-estimates at the national and regional levels (147), and/or local level differences. ANC surveillance across Magu District in 2008 identified very low usage of ARVs (33%) for PMTCT based on self-reports by pregnant women (26). Qualitative research in Kisesa and other African studies have identified many factors at the individual, community and health systems levels that may contribute to poor uptake of PMTCT services (33, 152).

Weaknesses in the PMTCT programme were evident throughout the cascade, but were notable at the point of testing, assessment for ART eligibility and receipt of ART or prophylaxis. Our analysis also identified some HIV-positive women who were aware of their status through earlier VCT but did not attend health services during pregnancy, calling for strengthened post-test counselling about the importance of PMTCT. The adjusted estimate for coverage with ANC was within the range of survey data for Mwanza region in 2010 (86%) (153) and Kisesa (98% in 2010 (sero6); 90% in 2013 (sero7)).

The sizeable proportion of HIV-positive women who were not enrolled in PMTCT or CTC services during pregnancy was primarily accounted for by women who attended ANC but were not diagnosed. This is most likely explained by frequent and persistent stock-outs of HIV test kits during the study time-frame (35, 152). Low coverage (64%) with HIV testing at ANC was also documented in Uganda in 2008-2010 (148), while Tanzanian programme statistics indicate that 20% of women attending ANC were not tested in 2011 (154). Some women may decline testing, fearing disclosure of HIV-positive results and consequent conflict in relationships (37, 152). Improvements in the distribution of HIV test kits, community-level interventions to reduce HIV stigma, as well as adequate pre-test counselling (sometimes omitted (35)) may help to reduce drop-outs at this stage.

Most women who enrolled in the PMTCT programme received ARV prophylaxis and were therefore covered with the minimum PMTCT intervention. However, this pre-supposes (for maximum efficacy) optimal adherence and initiation of ARVs from the recommended gestational age, while further analyses of PMTCT clinic records revealed that women were registering late (median 24 weeks (IQR 20-28) in 2012). As Tanzania rolls out Option B+, it will be important to emphasise the importance of attending ANC early, and to monitor the subgroup that registers for PMTCT but not CTC or ART services. Research from Malawi indicates that some pregnant women may avoid ART, for example because they feel in good health (19).

Access to CTC services, including the time to CTC attendance, improved each year following the availability of ART and PMTCT services in Kisesa, but remained a point of further attrition. Linkage to HIV care and treatment has been highlighted as a problematic step in the PMTCT programme (43), including in Mwanza city (84). Starting ANC at dispensaries was apparently a disadvantage, reflecting the need for referrals to the CTC and associated accessibility issues (152). Further decentralisation of ART services would help in this regard, and will be crucial to the success of Option B+. Improvements in the design, usage and storage of PMTCT transfer forms may also strengthen linkages between ANC and CTC (155).

A considerable weakness was the uptake of ARV drugs among those registered for CTC: losses to follow-up were partly responsible, while half the women who had not started ART had no CD4 count documented. Limited CD4 count testing was also reported in PMTCT programmes in Mwanza city hospitals (84). Point of care CD4 count tests have recently been introduced and should improve monitoring of immunological status, while implementation of Option B+ will simplify decisions regarding ART initiation for HIV-positive pregnant women. Nonetheless, women without CD4 counts or ineligible for ART should have received ARV prophylaxis. Documentation of prophylaxis in the CTC database was weak, with additional hand-written notes non-systematically present in patient files. The proportion receiving prophylaxis may therefore be under-estimated, highlighting the importance of robust and systematic approaches to routine data capture (147). Almost a quarter of women eligible for ART in 2012 had not received it, potentially reflecting adjustment to new (widened) eligibility criteria.

The increasing proportion of women who were already on ART before pregnancy (14% in 2012) is noteworthy, as this population presents new challenges for PMTCT programmes, including monitoring of treatment adherence and virologic suppression

(156), and will grow with Option B+. It was encouraging that most were still taking ART continuously and that CD4 counts were rising among this group.

Linkage of cohort and clinic data was the key strength of this analysis, although there were inherent limitations. The proportion of clinic records that was not linked to the DSS was accounted for, but was a potential source of bias given differences observed in the characteristics of linked and unlinked clinic records: uptake of services before 2008 or in the dispensaries may be under-estimated, although this is unlikely to have altered our conclusions. Confidence intervals were not calculated for the adjusted coverage estimates as this would not be statistically valid without further investigation of the scales for the transformation of the proportions and adjustment factors. Poor quality of some routine clinic data (e.g. missing or duplicate identifiers) complicated the linkage of records from different registers and tracking of women who had switched facilities (147), potentially under-estimating the proportions tested and enrolled in care, although mis-matches are likely to have resulted in random misclassification of outcomes. The large proportion (approximately 20%) of delivery registers missing ANC numbers and difficulties linking infant and maternal records also restricted our analysis to PMTCT service components during pregnancy. Estimated HIV sero-conversion dates or self-reported pregnancy dates may be inaccurate, and HIV-positive pregnancies may have been erroneously included in or omitted from the denominator, leading to under- or over-estimates of coverage respectively.

In conclusion, population-level uptake of PMTCT services in this rural Tanzanian setting was disappointingly low and below national-level estimates, but improved markedly over time. Given the proportion of women who fully adhere to regimens and the proportion of mothers *and* infants receiving ARVs is likely to be even lower, the number of infants potentially at risk of acquiring HIV is a concern. Implementation of Option B+ is likely to simplify decisions for initiating HIV-positive pregnant women onto ART, while further decentralisation of CTC services and careful management of stocks of HIV test kits will be key to overcoming other weaknesses in the PMTCT programme.

6 Paper D. Factors associated with uptake of services to prevent mother-to-child transmission of HIV in a community cohort in rural Tanzania

Introduction to the paper

Paper C identified low levels of uptake of PMTCT services among HIV-positive pregnant women in Kisesa. Although these levels improved over time, weaknesses remained throughout the service cascade, and the proportions of HIV-positive women who enrolled in HIV care and accessed antiretroviral drugs during pregnancy in 2012 were still well below the goals for universal coverage and zero new HIV infections in children. It is therefore important to investigate the factors associated with not accessing the services, and to characterise the women who did or did not access services, in order to target interventions to improve PMTCT service access among these groups. This is the premise of the following paper (D), which presents an analysis of the factors associated with uptake of PMTCT services in Kisesa, using the linked clinic-cohort datasets. Sero-survey and DSS data are used to construct the explanatory variables for investigation, including basic socio-demographic characteristics and more complex risk factors such as HIV knowledge, experience of HIV, and duration of HIV infection. The decisions over which variables to investigate in the analysis were also guided by the results of the systematic review (paper A). That paper showed that the synthesis of results from the included quantitative studies was not conclusive, with heterogeneity in the findings. Variables were therefore included in the analysis for the following paper (C) which had been explored in other studies, as well as other new factors that were hypothesised to play a role in access to PMTCT services in this setting (e.g. duration of HIV infection, as qualitative studies included in the review, and conducted in Kisesa, had suggested that perceived disease severity and presence of symptoms may drive attendance at HIV services or adherence to antiretroviral drugs (38, 39)).

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I managed the collection and entry of routine clinic data, I linked the clinic data to the Kisesa cohort data and designed the antenatal clinic data matching algorithm, I analysed the data and wrote the manuscript.

NAME IN FULL (Block Capitals) ANNABELLE GOURLAY

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Submitted manuscript

6.1 Abstract

Objectives: This study aimed to identify factors associated with uptake of PMTCT services among HIV-positive pregnant women in a community cohort in rural Tanzania (Kisesa).

Methods: Kisesa-resident women who tested HIV-positive during HIV sero-surveillance and were pregnant (while HIV-positive) between 2005 and 2012 were eligible. Community cohort records were linked to PMTCT and HIV care and treatment clinic (CTC) data from four facilities (PMTCT programme implemented in 2009; referrals to city-based hospitals since 2005) to ascertain service use. Factors associated with access to HIV care and antiretroviral (ARV) drugs during pregnancy were analysed using logistic regression.

Results: In multivariate analyses based on 756 pregnancies to HIV-positive women, never married (adjusted OR (aOR) 0.2 [95%CI 0.0-1.1]) and previously married women (aOR 0.4 [95% CI 0.1-1.0]) were less likely to access HIV care compared to married women. Other factors independently associated with access to care were prior VCT (aOR 2.5 [95%CI 1.0-6.3]), increasing age (aOR 1.1 [95%CI 1.0-1.2] for each year increase in age), year of pregnancy (aOR 59 [95%CI 13-263] for 2009-2010; aOR 125 [95%CI 23-672] for 2011-2012, versus 2005-8), duration of infection (aOR 1.6 [95%CI 0.5-4.5] for 2-4 years; 7.2 [95%CI 2.2-24] for >4 years, versus ≤2 years), and residence in roadside areas (aOR 3.1 [95%CI 1.0-9.8] versus rural areas). Factors independently associated with HIV care, with the exception of area, were also independently associated with access to ARVs.

Conclusions: Access to PMTCT services was low in this rural setting but improved markedly over time. Service access was reasonably equitable although support for young women and those without partners may be needed. Further decentralisation of HIV services to more remote areas, promotion of VCT and implementation of Option B+ are likely to improve uptake and may bring women into care and treatment sooner after infection.

6.2 Background

Services for prevention of mother-to-child transmission (PMTCT) of HIV have been scaled up rapidly amidst recent global attention and commitments to eliminating vertical HIV transmission, particularly from sub-Saharan Africa where most new paediatric HIV infections occur (1).

PMTCT programmes, through the provision of antiretroviral (ARV) drugs to HIV-infected mothers and infants, have the potential to substantially reduce the chances of vertical HIV transmission from over 40% to <5% (4). However, the availability of this life-saving intervention has not necessarily translated into service uptake. Coverage with ARVs for PMTCT was estimated to be 65% across 21 priority countries in sub-Saharan Africa in 2012, but is below 50% in some instances (e.g. Chad, Nigeria) (1, 5). Reasons for poor uptake of PMTCT services are complex, as barriers exist at multiple levels (33).

Most quantitative studies investigating PMTCT service outcomes are restricted to individuals enrolled in health services. However, it is important to include and characterise women who do not access antenatal clinics (ANC) or HIV clinics, in order to design programmes to better reach *all* women in need of services. Clinic-based studies are also limited by data available in clinic records or self-reported in interviews, whereas unexplored factors such as duration of HIV infection and previous HIV testing may also predict service use.

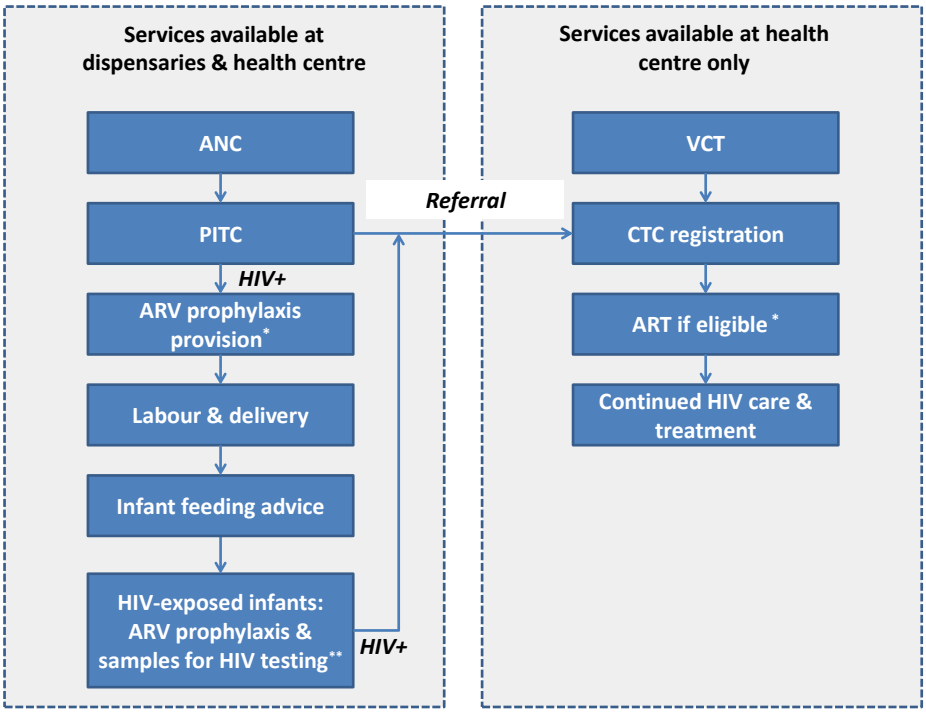
Analyses of access to health services at a population level can be done by linking community-level data, such as demographic surveillance systems (DSS), to health facility records, but are rarely undertaken. Two such studies in Malawi and Kenya reported population-level coverage of PMTCT or HIV services but did not investigate factors associated with service use (19, 157). Research in a community-based cohort in Uganda documented an association between distance from health services and not receiving an HIV test (148), but did not investigate factors associated with receiving ARV drugs. To our knowledge, no studies have investigated factors associated with enrolment into PMTCT programmes or uptake of ARVs among all HIV-positive pregnant women at a population level, despite the importance for optimising PMTCT programmes. Identifying local barriers to PMTCT service use is also essential to tailor programmes to the context. We therefore aim to identify factors associated with accessing PMTCT services, including ARV drugs, among HIV-positive pregnant women in a community cohort in rural Tanzania.

6.3 Methods

6.3.1 Setting

Kisesa is a rural community in north-western Tanzania, east of Mwanza city. Approximately 30,000 inhabitants live in the DSS area that includes a trading centre and five other villages stretching from roadside to more remote areas. There are four government-run clinics: a health centre in the trading centre and three dispensaries in other villages. Implementation of PMTCT services started in 2009, including provider-initiated HIV testing and counselling (PITC), provision of ARV prophylaxis at ANCs, and referrals to the HIV care and treatment clinic (CTC) in the health centre (see Figure 6.1 for PMTCT protocols).

Figure 6.1. Cascade of PMTCT services available in the dispensaries and/or health centre in Kisesa.



ANC antenatal clinic; PITC provider-initiated testing and counselling; ARV antiretroviral; CTC HIV care and treatment clinic; VCT voluntary counselling and testing
From 2005-2009, pregnant women diagnosed with HIV at VCT services in the health centre were referred to hospitals in Mwanza city for PMTCT services.
*In 2005-2011, HIV-positive pregnant women with CD4 counts <200 cells/mm^3 were eligible for antiretroviral treatment (ART) for their own health, otherwise ARV prophylaxis was provided from 28 weeks gestation until 7 days postpartum. The treatment threshold was raised to 350 cells/mm^3 in 2012 (ARV prophylaxis from 14 weeks, 'Option A').(134)
**Until 2011, infants received nevirapine for 1 week after birth and AZT for up to 4 weeks. Under 'Option A' they received prophylaxis until 1 week after cessation of breastfeeding (4-6 weeks if replacement feeding). Infant dried blood spot samples were sent for HIV testing to the national referral hospital in Mwanza city.

6.3.2 Data collection

The Kisesa cohort study started in 1994 (151), with DSS enumeration of the entire population every six months, whereby enumerators visit households to record all births, pregnancies, migrations and deaths. HIV serological surveys are conducted at approximately 3 yearly intervals (7 to date, most recently in 2013) at a central location within each village. Resident adults aged ≥15 years are eligible to participate in the sero-surveys. Participants consent to give blood for HIV testing for research without results disclosure, are offered VCT, and are interviewed about topics including economic activities, child-bearing, use of health services, and knowledge of HIV.

Routine clinic data were collected retrospectively from all four Kisesa facilities. All records from 2005 to 2012 were abstracted from ANC pregnancy registers (some records (<10%) from different clinics and time periods were missing), PMTCT programme registers, and the CTC (including patients who enrolled at city-based CTCs and transferred back to Kisesa). Data were double-entered at the National Institute of Medical Research (NIMR) in Mwanza, with the exception of CTC data which are locally maintained in an electronic database by government CTC personnel.

Community cohort data were linked to clinic datasets by matching on personal attributes (e.g. age, sex, village of residence, and pregnancy dates), using an algorithm developed from a gold standard of ANC patient identifier numbers captured from women's ANC cards during DSS round 27 (2012). The algorithm had a sensitivity of 70% and positive predictive value of 98% for matching ANC clinic records, with a similar algorithm used to match CTC data. PMTCT register records were linked to ANC and CTC records using ANC or CTC registration numbers respectively.

Sources of pregnancy data were dates of birth of children in the DSS (linked to mothers), mothers' self reports of pregnancies or births in the DSS or sero-surveys, and clinic pregnancy records.

6.3.3 Statistical analysis

Women residing in Kisesa in 2005-2012, testing HIV-positive during any sero-survey, and pregnant during this interval were eligible for inclusion. HIV sero-conversion dates were estimated using the mid-point between first positive and last negative test dates. Prevalent cases were assumed to have sero-converted three years prior to their first positive test date (based on data for average duration of infection for sero-incident cases). The denominator comprised HIV-positive pregnancies, excluding pregnancy records that lacked sero-survey interview data within five years.

Two outcomes were assessed: 1) enrolled in a PMTCT programme and/or CTC ('HIV care') during or before pregnancy, and 2) accessed ARV drugs during pregnancy. Enrolment in HIV care was defined as linkage of a DSS record to a PMTCT or CTC clinic record. Dates of clinic registration were aligned with pregnancy dates to verify service access during each pregnancy. Maternal ARV drug access was defined as receipt of ARV drugs documented on any ANC visit in PMTCT registers, or a CTC record indicating initiation or continuation of ART during pregnancy (before the recorded or estimated delivery date). Data on infant ARVs could not be linked to mother's records.

Explanatory variables were constructed using DSS data or sero-survey questions, taking information from the round closest to the pregnancy. Knowledge of HIV transmission was assessed by asking respondents to mention any modes of HIV transmission they were aware of. ART knowledge was assessed using the number of correct answers to 5 true or false statements about ART (detailed in Table 6.1). Responses to knowledge questions after the pregnancy date were used but distinguished, as knowledge was hypothesised to change as a result of attending the clinic. Death of a child was defined as any self-reported miscarriage, stillbirth, or death of a child any time after birth. Use of VCT services prior to pregnancy was based on recorded attendance at VCT in an earlier sero-survey, or self-reported VCT use before the pregnancy date. Age was modelled as a continuous variable; all other quantitative variables were categorised. Year of pregnancy was re-categorised for use in the models, collapsing the earlier year groups in which there were few individuals with the outcomes.

Descriptive analyses, followed by bivariate and multivariate logistic regression analyses (deemed appropriate given the short and homogeneous follow-up time per pregnancy) were performed in Stata12 (StataCorp LP, Texas, USA) to identify independent predictors of access to HIV care or ARVs. All factors associated with the outcome ($p \leq 0.1$) in bivariate analyses were assessed in multivariate models, using a forwards step-wise approach in which variables were retained if they significantly improved the model fit ($p \leq 0.1$, based on likelihood ratio tests). Clustering due to multiple pregnancies per woman was accounted for using random effects, checking for quadrature stability. Interactions with calendar year of pregnancy or age were assessed. For continuous variables, departure from linearity was assessed using likelihood ratio tests.

6.3.4 Ethical considerations

Ethical approval was granted by the Tanzania Medical Research Coordinating Committee and the London School of Hygiene and Tropical Medicine review boards. Informed consent was obtained from all sero-survey participants. Data entry clerks and managers received ethics training. HIV patients' names were not visible to NIMR data entry clerks (encrypted or indexed by registration number). Datasets were stored on computer networks with password-restricted access. Analytical datasets excluded names and other personal identifiers.

6.4 Results

6.4.1 Participants

Among 9692 women of child-bearing age residing in Kisesa in 2005-2012 who had ever attended a sero-survey, 848 (8.7%) had tested HIV-positive. Of these women, 520 were pregnant between 2005 and 2012; 443 since (estimated) HIV sero-conversion (n=810 pregnancies). Fifty four pregnancy records lacking sero-survey data within five years were excluded, yielding 756 pregnancies for analysis.

The pregnant women had an average age of 30 years. Most were married (70%), educated to primary level (73%), and identified themselves as Christians (94%) and from the Sukuma tribe (91%) (Table 6.1). Half were living in remote rural villages. Women primarily earned money through farming (58%), and/or small businesses (28%) (e.g. selling agricultural produce). Few had used VCT (32%) prior to pregnancy.

6.4.2 Factors associated with enrolment in HIV care

Overall 180 HIV-positive women accessed HIV care (24% of 756 HIV-positive pregnancies); a range from 2% in 2005-6 (n=3 out of 167) to 46% in 2011-12 (n=90 out of 197) (Table 6.1). In crude analyses, access to HIV care increased with increasing age ($p<0.001$, Table 6.2). No women aged <20 accessed care. Year of pregnancy was strongly associated with accessing care, increasing sharply in 2009 ($p<0.001$). Compared to women from remote rural villages, those from roadside areas (OR 2.5 [95%CI 1.3-4.8]) or from the trading centre (OR 1.6 [95%CI 0.8-3.2]) were more likely to enrol in care. Unmarried women had lower odds of being in care than married women ($p=0.09$). VCT prior to pregnancy (OR 6.7 [95%CI 3.5-13.0]), higher gravidity ($p<0.001$), and increasing duration of HIV infection ($p<0.001$) were also associated with being in care. Women who named modes of HIV transmission (OR 5.3 [95%CI 1.2-24] for mother-to-child, OR 6.5 [95%CI 2.2-19] for other modes, versus none) and women

who correctly answered ≥4 statements about ART (OR 4.5 [95%CI 1.6-13] versus ≤2 correct statements), were more likely to access care. Having a relative with HIV (alive or dead) or knowing someone taking ART was associated with higher odds of being in care (OR 1.5 [95%CI 0.9-2.7] and OR 2.1 [95%CI 1.2-3.8] respectively)). There was no statistical evidence for an association between enrolment in care and educational level, religion, ethnicity, source of income or having a child who died. In multivariate analyses, age, year of pregnancy, area, marital status, duration of infection and prior VCT were the factors independently associated with access to care (Table 6.2).

6.4.3 Factors associated with accessing ARV drugs

Eighty-eight women accessed ARV prophylaxis or ART during pregnancy (12% overall, 49% out of 180 in care). In bivariate analyses, factors associated with ARV access mirrored those associated with enrolment in care, except for area. Women with children who had died appeared more likely to access ARVs (p=0.1). Age, year of pregnancy, marital status, duration of infection and prior VCT remained independently associated with ARV access in final models.

Table 6.1. Characteristics of pregnancies (n=756) to HIV-positive women in Kisesa and proportions accessing HIV care/ ARVs by factor.

Factor	Category	total number (%) of pregnancies		number (%) in 'HIV care'		number (%) accessed ARVs	
Age	<20	36	4.8	0	0.0	0	0.0
	20-29	339	44.8	73	21.5	29	8.6
	30-39	347	45.9	97	28.0	53	15.3
	40+	34	4.5	10	29.4	6	17.6
Year of pregnancy	2005-6	167	22.1	3	1.8	2	1.2
	2007-8	209	27.6	21	10.0	11	5.3
	2009-10	183	24.2	66	36.1	23	12.6
	2011-2012	197	26.1	90	45.7	52	26.4
Residence area	Rural	371	49.1	70	18.9	44	11.9
	Roadside	202	26.7	61	30.2	23	11.4
	Trading Centre	183	24.2	49	26.8	21	11.5
Marital status	Married now	529	70.0	138	26.1	67	12.7
	Never married	69	9.1	10	14.5	3	4.3
	Married before	158	20.9	32	20.3	18	11.4
Education	At least P5	472	62.5	119	25.2	60	12.7
	P1-4	80	10.6	13	16.3	8	10.0
	no education	203	26.9	48	23.6	20	9.9
Religion	Catholic	311	41.9	80	25.7	37	11.9
	Other Christian	386	52.0	84	21.8	38	9.8
	Muslim	21	2.8	7	33.3	5	23.8
	Traditional	25	3.4	4	16.0	4	16.0
Ethnicity	Sukuma	688	91.1	167	24.3	83	12.1
	Other	67	8.9	13	19.4	5	7.5
(Personal) income	Farming or manual work	438	58.2	102	23.3	51	11.6
	Some business	208	27.6	48	23.1	28	13.5
	None	107	14.2	30	28.0	9	8.4
Gravidity (pregnancy number)	1	86	11.4	10	11.6	4	4.7
	2	125	16.5	24	19.2	10	8.0
	3	150	19.8	24	16.0	11	7.3
	4	130	17.2	36	27.7	15	11.5
	>=5	265	35.1	86	32.5	48	18.1
Any children died	No	401	54.3	86	21.4	39	9.7
	Yes	338	45.7	89	26.3	46	13.6
Duration of HIV infection	<=2 years	219	29.0	25	11.4	12	5.5
	>2-4 years	209	27.6	39	18.7	12	5.7
	>4 years	328	43.4	116	35.4	64	19.5
Prior VCT	No	512	67.7	86	16.8	36	7.0
	Yes	244	32.3	94	38.5	52	21.3
Knowledge of HIV transmission	None	96	12.7	11	11.5	6	6.3
	MTCT	35	4.6	12	34.3	6	17.1
	Other modes	314	41.5	87	27.7	46	14.6
	No prior report [a]	311	41.1	70	22.5	30	9.6
ART knowledge [b]	<=2 correct statements	119	15.7	36	30.3	17	14.3
	3 correct statements	88	11.6	26	29.5	11	12.5
	4-5 correct statements	87	11.5	42	48.3	26	29.9
	No prior report [a]	462	61.1	76	16.5	34	7.4
Relatives with or died from HIV	No	493	66.7	107	21.7	47	9.5
	Yes	246	33.3	68	27.6	39	15.9
Know someone taking ART	No	515	71.7	113	21.9	53	10.3
	Yes	203	28.3	64	31.5	34	16.7

Missing values: education (1); religion (13); ethnicity (1); income (3); children died (17); relatives died (17); know someone on ART (38). ART antiretroviral treatment; MTCT mother-to-child transmission; P1-4 primary level 1-4 years; P5 primary level 5 years
a No prior report: knowledge data point after pregnancy, or from an earlier sero-survey questionnaire lacking the same question
b Statements: "Drugs can only slow down HIV illness not stop it"; "ART drugs are very dangerous and can kill people"; "ART drugs have to be used for life"; ART drugs are available free of charge in Tanzania"; "Everyone who is infected with HIV needs drugs"

Table 6.2. Crude and multivariate logistic regression models for factors associated with access to HIV care and ARVs during pregnancy (n=756 pregnancies).

		Enrolled in HIV care						Accessed ARV drugs					
Factor	**Category**	**OR**	**95%CI**	**p (LRT)**	**aOR**	**95% CI**	**p (LRT)**	**OR**	**95%CI**	**p (LRT)**	**aOR**	**95% CI**	**p (LRT)**
Age*		1.2	1.1, 1.3	<0.001	1.1*	1.0, 1.2	0.04	1.1	1.1, 1.2	<0.001	1.1	1.0, 1.2	0.04
Year of pregnancy	2005-8	1		<0.001	1		<0.001	1		<0.001	1		<0.001
	2009-10	100	20, 506		59	13, 263		9.3	3.0, 29		7.2	2.3, 23	
	2011-2012	370	51, 2685		125	23, 672		46	12, 180		26	7.3, 90	
Residence area	Rural	1		0.02	1		0.09	1		0.9			
	Roadside	2.5	1.3, 4.8		3.1	1.0, 9.8		1.0	0.5, 2.0				
	Trading Centre	1.6	0.8, 3.2		2.6	0.8, 8.8		0.9	0.4, 1.9				
Marital status	Married now	1		0.09	1		0.04	1		0.1	1		0.1
	Never married	0.3	0.1, 1.0		0.2	0.0, 1.1		0.3	0.1, 1.1		0.2	0.0, 1.3	
	Married before	0.8	0.4, 1.5		0.4	0.1, 1.0		1.0	0.5, 1.9		0.7	0.3, 1.7	
Education	At least P5	1		0.2				1		0.7			
	P1-4	0.4	0.2, 1.2					0.7	0.3, 1.9				
	No education	1.0	0.6, 1.9					0.8	0.4, 1.5				
Religion	Catholic	1		0.6				1		0.4			
	Other Christian	0.8	0.4, 1.4					0.8	0.5, 1.5				
	Muslim	1.5	0.3, 7.1					2.6	0.6, 11				
	Traditional	0.5	0.1, 2.6					1.6	0.4, 6.5				
Ethnicity	Sukuma	1		0.7				1		0.7			
	Other	0.8	0.3, 2.2					0.8	0.3, 2.2				
Personal income	Farming/manual	1		0.7				1		0.6			
	Some business	1.0	0.5, 1.9					1.1	0.6, 2.2				
	None	1.4	0.6, 3.0					0.7	0.3, 1.7				
Gravidity (pregnancy number)	1	1		<0.001				1		<0.001			
	2	2.4	0.7, 8.0					1.7	0.4, 6.7				
	3	2.3	0.7, 8.1					1.7	0.4, 7.0				
	4	9.9	2.4, 40					3.8	0.9, 15				
	>=5	21.2	4.6, 99					7.7	1.9, 31				
Any children died	No	1		0.3				1		0.1			
	Yes	1.4	0.8, 2.3					1.6	0.9, 2.8				
Duration of HIV infection	<=2 years	1		<0.001	1		0.001	1		<0.001	1		0.001
	>2-4 years	3.3	1.4, 7.6		1.6	0.5, 4.5		1.1	0.4, 2.8		0.7	0.2, 2.2	
	>4 years	20.7	6.9, 61		7.2	2.2, 24		6.4	2.7, 15		3.7	1.2, 11	
Prior VCT	No	1		<0.001	1		0.05	1		<0.001	1		0.01
	Yes	6.7	3.5, 13		2.5	1.0, 6.3		5.4	2.8, 11		2.7	1.2, 6.3	
Knowledge of HIV transmission	None	1		<0.001				1		0.02			
	MTCT	5.3	1.2, 24					5.8	1.2, 29				
	Other modes	6.5	2.2, 19					3.5	1.1, 11				
	No prior report [a]	2.6	1.0, 7.3					1.7	0.6, 5.1				
ART knowledge [b]	<=2 correct	1		<0.001				1		<0.001			
	3 correct	0.9	0.3, 2.5					1.1	0.3, 3.3				
	4-5 correct	4.5	1.6, 13					5.3	1.8, 16				
	No prior report [a]	0.2	0.1, 0.4					0.4	0.2, 0.9				
Relatives with/ died from HIV	No	1		0.1				1		0.02			
	Yes	1.5	0.9, 2.7					2.0	1.1, 3.6				
Know someone taking ART	No	1		0.01				1		0.02			
	Yes	2.1	1.2, 3.8					2.0	1.1, 3.7				

OR odds ratio (crude); aOR adjusted odds ratio; CI confidence interval; LRT likelihood ratio test; MTCT mother-to-child transmission; P1-5 primary level

*Age modelled as a continuous variable, no evidence for departure from linearity (p=0.4 likelihood ratio test)

a No prior report: knowledge data point after pregnancy, or from an earlier sero-survey questionnaire lacking the same question

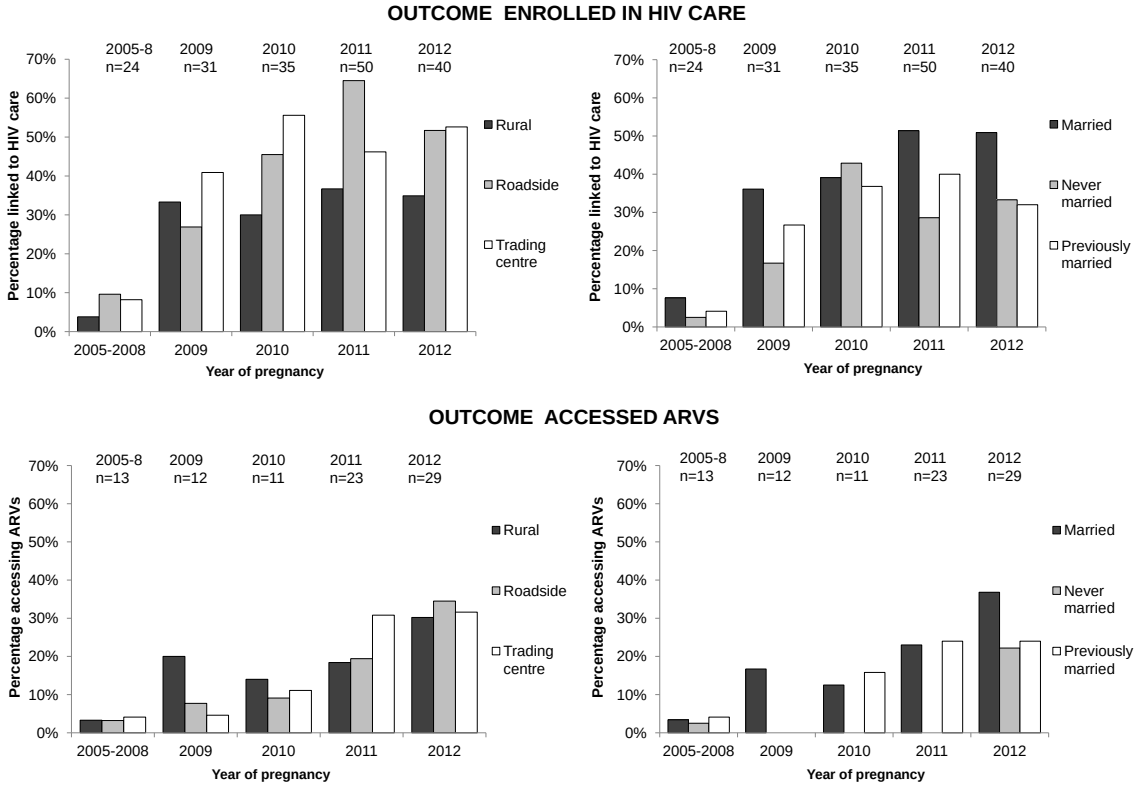
b Statements: "Drugs can only slow down HIV illness not stop it"; "ART drugs are very dangerous and can kill people"; "ART drugs have to be used for life"; ART drugs are available free of charge in Tanzania"; "Everyone who is infected with HIV needs drugs"

6.4.4 Factors over time

Patterns of access to care and ARVs by area or marital status were broadly similar over time (Figure 6.2). Rural women were generally at a disadvantage, although the pattern was inverted in 2009-2010 for ARV usage. There was no statistical evidence for an interaction between year of pregnancy (or age) and area or other variables.

Out of 50 women who had PMTCT in an earlier pregnancy, 42 (84%) accessed HIV care in their subsequent pregnancy.

Figure 6.2. Proportion accessing HIV care by area or marital status, over time (top row); proportion accessing ARVs during pregnancy by area or marital status over time (bottom row).



6.4.5 Comparison of linked and non-linked clinic records

Kisesa-resident ANC records that were not linked to the DSS (n=2579, 21%) did not differ in terms of age or year of ANC registration (marital status not recorded at ANC) to the linked ANC records (n=9842). However, compared to linked CTC records, a greater proportion of non-linked CTC records (n=174) were separated/widowed (n=661) (19% vs 9%, p=0.003), or were registrations prior to 2008 (25% vs 3%, p<0.001) (data not shown), but there was no difference in age.

6.5 Discussion

In this rural setting in Tanzania, access to PMTCT services was low but increased over time, with fairly few though sometimes strong inequities in service access. Area, marital status and age were the socio-demographic factors that predicted service use, alongside previously unexplored factors including prior VCT and duration of HIV infection; findings that could not have been deduced from a clinical cohort. Year of pregnancy was, perhaps unsurprisingly, the strongest predictor of access to care and ARVs, the large effect sizes reflecting the availability of PMTCT services in Kisesa from 2009.

Pregnant women living in rural areas were less likely to enrol in HIV care, with disparities persisting over time, likely reflecting the greater distance, time and cost of travel to health services; barriers that emerged in qualitative research on PMTCT in this setting (152). Poorer uptake of VCT in remote villages in Kisesa has also been documented (48, 49). Further decentralisation of CTC services to more rural areas, whilst maintaining a regular supply of HIV test kits and drugs (a major issue during the study time frame, particularly in dispensaries) (35, 152), will be important in ensuring all women in need of PTMCT services are reached. Surprisingly, area of residence was not associated with uptake of ARV drugs. This may be explained in part by the opposing patterns of access to ARVs by area when disaggregated by time period.

Unmarried HIV-positive pregnant women were less likely to access care and acquire ARV drugs than married women, with little change over time, potentially reflecting an absence of support from male partners – an important determinant of PMTCT service use in qualitative research in Kisesa and elsewhere (33, 158). In contrast, a few studies in sub-Saharan Africa found married or co-habiting women were less likely to use ARVs for PMTCT or other HIV services (48, 74, 86), perhaps due to perceived negative reactions from partners when disclosing their HIV status. Support for HIV-positive women for example through NGOs or community-based organisations (e.g. Mothers2mothers (115), and further involvement of relatives in PMTCT programmes may improve access.

Young pregnant women were a disadvantaged group for access to PMTCT interventions, mirroring findings from several African studies (42, 79, 88). Qualitative research in Kisesa and South Africa suggests that young HIV-positive pregnant women are sometimes discriminated against in health facilities, or fear negative reactions from health workers (35, 42). Providing additional support tailored to young HIV-positive

pregnant women, raising the profile of PMTCT services among this group, and improving behaviour of health workers through training and supervision may encourage attendance.

Increasing duration of HIV infection was a strong predictor of access to HIV care in pregnancy, presumably reflecting development of symptoms driving individuals to seek care. Shortages of HIV-test kits and consequent prioritisation of testing and enrolment for symptomatic women may have contributed to this finding. Some women who accessed HIV care were already attending the CTC prior to pregnancy, and may have been referred from VCT services after presenting with symptoms. The association between duration of infection and ARV uptake is also likely to reflect eligibility for ART with increasing disease progression, although ineligible women should have been offered prophylaxis. Qualitative research in East Africa suggests that asymptomatic HIV-positive pregnant women sometimes feel that ARVs for PMTCT are unnecessary (41, 91, 95), further supporting our findings. Promoting VCT attendance - independently associated with access to HIV care and ARV drugs during pregnancy - may bring women into care and treatment earlier in their infection. Implementation of Option B+ (life-long ART for all HIV-positive pregnant women) could also provide an incentive for pregnant women to seek care and treatment earlier (16).

In contrast to studies of VCT uptake in Kisesa (48, 50), we found no evidence that HIV knowledge or education predicted enrolment in PMTCT services. However, our findings are broadly consistent with recent quantitative research on uptake of PMTCT services (33). Contrasting findings between different HIV services may reflect differences in service models and motivations for clinic attendance, in which individuals seeking VCT actively decide to learn their status, compared to pregnant women seeking routine ANC services.

The primary strength of this analysis was the linkage of community cohort and clinic data, enabling a population-level investigation of factors associated with PMTCT service use and inclusion of women who did not access health facilities. Nevertheless, we were unable to link a portion of clinic records to the DSS (adjusted coverage estimates are presented elsewhere (159)). Unlinked clinic records did not differ in terms of age, but were more likely to be separated/widowed women, potentially biasing our estimates for marital status. Fewer clinic records from earlier time periods were linked, so the association with year of pregnancy may be over-estimated, although this is unlikely to have affected our conclusions. Selection bias is conceivable as sero-survey attenders might be in worse health than non-attenders (free treatment for

common health problems other than HIV is provided). The small proportion of missing records may have weakened some associations. Estimated HIV sero-conversion dates may have been inaccurate, although a sensitivity analysis limited to sero-incident cases revealed the same associations. The sample size limited the power to investigate factors by time period, and was possibly too small to detect smaller effects in multivariate analyses. While the set of factors associated with service use will vary by location, our findings may inform PMTCT programmes elsewhere in Tanzania and rural Africa.

In conclusion, we found access to PMTCT services was low but improved substantially over time, with a few strong socio-demographic differentials. Additional support for young or unmarried women may be needed. Programmatic factors such as accessibility, availability of HIV-test kits and drugs, previous contact with HIV services, and patient-provider interactions may be the strongest drivers of service use in this setting. Further decentralisation and strengthening of PMTCT services is necessary, while promotion of VCT and implementation of Option B+ may help to bring women into care and treatment sooner after HIV infection.

7 Qualitative research methods

This chapter provides an overview of the aims of the qualitative research and methods used, the objectives and design of the data collection tools, fieldwork recruitment and training, piloting, sampling and recruitment, data collection, preparation of the data and analysis of results.

7.1 Aims and overview

The broad aim of the qualitative study conducted for this thesis was to investigate barriers and facilitating factors to the use of PMTCT services in Kisesa, rural Tanzania. A variety of qualitative methods and participant types were used: participatory learning and action (PLA) group activities with female and male community members, in-depth interviews (IDI) with HIV-positive and HIV-negative women, partners/ relatives of HIV-positive mothers, and IDIs with health workers and officials. Structured observations of public areas of Kisesa health centre antenatal clinic (ANC), delivery ward, child clinic and HIV care and treatment clinic (CTC) were also conducted.

The use of multiple methods within the qualitative component of this PhD research allows for 'methodological triangulation' ('within-method'), where the findings emanating from two or more methods used to address the same broad research question are compared, in order to enhance the validity of the findings and deepen the understanding of the data (160, 161). A further layer of triangulation was also possible within this thesis through the inclusion of quantitative methods, enabling 'between-method triangulation', where the findings from the qualitative and quantitative methods (for example, factors influencing the uptake of PMTCT services) could also be compared. The design of the qualitative study to include different sources of information and perspectives, in this case different types of participants, also allows for 'data triangulation' in which insights from these different sources are compared to bring a deeper meaning to the data and raise their validity.

Fieldwork took place in May to June 2012. The design of the data collection tools, fieldwork processes and analysis of the results were carried out in collaboration with local fieldworkers and scientists, while fieldwork methods were inherently participatory, enhancing the relevance of the work to the local context and community ownership.

7.2 Objectives and design of the data collection tools

7.2.1 PLA activities

PLAs resemble more commonly used focus group discussion methods, often incorporating an element of group discussion, but including further participation from participants such as role playing or creating pictures and maps. PLA approaches are particularly effective with rural and sometimes illiterate populations in Africa, as they combine the collection of information and beliefs from communities with the provision of new information, and can mobilise support around relevant issues. PLAs had been conducted previously in Kisesa to investigate barriers to retention in other HIV programmes, and ART access (37, 38).

The objectives of the PLAs were to (1) Identify barriers and facilitating factors to the uptake of PMTCT services (data generation); (2) Identify strategies to reduce barriers to accessing PMTCT services (data generation); (3) Develop a vignette for the IDI discussion guides; (4) Recruit HIV-positive and HIV-negative mothers from the community for IDIs; (5) Raise awareness and encourage support for prevention of mother-to-child transmission (PMTCT) and antiretroviral treatment (ART) services. In order to address these objectives, the PLA protocol included 5 sections, outlined in Table 7.1. The full PLA fieldwork protocol is presented in appendix 12.4.7.

Table 7.1. Summary of activities included in the PLA activities with groups of male or female community members.

Section	Activity	Objectives addressed	Summary
1 (day 1)	Group discussion	1	Discussion focussing on knowledge of vertical transmission of HIV and the PMTCT programme
2 (day 1)	PMTCT 'journey'	Platform for section 3 & 4	Arrangement of cards representing components of PMTCT services (ANC attendance; HIV testing; provision of antiretroviral drugs to mothers and infants; delivery in the health centre; infant feeding advice)
3 (day 1)	Storyline and role-play	1, 3	Character and storyline development, role-play of the story composed, followed by group discussion reflecting on the play
4 (day 2)	Barriers brainstorm & 'wall of challenges'	1, 3	Group discussion of barriers at each step of the PMTCT 'journey' and creation of cards representing each barrier; ranking of barriers by arranging barrier cards on a wall, with those most important at the top
5 (day 2)	Hanging fruits tree	2	Brainstorming of possible solutions to overcome the barriers identified, with solutions represented on fruit shaped cards; fruits placed on a tree diagram, according to how easy or difficult to achieve

Each group completed all or a selection of the activities (see section 7.6)

The first activity was included as a logical starting point for the activities, and to explore knowledge of vertical transmission and PMTCT services (as limited knowledge of vertical transmission and PMTCT was identified as a barrier to uptake of ARV drugs for PMTCT in the systematic review, but was unlikely to be raised by women during brainstorming discussions about barriers). The second activity was intended to further explore knowledge of PMTCT services, while also providing a foundation for subsequent activities – to situate the discussions of barriers and facilitating factors at each step of the PMTCT cascade, and to provide a base on which to place and photograph barrier cards at the appropriate point of the PMTCT cascade. The concept of a hypothetical woman on a 'journey' was used to provide a non-threatening environment (by allowing participants to discuss challenges for a third person), and imagery relevant to the local culture. The storyline and role-play activity (section 3) was included to inform the development of a vignette for use in the IDIs (objective 3). The recruitment strategy for the IDIs (objective 4) is outlined below (see section 7.5).

The participatory nature of all the activities was intended to raise awareness among community members about PMTCT and ART services for pregnant women (objective 5).

7.2.2 In-depth interviews

The primary aim of the IDIs with HIV-infected women was to enable a private and detailed discussion of personal experiences of the PMTCT programme, thus exploring personal challenges and facilitating factors to involvement in the programme. Interviews with HIV-negative women aimed to explore personal experiences of ANC, delivery and infant care services more broadly, serving as a comparison with the challenges faced by HIV-positive women. These interviews were also included to enhance the ethical standards of the recruitment procedure. Details of recruitment procedures and the number and characteristics of participants are provided in sections 7.5 and 7.6.

It was expected that support, or lack of support, from male partners and relatives could play an important role in uptake of PMTCT services in Kisesa, based on results from the systematic review (33). A few (n=3) IDIs with male partners and female relatives of HIV-infected women were therefore included, aiming to explore involvement in their partner's/ relative's pregnancy, delivery and infant care, and attitudes towards their inclusion in the PMTCT programme.

The discussion guides for the interviews with mothers, partners and relatives included a vignette about an HIV-positive pregnant woman, composed on the basis of the PLA activities. Vignettes are short stories about a hypothetical person, presented to participants to understand their own set of beliefs, and can be useful for discussions of sensitive topic areas as the focus is on a third person (162, 163). The primary aim of including the vignette was therefore to build a comfortable atmosphere for the interview, and encourage HIV-positive mothers to admit, at any time during the interviews, to any difficulties that they had faced in using PMTCT services. A secondary aim of the vignette was the generation of data on barriers and facilitating factors to using PMTCT services from the perspectives of HIV-positive women, as well as HIV-negative mothers, partners and relatives who lacked personal experience of the programme (perceptual data). Further details of the aims and process for development of the vignette are included in chapter 8 (paper E).

The discussion guide (appendix 12.4.8) for IDIs with mothers was divided into 4 sections: personal background (serving as an 'ice-breaker'), the vignette, personal experiences with PMTCT or MCH services, and overall perceptions of services and suggestions for possible improvements. Discussions with partners and relatives included the same general sections, but in a different order, beginning with personal

experiences which focussed on involvement in their partner's or relative's pregnancy, delivery and HIV care (appendix 12.4.9). The vignette was included after the personal experiences section, to avoid partners potentially overstating their involvement after hearing the vignette which depicted an unsupportive partner (and thus primarily served as a tool for generating data on perceived challenges to using PMTCT services for HIV-positive pregnant women, rather than creating a comfortable atmosphere).

Interviews with health workers and officials were designed primarily to investigate the challenges to delivering PMTCT services, and possible ways to overcome these challenges. The health worker and official IDI discussion guide (appendix 12.4.10) captured details of the respondent's own role in relation to the PMTCT programme (an 'ice-breaker' and providing context for the remaining discussion), evolution of the PMTCT programme in the area, strengths and weaknesses of the programme, perceived barriers for women participating in PMTCT services, challenges with delivering or coordinating services, and possible ways of overcoming these challenges.

7.2.3 Observations

Observations were planned to contribute to an understanding of health systems barriers to the uptake of PMTCT services, and to facilitate a deeper understanding of how the PMTCT programme operates in reality, in comparison with processes envisioned by national protocols. They were also intended for triangulation with the other qualitative data sources, as interviews with health providers and community members were expected to be influenced by self reporting and social desirability biases.

Structured observation sheets were prepared (appendix 12.4.11) which included prompts for observation of staff and client behaviour and interactions, privacy, procedures carried out, client volume and waiting times.

7.3 Fieldworker recruitment and training

Local Tanzanian fieldworkers in the ratio of three females to one male were recruited in order to reflect the greater number of interviews planned with female participants, so that the interviewees could be matched by sex to their interviewer. The selected fieldworkers had prior experience of conducting qualitative research in Kisesa or elsewhere in Tanzania, including in-depth interviews and focus group discussions. They had less experience of participatory group methods and no experience of using vignettes. The theory underlying these methods and practical guidance was therefore included in fieldworker training sessions, particularly highlighting the participatory

element of PLAs that distinguishes this technique from focus group discussions. Fieldworkers had prior knowledge of HIV services based on involvement in previous research projects, but little or no knowledge of PMTCT services, so training sessions also covered vertical transmission of HIV, and PMTCT services.

Initial training took place over one week, prior to commencement of the PLAs. A further day of training on the use of vignettes in qualitative research was planned after completion of the PLAs, and before initiation of the IDIs. This was primarily so that fieldworkers had the chance to discuss and practise the vignette developed, and so that methodological issues were fresh in fieldworker's minds, given the lag time between the initial training session and completing the PLAs. I designed the fieldworker training tools (including Microsoft PowerPoint presentations, printed information sheets and slides, and a few selected examples of other studies using vignettes (42, 117)), and delivered the sessions in collaboration with a Tanzanian social scientist. The training sessions were interactive: fieldworkers shared experiences of prior research projects which allowed me to gauge individual skills, and to learn from past successes and challenges in order to optimise the fieldwork schedule and recruitment protocols. Specific goals for each part of the fieldwork were also discussed.

Fieldworkers translated the data collection tools. This enabled further familiarisation with the tools and the opportunity to provide feedback (thus original drafts were sometimes modified, see section 7.4), as well as the selection of language which they understood and would be understood by respondents in this study setting. Translations were shared and discussed amongst themselves, in order to verify the integrity of the translations.

7.4 Piloting

Fieldworker training days also included the opportunity to review, practise and pilot the materials on volunteer participants (e.g. cleaning and cooking personnel from the National Institute of Medical Research, Mwanza). I observed these practice sessions and subsequently discussed with the fieldwork team any difficulties encountered. Refinements to the PLA protocol were made on the basis of these pilots and discussions. For example, the methods for facilitating the storyline development and role-play were simplified (further details provided in paper E).

7.5 Sampling and recruitment

7.5.1 PLA activities

Participants were selected for the PLAs from a sampling frame of men and women aged 15-60 who had at least 1 child, and thus were likely to have views or experiences of MCH services. The sampling frames were constructed using Kisesa cohort datasets, and divided by geographical area (remote villages, roadside, and trading centre). The selection of participants from the sampling frames was random (using the facility for random number functions in Stata software), with the exception of a few female HIV-positive individuals ('seeds'): these women were purposively selected from the sampling frame based on a positive test result from research HIV testing, and a recorded pregnancy or delivery since 2009 (when the PMTCT programme was fully implemented in Kisesa), and since testing HIV-positive. The seeded focus group method has been used previously in Kisesa to enhance confidentiality in the recruitment of HIV-positive individuals for research (164). I aimed to include 2-4 HIV-positive women in each female PLA group, who could subsequently be invited to attend IDIs (detailed below).

I prepared recruitment lists for each PLA group, and provided them to one fieldworker who made home-visits to those listed. Between 25 and 30 individuals, including approximately 8 HIV-positive women, were included on each recruitment list, allowing for absence when visited, or refusals to participate. Recruitment stopped once 12 participants had been recruited for each group. The study aims were explained to potential participants, and the date and timings of the activity recorded on an invitation slip (appendix 12.4.12). Only participants who were able to attend on both days were invited. Overall, 29% of individuals visited could not be located, and 2% refused to participate due to lack of time or inclination. Fieldworkers were unaware of the HIV status of all individuals on the recruitment lists and those participating in the activities.

7.5.2 Interviews with women from the community

Women were recruited purposively for interview from the community, via the PLA activities, and from each health facility in Kisesa, by clinic nurses. The aim was to recruit approximately 15 HIV-positive women for interview. Both methods of recruitment were chosen in order to include a mixture of women with and without experience of MCH or PMTCT services.

After the PLA activities, all participants were invited one by one to receive their travel compensation (5000 Tanzanian shillings, approximately 3 US dollars (USD)) and asked if they would be willing to be contacted again to attend an interview, while specific interview appointments were only made discreetly with those who were labelled with appropriate codes (by myself) on a pre-prepared PLA participation sheet (appendix 12.4.13). This procedure was designed, in a variation of the seeded focus group method, to lessen the suspicion or disappointment of other women, had they not even been invited for interview. To further protect the anonymity of HIV-positive women, a few HIV-negative women were also invited for interview. These women were also indicated on the coded sheet, selected at random based on a recent pregnancy or birth recorded since 2009 in the cohort data. Formal invitation slips were not provided to these women, so that the interview appointments remained discreet. Instead, reminders of the appointment date were made by a fieldworker, by phone call or home-visit, as preferred by the participant. Facilitators explained the aims of the interviews, including exploration of personal experiences with MCH services. Two women declined to be interviewed (both HIV-positive, of the 8 HIV-positive women invited for interview). All 5 HIV-negative women invited for interview accepted.

MCH clinic staff from each facility in Kisesa were informed of the study aims and objectives, and asked if they would be willing to assist in the recruitment of HIV-positive women for interview. Compensation of 10,000 Tanzanian shillings (approximately 7 USD) was offered for their time. They were instructed to recruit, during private consultations with their patients at ANC or MCH clinics, HIV-positive women who had recently given birth (since 2009), otherwise currently pregnant women. One MCH nurse at Kisesa health centre was asked to recruit four women, while a nurse from each dispensary was asked to recruit two women, to ensure a balance of women by residence area and facility type attended. Potential recruits were informed of the study aims verbally, and appointments scheduled, with reminders written on invitation slips (appendix 12.4.14). Nurses were instructed to make appointments for interview during specified time windows, and alert the fieldworker in charge of recruitment once appointments had been made. This (male) fieldworker did not conduct any interviews with women, whose HIV status therefore remained concealed from the (female) interviewers unless participants voluntarily disclosed their status during the IDIs. A log sheet was also prepared, on which recruiters were requested to record all appointments.

7.5.3 Interviews with partners and relatives

HIV-positive women who had disclosed their HIV status to the interviewer and to their partner or relatives were asked if they were willing for their partner, or if not a female relative, to be invited for interview (snowball sampling). Details of the potential participant were recorded on the IDI discussion guide document. A fieldworker then phoned or visited these suggested participants to explain the study and invite them for interview. Of the 6 partners/ relatives referred, 3 were interviewed. Three refused due to excessive work commitments or extended travel, or were not located.

7.5.4 Interviews with health workers

Health workers involved in the PMTCT programme were selected purposively by consulting with the clinicians in charge of Kisesa facilities. Those selected were:

- MCH nurses at Kisesa health centre (one senior and one junior) and each dispensary (one from each) overseeing antenatal care, delivery and infant follow-up
- CTC clinician responsible for long-term HIV care and treatment of HIV-positive pregnant patients, including those referred from ANC at Kisesa health centre and the neighbouring dispensaries

Health officials were identified initially by discussion with the TAZAMA clinician, and by referrals from the interviewees (snowball sampling). Three appropriate respondents were identified:

- District AIDS coordinator
- District reproductive and child health (RCH) coordinator
- Bugando Medical Centre obstetrician, one of the founders and site coordinators of the national PMTCT programme, and consultant to the Ministry of Health regarding national PMTCT policy

Invitations for interview were made in person (either by me, or the TAZAMA clinician) by visiting these individuals at their work place, or by phone call. The study aims and procedures were discussed verbally with the respondents, and detailed information sheets were also provided at the time of consent, as detailed further below.

A summary of the recruitment procedures and characteristics of individuals who participated in the research are provided in the following section (Table 7.2 to Table 7.4).

7.6 Data collection procedures

7.6.1 Sequencing of methods

PLAs were conducted before the IDIs, so that the findings could be used to develop the vignette and IDI guides. Interviews with mothers and health providers were conducted concurrently. IDIs with partners and relatives were conducted after the interviews with HIV-infected mothers, reflecting snowballing recruitment procedures.

7.6.2 PLAs

PLA activities were conducted with three male and three female groups from different residence areas (remote rural villages, roadside villages and the trading centre) in Kisesa ward. Each group comprised 8-12 participants. Between 1 and 5 HIV-positive women ('seeds') attended each female PLA group. The activities for each PLA group were split over two consecutive days, lasting approximately three hours per day, with the same group of participants attending on both days. The activities for the male trading centre group were condensed into one day, eliminating the storyline and role-play activity, and shortening the hanging fruits tree activity to only brainstorming of solutions, as local business men would find it difficult to commit to attending over two days.

PLA activities were conducted in Kiswahili by a facilitator and note-taker matching the sex of participants, with the exception of male PLA groups, where the note-taker was female. I observed most of the PLAs. Fieldworkers organised the activities according to the numbers of participants attending: participants remained in one group for most of the activities, including the role-play, but were split into two groups to brainstorm solutions (activity 5) to different sets of barriers. Solutions conceived by each group were then presented to, and discussed with, the other group and the facilitator. Fieldworkers assisted participants with writing on the cards representing different barriers or solutions that were affixed to the PMTCT journey map, wall of challenges, and hanging fruits tree, to convey the suggestions made by participants. When referring back to the cards created, fieldworkers and participants recapped the challenges or solutions that were represented on each card. Details of and reflections on the methods used to facilitate the storyline and role-play activity are presented in paper E.

Following consent from participants, each PLA group session was audio-recorded. Within each PLA session, a minority of activities could not be recorded, for example the role-plays, because the participants were allowed to move around the room,

compromising sound quality. Note-takers recorded the content of discussions, details of the storyline and role-play activity, and behaviours observed. These notes were subsequently typed up in English for the research team. Photographs were also taken of all the physical outputs from the activities (Figure 7.1). De-briefing discussions were held with the fieldwork team following every PLA group. I recorded notes from these discussions.

Figure 7.1. Examples of photographed outputs from the PLA group work.

(Left, hanging fruits tree; right, PMTCT journey)

7.6.3 In-depth interviews

Thirty-three IDIs were conducted in total: 21 with mothers (16 HIV-positive and 5 HIV-negative) who recently gave birth, 2 with male partners of HIV-infected mothers and 1 with a female relative, 6 with health-workers, and 3 with health officials. Interviewers were matched to the sex of the respondent, with the exception of the health worker and health official interviews: health workers were interviewed by the male fieldworker (a qualified clinical officer who could therefore engage in more complex discussions with health providers). I conducted the interviews with health officials. All interviews with community members were conducted in Kiswahili (although a few included interchanges in Kisumuka, the local tribal language, for participants who were less familiar with Kiswahili). IDIs with health officials were conducted in English, as these respondents regularly conversed in English as part of their professional role. All IDIs were audio-recorded, following informed consent from each participant. After each IDI, I held and documented de-briefing sessions with the interviewer.

A summary of PLA and IDI sample sizes and recruitment procedures is provided in Table 7.2. Basic demographics of the PLA participants and women recruited for IDIs are shown in Table 7.3 and Table 7.4.

Table 7.2. Summary of sample and recruitment procedures for IDIs and PLAs.

Method	Total sample size	Respondent type and numbers	Recruitment
PLA	61 (6 groups of 8-12 participants)	Men (3 groups) & women (3 groups)	Random, from cohort data sample frame of community members aged 15-60 with >1 child, plus purposive selection of a few HIV+ women with births or pregnancies since 2009
IDI	21	HIV+ (16) and HIV- women (5) who were pregnant or gave birth since 2009	Purposive: 11 from PLAs (community recruits); 10 from clinics, recruited by nurses (≥2 participants from each Kisesa clinic)
IDI	3	Partners or relatives of HIV-positive women	Snowball sampling as suggested by HIV-positive IDI participants
IDI	9	Health workers (6, including MCH nurses and HIV clinic doctor) & health officials (3)	Purposive; from each Kisesa facility, and relevant coordinators at district and referral hospital levels

Table 7.3. Characteristics of PLA group participants.

	Female PLA groups	Male PLA groups
Characteristic	**Number (%) of participants (n=30)**	**Number (%) of participants (n=31)**
Age		
19-29	7 (23)	5 (16)
30-39	13 (43)	8 (26)
40-49	7 (23)	12 (39)
50-59	2 (7)	6 (19)
Unknown	1 (3)	0
Mean (range)	36 (19-54)	42 (24-59)
Area of residence		
Remote rural	12 (40)	10 (32)
Roadside	10 (33)	9 (29)
Trading centre	8 (27)	12 (39)
HIV status		
HIV-positive	8 (27)	0
HIV-negative	21 (70)	15 (48)
Unknown	1 (3)	16 (52)

3 male and 3 female groups each with 8-12 participants, N=61 participants in total

Table 7.4. Summary of the characteristics of women participating in IDIs.

Characteristic	Number (%) of participants (n=21)
Recruitment method	
From community (PLA)	11 (52)
By clinic nurse	10 (48)
Age	
20-29	4 (19)
30-39	11 (52)
40+	4 (19)
Unknown	2 (10)
Mean (range)	34 (20-47)
Area of residence	
Remote rural	10 (48)
Roadside	5 (24)
Trading centre	6 (29)
HIV status	
HIV-positive	16 (76)
HIV-negative	5 (24)
Year of most recent delivery	
2009	3 (14)
2010	5 (24)
2011	11 (52)
2012	2 (10)
Education	
None	1 (5)
Primary	10 (48)
Secondary +	0
Unknown	10 (48)

7.6.4 Observations

Structured observations were conducted at Kisesa health centre ANC and child follow-up clinic approximately once per week during the fieldwork period, documented using the structured observation sheets. Antenatal and under 5 child follow-up clinics are provided within communal areas of the same open-plan building, thus observations could be made of both during one visit. I was the primary observer, and was accompanied by a female fieldworker, fluent in Swahili, on a few occasions. This fieldworker also made a few visits alone. I also made informal observations throughout the fieldwork period, at each visit to the health centre and dispensaries, including observations of other communal areas of Kisesa health centre: the delivery ward, CTC and VCT buildings. Informal observations were also documented. All observation notes were documented in English.

7.7 Data preparation and analysis

Audio-recordings from PLAs and IDIs were transcribed verbatim in Kiswahili (or Kisukuma where used), and then translated into English. Translations, photographed outputs from PLAs, fieldworker notes, and de-briefing documents were all uploaded into NVIVO9.

Preliminary analysis was conducted during the fieldwork period: de-briefing and fieldworker notes were used to identify key themes arising, so that probes could be added or modified in the remaining activities, to clarify information or explore new concepts emerging. PLA de-briefing notes also informed development of the vignette for the IDIs (details of and reflections on this process are described in paper E).

Final analyses after the fieldwork period were carried out using all sources – translations, fieldworker and de-briefing notes, and photographs. The analysis was conducted in stages. The aim of the first stage was familiarisation with the data and identification of the balance of barriers and facilitating factors affecting the use of PMTCT services in Kisesa. After reading through all the translations, I made summary notes for each IDI, including background details of each respondent (e.g. village, marital status, last pregnancy), the timing, location and nature of services accessed, and outcomes in terms of PMTCT (e.g. receipt of ARV drugs, infant HIV testing and diagnosis). A framework approach was adopted, using the socio-ecological framework arising from the systematic literature review (paper A) to organise the coding. Using the initial socio-ecological framework, I coded all translated documents. Coding was also done inductively, to allow for any new barriers and facilitating factors that had not been included in the original framework.

A second stage of analysis was conducted to critique the successes and challenges associated with using the vignette method in this setting (paper E). I reviewed all translations of IDIs with mothers and IDIs with partners or relatives again, creating codes to capture the different ways that participants responded to the vignette, and how fieldworkers dealt with their answers. The interpretation of the vignette by respondents or by fieldworkers was assessed, including difficulties such as confusion, misunderstandings, or delays during the vignette section of the interviews, or conversely, the ease of understanding and transitioning through the discussion questions. Whether participants considered the final vignette to be realistic was also examined. To determine whether the vignette made participants feel more comfortable during the IDIs, transcripts were assessed for examples of personal information or

experiences, or experiences of acquaintances, that were voluntarily raised during the interviews. The stage of the interview (before, during or after the vignette discussion) at which such information was shared was considered. Any signs of discomfort were also captured. Responses to the vignette were compared by respondent type. Comparisons were also made within cases, between responses to the vignette and the personal experiences section.

The final analysis stage aimed to explore in detail the nature of patient-provider interactions in the context of PMTCT services in Kisesa, and their influence on the use of PMTCT services. A patient-centred care framework was used as a starting point for the analysis, to organise the initial code-frame. Five dimensions of patient-centred care proposed by Mead and Bower were used: bio-psychosocial perspective, patient-as-person, doctor-as-person, therapeutic alliance, and sharing power and responsibility (described in further detail in paper F). Other key elements that were identified in a literature review of patient-centred care models, including disparities in care, continuity of care and structural influences, and that were expected to play a role in this setting, were included, as well as relevant outcomes (e.g. adherence to PMTCT programme step) (165-167). After applying the code-frame to the first few transcripts it was refined, for example by sub-dividing or combining codes to integrate concepts. Coding was also done inductively, allowing for new codes to be added to the code-frame, to capture new concepts emerging. In-vivo codes were also used to document participants' own terminology (in-vivo coding describes the process of using participants' own words or phrases as codes, rather than assigning codes that are labelled with the researcher's terms and interpretation of the data (168)). Codes were then grouped into overarching themes and the resulting code-frame applied to all IDI and PLA transcripts ('indexing'). Transcripts were assessed for content describing conversations between providers and patients, or their behaviour, for example the way in which patients described being treated and questioned by providers (and vice versa). Content revealing the approach to care was scrutinised, for example by checking for discussions of non-medical matters, patients asking questions, or statements suggesting empathy, which are suggestive of a patient-centred approach and have been included in most coding schemes for analysing verbal behaviour and patient-centred care (169)). Links to outcomes related to use of PMTCT components were also made. To reinforce perspectives from personal experiences, perceptual data, such as that arising from the vignette, were included in the analysis. Charts were created in Microsoft Excel to compare data across and within cases (e.g. between different sections within an interview with one individual, or comparisons between interviews with different individuals). Four translations were also read and double-

coded by another researcher (Alison Wringe), using the same initial patient-centred care framework. We compared and discussed our revised code-frames, to verify that all emerging concepts were captured.

7.8 Ethical considerations for the qualitative research

Ethical approval for qualitative study was received from the LSHTM and Tanzanian ethical review boards (appendix 12.2.3). Recruitment procedures, using an adaptation of the seeded focus group method and including some HIV-negative women, were designed specifically to maximise confidentiality for HIV-positive women. Interviews took place in private central locations in the trading centre, roadside and rural villages (eg. health centre or dispensary private rooms, or community meeting venues). In the case of health workers, interviews were conducted in their office, another private room in the facility, or their home, as preferred by the participant. PLA participants, and women and their partners or relatives attending interviews were reimbursed 5000 Tanzanian shillings (approximately 3 USD) to cover travel expenses, and were provided a soft drink.

All PLA and IDI participants were informed about the study, before commencing the activities or interviews. They were advised that discussions were confidential, although PLA participants were told they were not required or expected to share personal information. Participants were told they could decline to answer any questions, or leave the activity at any time. Verbal consent was recorded from all PLA participants, and written consent obtained for IDIs (appendix 12.4.15). The alternative option of verbal consent was also provided for illiterate IDI participants. Consent was also obtained for audio-recording the activities or interviews.

At the start of each PLA activity, fictitious names, such as an animal or fruit, were chosen by participants, and were used to protect respondent anonymity. Generalised names such as ‘dada’ (Swahili for sister) were also used to refer to respondents during PLAs or IDIs. All documentation was labelled with codes. For example, interviews with women were labelled with a number, the village and date (e.g. IDI_01_Kisesa_May31), and interviews with health workers labelled with a number and date (e.g. ‘IDI_HW1_June01’). Published quotations by health workers and officials were not identified by job role or centre, which could otherwise reveal their identity due to the small number of staff within some facilities. No documented observations were linked to a named provider or patient. Audio-recordings, transcriptions, translations, notes

and photographs of physical outputs were stored on the secure server in NIMR, my personal laptop, or the LSHTM secure server, all with password-restricted access. Arrangements for data sharing are discussed in chapter 10.

8 Paper E. Using vignettes in qualitative research to explore barriers and facilitating factors to the uptake of prevention of mother-to-child transmission services in rural Tanzania: a critical analysis

Introduction to the paper

The systematic literature review (paper A) highlighted the delicate nature of the topic area, with particularly sensitive issues at the individual and community levels such as denial of HIV status, fear of status disclosure to others, HIV stigma and relationship issues. Qualitative studies included in the literature review were generally appraised as good quality and succeeded in drawing out some of these more subtle barriers, although authors of qualitative and quantitative studies acknowledged the possibility of reporting bias and social desirability of responses. Under-reporting by women of other socially sensitive outcomes, such as the number of sexual partners, has also been reported in previous studies conducted in Kisesa (170).

In order to maximise the detail, accuracy and quantity of information captured about barriers and facilitating factors to the use of PMTCT services in this rural African setting, I chose to incorporate a vignette (short story and associated questions) into the qualitative study design. I hypothesised that women would be encouraged to admit to any difficulties they faced after hearing the story of another person experiencing issues with accessing PMTCT, or alternatively, would at least be able to discuss barriers from the perspective of the character in the story.

However, I found that very few studies had used vignettes within the context of HIV research, or health research in Africa, and there were no detailed methods reported to aid the design and implementation of the technique in the field. One paper, included in the systematic literature review, had used vignettes to draw out barriers to PMTCT services among HIV-positive pregnant adolescents (42). I used this paper to guide the design of my qualitative data collection tools and fieldwork protocols, but it lacked practical recommendations or reflections on feasibility in the setting.

While piloting the fieldwork tools, it became apparent that the methods planned for developing the vignette needed to be simplified and condensed for fieldworkers and

participants in this setting. Discussions during fieldwork de-briefings and analysis of transcripts also suggested challenges in implementing the technique during in-depth interviews and in interpretation of results.

The critical analysis presented in paper E was therefore conducted to critique the successes and challenges with developing and implementing vignettes in this setting, aiming to provide practical advice and recommendations for future use of the method. The paper also aimed to assess the quality and quantity of data generated by using the vignette, and to reflect on data interpretation issues. This aided the analysis and interpretation of the findings about barriers to PMTCT service uptake in Kisesa, and about the nature and consequences of patient-provider interactions within PMTCT services presented in paper F.

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   I conceived and designed the study including data collection tools (in collaboration with co-authors including Tanzanian researchers), I trained the fieldworkers, managed the fieldwork, interviewed health officials, analysed the data, and wrote the manuscript.

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8.1 Abstract

Background: Vignettes are short stories about a hypothetical person, traditionally used within research (quantitative or qualitative) on sensitive topics in the developed world. Studies using vignettes in the developing world are emerging, but with no critical examination of their usefulness in such settings. We describe the development and application of vignettes to a qualitative investigation of barriers to uptake of prevention of mother-to-child transmission (PMTCT) HIV services in rural Tanzania in 2012, and critique the successes and challenges of using the technique in this setting.

Methods: Participatory Learning and Action (PLA) group activities (3 male; 3 female groups from Kisesa, north-west Tanzania) were used to develop a vignette representing realistic experiences of an HIV-infected pregnant woman in the community. The vignette was discussed during in-depth interviews with 16 HIV-positive women, 3 partners/relatives, and 5 HIV-negative women who had given birth recently. A critical analysis was applied to assess the development, implementation and usefulness of the vignette.

Results: The majority of in-depth interviewees understood the concept of the vignette and felt the story was realistic, although the story or questions needed repeating in some cases. In-depth interviewers generally applied the vignette as intended, though occasionally were unsure whether to steer the conversation back to the vignette character when participants segued into personal experiences. Interviewees were occasionally confused by questions and responded with what the character *should* do rather than *would* do; also confusing fieldworkers and presenting difficulties for researchers in interpretation. Use of the vignette achieved the main objectives, putting most participants at ease and generating data on barriers to PMTCT service uptake. Participants' responses to the vignette often reflected their own experience, (revealed later in the interviews).

Conclusions: Participatory group research is an effective method for developing vignettes. A vignette was incorporated into qualitative interview discussion guides and used successfully in rural Africa to draw out barriers to PMTCT service use; vignettes may also be valuable in HIV, health service use and drug adherence research in this

setting. Application of this technique can prove challenging for fieldworkers, so thorough training should be provided prior to its use.

8.2 Background

Vignettes are short stories about a hypothetical person, presented to participants during qualitative research (e.g. within an interview or group discussion) or quantitative research, to glean information about their own set of beliefs. They are usually developed by drawing from previous research or examples of situations which reflect the local context, creating a story that participants can relate to. Participants are typically asked to comment on how they think the character in the story would feel or act in the given situation, or what they would do themselves. As the focus is on a third person, vignettes can be advantageous in research on sensitive topics where the participant may not feel comfortable discussing their personal situation and may conceal the truth about their own actions or beliefs. They can also, through normalisation of the situation, encourage participants to reveal personal experiences when they feel comfortable to do so (162, 163, 171, 172).

Vignettes have traditionally been used in the developed world in (predominantly quantitative) research on psychology and potentially sensitive social and health issues such as sexual health, HIV, mental health, stigmatisation, violence, and in specific vulnerable populations such as children and drug users (162, 163, 172-181). Hughes, and Barter and Renolds reflected critically on the methodology of vignettes with reference to their own research and other studies conducted in the developed world, concluding that the technique can be a valuable research tool despite debates surrounding their use: primarily the extent to which vignette responses mirror social reality. (162, 172). Studies from the developing world (including Africa) using vignettes have emerged more recently (42, 182-191), but none have critically examined the use of vignettes in such settings. These studies have mainly focussed on similar topics to those investigated traditionally in North America and Europe, such as sexual health, mental health and stigma, but also include areas such as malaria and public health campaigns.

Very little qualitative research about HIV services in this setting, particularly prevention of mother-to-child transmission (PMTCT) of HIV or drug adherence (in the push for universal testing and treatment), has used vignettes to elicit perspectives of patients (or providers) regarding service or drug use. The few examples include Varga and

Brookes' study in South Africa, based on the narrative research method of the World Health Organisation (192): vignettes were developed during workshops with 'key informants' and presented during focus groups and surveys with pregnant HIV-positive adolescents to investigate barriers to participation in PMTCT services (42). Bentley et al. also used vignettes to investigate perceptions of HIV-positive mothers regarding breastfeeding practices and nutrition in Malawi (193). Varga and Brookes discussed methodological implications of their approach, reflecting that adolescent mothers spoke more easily about their own experiences after discussing the story of another teenager, and suggesting that in-depth interviews (IDI) exploring personal experiences can be useful in verifying and understanding responses towards the vignette. However, neither paper evaluated the specific challenges nor advantages of applying vignettes in their setting, for example the extent to which respondents understood the directions they were given, or how well fieldworkers facilitated discussions or interviews containing vignettes.

Global commitments have been made to improve uptake of PMTCT services (2) in view of the low coverage noted in many African countries (53). An emerging body of research is exploring reasons for low access and usage of PMTCT services: barriers include sensitive issues such as stigmatisation regarding HIV status, fear of disclosure to partners or other relatives, and psychological barriers including denial (33).

The potential for reporting bias in studies on barriers to PMTCT service use in sub-Saharan Africa has been noted (33), and in our study setting, under-reporting by women of other socially sensitive outcomes (e.g. number of sexual partners) was reported (170). We therefore expected that a number of HIV-positive women would not admit to difficulties they faced when accessing PMTCT services, or would feel uncomfortable discussing such issues during interviews. Vignettes could consequently be a valuable and under-used tool in PMTCT/HIV research and drug adherence more widely. They may also offer a contribution to the range of methods available to reduce the social desirability biases encountered with self-reporting of outcomes in HIV, sexual and reproductive health research (194-196). There is some discussion over whether responses to vignettes may also be socially desirable, particularly when respondents are asked how they themselves would act in the scenario presented. However, asking first how the fictional character would behave and why is thought to reduce the pressure to answer with socially desirable outcomes (172). In this paper we describe the development and application of a vignette to an investigation of barriers and facilitating factors to uptake of PMTCT services in rural Tanzania. Our objectives for using the method were 1) to create a comfortable environment for IDIs and encourage

women to openly discuss difficulties they or acquaintances faced in using PMTCT or maternal and child health services, and 2) to generate data on barriers and facilitating factors to uptake of PMTCT services from the perspective of HIV-positive and HIV-negative mothers, fathers and relatives. We critique the successes and challenges associated with employing vignettes in this setting, in order to determine the feasibility and utility of using this technique in qualitative investigations more widely in sub-Saharan Africa.

8.3 Methods

Study purpose and context

The study fieldwork was conducted between May and June 2012 in Kisesa, a rural area in north-west Tanzania, to identify barriers and facilitating factors to the uptake of PMTCT services, and ways of overcoming the issues identified. Demographic surveillance and HIV sero-surveillance has been conducted in this community since 1994 (136). Four health facilities offer antenatal clinic (ANC) and PMTCT services in the community: a health centre in the trading centre (also including an HIV care and treatment centre), and 3 dispensaries in rural villages (providing an intermittent PMTCT service depending on availability of HIV test kits and prophylactic drugs).

Study procedures

A variety of qualitative methods were used, including participatory learning and action (PLA) group activities, and IDIs incorporating a vignette. Before commencement of the study, fieldworkers received one week of training on relevant research methods and the topic (PMTCT). Training emphasised the participatory element of the PLA activities, as fieldworkers had prior experience of and training in conducting interviews and facilitating focus group discussions, but less experience of leading participatory fieldwork. After familiarisation with the PLA protocol, fieldworkers practised the activities with volunteer participants. The protocol was revised after observing practice sessions and listening to feedback from fieldworkers, (to shorten or simplify some activities), and after conducting the first PLA activity.

Development of the vignette

The vignette was developed through PLA activities conducted with 3 groups of men and 3 groups of women from different residence areas, each group comprising 8-12 participants. Participants were selected from a sampling frame of men and women aged 15-60 who had at least 1 child. This selection was random, with the exception of

a few female HIV-positive individuals ('seeds') who were purposively selected from the sampling frame by the principal investigator using the community HIV sero-surveillance data. Female groups included 1-5 HIV-positive 'seeds' (see Buzsa et al. for details of the seeded focus group method (164)). Fieldworkers were unaware of the HIV status of all individuals on the recruitment lists and those participating in the activities. Each PLA was facilitated in Kiswahili (commonly spoken national language) by an experienced fieldworker of the same sex as participants. A second fieldworker took notes on the content of discussions, details of the role-play storyline and behaviours of characters, as well as general observations of the group dynamic. The majority of sessions were attended by the principal investigator. Activities were audio-recorded following informed consent from participants.

PLA activities included brainstorming and ranking of barriers, role-playing and group discussion (Table 8.1). Before the role-plays, fieldworkers facilitated a discussion to identify the central characters that would be involved in a woman's pregnancy and delivery. Thereafter, the participants were instructed to invent a storyline of a (fictitious) woman who discovers she is HIV-positive at ANC, thinking of the issues that a real woman in their village would face and the decisions she would make when trying to use PMTCT services. Participants then acted the play to the facilitator and observers. De-briefing sessions with fieldworkers were conducted following each PLA activity, informing an initial analysis of emerging themes which was used together with PLA notes by the principal investigator to draft the vignette.

Table 8.1. Outline of activities conducted during PLA group activities.

Section	Activity	Summary
1 (day 1)	Group discussion	Discussion focussing on knowledge of vertical transmission of HIV and the PMTCT programme
2 (day 1)	PMTCT 'journey'	Arrangement of cards representing components of PMTCT services (ANC attendance; HIV testing; provision of antiretroviral drugs to mothers and infants; delivery in the health centre; infant feeding advice)
3 (day 1)	Storyline and role-play	Character and storyline development, role-play of the story composed, followed by group discussion reflecting on the play
4 (day 2)	Barriers brainstorm & 'wall of challenges'	Group discussion of barriers at each step of the PMTCT 'journey' and creation of cards representing each barrier; ranking of barriers by arranging barrier cards on a wall
5 (day 2)	Hanging fruits tree	Brainstorming of possible solutions to overcome the barriers identified, with solutions represented on fruit shaped cards; fruits placed on a tree diagram, according to how easy or difficult to achieve

To compose the vignette storyline, unifying and contrasting elements of the role-plays were identified. Discussions following the role-plays, during which facilitators discussed how realistic the storylines were, were then analysed to confirm unifying elements, or resolve differences between the stories. Themes emerging from other activities, particularly barriers deemed most important in the ranking exercise, were also considered. The final vignette also needed to be viable given the character's profile, for example, to represent the issues that the character would face considering their residence, marital status or family circumstances. The aim was to present a story that was familiar to most participants (touching on personal experiences, or experiences of acquaintances in their community), but that also achieved the objective of making women feel comfortable to admit to any difficulties they faced (so, for example, a more extreme case of a woman failing to access several of the services was chosen). Overly emotional circumstances or events (e.g. teenage pregnancy or death of a baby) which might derail the interview were avoided.

Once developed, the vignette and associated questions were incorporated into an interview discussion guide, along with open-ended questions about the personal experiences of the respondent during pregnancy, delivery and infant feeding. As conceived in the original study design, fieldworkers then received an additional day of training on the concept and use of the vignette, including examples of other studies employing this technique (42), and on confidentiality (particularly if participants disclosed their HIV status during the interviews). This additional training session was intended to give fieldworkers the chance to familiarise themselves with and discuss the vignette developed from the PLAs, and to ensure the associated methods were fresh in fieldworkers' minds prior to commencing the interviews. Fieldworkers were asked to review the vignette, and comment on how well it reflected the role-plays and major themes identified from the PLAs (no amendments were suggested). They were instructed to probe for whether responses to the vignette (what participants thought the character in the story would do) reflected real life in their community. After training, fieldworkers practised the questionnaire among themselves and with volunteer participants.

Use of the vignette

Twenty-one IDIs with HIV-positive (n=16) and HIV-negative mothers (n=5) who had recently delivered a child (since 2009) were conducted in Kiswahili by the same fieldworkers that facilitated the PLAs. Mothers were recruited purposively for interview from the PLA activities (and had therefore not necessarily attended clinic-based services, n=11), and from each of the 4 health facilities in Kisesa by clinic nurses

(n=10). On completion of the PLA activities, each participant was asked to come forward, separately, to receive their travel compensation (5000 Tanzanian shillings, or approximately 3 USD), and asked if they were interested in being contacted for personal interviews in the future. Facilitators only scheduled specific appointments for interview with selected HIV-positive and negative participants, based on coded lists prepared by the principle investigator using community surveillance data. Facilitators were unaware of the HIV status of participants at the time of recruitment. For the clinic-based recruitment, each nurse was asked to invite and schedule interview appointments for at least two HIV-positive women who were pregnant or had recently given birth, during private consultations with their clients at antenatal or child follow-up clinics. Researchers did not have access to any clinic data for the recruitment.

Three interviews with partners/relatives of HIV-infected mothers were also conducted: women who had disclosed their HIV status during the IDIs were asked if their male partner, or otherwise a female relative, could be contacted for interview.

The same vignette was used in all interviews, and was read out to participants. Interviews lasted between one and three hours, and were audio-recorded after obtaining consent from the participant.

Critical Analysis

Critical analysis of the vignette methodology was guided by the following key questions:

1. Was the vignette method developed and implemented as intended? This includes how well the vignette was developed for the study context, delivered by interviewers and received by participants, in order to assess the feasibility of the approach. To answer this evaluation question, we: a) reflected on the successes and challenges in developing the vignette; and b) assessed IDI transcripts for any difficulties in interpretation of the vignette by the participants or fieldworkers, including confusion, misunderstandings or delays during the vignette section of the interviews, and whether participants considered the final vignette to be realistic. In analysis of the transcripts (audio-recordings were transcribed verbatim, translated into English, and the resulting data managed using NVIVO 9), codes were created to capture the way participants responded to the vignettes, and how fieldworkers dealt with their answers.

2. Did the vignette method achieve its intended objectives? To this end, we gauged from transcripts whether the vignette helped to: a) make participants comfortable during the interview, e.g. to discuss their personal experiences with ANC/PMTCT services and HIV status; and b) generate useful findings (data) about barriers and facilitating factors to PMTCT uptake, analysed through a framework approach which included thematic analysis to develop the coding scheme for barriers to PMTCT service uptake. We considered data quantity and quality, including any difficulties in interpretation of the data during analysis.

Ethical approval

This study was approved by the Lake Zone ethical review board of Tanzania, the Tanzanian Medical Research Coordinating Committee, and by the London School of Hygiene and Tropical Medicine ethics committee.

8.4 Results

Summary of the vignette developed

The final vignette described the story of a pregnant woman living in a remote rural village who discovers her HIV-positive status at ANC, faces negative reactions from her partner upon disclosure of her HIV status, is unable to return to the clinic for further PMTCT services (including antiretroviral drugs) and gives birth at home fearing involuntary disclosure to other relatives. The story was split into 3 sections, with questions after each section about what the woman would most likely do in her situation. Details of the vignette and questions used in the in-depth interviews, excluding probes, are presented in the following section.

Details of the vignette

I'd now like to tell you a story about a pregnant woman called [Flora] and her experiences in trying to access antenatal clinic (ANC), delivery and infant health services. I will tell you part of the story, then I would like you to help me complete the story.

Flora lives in a remote village in Welamasonga, she is 27 years old. She is married to Paulo and she has 3 children. She becomes pregnant and after a few months decides to attend an antenatal clinic by herself. At the ANC she receives a test for HIV. The nurse tells her that she is HIV-positive but explains that there are medicines that she can take to save the baby from being infected with HIV. She also tells Flora that it is important that she delivers the baby in the health centre so that it can also receive medicine to reduce the chances of it being infected. She gives the woman the medicines to take during her pregnancy, and also tells her to persuade her husband to come for an HIV test. She also discusses options for feeding the infant, and advises Flora to breastfeed the child for 6 months without any replacement food. The nurse explained all this information very quickly.

What do you think happens next? Please think for Flora, as a woman in your community, and imagine what she would be thinking and feeling at this time.

In the next part of the story, Flora goes home to her husband and tells him the result of her HIV test, and what the nurse advised her. He is angry and denies her status because he believes he is not infected, and questions whether she has had other partners. Flora decided to disclose her status to her sister and get her support, but she decides not tell to any of her other relatives about what happened.

Do you think Flora would go back to the clinic for more ANC appointments? Why/ why not?
Do you think Flora would be able to go to the HIV care and treatment clinic? Why/ why not?
Do you think Flora would be able to take the treatments during her pregnancy? Why/ why not?
Where do you think Flora will give birth to her child? Why?
Do you think she would be able to swallow the HIV medicines during labour and delivery? Why / why not?

I'll now tell you the next part of the story:
Unfortunately Flora didn't manage to take the medicines during her pregnancy because she feared the reaction of her husband. She gave birth at home because she was unable to get the support of her husband for the transport fare and to buy gloves and other items which might be needed when she arrives at the delivery ward. She also fears the suspicion of her relatives who might escort her to the delivery ward: they might see her swallowing the HIV medication during labour pain, and she might have to wash her own clothes or sheets after delivery.

Do you think Flora will be able to take the baby back to the clinic for ARVs in the first few days after it is born? Why/ why not?
Will she be able to take the baby to a clinic to be tested for HIV after one month? Why/ why not?
Will she be able to follow the advice about breastfeeding? Why/ why not?
Does Flora's story reflect what can happen in real life? Why/ why not?

1) Was the vignette method developed and implemented as intended?

1a) Lessons from developing the vignette

The original protocol for the PLA storyline and role-play activity started with participants developing a tree diagram, where participants discussed all possible outcomes at each step of the PMTCT service chain and agreed on the most likely scenario (using the approach of Varga et al. (42)). However, fieldworkers and participants struggled with this approach during practice and piloting, and the activity exceeded the allocated time. The activity was therefore simplified: participants were given a starting point (a pregnant woman discovering her HIV-positive status at ANC) and ending point (delivery of the child, and potentially accessing infant PMTCT services after delivery), and encouraged to create their own story. The majority of groups easily grasped the new instructions for creating and enacting the storyline, while a few groups required further guidance from the facilitator initially.

The participatory group work was instrumental in developing a vignette that was locally relevant. The role-plays generated content for the vignette, and the importance of certain issues came to light through the observation of characters' behaviour. However, it could be argued that other PLA activities and discussions, aside from the role-plays, were equally useful in developing content for the vignette and helping to 'merge' multiple role-plays into one final story – a process which presented challenges. For example, as expected, there were differences between the storylines from each group. Discussions following the role-plays occasionally revealed that elements of the storylines did not reflect real life, and were therefore important in resolving differences between the plays. Deciding whether or not to include themes/ scenarios that emerged in only one or two plays was also challenging. Other activities such as barriers brainstorming and ranking exercises were valuable in these decisions: themes that emerged infrequently in the plays, but that were ranked as highly important by several groups, were selected for inclusion in the final vignette.

1b) Lessons from implementing the vignette – was it delivered and received as intended?

The majority of in-depth interviewees understood the concept of the vignette and follow-up questions, although some had difficulties understanding and the story or questions had to be repeated. Some participants (a minority) said they had 'failed' to understand or give an answer, remained silent, or asked the interviewer to help them when asked what Flora would do or be thinking. One respondent who had difficulties understanding the vignette arrived late for the interview and appeared tired before

beginning, while another had limited knowledge of Kiswahili, based on de-briefing discussions. However, in most cases interviewers re-phrased the story or instructions and the respondent grasped the concept.

I: ...She [Flora] has now returned home, what in general do you think will happen afterwards?
R: Maybe a quarrel with her husband - Her husband refusing to go to test.
(HIV-negative mother)

I: ...Yes, this is a story about Flora... What do you think happened afterwards?
R: [silence]
I: Have you understood the story well or shall I repeat it so that you may understand it?
R: Yes, please repeat it.
(Male partner)

I: ...I want you to tell me if there is anything which will prevent Flora [from going to the clinic]...
R: Mm, I have failed to give the answer.
I: Don't you know what it is called in Kiswahili?
(HIV-negative mother)

Further engagement with the story was illustrated by one respondent who referred to Flora spontaneously later in the interview (after the vignette discussion): "*Like we said about Flora, she went there [the clinic] alone".* Interviewers also referred to Flora within the context of discussions about personal experiences and perceptions of PMTCT/ antenatal service provision.

Interviewees occasionally relayed what the character *should* or *must* do, offering her advice, rather than what they thought she *would* actually do. Further questioning sometimes clarified perspectives, but on other occasions yielded similar responses.

I: Is there perhaps anything that has made Flora fail to swallow the drugs?
R: No there isn't. Perhaps she should just continue taking them, she shouldn't stop taking them.
(HIV-positive mother)

R: According to my opinions...the only way is to use medicine.
I: Yes, you are saying that according to your opinions...Now we want your opinions but you have to involve Flora...
R: I would only advise Flora to continue using... [the drugs]
(HIV-positive mother)

The quote above also illustrates a challenge faced by the interviewers - how to steer the conversation when respondents spoke of their own beliefs, or actions, rather than what Flora would think or do. In some cases, the interviewer cut off replies expressed in the first person and immediately returned the conversation to Flora's perspective.

R: I would not tell anybody [test result].
I: No, it is Flora, not you. We are first talking about Flora.
(HIV-negative mother)

However, fieldworkers mostly probed further into personal experiences before returning to the vignette.

Four participants did not think the vignette overall was realistic, and a few others did not think Flora would face many challenges with participating in the PMTCT programme despite her circumstances. These were typically HIV-positive women who had reported accessing PMTCT services and complying with appointments themselves, as well as a few HIV-negative women and both male partners.

I: And do you think the story represents actual life?
R: No it does not represent it.
I: Why?
R: Because Flora...she stopped going to use the medicine.
(HIV-positive mother, used ARVs during pregnancy)

However, most participants agreed that the vignette was a realistic example of the issues faced by an HIV-infected woman in their community. Participants sometimes anticipated the next section of the vignette. For example, several women predicted that Flora's husband would react badly to her HIV results, including refusing to test or blaming her, while a few anticipated that Flora would deliver at home.

I: Do you think it [the story] shows the actual life of many women who are pregnant... and discovered to be HIV-positive?
R: This story shows the truth.
(HIV-positive mother)

Responses to the vignette were compared across interviews, between HIV-positive and negative women, and between mothers and male partners/relatives. However, there were few identifiable differences in reactions to the vignettes by respondent type or place of recruitment.

2) Did the vignette method achieve its research objectives?

2a) Did the vignette make participants more comfortable during IDIs?

For the IDI discussion guide with mothers, the vignette was placed after personal background questions (place of residence, marital status and children), but before the section on personal experiences with ANC services. It was hoped that participants would talk more freely about their own experiences and admit to difficulties that they or acquaintances faced in using PMTCT services, after hearing the story and challenges of another woman in their community. For the partner/relatives IDI discussion guide, the vignette appeared *after* the section on personal experiences (of assisting their female partner/relative during their pregnancy), because the descriptions of negative partner reactions and lack of support might influence partners' responses (e.g. over-stating their involvement).

Five out of sixteen known HIV-positive women voluntarily disclosed their status to the interviewer before or during the vignette discussion, and gave examples of their own experiences receiving HIV-positive test results or using PMTCT services. Another seven voluntarily disclosed their status later in the interview, while discussing their own experiences of antenatal care. Three said they had tested HIV-negative, and one said she had not received an HIV test at ANC. Several participants (HIV-positive and HIV-negative) also described experiences of HIV-positive relatives or friends.

I: Can there perhaps be an obstacle that can make her fail to deliver at the hospital?
R: Yes
I: Like what obstacle?
R: For example myself, I delivered at home because it was at night. The birth pains started at night and there was no one to take me to the hospital...
(HIV-positive mother)

I: And do you think that what we have been talking about together is what occurs in our community?
R: I have happened to see one – there is one woman. She was born having HIV...They started giving her medicine but she failed to swallow the tablets and instead she was throwing them away.
(HIV-negative mother)

A few participants appeared to be unsettled or uncomfortable during the vignette discussion. For example, some respondents said they had 'failed' (as illustrated above, section 1b). One respondent (known HIV-positive but who did not disclose her status) seemed unwilling to answer some probing questions that verified if the response was realistic, although she appeared willing to answer subsequent questions.

2b) Did the vignette generate data about barriers to PMTCT service uptake?
Discussions during the vignette sections of all IDIs produced data that could be coded to inform the analysis of barriers and facilitating factors to PMTCT service uptake (33). Most data came directly from probes asking what challenges or motivating factors Flora would face at each step (e.g. returning to the clinic or taking medicine).

I: ....What challenges do you think Flora will encounter?
R: There will be challenges at the time when she is going to deliver. Sometimes the health centre may be far away from home.....
(HIV-negative mother)

Data was also generated indirectly, for example when asking 'what would happen next', after reading the first part of the story, or probing for what Flora would be thinking or feeling.

I: What do you think this woman will be thinking of.....?
R: She will just be thinking - Because she has already told her elder sister [her result], her elder sister will be giving her advice just to use those drugs so that you protect the baby.
(HIV-positive mother)

The vignette provided context and situated the discussions. This allowed respondents to share their own experiences, or those of others, including barriers or facilitating factors. It also facilitated discussion of barriers to PMTCT service use among HIV-

positive women who did not disclose their status to the interviewer, and among HIV-negative women based on their experiences of pregnancy and maternal and child health services. The perceived reality of the vignette (illustrated in section 1b) also affected data generation: where respondents thought the vignette was realistic, they sometimes gave reasons that could be coded as data.

I: Why did you say that this story really shows the things that occur?
R: This story shows the truth, and it usually occurs in the family...there are others...she can go with her husband for treatment. There is another [partner] who can refuse and then a quarrel ensues.
(HIV-negative mother)

Comparison within cases between the vignette and personal experiences sections of the IDI revealed that responses to questions about the vignette often reflected the respondent's own experiences. For example, one female participant told her husband about her positive HIV test result, but he refused to test and deserted her. After hearing the first part of Flora's story and being asked what would happen next, she replied: *"She [Flora] can tell him [her husband]... You know, some men if you tell them, they become angry...Some do not want to show up at the service."* Another participant was asked if Flora could disclose her test results, and responded: *"No...She will decide to remain quiet...she wants to see first...if it is true"*. This participant later revealed that she had initially denied her own positive HIV test result and delayed disclosure to her partner.

When respondents answered with what they thought Flora *should* do (section 1b), this also presented difficulties in interpretation of the data for the researchers (for example, if the participant suggested reasons why she should access services (potential facilitating factors), it was not clear if these were realistic).

8.5 Discussion

This is, to our knowledge, the first methodological paper to critically examine the development and use of vignettes in Africa, and one of few studies to apply this technique within the context of HIV research in Africa. Overall, the development of vignettes through participatory group work, and use of vignettes within IDIs by locally trained fieldworkers, was feasible and useful in this setting. We believe it could be a valuable tool for future qualitative research in the field of PMTCT and other health or social issues in Africa.

Storyline development and role-play was a practical way of generating ideas for the vignette, although a simplified, more structured approach was required. It is possible that the more open-ended approach used by Varga et al. in South Africa was feasible in their study because participants had a greater knowledge of PMTCT services and a higher level of education: respondents included health workers, and eligibility was based on having "experience and knowledge of the health issue", while our study included rural community members with no experience of the programme. Alternatively, differences in the experience level of fieldworkers may explain the variation in success of this approach. While our fieldworkers were generally experienced in qualitative methods, including focus group discussions and IDIs, they had less experience of participatory methods and no experience of using vignettes. In addition, they had been involved in HIV research, but were less familiar with PMTCT specifically. Intensive training was provided, but more practical experience, including more time for practice and piloting prior to the fieldwork, may have been needed to better facilitate the storyline development and role-plays.

While our approach to creating the storylines was simpler for the facilitators and participants, decisions of what to include in the final vignette were not straightforward. However, triangulation with results from other activities and discussions during the PLAs facilitated this 'merging' process. It could also be reasoned that the final vignette does not need to represent the majority of women in the community, but should at least be a realistic example of some women, so that it can successfully be used to build discussion in the interviews and encourage women to admit to their own experiences.

Most interviewees appeared to understand the concept of the vignette. This may partially reflect the fact that roughly half of the interviewees had participated in the PLA activities used to generate the vignette, although a similar proportion of interviewees recruited by other means comprehended the task. Prior participation in the PLAs may also have affected responses to the vignette more generally, for example coloured by views of other PLA participants regarding PMTCT service use, though interviewees would only have recognised small elements of their role-play in the vignette. Believing the vignette was realistic or anticipating the next section of the vignette may also reflect comprehension of the story, while this also generally facilitated the discussions.

The minority of cases where the story had to be repeated, or instructions had to be clarified, may have been due primarily to unclear questioning by interviewers, language barriers (poor command of Kiswahili), general shyness, or lack of readiness for the

interview, rather than difficulties with the vignette technique itself. Encouraging the participant to think of the character as a woman in their community was especially helpful in enabling them to grasp the concept. Allowing time for the participant to digest information in the vignette and to seek clarification before proceeding with any questions or discussions may also be beneficial, particularly with longer vignettes (162). A few participants misinterpreted questions about the vignette, thinking they were being asked what Flora *should* do, while fieldworkers also found these unexpected responses confusing (discussed further with regard to data interpretation below).

Use of the vignette achieved the main objectives. Firstly, we hoped that the vignette would encourage participants, particularly HIV-positive women, to feel comfortable and freely discuss their own situation and any difficulties they faced in accessing maternal health or PMTCT services: several respondents offered examples from their own experience, or that of family or friends, or commented on what they would do in Flora's situation. Renolds noted that respondents were encouraged to voice more extreme concerns when the story was real (163). While our vignette did not give a biographical account of one person, it was based on discussions with the community and their own stories, and was considered realistic by the majority of interviewees. This emphasises the utility of developing the vignette through participation of community members. While the expression of personal experiences was a benefit, interviewers occasionally struggled to deal with this and were reluctant to digress from the discussion guide and Flora's perspective. Fieldworker training should therefore stress the importance of drawing out the respondent's own experiences, before returning the conversation back to Flora. Ideally, transcripts should be analysed during the course of fieldwork to identify and deal with these issues immediately. The use of questions such as "does this really happen in your community?" was particularly effective in drawing out personal experiences.

An unusual and interesting feature of this study was the knowledge of participant HIV-status by the principal investigator, thus allowing exploration of whether the technique may have encouraged or hindered disclosure of positive results. Most women disclosed their positive status during the vignette or personal experiences section of the interview, although they may have disclosed their status regardless of whether or not the vignette was included. A few women disclosed their status to the interviewer before the vignette discussion, in which case the vignette may not have offered any extra benefit. Some participants chose not to disclose their status (or they had not received their results, or research testing results were false positives). Therefore it is

possible that presenting the case of a woman diagnosed with HIV who faces difficulties accessing PMTCT care, is sometimes insufficient to encourage disclosure. However, in such situations, the vignette at least enables discussion of the topic in a non-threatening way in the third person. While other factors will influence disclosure during the interview (such as the interviewer, the environment in which the interview is conducted, the respondent's disclosure history and their willingness to disclose to strangers), the majority of HIV-positive respondents disclosed their status during or following the vignette discussion, suggesting that the vignette may have contributed to creating a comfortable atmosphere for the interviewee.

It is worth noting that a few participants said they had 'failed' to answer questions, suggesting that they perhaps felt 'tested' by the questions. This has been described in vignette studies from North America and Europe, particularly when respondents felt the story outcomes differed from what they had anticipated (162). In order to avoid making participants feel nervous, it may therefore be important to reiterate that there are no 'wrong' answers in the introduction: an approach adopted in one study in Ghana (184). Secondly, the vignette facilitated the discussion of barriers to using PMTCT services by focussing on a third person: most participants spoke freely about potential challenges that Flora would face. This meant that barriers could be discussed in all the interviews, including those with HIV-negative mothers, partners and relatives who had no direct experience of PMTCT services, but who were able to contribute useful information based on experiences of acquaintances, or their own experiences of maternal and child health services (into which PMTCT services are usually integrated). This advantage has been noted previously in developed world studies (163), and also contributed to boosting the quantity of data generated.

The direct comparison between the vignette and personal experiences section of the IDIs was another strength of this study, contributing to an understanding of the extent to which responses to the vignette (what Flora would do) reflected participants' own actions and thus data quality. Participants' responses to the vignette often appeared to mirror their own experiences. This suggests that the vignette can be a useful tool to capture (indirectly) the perceptions and actions of shy respondents, for example HIV-positive individuals who do not wish to reveal their status or personal experiences. It also suggests that vignettes may be a valuable method for reducing the social desirability biases associated with self-reporting in HIV and reproductive health research.

Some participants gave advice to Flora and stated what she *should* or *must* do, and it was only through further questioning that what she *would* do, or likely difficulties that she would face, came to light, if at all. This may reflect the respondent's own actions, or illustrate a social desirability bias (what they think they should have done themselves). This distinction between 'belief' and 'action' is important and is one of the most common problems reported in developed world studies when using vignettes and interpreting their findings (162, 163). However, Renolds and Finch argue that the process of the discussion is more important than the stated outcome/action, and that vignettes can still yield useful information, particularly when integrated with other methods such as interviews (163, 171). None-the-less, interviewers should be prepared for and probe further when '*should'* responses are given, to determine if the answer is realistic. While this was included in training for our fieldworkers, further emphasis and practice may be required.

8.6 Conclusions

Participatory group research is an effective method for developing vignettes. Vignettes can be incorporated into qualitative interview discussion guides and used successfully in rural African settings to draw out barriers to PMTCT service use, indicating potential usefulness in other areas of research on HIV, health service use, and drug adherence. This method is often overlooked in HIV research, and should be considered more often. Issues experienced with the technique largely mirror those reported in developed world settings. Fieldworkers experienced in qualitative research methods but without prior experience of vignettes can be used. However, application of this technique can prove challenging so supervision and thorough training should be provided, including the importance of probing for the reality of the suggested outcome, and preparation for the different ways that participants may respond to the vignette questions, particularly when personal experiences are brought up. Methods (e.g. participatory group work) to develop vignettes must also be carefully piloted.

9 Paper F. “It is like that, we didn’t understand each other”: exploring the influence of patient-provider interactions on prevention of mother-to-child transmission of HIV service use in rural Tanzania

Introduction to the paper

Many qualitative papers included in the systematic review (paper A) identified interactions between patients and providers as barriers or facilitating factors to the uptake of PMTCT services, but they were summarised alongside numerous other factors at different levels of the socio-ecological framework. The nature and role of these interactions were not reported in depth, and most research focussing on health systems barriers primarily documented service accessibility and resource issues from the perspective of providers.

Initial analyses of the qualitative study I conducted, which broadly aimed to identify the specific balance of barriers and facilitating factors to PMTCT service use in Kisesa, also indicated that patient-provider interactions had a strong influence in this setting. In particular, poor health worker behaviour exacerbated by lack of materials in the health facilities emerged as one of the greatest barriers to use of PMTCT services, based on ranking activities during the PLA group work.

I therefore conducted an in-depth analysis, using the qualitative data collected, to explore the nature of interactions between patients and providers within the context of the PMTCT programme in Kisesa, and their influence on service use. These findings are described and discussed in paper F, including recommendations for strategies to optimise patient-provider relations and improve PMTCT uptake in the local community and the wider region.

The critical analysis of the vignette method (paper E) facilitated in the generation, analysis and interpretation of data for paper F. Paper E suggested that use of the vignette helped to enhance the validity of the findings and to reduce social desirability and reporting bias, by encouraging women to speak out truthfully about their own experiences with PMTCT or MCH services. Many first-hand experiences with

providers were shared during the interviews (mostly in the personal experiences section of the discussion guide, or occasionally the vignette, when providing examples to illustrate their points of view) and were of primary interest for the analysis presented in paper F.

The vignette also generated perceptual data regarding interactions with providers, from the perspectives of both HIV-positive and HIV-negative women; another benefit of the vignette method identified in paper E. For example, when asked whether Flora (fictional vignette character) would go back to the clinic given her situation, relations with providers were sometimes spontaneously cited as reasons. Perceptual data was compared to data on personal experiences of patient-provider interactions, and compared between respondents, to strengthen the findings, especially given some of the complexities identified in interpreting data from the vignette discussion. Careful consideration was given to the issue uncovered in paper E where respondents sometimes answered with what Flora *should* do rather than *would* do. However, it became apparent that this distinction was not necessarily problematic in the context of the analysis of patient-provider interactions, as beliefs inferred from such answers, or terminology, still yielded interesting insights. For example, a few women said Flora 'should' follow the 'conditions' or 'directions' given by the nurse and go to the clinic, or take medicine. This revealed informative terminology and possible power hierarchies that were subsequently confirmed in interviews with many other respondents, in other sections of the interviews, and in PLAs (described further in paper F).

The process of *developing* the vignette also generated useful data for the analysis of patient-provider interactions. PLA group work, particularly the role-plays which were designed primarily to develop the vignette, gave important insights into the nature of patient-provider interactions and their influence on PMTCT uptake. For example, the women's trading centre PLA group enacted a fierce health worker who insulted the woman when she arrived at the delivery ward without gloves or a plastic sheet, and would only provide assistance once the baby was delivered (when challenged by the facilitator, the group agreed that this was realistic). Findings from PLAs were compared with data from interviews, further strengthening results.

In the thesis discussion (chapter 10), findings from this qualitative investigation (paper F) are also compared to factors associated with PMTCT service use emerging from the quantitative analyses (paper D). The findings help to explain and contextualise the levels of PMTCT service use documented in paper C.

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9.1 Abstract

Interactions between patients and service providers frequently influence uptake of prevention of mother-to-child transmission (PMTCT) HIV services in sub-Saharan Africa, but this process has not been examined in depth. This study explores how patient-provider relations influence PMTCT service use in four government facilities in Kisesa, Tanzania. Qualitative data were collected in 2012 through participatory group activities with community members (3 male, 3 female groups), in-depth interviews with 21 women who delivered recently (16 HIV-positive), 9 health providers, and observations in antenatal clinics. Data were transcribed, translated into English and analysed with NVIVO9 using an adapted theoretical model of patient-centred care. Three themes emerged: decision-making processes, trust, and features of care. There were few examples of shared decision-making, with a power imbalance in favour of providers, although they offered substantial psycho-social support. Unclear communication by providers, and patients not asking questions, resulted in missed services. Omission of pre-HIV test counselling was often noted, influencing women's ability to opt-out of HIV testing. Trust in providers was limited by confidentiality concerns, and some HIV-positive women were anxious about referrals to other facilities after establishing trust in their original provider. Good care was recounted by some women, but many (HIV-positive and negative) described disrespectful staff including discrimination of HIV-positive patients and scolding, particularly during delivery; exacerbated by lack of materials (gloves, sheets) and associated costs, which frustrated staff. Experienced or anticipated negative staff behaviour influenced adherence to subsequent PMTCT components. Findings revealed a pivotal role for patient-provider relations in PMTCT service use. Disrespectful treatment and lack of informed consent for HIV testing require urgent attention by PMTCT programme managers. Strategies should address staff behaviour, emphasizing ethical standards and communication, and empower patients to seek information about available services. Optimising patient-provider relations can improve uptake of maternal health services more broadly, and ART adherence.

9.2 Background

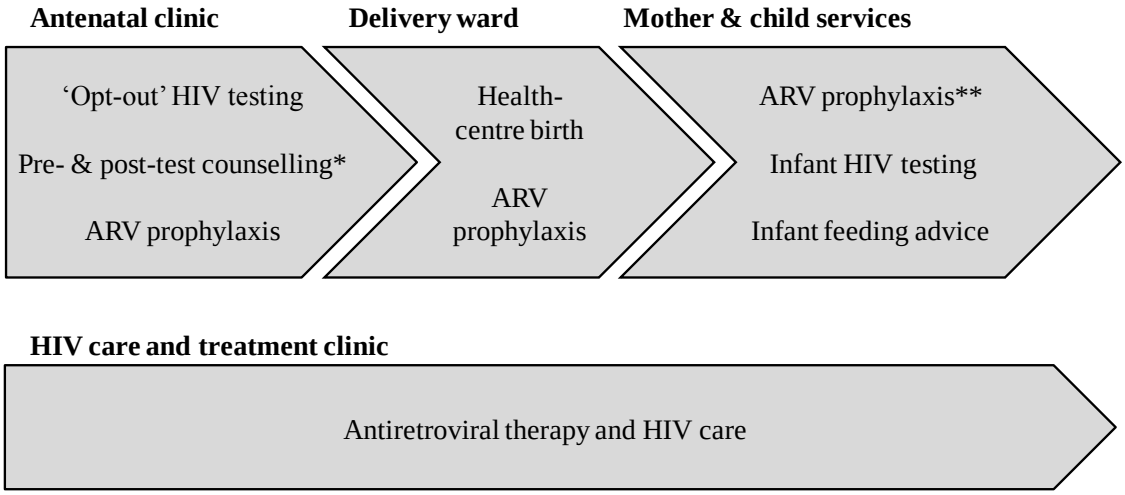
Interactions between health care providers and their patients are widely recognised to play an important role in determining the uptake of health services (197). The providers' role in influencing medication adherence, health-seeking behaviour, and satisfaction with health services has been documented (198, 199), with studies on patient-provider interactions focussed predominantly on the developed world primary care setting and treatment of chronic conditions such as cancer (200).

Interest in patient-provider interactions in the context of HIV care has grown as HIV infection has been transformed from an acute to a chronic condition with the advent of antiretroviral therapy (ART). Several studies from the developed world have reported quantitative associations between measures of patient-provider relations and patient satisfaction with HIV care, and ART or appointment adherence (201-204). Qualitative research on this topic is less common, but is helpful in revealing *how* interactions between patients and providers influence HIV service use, offering insight for health system strengthening (205, 206).

Evidence of links between patient-provider interactions and uptake of HIV services in the developing world has been presented in recent systematic reviews of qualitative and quantitative literature investigating barriers and facilitating factors to ART access and adherence (33, 58). One review, focussing on uptake of antiretroviral (ARV) drugs in the context of prevention of mother-to-child transmission (PMTCT) HIV services in sub-Saharan Africa, highlighted the importance of interactions between pregnant HIV-positive patients and health workers (33). However, despite the potential influence of these interactions on PMTCT outcomes, no studies have examined their consequences in detail.

The PMTCT programme comprises multiple potential contact points with providers within a cascade of services, including antenatal clinic (ANC) visits, 'opt-out' HIV testing with pre- and post-test counselling, ARV drugs for those diagnosed HIV-positive, facility-based deliveries, infant ARV prophylaxis and infant HIV testing (Figure 9.1). As HIV-positive women are encouraged to initiate prophylaxis or ART early in pregnancy to prevent vertical HIV transmission, and continue treatment for life for their own health (207), PMTCT services are shifting towards a chronic care model, with the need for repeated clinic visits for drug refills and adherence monitoring. As such, patient-provider interactions within the PMTCT programme are increasing in frequency and importance.

Figure 9.1. Cascade of PMTCT services by clinic location.



*pre-test counselling in groups or individually; individual post-test counselling
**maternal (post-partum) and infant

In Tanzania, government HIV treatment programmes were introduced nationally in 2004, with ART provided free of charge to all HIV-positive individuals (208). Maternal and child health (MCH) services are also provided (theoretically) without cost. However, despite decentralisation efforts, HIV care and treatment clinics (CTC) remain largely restricted to hospitals and health centres in urbanised areas, due to a lack of funding and personnel. PMTCT services, first implemented nationally in 2000, have since been extended to include HIV testing and ARV prophylaxis provision in health centres and rural dispensaries, although stock-outs are frequent (134). In Tanzania, as in many other African countries, low PMTCT service use remains a major obstacle to global targets for elimination of new paediatric HIV infections and reduction of maternal mortality (2).

We therefore sought to explore the nature of patient-provider interactions within PMTCT service provision in rural Tanzania, and ways in which these interactions influence the uptake of PMTCT services, with the aim of providing recommendations for optimising patient-provider relations and PMTCT uptake.

9.2.1 Theoretical perspectives

Patient–provider interactions have been conceptualised with a range of theoretical models, evolving over time from traditional paternalistic or biomedical models of care, towards a more 'patient-centred' approach. Balint first introduced the theory of patient-

centred medicine in the 1950s (209); more recent definitions include "seeing the illness through the patient's eyes" (210). The approach is thus distinct from paternalistic or biomedical models, in which physicians make decisions in the best interest of the patient with minimal patient involvement and a focus on the patient's biomedical problems.

A literature review by Mead and Bower identified five dimensions of patient-centred care: bio-psychosocial perspectives, 'patient-as-person', 'doctor-as-person', a 'therapeutic alliance', and 'sharing power and responsibility' (169) (Table 9.1). Shared decision-making, a feature of shared power, has been described as the 'crux of patient-centred care' (211), and was considered a key indicator in an evaluation of interventions to promote patient-centred care (199). An element of shared decision-making and an essential component of patient-centred care is effective communication and information sharing (212). Researchers have also discussed how patient-centred approaches can alleviate disparities in care based on ethnicity, race and socioeconomic status (165, 166). Other components of patient-centred care frameworks include continuity of care (165) and structural factors such as the availability of resources and time (167).

Table 9.1. Key elements of patient-centred care conceived by Mead and Bower.

Dimensions of patient-centred care	**Description or examples**
Bio-psychosocial perspective	Covering social and psychological issues, not only medical aspects of care
Patient-as-person	Differences in individuals' experience of illness
Doctor-as-person	Personal qualities of the doctor and self-awareness
Therapeutic alliance	Including personal bond between doctor and patient; doctors being caring and empathetic
Sharing power and responsibility	Including shared-decision making
Influencing factors	**Examples**
Doctor factors	Personality, gender, age
Patient factors	Attitudes or expectations, age, knowledge
'Shapers'	Cultural norms
Professional context influences	Performance incentives, government policy
Consultation-level influences	Workload pressures, time limitation

The philosophy of patient-centred care is now widely adopted in medical practice in the developed world, for example in general practice and nursing (213), reflecting a growing recognition of its importance in delivering high quality care services. Frameworks for patient-centred care have therefore been extended to include measurable outcomes such as patient satisfaction with care and quality of life (165, 213). A Cochrane review concluded there was some evidence that interventions promoting patient-centred care (e.g. training health workers) were associated with increased patient satisfaction (199). There are fewer examples of the application of the patient-centred care model in the developing world, although authors have recently advocated for a shift towards patient-centred approaches in infectious disease and reproductive health services in lower income countries (214).

9.3 Methods

9.3.1 Study setting and design

Kisesa is a relatively poor rural area in north-western Tanzania with a low GDP per capita of <500 US dollars (USD). Most residents earn a living from subsistence farming or small businesses selling local produce. There are four government health facilities in Kisesa: three rural dispensaries in remote villages and one health centre in the trading centre. The district and regional referral hospitals are ≥20km away. PMTCT services have been operating (intermittently) in all four facilities since 2009, although comprehensive HIV services are only offered in the health centre (since 2008). Regular rounds of demographic and HIV serological surveillance have been conducted in Kisesa, among a population of approximately 30,000, since 1994.

A variety of qualitative methods - participatory learning and action (PLA) group activities with mothers and fathers, in-depth interviews (IDI) with HIV-positive and HIV-negative women as well as health providers, and observations of procedures and patient-provider interactions in ANC and MCH clinics - were used in a broader study investigating barriers to PMTCT service use in Kisesa in 2012. PLAs extend more commonly used focus group discussion methods to include further participation from participants, such as role-playing or creating charts or maps, promoting a two-way exchange of knowledge and information between researchers and participants. PLA methods had been useful previously in this setting, to investigate barriers to accessing other HIV services, engaging community members and capturing prevalent community-wide beliefs which complement individual perspectives from IDIs (37). PLA activities were also designed to generate a locally relevant vignette (short story) about a

hypothetical pregnant woman diagnosed with HIV to aid discussion during the IDIs given the sensitive topic area, and limit reporting bias (34).

The study was designed to maximise learning from different methodologies and perspectives, including those of HIV-positive women, to explore direct experiences with PMTCT services, and HIV-negative women, for more general experiences of MCH services, and the wider community and health service providers.

9.3.2 Sampling and recruitment

PLA activities were conducted with 3 male and 3 female groups from different residence areas (remote (RE), roadside (RD), trading centre (TC)). Participants were randomly selected from a sampling frame, constructed using demographic and HIV sero-surveillance datasets, of 3102 community members aged 15-60 who had ≥1 child, for experiences or views on MCH services. A few HIV-positive women were purposively included in each female PLA group using an approach based on the 'seeded' focus group (164). Fieldworkers were unaware of the HIV status of any individuals. Overall, 30% of 105 individuals visited were not found, and 2% refused to participate. Each group included 8-12 participants. Demographics of PLA participants are summarised in Table 9.2. Male participants were slightly older than female participants, with an average age of 42 years compared to 36 years respectively.

Table 9.2. Characteristics of PLA group participants.

	Female PLA groups	**Male PLA groups**
Characteristic	**Number (%) of participants (n=30)**	**Number (%) of participants (n=31)**
Age		
19-29	7 (23)	5 (16)
30-39	13 (43)	8 (26)
40-49	7 (23)	12 (39)
50-59	2 (7)	6 (19)
Unknown	1 (3)	0
Mean (range)	36 (19-54)	42 (24-59)
Area of residence		
Remote rural	12 (40)	10 (32)
Roadside	10 (33)	9 (29)
Trading centre	8 (27)	12 (39)
HIV status		
HIV-positive	8 (27)	0
HIV-negative	21 (70)	15 (48)
Unknown	1 (3)	16 (52)

(3 male groups and 3 female groups each with 8-12 participants, N=61 participants in total)

IDIs were conducted with 21 women who had been pregnant or given birth since 2009. Ten HIV-positive women were recruited purposively by nurses from each clinic, while eleven women (5 HIV-negative, 6 HIV-positive) were recruited from the community via PLAs, ensuring a mix of women with and without experience of ANC or PMTCT services. Women were discreetly invited for interview by fieldworkers after the PLAs, using a coded list. Fieldworkers were unaware of participants' HIV status, unless participants voluntarily disclosed their status during interviews. Of 8 HIV-positive women invited, 6 accepted. All 5 HIV-negative women accepted. Recruitment continued until data saturation was reached, based on preliminary analyses. Characteristics of women participating in the IDIs are presented in Table 9.3. Participants were aged between 20 and 47 years, with an average age of 34 years. Roughly half lived in more remote rural villages, the other half residing in the trading centre or roadside villages. Among the subset of women recruited from the community for whom data on education was available, most were educated to primary level (as for the majority of women in this community).

Six health workers and three officials were interviewed; recruited purposively to include most of the providers directly involved in delivering PMTCT services in the study area, and to provide perspectives from different facility levels and cadres. Five MCH nurses, a doctor at the CTC, and coordinators at the district and referral hospital were selected and agreed to participate. The health workers interviewed were mostly female (5 out of 6), while two out of three health officials were male. Half of the health workers practised in smaller dispensaries and half worked in the health centre.

Table 9.3. Characteristics of female community members participating in IDIs.

Characteristic	Number (%) of participants (n=21)
Recruitment method	
From community (PLA)	11 (52)
By clinic nurse	10 (48)
Age	
20-29	4 (19)
30-39	11 (52)
40+	4 (19)
Unknown	2 (10)
Mean (range)	34 (20-47)
Area of residence	
Remote rural	10 (48)
Roadside	5 (24)
Trading centre	6 (29)
HIV status	
HIV-positive	16 (76)
HIV-negative	5 (24)
Year of most recent delivery	
2009	3 (14)
2010	5 (24)
2011	11 (52)
2012	2 (10)
Education	
None	1 (5)
Primary	10 (48)
Secondary +	0
Unknown	10 (48)

9.3.3 Data collection

PLAs were facilitated in Kiswahili by fieldworkers following a written protocol of activities, including group discussions, role-plays about a woman attempting to access PMTCT services (participants created their own characters and stories), brainstorming of barriers along the PMTCT cascade, and ranking of barriers.

Trained interviewers conducted IDIs lasting 1-3 hours in Kiswahili. The semi-structured discussion guide included a vignette (34), personal experiences of recent pregnancies, and overall perceptions of services received. Interviewers probed for MCH services accessed, health worker conduct, privacy, counselling offered, and clarity of medical advice. Twelve of sixteen known HIV-positive interviewees voluntarily disclosed their status and discussed PMTCT services.

A fieldworker interviewed health workers in Kiswahili, while the principal investigator interviewed health officials in English. Discussions included challenges with delivering PMTCT services, and perceived difficulties for patients.

Observations were also conducted in communal areas of Kisesa health centre ANC and MCH clinic by the principal investigator and one fieldworker. Structured observation sheets included prompts for patient-provider interactions, privacy, procedures, patient volume and waiting times.

9.3.4 Data analysis

Photographs of physical outputs and detailed notes were taken during PLAs. After each PLA or interview, debriefing sessions were held to discuss emerging themes. PLAs and interviews were digitally audio-recorded, following consent from participants, transcribed verbatim, then translated into English.

Analysis was conducted in NVIVO9, guided by a framework approach (215). Mead and Bower's patient-centred care framework (table 1) was used to organise the initial code-frame, which also incorporated aspects of patient-centred care emphasized by other researchers (165-167). The code-frame was refined after applying it to the first few transcripts; adding, sub-dividing and combining codes. Coding was also done inductively to capture new concepts, and participants' own terminology was documented through in-vivo codes. Codes were then grouped into overarching themes.

The resulting code-frame was applied to all transcripts ('indexing') by identifying content that described dialogue or other interactions between patients and providers, and the extent to which interactions were patient-centred (e.g. discussion of non-medical matters, question-asking by patients, statements suggesting empathy, included in most coding schemes for analysing verbal behaviour and patient-centred care (169)). The manner in which patients described being treated and questioned by providers (and vice versa), and links to outcomes (e.g. adherence to PMTCT components) were also scrutinized. Perceptual data, for example generated when discussing the vignette, was also analysed to reinforce perspectives from personal experiences. Charts were created using MS Excel to compare data across and within cases.

The principal investigator read and coded all translated documents. A sub-sample of transcripts was double-coded (by AW) using the same initial code-frame. Each

researcher's revised code-frame was then compared and discussed to ensure all emerging concepts were captured.

9.3.5 Ethics statement

Ethical approval was granted by the London School of Hygiene and Tropical Medicine, Tanzanian Lake Zone and Medical Research Coordinating Committee ethics review boards.

All participants were informed about the study. Before commencing the PLAs, verbal consent was recorded from all participants using a digital audio recorder. It is important to offer verbal consent in this setting due to the expected low level of literacy of some of the participants and the fact that people are not used to signing their name as a form of consent. For some HIV-infected women, the existence of a signed consent might be perceived as an unjustified threat to the subject's confidentiality. All IDI participants were given the option of written or verbal consent, for the same reasons outlined. No participants recruited for interview or PLAs were minors aged <18, therefore consent was obtained from all individuals in person, rather than from next of kin, guardians or caretakers. These procedures for obtaining participant consent were approved by the ethical review boards.

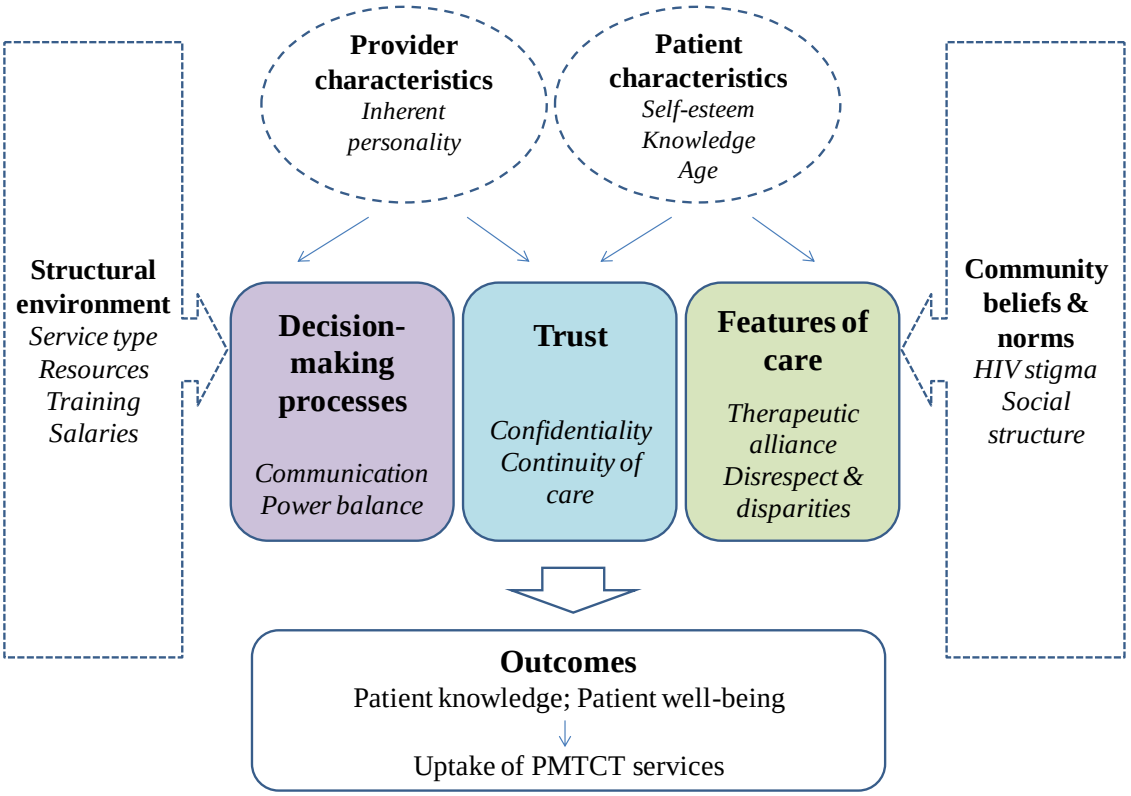
Recruitment procedures, using the seeded focus group method and including HIV-negative women, were designed specifically to maximise confidentiality for HIV-positive women. PLA participants were advised that the discussion was confidential, but they were not expected to share personal information. Compensation was provided for travel expenses (5000 Tanzanian shillings, 3 USD). Participant anonymity was maintained by using fictitious or generalised names, and labelling recordings, transcripts and quotations with codes (e.g. 'health worker#1').

9.4 Results

Three themes emerged relating to patient-centred care: decision-making processes, trust, and features of care. Decision-making processes encompassed the sub-themes of communication, including psycho-social support, and power balance; clear and non-threatening communication by providers, and willingness of patients to engage in discussion and clarify information, both necessary for shared decision-making. Trust in providers was related to continuity of care with a single provider. Features of care included the therapeutic alliance and disparities in care. We also identified provider and

patient characteristics that influence the process and nature of interactions. Interactions are shaped by the structural environment and community perceptions and norms. Patient-provider interactions affected patient knowledge, well-being, and ultimately access to and retention in PMTCT services. Building on the patient-centred care model, our adapted framework is presented in Figure 9.2, and was used to guide synthesis of our findings.

Figure 9.2. Conceptual framework for the analysis of patient-provider interactions in Tanzania.



9.4.1 Decision-making processes

9.4.1.1 Communication

All IDIs with health workers and a few with HIV-positive women revealed examples of providers offering psycho-social support. Nurses described assisting HIV-positive patients to come to terms with their diagnosis, in one case helping a patient to adhere to the PMTCT programme, take ARV drugs and deliver an HIV-negative baby.

I became very sad when I saw my results, but I gave myself courage...I just consoled myself because of that counselling.
(IDI, HIV-positive women#16)

Health workers showed intricate knowledge of their patients' personal lives including relationship challenges and family circumstances. The goal of testing male partners for HIV sparked further discussions about psycho-social issues, including disclosure strategies and personal plans for their involvement in testing and support during pregnancy.

The woman was getting the treatments here...she was beaten by her husband when she said 'I'm stopping breastfeeding the child'. We talked with her- she said I don't want to infect the child.
(Health worker#4)

Some health workers explained that psycho-social counselling could galvanise support from relatives, thus improving a woman's chances of accessing services such as delivery.

Effective communication, through the transfer of knowledge to the patient or psycho-social support, influenced the uptake of PMTCT services. A few HIV-positive women, who described advice as encouraging or helpful, or apparently understood instructions for taking medicines, said this motivated them to take the drugs or attend the clinic. Simply being given advice by the provider, regardless of quality, was often linked to perceived or actual use of PMTCT services, such as ARV drugs and infant testing. However, receiving and understanding advice did not always improve PMTCT service adherence, in light of more influential factors such as economic constraints, distance from facilities or partnership issues. Some providers explained how despite their efforts to provide counselling, patients could still refuse to take prophylaxis.

You counselled her from the first months up to the last, but she didn't like to use [the drugs] at all, someone can completely reject those medicines.
(Health worker#3)

A minority of women interviewed received basic explanations for HIV testing during pregnancy, and a nurse reported providing education about HIV transmission at ANC. However, the majority of women reported not receiving any formal pre-test counselling, or explanations of the testing process. This concurred with observations in the health centre, where formal group counselling sessions were rarely observed. A few women said there were sometimes group classes before HIV testing, but that they had arrived late, missed the counselling and were just tested (without individual counselling).

I: Before they test, don't they give you any counselling?
R: They just tell me 'sit there so we can check your health'.
(IDI, HIV-negative woman#5)

Poor communication about the HIV testing process and the right to opt-out appeared to have an impact on patient understanding, since many women believed they could not opt-out and had often received no counselling or explanations about testing. Some female PLA participants also articulated there was no possibility of declining the test. A common belief was not receiving further pregnancy services if they did not test.

You won't be provided service if you are not tested...you can't refuse, you must be tested.
(IDI, HIV-positive woman#12)

When I went to test I remember the nurse didn't tell me anything....others are saying that when you go there to test, the nurse will first give you counselling – she will ask you 'are you ready', but I remember she didn't ask me. I didn't get any counselling.
(IDI, HIV-negative woman#6)

Health workers generally inferred that patients could decline the HIV test, though one male PLA participant suggested providers communicated in a coercive style.

It [HIV test] is voluntary, but there is a language which is used to convince her.
(Male PLA participant, TC)

Other examples of unclear communication, resulting in confusion or lack of understanding for patients, included a woman who did not understand what was happening when she was admitted to hospital for a labour complication because doctors were speaking in English. In other cases, scant explanations were given about the reasons for performing medical examinations, for issuing advice regarding facility-based deliveries or breastfeeding, or for prescribing drugs including ARVs.

I don't know what those tablets help; you are just given and you swallow them.
(IDI, HIV-negative woman#1)

However, unclear communication did not necessarily impede PMTCT service use. For example, some women reported taking drugs despite confusion over their purpose. Lack of pre-test counselling and misunderstandings about the right to opt out of the HIV

test may, controversially, have improved uptake of testing. Nonetheless, thorough explanations about testing had positive implications: a few interviewees received some explanation which motivated them to test. The perception that HIV testing is compulsory and associated fear of results could also deter women from attending ANC, as discussed by several PLA participants.

9.4.1.2 Power balance

The best example of shared decision-making, patient autonomy and power sharing was the case of one woman who negotiated with the nurse to receive the labour dose of antiretroviral prophylaxis in advance, which she consequently took, despite delivering at home at night.

They asked me when I was 8 months pregnant – 'where do you live, do you have a person at home who can help you?' I said I do not, and home is far away...maybe I can fail to get there [hospital delivery ward]...That is why I explained openly to the nurses. They gave me those medicines [ARVs].
(HIV-positive woman#7)

Patients and providers occasionally described discussing personal plans for what time of day to take ARV medication, or infant feeding options. All health workers and a few women mentioned asking or being asked questions, particularly in discussions around ARV drug adherence or disclosure plans. An HIV-positive woman said '*you can even remind the nurse*' to dispense ARV drugs. Some nurses also mentioned receiving reminders from patients about ARVs, particularly when they were busy and had forgotten, clearly facilitating drug adherence. One provider noted that when HIV test kits were unavailable, patients occasionally asked why they were not tested.

However, overall there were very few examples of patients asking questions, resulting in missed opportunities to receive vital services or drugs. One HIV-positive woman specifically stated it was not her place to question the provider.

They didn't tell me [infant's HIV test results]...the problem is that they [health workers] are the people who have to say'.
(IDI, HIV-positive woman#17)

In several cases, women said they had not questioned or clarified with the provider, despite not receiving information (e.g. test results) nor fully understanding (e.g. about the purpose of prescribed drugs). A combination of poor provider communication and

patient subservience led to one woman not receiving her positive HIV test result until after delivery, and no ARV prophylaxis.

R: The nurse didn't tell me if I was supposed to wait or come back tomorrow [for HIV test results]...when I finished [testing] I left.
I: So why didn't you ask about your results?
R: It is like that, we didn't understand each other.
(HIV-positive woman#18)

A male PLA participant said some women were unable to express themselves in the presence of a doctor, relating this to lack of education.

Terminology used by interviewees and community members to describe providers reflected the attributed power: terms such as 'experts', 'specialists' and 'experienced' were frequently used. Information from providers was referred to as 'conditions', 'directions', and 'instructions', while phrases like being 'ordered' by health workers, or 'violating the conditions' were also common.

This appeared to have both negative and positive consequences for PMTCT uptake. Fear of being reprimanded for 'violating the conditions' was commonly perceived to hinder clinic access, yet the provider's power and their 'instructions' also facilitated adherence to advice. Many patients said they had followed or accepted advice because they were told to, or imagined this would enable adherence to PMTCT services.

I told her [nurse] that I am ready to know my status, because you are the one who made the diagnosis and found I am infected, I will not deny the results.
(HIV-positive woman#7)

I: But what do you think will make her [vignette character] swallow the drugs?
R: It is only the directions; they [nurses] tell her that you must follow these directions.
(HIV-positive woman#13)

9.4.2 Trust

9.4.2.1 Confidentiality

One participant explicitly expressed trust in her provider, while lack of trust in health workers emerged more frequently, for example not trusting providers to keep a woman's HIV status confidential, particularly because they were 'local people'. However, confidentiality breaches were not documented. All women said their consultations were private, where discussed. Several nurses mentioned keeping their patients' HIV status secret, or reiterating this to patients. One commented *"I don't think there is a worker giving secrets out"*, while another acknowledged the potential implications for patient retention: *"when you let out that secret that patient will not come again"*. Lack of trust in health workers due to incompetency (e.g. apparent loss of test results, or scepticism regarding HIV test results) was also mentioned, and contributed to patients defaulting from HIV care.

9.4.2.2 Continuity of care

Trust in providers was also related to continuity of care and familiarity with staff. A few nurses described how pregnant HIV-positive women were anxious about being referred to other providers (e.g. due to lack of ARVs or HIV test kits), after having established trust in their original provider.

If she starts being given the service by you, it will be you only..., she doesn't want another worker to know that thing [her status]. Now if you send her to another place, she sees as if I'm going to start there afresh.
(Health worker#2)

Lack of continuity in care also occurred when the usual nurse was not on duty, because nurses were expected to cover a range of services owing to staff shortages, leading to drop-outs or missed PMTCT components.

One [patient] can need only you to serve her. She can find you not present, and doesn't trust the other who is present, so she turns back.
(Health worker#6)

I tested that day, I didn't get the results, I went back home, I came the next month but I didn't find the nurse who tested me. I returned for the third time then I was given the results: my result was positive.
(IDI, HIV-positive woman#18, did not receive ARV prophylaxis during pregnancy)

9.4.3 Features of care

9.4.3.1 Therapeutic alliance

Women occasionally portrayed helpful, caring, polite, kind, compassionate or forgiving staff, or a personal bond with their provider.

The nurse herself was very kind, she received me well...she just looks for me; she asks me.
(IDI, HIV-positive woman#21)

Interviews with some nurses also revealed empathetic conduct, for example paying for patients' delivery materials with their own money (confirmed by two women), and expressions of sympathy regarding their patients' personal circumstances.

You even go to buy [gloves] if you have some money, your own money, because you love the job.
(Health worker#6)

Participants often described being 'well received', 'well attended', welcomed or helped, or expressed satisfaction; sometimes specified as reasons for returning to PMTCT facilities. However, this was usually explained by the receipt of services, such as pregnancy checks or drugs, lack of scolding, or the health workers not having any 'problems'.

She [the nurse] was of help to me... because she was giving me all the services
(IDI, HIV-positive woman#13)

I: How did the health workers attend you?
R: Just good.
I: When you say good what do you mean?
R: Because they didn't scold me.
(IDI, HIV-positive woman#7)

9.4.3.2 Disrespect and disparities in care

Many HIV-positive and HIV-negative women gave accounts of disrespectful and demeaning staff behaviour including scolding, insulting language, not being provided services, nor being treated with dignity, particularly during delivery. Lack of materials (e.g. gloves, sheets, basins) at facilities, and the need for women to purchase and bring these items for delivery, exacerbated the situation and fuelled corruption.

I went to the health centre and at the time of delivery...they asked me for the rubber sheet and I told them I didn't have anything. I had a lot of problems getting her [the nurse], I had to deliver on the floor.
(IDI, HIV-negative woman#8)

Every nurse has his/her price... they totalled the whole cost: it was 17,000 Tanzanian shillings [10 USD]....the injection, gloves, everything. Some nurses will order you to pay 5,000 only [3 USD], others 6,000 [3.6 USD], and others reach up to 20,000 shillings [12 USD].
(Female PLA participant, TC)

HIV test kit and drug stock-outs caused further tensions, including blame on both sides, while health workers also expressed disappointment at not being able to test pregnant women for HIV.

But now there are no medicines, the woman will just ask you 'how is it that my child stops taking the medicines'?
(Health worker#1)

Inappropriate health worker behaviour related to stock-outs of materials was ranked among the greatest barriers to using PMTCT services by two female PLA groups (TC, RD). Women and men from remote villages recognised these issues, but they were ranked below factors such as distance from services and economic hardship. Health officials also identified staff behaviour as a major challenge for pregnant women participating in the PMTCT programme.

What is important is the staff at the MCH clinic. When someone is harsh or rude, it can hamper your service - some [staff] are very rude, and do not use good language, so the woman is fearful...she may return home... so the language and behaviour of those providers is very, very, very important.
(Health official#1)

Several HIV-positive interviewees experienced discrimination by health workers or anticipated stigmatising attitudes. Discrimination was manifest in verbal insults, not receiving services, or being told by nurses to wash their own clothes after delivery.

That nurse...sometimes she would tell you...'you are suffering from AIDS, you will also give birth to a baby with diseases, you will suffer'.
(IDI, HIV-positive woman#21)

You are supposed to wash them [delivery clothes] yourselves...so that you may not infect the person who is attending you.
(IDI, HIV-positive woman#13)

Discrimination at health facilities towards pregnant women in general, particularly young or old women, and was also described occasionally.

I am too old [38], we are very much insulted at the hospital.
(IDI, HIV-positive woman#7)

After that she touches you, then she will tell you...to raise your dress, she can't touch your body because she feels you are dirty...This is one way of stigmatising someone irrespective of whether she is HIV infected or not. In short...pregnant women are just really being harassed.
(Female PLA participant, TC)

Pregnant women were also scolded when going to ANC too early or too late (e.g. 3 months, or 7-8 months gestation respectively).

Perceptions of poor behaviour by staff, expressed in responses to the vignette, or PLA role-plays and discussions, were also frequently described and mirrored individuals' own experiences. Experienced negative staff behaviour during pregnancy, or fears of scolding, (e.g. for failing to take ARVs, or home-births) influenced adherence to subsequent steps of the PMTCT programme, such as facility-based deliveries, returning for infant prophylaxis, or infant HIV testing. For example, one HIV-positive woman became fearful, discontinued ART and did not take her child for an HIV test after having blood drawn by a 'rude' nurse.

She is afraid of going to the clinic because she was not going there during her pregnancy, and if you were not going to the clinic it will be difficult to go to the hospital to deliver...They will ask for your clinic card... it will show that she was not attending...they will scold you.
(IDI, HIV-positive woman#10)

9.4.3.3 Provider characteristics

The provider's inherent character was proposed by PLA and IDI participants as a reason for poor behaviour and differences in conduct, though some felt health system factors (e.g. low salaries, lack of resources, poor training) were largely to blame.

Insults are just about someone's character. Money can't change someone who has that habit...the habit is something inborn.
(Male PLA participant, TC)

Provider character and care quality were also linked to service type, with a few HIV-positive women noting more respectful care in HIV services compared to general MCH services.

They [HIV-nurses] are not rude like our nurses who render ordinary services.
(HIV-positive woman#19)

9.5 Discussion

This is the first qualitative study to explore in depth the ways in which patient-provider interactions influence the uptake PMTCT HIV services in Africa, providing specific evidence to guide approaches to optimise PMTCT service provision.

Overall, there were few examples of shared decision-making. Instead, breakdowns in communication were common, and the balance of power leaned strongly towards the provider. Women generally perceived their social status below that of the provider. This has been described in another Tanzanian nursing study (216), and reflects wider gender and cultural norms, respect for those in positions of authority and the inherent and assumed power structure, although power differentials between patients and health service providers are not uncommon in developed world settings (217). Our observations may also relate to the socio-demographic profile of women in our study who were from a relatively poor rural area and had a fairly limited education. The few

examples of patients questioning or negotiating with providers, thereby averting missed opportunities, suggest that empowering women may be an important strategy to improve PMTCT service use. Women have increasingly been involved in the AIDS activist movement in South Africa, lobbying for improved access to ART and a national PMTCT programme (218). Links between empowerment of HIV-positive women and enhanced patient-provider relationships have also been suggested by research in the USA (219). Another American study demonstrated the intermediary role of ancillary services (e.g. treatment advocacy groups) in facilitating patient-provider relationships by, indirectly, assisting HIV-positive patients to develop self-advocacy skills and providing a discussion forum for clarification of medical advice, or directly, by communicating on behalf of patients and accompanying them in medical consultations (220). In our setting, home-based care workers or support groups may offer potential alternatives to this approach. However, empowerment will inevitably take time, and may not always be desired, as researchers in similar settings have documented that patients appreciate assertiveness (216, 221). Interestingly, we found that issuing instructions in an authoritative manner sometimes *positively* influenced PMTCT service use. Nonetheless, providers should distinguish giving clear advice and exerting superiority, which may frighten women from returning if they fail to comply with instructions.

Knowledge transfer to the patient appeared to be a pathway through which effective communication might lead to uptake of PMTCT services. Communication effectiveness was quite clearly linked to knowledge transfer, although the link between knowledge acquisition and PMTCT service uptake was less predictable. Women sometimes followed advice without apparently understanding details or reasoning, potentially reflecting the power imbalance. Conversely, other more influential factors (e.g. partnership issues) could override the provision or understanding of advice and ultimately determine adherence to the PMTCT programme, suggesting that high quality counselling and strong patient-provider relationships alone may not suffice. Unclear communication about the HIV testing process and lack of pre HIV-test counselling evidently compromised women's understanding, resulting in misconceptions about the possibility of opting out and, controversially, greater uptake of HIV testing (although this may not necessarily translate into adherence to subsequent PMTCT services). Such results may be a consequence of staff being overburdened; an issue raised by providers in our study, reflecting the difficulties of operating the service under such conditions (152). Alternatively, health workers may believe they know what is best for their patients, exploiting their assumed superiority, and that minimal explanations may ultimately improve health outcomes for women by increasing testing rates. However, it

is imperative that in the quest to achieve high coverage of ARVs for PMTCT, the HIV testing consent process and women's rights are not jeopardised. This calls for clearer guidance on ethical procedures for administering HIV tests at ANC, and attention to the ethics of care within nursing courses. It should be made clear to pregnant women that a decision to opt-out of HIV testing will not affect their eligibility to receive further routine antenatal services. Practices that account for women arriving at ANC at different times should also be implemented, ensuring multiple group pre-test counselling sessions are offered, or individual pre-test counselling and consent for latecomers. Investments in staffing may help to ensure ethical standards are maintained by reducing time pressures resulting from staff shortages.

Amidst a principally paternalistic approach, the detailed knowledge health workers had of patients' personal situations was striking, and reflected an important aspect of patient-centred care. The social implications of an HIV diagnosis and holistic components of HIV programmes, such as HIV testing of male partners at ANC and involvement of relatives in ART adherence training, will naturally trigger discussions about relationship or family circumstances. Although there was little evidence for the direct benefit of such discussions on PMTCT service uptake, this may be mediated through enhanced family support. Support from partners and relatives was an important facilitating factor to uptake of PMTCT services in similar settings (33) and in our broader study findings (152). The intimacy of some patient-provider relationships, uncommon in most medical contexts, may also partly reflect the rural study setting with low tier health facilities and moderate patient volumes, providing the opportunity to become familiar with the same patients. This dynamic is also likely to echo the local cultural context, as it has been noted previously with nurses in Tanzania (216).

Concerns over lack of provider confidentiality appeared unfounded but are likely to reflect prevailing beliefs and HIV stigma in the community. Tackling HIV stigma at a community level is therefore important, and may also help to shift prejudicial health worker attitudes and practices. Referrals to other facilities disrupted established patient-provider relationships, exacerbated lack of trust, led to anxiety and ultimately drop-outs. Strengthening the PMTCT programme at the primary care level through sufficient stock of HIV test kits and ARV drugs, and continued decentralisation of HIV care services, are therefore likely to facilitate patient-provider interactions and patient retention. Decentralisation, and integration of HIV and ANC services, will be critical to the programme's success as changing global policies, advising all women diagnosed HIV-positive during pregnancy to initiate lifelong ART (207), are implemented. Promoting respectful care, identified as a central component of patients' trust in South

African health workers, may also improve trust in providers (222). Enhancing trust in providers also has the potential to improve ART adherence (204).

Accounts and fears of disrespectful care by health workers were widespread, affecting HIV-positive and negative women, and were particularly shocking at the time of delivery. Disrespectful treatment including scolding, insulting remarks and deliberate non-attendance of deliveries, as well as discrimination of HIV-positive women, have previously been reported in African PMTCT, delivery and primary care services (91, 222), including Tanzania (223). Disrespectful behaviour was a major deterrent to further participation in PMTCT services, and also requires urgent attention on moral grounds by PMTCT programme managers and policy makers. Addressing this issue also has the potential to improve uptake of maternal health services more broadly, particularly skilled delivery attendance. Strategies to tackle poor health worker behaviour might include enhanced education on patient rights and ethics of care in clinical training courses, accountability for misconduct, incentives for good conduct, and thorough on-job supervision with feedback. Tanzanian primary care workers desired feedback after supervisory visits from district-level staff (224), while the need for more training and feedback was also highlighted by providers in our broader study (152). Investing in and ensuring appropriate distribution of resources, particularly essential but inexpensive materials for delivery such as gloves, should also be a priority. Our findings suggest it is not only the lack of materials and associated costs that deter women from accessing delivery services, but the resulting tensions between patients and providers. Comments about better care in HIV services, compared to maternal health services more generally, potentially reflect the extra investments made in HIV services. However, if PMTCT HIV services are to be successfully integrated within maternal health services, investments are also needed in the latter. Systemic issues that may exacerbate poor behaviour such as staff shortages, low salaries and lack of incentives, are inherently complicated and challenging to address, but improvements in these areas could reap dividends in improving the uptake of PMTCT services.

The patient-centred care framework was a useful starting point to guide our analysis. Most dimensions of Mead and Bower's model were identified, although other elements of patient-centred care including disparities and continuity in care, the structural backdrop and community-based factors, were also important in shaping patient-provider interactions in this setting. 'Doctor-as-person' and 'patient-as-person' were not distinguished in our data, potentially reflecting difficulties in measuring these dimensions (169), or the context, in which illness is also seen and experienced through

relatives and significant others. We also extended the original framework to include PMTCT outcomes, and intermediary pathways. Our conceptual framework therefore provides a contribution to the evaluation of patient-provider relationships and healthcare delivery, particularly within developing world HIV programmes. While we used this framework as a lens to explore patient-provider interactions, we did not specifically set out to evaluate the extent to which medical interactions were patient-centred, nor presumed patient-centred care to be the ideal model for clinical care in our setting. Vaga et al. specifically challenged the expectations regarding approaches to caring in different socio-cultural contexts such as Tanzania (216). Nonetheless our findings document a largely paternalistic style of medical care, interspersed with elements of a patient-centred approach.

The range of qualitative techniques and respondent types were strengths of this study, enabling a synthesis of findings from different methodologies and perspectives to enhance validity. Community surveillance datasets facilitated recruitment of HIV-positive women for IDIs who were not necessarily enrolled in PMTCT care, improving validity of findings, and maximising confidentiality. The vignette was designed to minimise social desirability bias and uncover difficulties in using PMTCT services. Nonetheless, self-reported drug adherence and understanding of instructions could not be validated. Health workers are also more likely to report positive interactions with patients. Recall of details relating to pregnancies over a year before fieldwork may also be limited in accuracy. The presence of the (European) principal investigator may have influenced participants' behaviour and interpretation of results, although Tanzanian fieldworkers and researchers were involved in discussions of results.

9.6 Conclusions

The patient-provider relationship plays a pivotal role in PMTCT service use. Addressing the ethical issues surrounding informed consent for HIV testing at ANC, and disrespectful treatment of pregnant women, must be priorities for PMTCT programme managers and policy makers. Strategies should focus on improving staff behaviour, with emphasis on the ethics of care and communication, while empowering women to seek information about essential services. Optimising patient-provider relations can improve uptake of maternal health services regardless of HIV status, and ART adherence beyond PMTCT. Strengthening the capacity of health services, in particular overcoming the equipment shortages that underlie some negative patient-

provider interactions, is likely to be very challenging in this setting, but could substantially improve access to and retention in PMTCT and MCH programmes.

10 Discussion

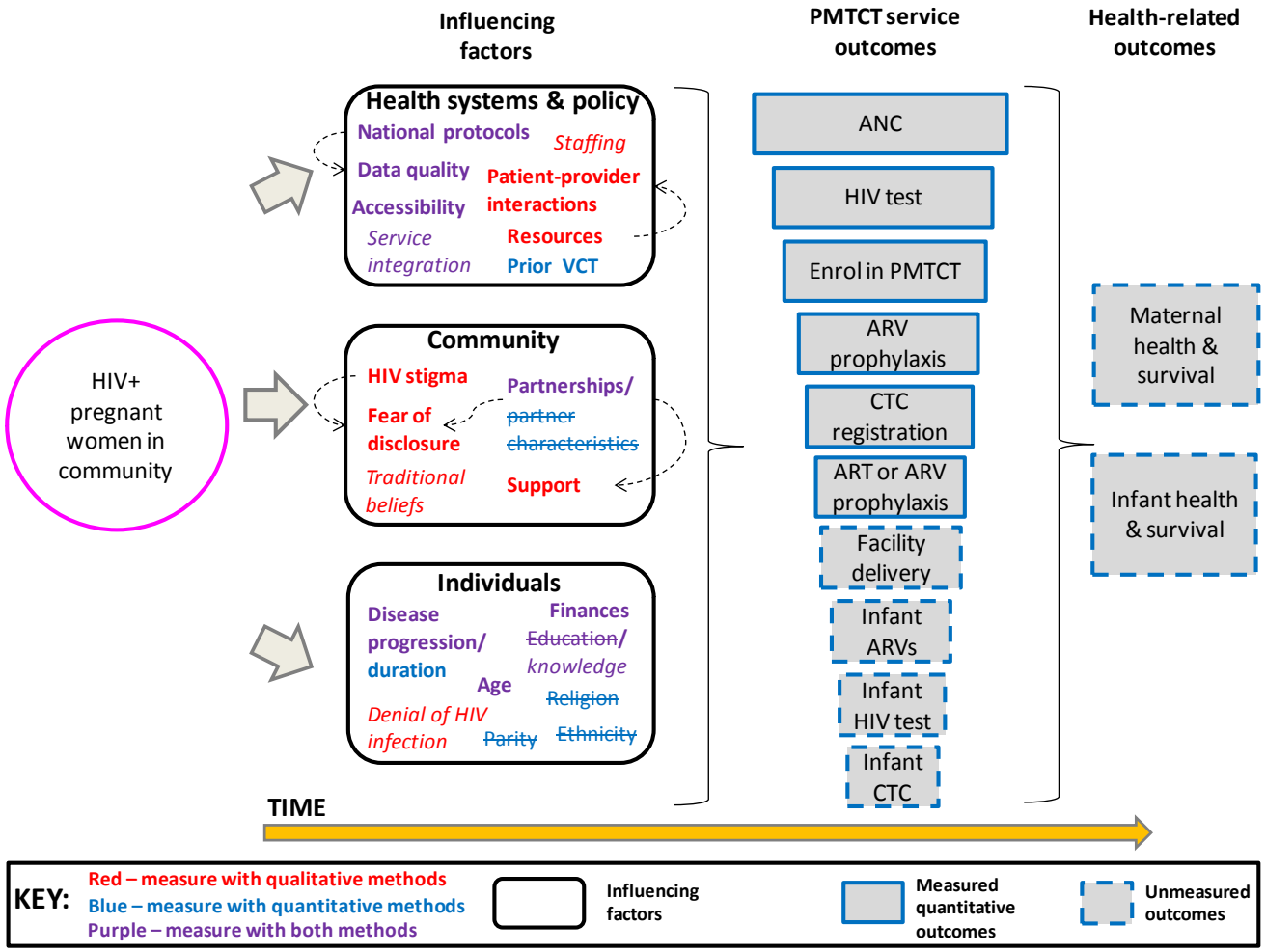
10.1 Introduction

This chapter draws together the most important findings from each paper presented in this thesis, although detailed findings and conclusions presented within each individual paper will not be repeated. Recommendations for programmes, policy, and further research will be given, followed by an overview of strengths and limitations of the methods and data sources used. Efforts to disseminate findings will be discussed, and conclusions presented.

10.2 Synthesis of findings

Table 10.1 summarises the main findings from each paper. This section aims to synthesise these findings in relation to the overall aim of this thesis: 'to investigate uptake of PMTCT services in a rural community in Tanzania (Kisesa), and the reasons hindering or facilitating service use, the ultimate goal being to recommend strategies for optimising access to and retention in the PMTCT programme'. The discussion is guided by the individual objectives presented in the introduction. The conceptual framework developed for the thesis (chapter 1) is also referred to and adapted in light of the findings (Figure 10.1).

Figure 10.1. Adapted conceptual framework for the thesis.



Factors that came through most strongly from the research in Kisesa are in bold font, those which played a lesser role are indicated in non-bold italics, while hypothesised factors included in the original framework, but which were not found to influence PMTCT service use in this setting, are crossed out. Arrows indicate the interplay of some of the factors.

Table 10.1. Summary of main findings from the papers included in this thesis.

	Paper title	Journal & date	Methods	Time frame of data collection	Main findings
A	Systematic review of barriers and facilitating factors to the uptake of ARV drugs for prevention of mother-to-child transmission of HIV in sub-Saharan Africa	Published JIAS, 2013	Literature review	2000-2012	Many barriers to uptake of PMTCT ARVs at the level of individuals, community and health systems. Key barriers e.g. limited service accessibility and staff, stigma, fear of disclosure and lack of support from partners changed little over time
B	Optimising routine data sources for PMTCT programme monitoring in Africa: lessons learned from Tanzania	Submitted to TMIH 2014	Reflection on quantitative data collection	N/A	PMTCT programme data is a rich source of information for monitoring PMTCT programmes but challenges such as lack of unique identification numbers, data quality issues and weak recording systems must be overcome
C	Uptake of services for prevention of mother-to-child transmission of HIV in a community cohort in rural Tanzania	Submitted to JAIDS 2014	Quantitative analysis	2005-2012	Low population-level uptake of PMTCT services in Kisesa below national estimates, but trending upwards over time
D	Factors associated with access to prevention of mother-to-child transmission HIV services in a community cohort in rural Tanzania	Submitted to STI 2014	Quantitative analysis	2005-2012	Age, marital status, area of residence, duration of HIV infection, prior VCT, and year of pregnancy independently predict PMTCT service use in Kisesa
E	Using vignettes in qualitative research to explore barriers and facilitating factors to the uptake of prevention of mother-to-child transmission services in rural Tanzania: a critical analysis	Published BMC Medical Research Methodology, 2014	Qualitative analysis	2012	Vignettes can be developed through PLAs and integrated within qualitative research to investigate barriers to HIV service use in Africa, but fieldworkers find the technique challenging and must be trained thoroughly
F	"It is like that, we didn't understand each other": exploring the influence of patient-provider interactions on prevention of mother-to-child transmission of HIV service use in rural Tanzania	Published PLOS ONE, 2014	Qualitative analysis	2012	Patient-provider interactions shape PMTCT service use through decision-making processes (e.g. communication and power balance), trust and features of care. Disrespectful treatment of pregnant women and lack of informed consent for HIV testing at ANC must be addressed

10.2.1 Objective 1

The first objective of this thesis was to 'critique methods used to investigate uptake of PMTCT services and factors associated with service use'. Overall, the integrated findings from this mixed-methods thesis suggest the dual importance of quantitative and qualitative methods to investigate PMTCT service use. While measures of uptake are clearly only possible with quantitative methods, factors associated with service use were identified through quantitative and qualitative investigations, as depicted in the conceptual framework. Reflecting the conclusions of the systematic review of qualitative and quantitative literature, qualitative work had the advantage of revealing *how* factors influenced PMTCT service uptake, as illustrated by the intricate analysis of patient-provider interactions, and was therefore particularly useful for providing programme and policy recommendations. Factors such as lack of support, stigma and disclosure issues - less easily measured by quantitative methods - could also be explored. However, quantitative methods, through larger and more representative samples, facilitated robust community-level analyses of predictors of PMTCT service use, and the investigation of factors such as duration of HIV infection which could not be explored through qualitative research. Quantitative methods were also useful for identifying groups of women who may be at most risk of not receiving PMTCT services (e.g. young or unmarried women, those lacking symptoms, or not previously diagnosed), thereby contributing information to inform the design of targeted interventions to improve uptake in these groups.

Paper B described the merits of routine clinic data for monitoring PMTCT programmes, but outlined numerous challenges associated with the collection and use of these data, based on challenges identified while collecting and analysing the data for this thesis (discussed further in section 10.3 with reference to recommendations for programmes and policy). The paper argued that improvements to routine data capture could ultimately improve outcomes for HIV-infected pregnant women and infants by facilitating the tracking of individual patients through the PMTCT service cascade, thus aiding their clinical management. Data quality was therefore included in the adapted conceptual framework as a health systems factor influencing PMTCT service use, concurring with discussions with health providers (who identified the volume of paperwork and data collection at individual sites as a weakness of the PMTCT programme), and with findings from other African studies that identified poor record keeping as a factor impacting on receipt of PMTCT services (104). National protocols that changed during the course of this PhD also influenced the quality of the data, leading to improvements in some of the registers over time but also complicating the data collection (e.g. more fields added into smaller spaces) and necessitating re-

training of staff with each new register series issued (appendix 12.1.1). Data quality issues also complicated the linkage of maternal and infant clinic records and use of the delivery registers, so outcomes from this point of the PMTCT cascade could not be included in the analyses (as indicated in the adapted framework). The analyses within this thesis (papers C and D), using novel methodology to link community cohort data to routine clinic data, nonetheless provide some of the first direct population-level estimates of coverage with PMTCT services and predictors of service use in an African setting.

Regarding qualitative methods, paper E presented a critical analysis of the use of vignettes within qualitative research for exploring factors that shape PMTCT service use. The technique was feasible and useful for drawing out barriers and facilitating factors in this setting, and appeared to reduce social desirability bias by relating a story that may have mirrored participants' own experiences, thus creating a comfortable environment in which women could express their own views or experiences. It was nonetheless challenging for fieldworkers to implement, for example creating confusion when respondents deviated from the perspective of the fictional character and introduced their own experiences, or suggested what the character *should* (rather than *would*) do, the latter also introducing complexities in data interpretation. Findings from this paper informed further analyses of the qualitative data exploring patient-provider interactions (paper F). Participatory methods were useful in generating the vignette, and also had other methodological advantages such as the inclusion of ranking exercises to provide a consensus on the hierarchy of barriers, the gathering of community-wide beliefs to complement individual viewpoints from IDIs, and two-way sharing of knowledge and information.

10.2.2 Objective 2

The second objective was to 'determine, at a community level, trends in the use of PMTCT services among HIV-positive pregnant women in Kisesa'. Quantitative analyses conducted for paper D (out of a denominator of all HIV-positive pregnancies to women who attended at least one sero-survey) and paper C (expanding the denominator to also include women who had not attended sero-surveys and were diagnosed with HIV in the clinic) found fairly low overall levels of uptake of PMTCT services in Kisesa in 2005-2012 (coverage with ANC services at 64% in the raw estimate or as high as 92% in the adjusted estimate, HIV care during pregnancy at 40% (raw) or as high as 57% (adjusted), and coverage with ARV drugs at 20% (raw) or as high as 29% (adjusted)). However, trends in service uptake (paper C), and regression modelling which demonstrated a strong independent association between

year of pregnancy and PMTCT service outcomes (paper D), each illustrated a marked improvement in uptake of PMTCT services over time, particularly in 2009 as the programme was fully implemented in Kisesa. It is not particularly surprising that PMTCT service uptake should increase as services became available within the study area, but the year on year increase and magnitude of improvement after 2009 was encouraging (for example, raw estimates rising from 44% in HIV care in 2009, to 54% in 2010, to 63% in 2011, and 68% in 2012 (paper C)).

Nevertheless, these findings (coverage with HIV care at 68% (raw) to >90% (adjusted) in 2012, and 44% (raw) to 62% (adjusted) for coverage with ARV drugs during pregnancy in the same year) were below national (UNAIDS) estimates for coverage with ARVs for PMTCT (73% [65%-83%] in 2013, (1)). This may reflect regional or local differences, for example between rural and urban areas. Although there are no regional or community-level estimates of coverage with HIV care or ARV drugs among HIV-positive pregnant women available for Tanzania, statistics from aggregated routine data suggest that the proportion of HIV-positive pregnant women (among those who attended health facilities) in care or receiving ARVs in Mwanza region was similar to the national level in 2011, and higher than the national level in 2013 (225). This suggests that any geographical differences are perhaps more likely explained by variations in coverage at a district or community level. This is certainly conceivable given Kisesa's rural location, where women may have to travel further with limited transport to attend services (particularly CTC services) compared to urban residents, and where availability of vital resources such as HIV test kits and drugs may be poorer than in city-based hospitals. Differences in the cadre of health workers in Kisesa, generally clinical officers, nurses, or nursing assistants compared to a greater number of medical doctors and infectious disease specialists in referral hospitals such as Bugando, as well as the extent of training and supervision of PMTCT programme staff, could also factor into lower uptake of PMTCT services in Kisesa compared to more urban areas.

Alternatively, differences between the estimates for Kisesa and those for Tanzania may point to an over-estimate at the national or regional level. Paper B discussed possible reasons for inaccuracies in national estimates, such as data quality issues associated with using aggregated routine PMTCT programme data (e.g. duplicate or multiple identification numbers assigned to women), and difficulties in modelling or estimating the number of HIV-positive pregnant women. Official Tanzanian HIV programme reports indicate the proportion of HIV-positive patients (pregnant women, or all adults) who accessed ARV drugs is over 100% in some regions, suggesting coverage based

on the programme data may be over-estimated (225, 226). It is also possible that the coverage estimates presented in this thesis were slightly under-estimated, due to limitations of the record linkage procedures, although coverage estimates were adjusted to account for the proportion of clinic data that could not be linked to community cohort records. In addition, the estimates for Kisesa did not account for women who only obtained ARV prophylaxis during labour and delivery, or post-partum (included within UNAIDS estimates), although the proportion of women who only entered the PMTCT cascade at these later stages is likely to be small.

Weighing up these potential alternative explanations, it seems most likely that the uptake of PMTCT services during the study time frame was lower in Kisesa than in Tanzania or Mwanza region on average, reflecting its rural location and associated issues discussed above, but that national estimates are also over-estimated to some extent, primarily as a result of challenges with aggregating programme data. As illustrated in the conceptual framework, there were weaknesses identified throughout the PMTCT service cascade, at the point of testing and diagnosis, linkage to CTC, assessment for ART eligibility and receipt of ART or prophylaxis, likely explained by a combination of barriers at different levels, which are discussed in the following section.

10.2.3 Objective 3

Objective 3 was to 'investigate barriers and facilitating factors to the uptake of PMTCT services, synthesising factors previously identified across sub-Saharan Africa, and exploring factors influencing PMTCT service use in a rural community in Tanzania (Kisesa)'. This objective was addressed with a variety of methods: firstly through a systematic review of barriers and facilitating factors to the uptake of ARV drugs for PMTCT in sub-Saharan Africa in 2000-2012 (paper A), secondly through qualitative research in Kisesa in 2012 (paper F, appendix 12.1), and thirdly through a statistical analysis of factors associated with PMTCT service use in Kisesa in 2005-2012 (paper D), allowing triangulation of the findings generated from each method.

The systematic review provided a contribution in its own right to the understanding of reasons for poor uptake of PMTCT services across sub-Saharan Africa, whilst also situating the findings from Kisesa. Many of the barriers and facilitating factors to PMTCT service use in Kisesa mirrored those from other settings around sub-Saharan Africa identified in the review; long-standing issues at the health systems level such as service accessibility, and prominent community-level factors such as stigma and lack of partner support, also played a strong role in Kisesa and featured in the adapted conceptual framework for this thesis. The main factors that emerged in Kisesa through

the analyses presented in the results papers will be discussed below, with occasional reference to other findings emanating from the qualitative study and sero-survey data presented at conferences (appendix 12.1).

Health systems issues appeared to be particularly strong determinants of PMTCT service use in Kisesa.

Limited accessibility of services came through as an important issue, even since the decentralisation of PMTCT services to the study area, based on the qualitative findings (appendix 12.1.1, paper F) that included associated issues with distance to facilities and transport fares (particularly for residents of more remote rural villages), lack of overnight delivery services at the dispensaries, and disruption to patient-provider relationships as a result of referrals to CTC services. Quantitative analyses also suggested access to HIV care during pregnancy was lowest among women from remote villages (paper D) and women who attended ANC at the village dispensaries (paper C). These findings are somewhat contrary to what was initially expected, as it was hypothesised that accessibility issues would diminish following decentralisation of HIV and PMTCT services to Kisesa. However, the findings are fairly consistent with the literature from sub-Saharan Africa, with the systematic review concluding that service accessibility issues did not appear to change over time, and particularly affected women in rural areas. It seems likely that accessibility will remain an issue in Kisesa while ART services remain confined to the centrally-located health centre, and while supplies of HIV test kits and drugs remain sporadic.

Stocks of materials including gloves and sheets for delivery, HIV test kits, and drugs, were particularly problematic, evidenced by the qualitative discussions with health providers and women from the community (paper F, appendix 12.1.1), and by quantitative research that indicated a substantial proportion of pregnant women were not tested (paper C, although this may also reflect a lack of communication from health providers and women not being offered a test, or refusals to test).

The qualitative analysis for paper F uncovered a very strong role for **patient-provider interactions** in Kisesa, influencing PMTCT service use through decision-making processes (e.g. communication and power imbalance), trust and features of care (e.g. support or disrespectful treatment). Patient-provider interactions were identified in the review as a factor influencing PMTCT service use in other settings across sub-Saharan Africa, but this process had not been explored in detail in the literature. Neither had this factor emerged from previous research into other HIV services in Kisesa. Patient-

provider interactions were perhaps more apparent within PMTCT services as they related to the broader context of maternal health services in Kisesa, for example notable issues with disrespectful treatment of pregnant women at the time of delivery. Patient-provider interactions were also influenced by resource issues (e.g. lack of gloves), with the interplay between these factors depicted in the diagram.

Attendance at VCT services prior to pregnancy – a previously unexplored factor in the literature – was also identified as an independent predictor of PMTCT service use (paper D), indicating that women were perhaps motivated to seek care at ANC or CTC following an earlier diagnosis. A few HIV-positive women who participated in the in-depth interviews and received PMTCT services mentioned that they had been tested and diagnosed at VCT services before their pregnancy (for example, because they suspected their partner was HIV-positive), and were already in care at the CTC before their pregnancy, or were in denial of their status until the next HIV test at ANC by which stage they were feeling unwell. However, the precise pathways to entering into HIV care prior to pregnancy and the dynamics linking VCT completion with subsequent attendance at PMTCT services were not explored and may require further investigation.

At the **community-level**, **(lack of) partner support** also emerged through the qualitative research as a highly influential factor to PMTCT service use in Kisesa, coming to light through communication between patients and health workers, described in the paper exploring patient-provider interactions (paper F), and examined in further depth in the analysis for a conference poster on male involvement in PMTCT services (appendix 12.1.2). This analysis revealed that male involvement was low in the PMTCT programme in Kisesa, and that partners of HIV-positive women were encouraged to attend the clinic for an HIV test but typically refused, often blaming or even abandoning the woman when she disclosed her status, at least in part a reflection of the stigma associated with HIV which was still rooted in the community. For this reason, women were often afraid of disclosing their status to their partner.

These negative repercussions were seen by health workers and women in the community as having a major impact on PMTCT service use across the cascade. For example, lack of partner support had implications for clinic attendance when women were not able to afford their own transport fare. The observed association between marital status and PMTCT service outcomes in the quantitative analysis was interesting, as women who were single, separated or widowed were less likely to access HIV care or ARVs than married women. Although there was a possibility that

the marital status effect was biased by the differences in the characteristics of clinic records that were linked versus not linked to the DSS, it is plausible that this association reflects the lack of support (e.g. financial) from a husband.

Whether *adherence* to the programme and to ARV drugs is also more likely among married women in Kisesa is unknown, although it is conceivable that they may be unable to return to the clinic or have difficulties taking their medication if their partner reacts negatively to their HIV status. It is also possible that women became separated from their partner *as a result* of finding out their HIV status at PMTCT services.

The lack of association between partner characteristics (HIV status) and PMTCT service outcomes in the quantitative analysis was not consistent with the results for uptake of VCT services in Kisesa (48), although the small numbers of women whose partners could be identified in the data and whose HIV status was known are likely to have limited the power to detect an effect.

However, the overall influence of partnerships and extent of support on women's use of PMTCT services, particularly apparent from the qualitative research, concurs with the initial hypotheses presented in the introduction, and with the literature on PMTCT services from sub-Saharan Africa, the systematic review identifying community-level factors including fear of disclosure to partners/others and stigma as the most common barriers. Other community-level factors identified through the systematic review such as cultural traditions and beliefs also emerged from the qualitative research in Kisesa, but were ranked lower in importance than partnership issues and fears of disclosure in PLA activities.

At the **individual level**, qualitative analysis investigating patient-provider interactions in Kisesa suggested that lack of **education** may potentially influence women's ability to communicate with providers and thus influence PMTCT service use, although there was no statistical evidence for an independent association between educational level and PMTCT service outcomes in the quantitative analysis. Similarly, while qualitative research uncovered misconceptions regarding MTCT of HIV, and sero-survey data indicated that levels of **knowledge** of MTCT were surprisingly low (only 9% of HIV-positive women of reproductive age who attended sero6 were aware of MTCT, appendix 12.1.4), knowledge of HIV transmission or ART did not independently predict PMTCT service uptake in the quantitative analysis (paper D). The quantitative findings also conflicted with research on VCT service use in Kisesa in 2003-2007 (48, 49). It is possible that knowledge and education affect PMTCT service use in this setting to a

small extent, but that the effects were too small to detect in the quantitative analyses, especially given the fact that very few women were aware of MTCT or had been educated above primary level. Knowledge of MTCT increased over time from 6% among women who gave birth before 2009 (or who had not given birth) to 9% among those who delivered in 2009 or later (appendix 12.1.4), so this factor may be diminishing in importance, although levels still remained very low, tying in with findings from the systematic review.

While there was no statistical evidence for an association between **socio-economic factors,** including education or personal income, and PMTCT service access in the quantitative analysis, the ability to explore socio-economic differentials in the statistical analysis was limited by the data collected in the sero-surveys. There may also be other unmeasured factors related to socio-economic status. The qualitative research, on the other hand, identified family finances as an important factor shaping women's access to PMTCT services (ranked among the top factors by several PLA groups (appendix 12.1.1)), related to costs of travel, and occasionally lack of supplies at the health facilities.

Age also came through as an influential factor in this setting, with young women less likely to access PMTCT services in the quantitative analysis (paper D). This is supported by the qualitative analysis of patient-provider interactions which suggested that young pregnant women were sometimes discriminated against by health workers, although older pregnant women (e.g. over the age of 40) were also insulted for being too old to be bearing children. The systematic review (paper A) also identified other studies in sub-Saharan Africa where young HIV-positive women were the least likely to access ARVs for PMTCT, or faced discrimination in health-facilities.

Duration of HIV infection had not been investigated previously in relation to uptake of PMTCT services and emerged as a strong predictor in the quantitative analysis, contributing new data on drivers of PMTCT service use. Further qualitative investigation would help to unlock the reasons behind this association, although it seems plausible that it is related to the development of symptoms. Women with a long duration of HIV infection are also more likely to have lost an earlier pregnancy due to HIV, which may also have driven them to seek care. There was a suggestion from the qualitative study that pregnant women who feel in good health might be sceptical about attending HIV services along with other sick patients, or may discontinue ARVs as they respond to treatment and start to feel well again (appendix 12.1.1), findings that were also reflected in the systematic review and in other recent studies (19). Related

psychological factors, including denial of HIV infection, emerged in the stories of a few HIV-positive women in the qualitative research, but were not among the factors considered most important by the community.

10.2.4 Objective 4

Objective 4, to 'identify and recommend strategies to improve access to and retention in PMTCT services, including long-term HIV care', is covered in the next section on programme and policy recommendations.

10.3 Programme and policy recommendations

This section presents programme and policy recommendations based on the key findings that emerged from this thesis, although combinations of solutions to address barriers at different levels are likely to be most effective. Potential solutions suggested by community members during the PLA activities, or by health providers, are summarised in Table 10.2, some of which are discussed further below. Programme and policy recommendations were also provided in paper A.

Table 10.2. Solutions to overcome barriers to using and delivering PMTCT services suggested during the qualitative fieldwork.

Barrier or challenge	Solutions
Lack of resources	Audit and inspect facility stocks; improve supply management; train staff in reporting and ordering; improve data quality; communicate and share with nearby facilities that have surplus stocks
Distance from services	Decentralise services; strengthen infrastructure; have more health workers resident in villages or 'on-call' for emergencies or over-night services; provide transport vouchers; train and cooperate with traditional birth attendants; stay with relatives closer to facilities near delivery due date; deliver medicines to users (e.g. through HBC workers)
Integration of services – ANC, CTC, infant services	Provide full service integration (e.g. CTC within ANC); use referral forms; provide personal escorts by peers or health workers from ANC to CTC; give priority for those referred to CTC in queues; follow-up (e.g. telephone calls by health workers who referred patients); use new technology (e.g. point of care CD4 tests and text messages for infant test results)
Health worker behaviour and lack of trained staff	Provide training and supervision; hold staff meetings to give feedback; organise task shifting
Lack of cooperation and involvement from male partners	Encourage couples counselling and testing; support from family, peers and home-based care workers; educate and sensitise towards ANC attendance through radio or community leaders; provide partner invitations from health workers; prioritise couples in queues; make clinic times flexible with a male friendly infrastructure
Poor knowledge of HIV; psychological barriers (e.g. fears, denial); stigma	Provide (participatory) education and enhanced psycho-social counselling (from health workers); organise peer & family support
Financial hardship	Improve education; give incentives, loans or materials (e.g. seeds) to support new small businesses or crops; give food aid for infant nutrition

Suggestions by health workers are shown in blue, those by community members in green, and suggestions by both health workers and the community in brown

- **Strengthening health systems for PMTCT and maternal health services** – Careful management and auditing of the supplies of HIV test kits, drugs, and delivery materials such as gloves and sheets is vital to ensure that PMTCT services and delivery services can be provided to all women that reach the health facilities. Stock-outs must be urgently addressed to prevent avoidable HIV transmissions. Although the reasons for stock-outs and limited materials in the health facilities were difficult to deduce, health officials thought they related at least in part to distribution issues at the Medical Stores Department, or issues with ordering and reporting, so overcoming this obstacle (e.g. through further training, and enhancing the accuracy of routine data which feeds into supply requests – see "Enhancements to PMTCT data collection and reporting" below) represents a realistic goal.

  Other changes will be very challenging to bring about in the context of generally weak health systems and infrastructure, but the potential benefits to maternal and infant health of investments in these areas would be great. Further decentralisation of the PMTCT programme, including the availability of long-term HIV care and treatment services in health facilities in more remote areas, is likely to have a big impact on PMTCT service use in Kisesa and other remote rural settings in Tanzania, given the barriers related to limited service accessibility. Increasing the number of health workers so that nurses do not have to cover several different services at once, and so that continuity with patients is maintained, as well as extending opening hours in the dispensaries for night-time deliveries, would also be likely to reduce drop-outs through the PMTCT cascade and to increase access to skilled deliveries for all pregnant women.

  Several reviews of studies in developing countries have investigated the impacts of integration of ANC and HIV services on linkage to care and treatment or HIV transmission (43, 127) suggesting that further integration (e.g. services offered on the same site) may be beneficial, although the evidence base was limited. Given that the complete integration of ANC and CTC services within all facilities is probably unrealistic in the near future in Kisesa and similar settings in rural Africa, other more basic improvements are needed to strengthen the integration of maternal health and CTC services, in order to reduce drop out at this step of the PMTCT cascade (highlighted as a particular challenge by health providers). Such approaches might include improved referral systems (e.g. optimised design and use of transfer forms (155)), health workers escorting women personally from one

service to the next (sometimes done where ANC and CTC services are on the same site, although involving relatives or peers might be an alternative where services are on separate sites), better follow-up of women referred from ANC services through mobile telephone calls by health workers or possibly by HBC workers, and investments in new technologies. For example, CD4 count machines were recently implemented in Kisesa health centre which may improve clinical monitoring of women in ANC and HIV clinics under Option B+, while text messages for infant test results (between health providers) may improve the integration between laboratories at the national referral hospital and Kisesa-based health facilities.

- **Improving the behaviour of health workers and raising ethical standards for opt-out HIV testing at ANC –** The importance of patient-provider interactions in PMTCT and MCH services in Kisesa, including concerns regarding the disrespectful treatment of pregnant women and lack of informed consent for provider-initiated HIV testing at ANCs, were raised in paper F. General improvements in health systems, particularly the availability of equipment and drugs, are likely to alleviate some of the tensions between providers and patients, while enhancements to clinical training courses, additional supervision and feedback (solutions that should be achievable within the existing framework without significant investment) are also needed to address the poor conduct of some health workers. Such solutions would likely be welcomed by health providers, as the need and desire for more training and feedback was raised by providers who participated in the qualitative study, and by other Tanzanian health workers (224).

  Attention to ethical standards for PITC is urgently needed and must be a priority for programme managers and policy makers. It is essential that adequate pre-test counselling is provided to all women, in groups or individually, and individual consent to test obtained. The procedures and purpose of the HIV test should be explained, while emphasising that women will be able to receive further pregnancy services if they opt-out.

- **Enhancements to counselling** – In addition to the improvements to pre- HIV test counselling recommended above, enhancements to post-test counselling (for example by providing further training for nurses, and tools such as topic check lists which are already included within national PMTCT guidelines (30) but did not appear to be readily available or used) and counselling throughout the PMTCT service cascade are likely to improve retention in the programme.

Low levels of knowledge of MTCT of HIV among women in Kisesa, confusion over the purpose of drugs prescribed, a lack of understanding of how an HIV-exposed baby can be saved, and failure to return for subsequent PMTCT components particularly after skipping earlier service steps (e.g. for fear of being told off by health workers), call for better communication from health providers and inclusion or optimisation of messages covering these aspects in counselling sessions. For example, the importance of attending later steps of the PMTCT service cascade (e.g. infant services), even if mothers are not able to deliver in the health centre or adhere to ARVs, should be conveyed. Simplified explanations of how MTCT of HIV can occur during pregnancy (particularly important, as several women in PLA groups did not think HIV transmission could occur at this stage (appendix 12.1.4)), delivery and breastfeeding should also be given. Other useful messages would be the importance of and reasoning for taking ARVs even if pregnant women are feeling well and lack symptoms of HIV infection, as well as simple explanations of how ARVs work and can prevent HIV transmission to the baby.

- **Improve knowledge of mother-to-child transmission of HIV and awareness of PMTCT services** – While knowledge of HIV transmission was not necessarily linked to enrolment in PMTCT services or access to ARV drugs, the disturbingly low levels of knowledge of mother-to-child transmission observed may have implications for access to subsequent components of the PMTCT cascade or adherence to ARV drugs. Low awareness of PMTCT services among young women was also a possible explanation for their lower access to PMTCT services (although this hypothesis could not be explored in the qualitative data given that virtually all participants were aged ≥20 years).

  As well as providing education on MTCT of HIV through health services, efforts to raise knowledge of HIV transmission and PMTCT services in the community would complement health facility-based approaches. Community-level approaches might include radio spots (the most common source of HIV knowledge after family in a recent study in Kisesa (50)), and discussions at community meetings with involvement from health workers, TAZAMA fieldworkers, and community leaders. Participatory discussions and workshops are another potential platform, as some PLA participants expressed that they had learned a lot from the discussions. Dissemination of information through leaflets or postcards with key information (represented pictorially so that illiterate women are also able to benefit), schools and youth groups may also provide alternative channels. Raising knowledge of

HIV through such approaches, and involving HIV-positive individuals in the community, may also help to reduce prevailing HIV stigma in the community (114) .

- **Enhanced support and strategies to improve male involvement** – In view of the quantitative findings highlighting lower access to PMTCT services for unmarried HIV-positive pregnant women, and qualitative findings suggesting that lack of partner support or negative reactions from male partners were considerable barriers to PMTCT service access and adherence, additional support mechanisms and strategies to improve male involvement in the PMTCT programme (or at least to negate the opposition from partners when women disclose their HIV-positive status during pregnancy) are needed. Although there is limited rigorous evidence for the effectiveness of male involvement on women's use of PMTCT services and maternal or infant health outcomes (227), the approach does appear to hold promise (228, 229), with additional benefits including the diagnosis of HIV-positive male partners or prevention of sexual transmission within sero-discordant couples (230).

  Partner HIV testing is already recommended in Tanzanian PMTCT guidelines (134) and attempted by health workers, but with limited success (appendix 12.1.2). Similar low levels of male involvement, typically in partner HIV-testing, have also been observed in many African settings (231). Strategies are therefore needed to optimise this approach.

  Research into different interventions to improve male involvement is emerging although formal evidence evaluating their impact is still fairly limited (231, 232). Drawing from results of other studies, and suggestions of men, HIV-positive women, and health workers who participated in the qualitative study for this thesis (views of men were not often captured in the papers included in the systematic review (33), nor were female partner perspectives on male involvement considered in a recent review of interventions for involving fathers in PMTCT (231)), strategies to improve male involvement might include:

  - Education for men (preferably from other men or community-based approaches) and sensitisation towards attending ANC with their partners (229), including the importance of their involvement for the health of the mother and infant (men were aware of their limited involvement in ANC/ PMTCT programmes due to cultural norms, but did not often recognise the potential impact on PMTCT service uptake (appendix 12.1.2)).

- Infrastructural improvements to maternal health units to make them more 'male friendly' (121, 229, 232).

- Encouraging couple HIV testing and counselling (107, 230) with the receipt of results at the same time to lessen blaming attitudes (recommended by health workers as well as male and female community members in the qualitative research), or 'couple-oriented' enhanced post-test counselling that aims to develop women's communication skills for discussions with their partner about HIV and partner testing (233).

- Facilitating access to counselling for fathers (as men also feared the implications of HIV-positive test results and disclosing their status to female partners)

- Encouraging earlier and longer-term involvement of men throughout pregnancy, delivery and post-partum, rather than focussing heavily on partner HIV-testing (231), and devising alternative approaches for partner HIV testing that do not rely solely on the mother inviting her partner (for example invitations written by health workers and given to partners (61, 234) - sometimes attempted by health workers in Kisesa – or home-visits to offer HIV testing to male partners (235)). Self-testing strategies may also be more acceptable to men (236).

Further details of the qualitative work on barriers to male involvement and strategies to overcome them are presented in appendix 12.1.2.

Support from other relatives was an important facilitating factor to PMTCT service use for many HIV-positive pregnant women, particularly those without supportive partners, based on the qualitative work conducted in Kisesa. As such, further efforts to involve other relatives in the PMTCT programme, for example during counselling sessions and as 'treatment buddies' (as is already recommended in the CTC programme) may improve access to and retention in PMTCT services, while family-centred approaches may also help in identifying and extending care and treatment to other HIV-infected family members (118). Support might be provided from other HIV-positive mothers, for example modelled on the Mothers2mothers scheme in South Africa (115), through support groups in Kisesa such as the post-test club for HIV-infected individuals,

HBC workers, and other relatives. A review of community based interventions for improving PMTCT service use and associated outcomes found evidence to support several of these strategies (e.g. peer-counsellors, participatory groups, and HBC) (61).

- **Promotion of VCT** – As attendance at VCT services before pregnancy was predictive of access to PMTCT services, VCT services should be further promoted in the community. This might be achieved through community events, meetings and engagement with community leaders, through schools, peer-to-peer communication, participatory discussion groups, mass media, leaflets, or regular mobile VCT clinics. Home-based VCT and HIV self-testing have also been investigated and appear to show promise, with high levels of uptake (e.g.>70% for home-based testing) in several studies in sub-Saharan Africa (236, 237).

- **Empowering women** – paper F revealed power dynamics between patients and providers in Kisesa that were partly explained by women's low self esteem and perceived status differences. As this impacted on women's ability to communicate with providers and ultimately resulted in missed opportunities to receive PMTCT services, empowering women to ask questions and seek information about PMTCT services may help to improve access to and retention in PMTCT services. This could potentially be achieved through support groups or HBC workers, helping women to develop self-esteem and advocacy skills, clarifying medical advice or communicating on their behalf, based on a similar approach in the US (220). However, strategies must be considerate of the local context and the fact that some women may not appreciate or desire such changes (216, 221). Empowering women may also help to alleviate power differentials between HIV-positive women and their partners, as qualitative research revealed that some women were determined to adhere to the PMTCT programme in spite of negative reactions and lack of support from their partners, facilitated by support from family and friends.

- **Implementation of Option B+** - Most of the findings in this thesis endorse the implementation of Option B+ (initiation of life-long ART for all pregnant women diagnosed with HIV), already underway in Tanzania and in other countries in sub-Saharan Africa (16, 19, 21). The potential benefits in terms of operational simplicity in this setting are apparent, overcoming issues with low availability and frequency of CD4 count testing, and permitting the continuation of ART through multiple pregnancies (for example overcoming difficulties with obtaining prophylaxis during labour and delivery for women who deliver at home, and late first attendance at

ANC and consequent delays in initiating prophylaxis). These and other potential advantages of Option B+ have been clearly outlined (15, 16), and have contributed to successes in improving the proportion of pregnant women accessing PMTCT services including ARV drugs (238, 239). The finding that duration of HIV infection was associated with access to PMTCT care also suggests a need for incentives to attract HIV-positive pregnant (or child-bearing age) women into care earlier in their infection. Option B+, by providing treatment for life to all HIV-positive pregnant women diagnosed with HIV, might serve as an incentive for women to seek care and treatment.

Meanwhile, some findings suggest challenges will be faced with Option B+, such as stock-outs of drugs, difficulties with repeated clinic attendance and adherence to ART for women with unsupportive male partners, challenges with integration of ANC and CTC services, frequently changing clinic registers and the requirement for continuous re-training of health workers, and healthy pregnant women who do not see the need for ART (19). Other programmatic challenges will likely include the cost implications of placing more patients onto life-long ART, the need for ongoing adherence monitoring, and ethical implications (e.g. HIV-positive women who use modern contraception effectively and do not fall pregnant will not automatically receive ART) (156). This reflects debates in the literature around the potential benefits and pitfalls of Option B+ (128), and data from other recent studies (19).

Success of Option B+ may therefore depend on overcoming these challenges, although some barriers may also apply to other recent guidelines including 'Option A' and 'Option B' under which women initiate ARV prophylaxis or ART from as early as 14 weeks gestation. Recent data emerging on the acceptability of Option B+ and retention in PMTCT programmes in Malawi suggests that a sizeable proportion (20%) of women provided with ART in the context of Option B+ did not actually start it (20, 240) and that a similar proportion were lost to follow-up within 6 months after ART initiation (20, 241). These findings highlight the importance of close monitoring of PMTCT programmes under the new guidelines, in order to capitalise on the potential benefits of the approach. The potential (positive or negative) influence of the changes in national protocols on uptake of PMTCT services is represented in the adapted conceptual framework.

- **Enhancements to PMTCT data collection and reporting** – Paper B outlined the challenges identified with using routinely collected PMTCT programme data and suggested ways in which some of these challenges might be overcome, in order to

make the most of this potentially rich data source. Other authors have advocated improvements to the collection and usage of routinely collected data in other public health programmes in low- and middle-income countries (242). The recommendations made in paper B are summarised again here, with specific reference to the situation in Kisesa.

At the national level in Tanzania, improvements have recently been made to the CTC database (to include details of maternal and infant prophylaxis, and registration numbers for HIV-exposed infants alongside those of mothers), and to the numbering system for HIV-positive mothers and infants who are enrolled into the PMTCT programme (unique registration numbers). Implementation of these systems within the health facilities in Kisesa (and elsewhere in Tanzania) will greatly facilitate the clinical management of patients, the linkage of maternal and infant records, the collation of data for programme statistics, and research efforts to link clinic data to community research data. Enhancements to PMTCT child follow-up registers, updated in 2012 to include the mother's ANC number alongside the child's under-5 card number, also greatly facilitated the linkage of maternal and infant records.

However, implementation of enhanced systems must be accompanied by a commitment from nurses and clinicians to use these systems properly and to record information accurately. Increasing their ownership of the data through thorough training and mentoring is likely to help in this regard. Although much needed improvements appear to be underway for the indexing and tracking of HIV-positive pregnant women and exposed infants, updated data collection systems with unique registration numbers are still needed within general MCH services to monitor other maternal and infant health outcomes. Enhancements to ANC cards to include more than one pregnancy and maintain the same number over time, similar to the 'health passport' system used in Malawi, would also be advantageous.

As many women in Kisesa apparently forget their ANC cards when attending for delivery, the importance of bringing these cards should be re-iterated to women and their relatives. As some registers were not located, or their condition was very poor (for example ripped or separated pages), improvements to the storage of records and filing systems used in the health centres would also ensure these data are useable. Delays with the delivery of new log books to the facilities, particularly at the start of a new calendar year, appeared to be another reason for issues with data collection such as duplicate or missing records, and should be easily

overcome with adequate planning at the district or higher levels. Health workers were burdened with an extraordinary volume of paper work and different registers to complete, so registers would ideally be streamlined, while also considering the layout and space to enter the required information. Computerised records in MCH services are probably unrealistic in the near future in the dispensaries, but may be an achievable goal in the Kisesa health centre or other higher tier facilities in Tanzania, given the successful use of computerised records in the CTC.

10.4 Recommendations for future research

Some of the findings in this thesis warrant further investigation, while rapid changes in PMTCT guidelines will also necessitate further research to monitor the implementation and impacts of new protocols. Recommendations for future research include:

- **Monitoring the implementation of Option B+** - The time frame for the analyses conducted within this thesis precedes the implementation of Option B+ in Kisesa in late 2013. As such, the uptake of PMTCT services and outcomes for HIV-positive women and HIV-exposed infants following the implementation of the new protocols will need to be closely monitored, particularly in light of recent data on challenges with retention in Option B+ PMTCT programmes (20, 240, 241), as described above. Potential challenges might arise with providing ART for life to all pregnant women, such as stigma and fear of disclosure associated with taking life-long treatment, maintaining the required stocks of ARV drugs, and monitoring treatment failures. Investigations of community perceptions regarding Option B+ would also be useful, in view of the fact that HIV-positive men and non-pregnant women with high CD4 counts will not be eligible for treatment, to ensure pregnant HIV-positive women are not stigmatised further.

- **Investigating repeated use of PMTCT services** – In conjunction with monitoring service provision and uptake during Option B+, it will be interesting to monitor the proportion of pregnant women attending ANC who are already on ART, and repeated use of PMTCT services in subsequent pregnancies, to determine whether women continue to seek these services after their first attendance or decide not to return. This might be achieved by further analyses using linked clinic and community surveillance data, and would build on provisional investigations presented in paper D which suggested that most women who had accessed PMTCT services in a previous pregnancy were also in care in subsequent pregnancies.

- **Monitoring adherence and retention in PMTCT services** – The quantitative analyses presented in this thesis were primarily concerned with access to PMTCT service components during pregnancy, although it will become increasingly important to monitor adherence (for example to follow-up appointments and ARV drugs) and longer-term retention in the PMTCT programme, particularly in light of Option B+. Adherence to ARV drugs was poorly recorded in the clinic data sources (for example a yes/no field) and may need to be monitored or validated using other sources such as self-reports from mothers (though with the potential for social desirability bias) or pill counts, or testing the concentration of ARV drugs in blood samples.

  Attendance at delivery services and uptake of PMTCT components for infants could also be investigated using PMTCT delivery and mother-and-child follow-up registers, analyses that were not possible within the time frame for this PhD, but which may be possible with more time dedicated to linking mother and infant records from earlier time periods (when direct links through ID numbers were not available), and linking delivery records with missing ANC numbers. Some of these records might be linked using the delivery dates or using name-based delivery registers (without HIV status), or in the case of mother-infant record linkage, using the dates of delivery recorded in delivery books and the dates of birth of children recorded in child registers.

- **Monitoring of maternal and infant health outcomes** – Additional analyses might investigate the health outcomes of mothers enrolled in the PMTCT programme and those of HIV-exposed infants, including HIV transmission. Such analyses may be feasible in the future with improvements to linkage of maternal and infant records.

- **Testing and monitoring of interventions to improve PMTCT service use** – Any interventions that were implemented in Kisesa, perhaps following recommendations presented in the previous section, could be monitored using linked community-clinic data to assess their impact on PMTCT service use. The acceptability and feasibility of alternative approaches to HIV testing, such as home-based testing (237), might also be explored in Kisesa, particularly in light of findings that prior VCT attendance was associated with access to PMTCT care during pregnancy.

- **Qualitative exploration of prior VCT use and duration of HIV infection as potential drivers of PMTCT service use** – The mechanisms that underlie the

associations between PMTCT service access and prior VCT or duration of HIV infection could be explored through further qualitative research, ideally through in-depth interviews with HIV-positive women (for example including women in the sample who were known to have accessed VCT services prior to pregnancy, and women who had been infected for varying lengths of time).

- **Development of record linkage techniques** – This thesis furthered the development of (retrospective) record linkage methodologies, although the procedures could still be optimised. Means of raising the sensitivity of the algorithm and reducing the number of DSS records that were matched to a single clinic record, weighted regression or use of multiple imputation to investigate the effect of selecting other potential matches, as well as other score weighting schemes or gold standard datasets could be explored. DSS migration reconciliation projects, to link together records of individuals who move households, would enormously facilitate linkage of clinic and DSS records by identifying which multiple matches genuinely identified the same woman. Methods for prospective record linkage, for example assigning DSS ID cards to all residents in the DSS area (in process) and recording the individual's DSS ID card number within health facility records, or real-time matching (e.g. using databases with photos) at the point that patients attend the clinic, could also be implemented.

- **Vignettes as a tool for investigating barriers to PMTCT service use** – Paper E concluded that vignettes were a viable method for use within qualitative research in African settings. Future qualitative research projects investigating barriers to other HIV services in Kisesa, or similar settings, should consider employing this technique.

10.5 Strengths and Limitations

The overall strengths and limitations of this thesis are presented in this section, with a focus on the key issues from the collective body of research and different study designs incorporated.

10.5.1 Strengths

One of the key strengths of this thesis is the mixed-methods approach to investigating uptake of PMTCT services, including quantitative and qualitative research conducted in the same community and in overlapping time periods. The quantitative component enabled the calculation of service coverage estimates, while both components contributed to the investigation of barriers and facilitating factors to PMTCT service

use. Findings generated using different methods could therefore be synthesised and compared to increase the validity and to gain a deeper understanding of PMTCT service use in this community. Qualitative findings were particularly helpful in contextualising the levels of coverage observed and explaining *how* particular factors, including those identified through quantitative research, might ultimately impact on PMTCT service use. Aside from the synthesis of findings, nesting the qualitative work within the broader context of the community cohort study also facilitated the recruitment of PLA and IDI participants through the use of sampling frames constructed from the cohort data. The variety of different methods incorporated within the qualitative study also enabled the triangulation of findings within this component, while the systematic literature provided a bench mark for comparison with results from sites across sub-Saharan Africa.

The quantitative and qualitative methods used in this thesis included novel techniques and provided methodological contributions. Research using data with links between community cohort and health facility records has rarely been undertaken in Africa, despite the potential value of this approach. The analyses in this thesis, using linked datasets to provide population-level estimates of coverage with PMTCT services and to explore predictors of service use, provide new insights into the performance of the PMTCT programme in Tanzania, as well as contributing to the development of record linkage techniques. The qualitative component included the development of a locally relevant vignette (rarely used in qualitative studies in Africa), developed through PLAs and integrated within interview discussion guides, which helped to create a comfortable atmosphere for interviewees and to draw out sensitive information on barriers to PMTCT service use. Paper E, critiquing the development and use of this vignette, provides a contribution to the literature on qualitative methodology, whilst providing practical guidance for using this technique in future research in Kisesa and the wider region. The paper on patient-provider interactions also provides a contribution to the social science literature on patient-provider interactions, by extending the theoretical model for patient-centred care to this context. This framework may be applied to the evaluation of patient-provider relationships and delivery of health care in developing world settings.

The use of data from a well established cohort study – one of the longest running HIV cohorts in Africa – was another key strength of this thesis. HIV sero-surveillance data was used to determine the HIV status of women in the community, enabling the direct calculation of PMTCT service use among the population of HIV-positive women. The recording of births and pregnancies through the DSS and sero-survey interviews meant

the analysis could be conducted per pregnancy, including trends over time by calendar year of pregnancy. The array of questions included in the sero-surveys and links to VCT services (at the survey) also enabled the assessment of a variety of potential predictors of PMTCT service use, including factors that had not been investigated previously. This PhD research also led to modifications to future versions of the sero-survey questionnaires, informing a section specifically on use of PMTCT services for those who are comfortable with disclosing their HIV status and discussing such issues.

Despite some of its drawbacks in terms of data quality, the use of routine clinic data enabled the effectiveness of the PMTCT programme to be monitored in real life, an advantage over PMTCT intervention studies including clinical trials. The inclusion of clinic data from all four government health facilities in Kisesa in the quantitative analyses, and the inclusion of participants from each of these facilities (or their catchment areas) for the qualitative research, was an advantage in that it provided a more complete picture of PMTCT service use in Kisesa. Had the quantitative data only been abstracted from Kisesa health centre, uptake of PMTCT services would have been under-estimated, with biases likely in access to health services by area of residence. The investigation of service uptake by type of ANC clinic (dispensary versus health centre) was also possible. Views and experiences of women from more remote areas of Kisesa who may not have been able to access the main health centre were incorporated, as well as the experiences of dispensary-based health workers in terms of delivering PMTCT services. Working with the dispensaries in Kisesa was a fairly new venture, as these sites had been included in ANC surveillance studies in previous years, but no formal links or regular contact had otherwise been made. The research for this thesis has therefore contributed to collaborations with these facilities which might serve as a platform for future research by the TAZAMA project.

10.5.2 Limitations

The use of observational data for the quantitative analyses is associated with the potential for bias and confounding. Participation was between 50-86% in sero 1-7, and selection bias is possible with regards to those who attended. For example, sicker (HIV-positive) individuals may have been attracted to attend the surveys due to the provision of free medical treatment for common health problems, leading to under- or over-estimates of coverage with PMTCT services if healthier individuals who did not attend were more or less likely, respectively, to attend PMTCT services. Conversely, HIV-positive women in the worst health may have been too ill to travel and reach the sero-survey sites. If these women were not included in the denominator and were also less likely to attend PMTCT services, then coverage may have been over-estimated, or

if they were more likely to be in care due to the advanced stage of their disease, then coverage may have been under-estimated. The observed associations between potential risk factors and access to PMTCT service components may also have been systematically biased if individuals who attended the surveys differed in terms of the characteristics explored, and in terms of their attendance at PMTCT services. For example, following from the example above, if women in the worst health (plausibly with a long duration of infection) did not attend the sero-survey, the association between duration of infection and access to PMTCT services may have been over-estimated if these women were excluded and were less likely to be enrolled in PMTCT services (or under-estimated if they were more likely to be in care).

This open HIV cohort study includes prevalent cases without a prior HIV-negative test date, as well as individuals with long intervals between sero-survey test dates. Because of this, dates of HIV sero-conversion may have been estimated inaccurately, although a sensitivity analysis restricted to sero-incident cases demonstrated the same associations. The dates of self-reported pregnancies may also be fairly approximate, especially pregnancies occurring several years prior to the survey in which they were reported. If HIV-positive pregnancies were erroneously included in the denominator, coverage with PMTCT services may be under-estimated, while HIV-positive pregnancies omitted from the denominator would mean coverage was over-estimated.

The availability of variables for the quantitative analysis was limited by questions contained in sero-survey questionnaires or information from the DSS, and by the extent to which factors could be measured through quantitative approaches. This rules out investigations of other factors that might predict PMTCT service use as suggested by qualitative research in this setting, for example personal experience of stigma or discrimination, disclosure of HIV-status (only available for a sub-set of respondents who reported attending VCT services in the sero-survey interview), past experiences at MCH services, perceptions of social status, or family finances. Confounding by unmeasured variables may have occurred. For example disclosure of HIV status could potentially confound the association between marital status and access to PMTCT services if unmarried women were less likely (or more likely) to disclose their status to a partner (or anyone else) and if disclosure were also associated with PMTCT service use. However, key confounders such as age and time period were included, and it is fairly unlikely that many other strong confounders were omitted from the analysis. Residual confounding by quantitative variables that were categorised is possible, although age was included as a continuous variable in the regression models, and the exploration of alternative categorisations had little effect on the results.

Limitations of the linkage algorithms must also be considered. Although the ANC linkage algorithm had a very high PPV (few false matches), the sensitivity was lower and approximately 30% of true matches may have been missed. This would have resulted in an under-estimate of coverage with PMTCT services if no adjustment had been made. As coverage estimates were adjusted to account for the sensitivity of the algorithm, or the proportion of clinic records that were not linked to any DSS record, this potential bias will have been reduced. The sensitivity and PPV of the CTC algorithm could not be calculated directly due to the lack of a gold standard dataset for CTC records. If the proportion of false matches was higher than for the ANC algorithm, enrolment in HIV care may have been over-estimated, while a lower sensitivity would have resulted in an under-estimate. However, the CTC records were also subjected to clerical review, and the proportion of Kisesa-resident CTC patients linked to the DSS was very similar to the ANC algorithm, so this is unlikely to have had a major impact on the results. There were differences between the characteristics of clinic records that were linked to the DSS and those that were not, which may have biased the associations for some of the risk factors investigated. For example, there were differences in terms of marital status (unlinked clinic records were more likely to be separated or widowed) and year of registration (a greater proportion of unlinked clinic records were from earlier years) which may have over-estimated the observed associations between these factors and PMTCT service outcomes. However, the strength of the association observed for year of pregnancy, and the fact that single women were also less likely to access PMTCT services than married women, suggests that the overall conclusions would not have been altered substantially.

Data quality issues in the clinic datasets limited the ability to link clinic records from different registers to one another. These placed constraints on the scope of analyses that could be conducted. For example, infant records could not be directly linked to records for the mother because the registration numbers for the infant *and* mother were not documented together until 2012 when new versions of the mother-and-child registers were introduced. The large volume of missing ANC numbers within PMTCT delivery registers, as well as missing books, also rendered this dataset unusable within the time frame of the PhD. Missing ANC pregnancy register data (<10%) may have led to the misclassification of outcomes (those who in reality attended the clinic classified as non-attenders), although the relatively small quantity of missing data were distributed fairly evenly across time periods and facilities, and so systematic bias in the findings for predictors of PMTCT service use is unlikely.

A small proportion (<10%) of PMTCT clinic records could not be linked back to the ANC registers or CTC dataset due to missing ANC and CTC registration numbers, or for other reasons such as missing ANC register data, or because they were clients from outside of Kisesa who had started ANC services elsewhere. Enrolment in PMTCT services could be slightly under-estimated for this reason, although some of these patients may have been picked up in the CTC directly through linkage to the DSS, and non-residents would not have been included in the denominator for analysis in any case. However, there were very few differences in terms of key characteristics between the PMTCT records that were not linked to other clinic services. It was assumed that ANC records that were not found in the PMTCT test books were not tested (as there were no PMTCT test books apparently missing). ANC records for known HIV-positive individuals (based on sero-survey data) that were apparently linked (by their ANC number) to a record with a negative test result were also assumed to be undiagnosed at ANC if they were not registered in PMTCT or CTC services. If these assumptions were incorrect, then the proportion of women who were tested at ANC may have been under-estimated.

Issues with the ANC numbering system that can give rise to duplicate IDs across different clinics and within each clinic raise the possibility that some of the records were mis-matched across the clinic registers, despite efforts to verify matches using other data such as visit dates and village of residence. However, any mis-matching would have been at random, leading to random misclassification of the outcomes and weakening observed associations. The same applies for CTC IDs that were sometimes poorly recorded, for example in abbreviated format with the digits that correspond to region or facility codes missing, although these cases were subjected to further checks. A few CTC IDs were invalid, or from another region, and could not be linked to the CTC database, so may have resulted in a slight under-estimation of the proportion in care at the CTC, although the fact that CTC records were also linked directly to the DSS lessens this possibility.

Classification of outcomes with respect to ARV uptake was reliant on recorded prescribing of ARVs by nurses at ANC, or clinicians in the CTC. Where columns in PMTCT registers for ARVs dispensed and date dispensed were both left blank, it was assumed that ARVs were not dispensed. If this was due to recording errors, then the proportion of women who accessed ARVs may have been under-estimated, although ARVs prescribed to women who were also registered at the CTC might still have been captured (recording of ART in the CTC database is likely to be more reliable), and any such errors were presumably at random. ARV usage may also have been under-

estimated due to apparent weaknesses in the reporting of ARV prophylaxis within the CTC database, and it is likely that the actual proportion of women who ingested the treatment or adhered to treatment throughout their pregnancy was lower.

Although clinic data were collected from all government-run facilities in Kisesa, there remains a possibility that some women attended PMTCT services outside the ward, for example at Magu District hospital or other facilities in Mwanza city such as Sekou-Toure hospital. This may particularly apply to women who moved to the area after attending ANC elsewhere, to those who lived on the periphery of the study area, or to women who wished to conceal their HIV status and feared being seen at HIV services within Kisesa. The proportion of women who attended HIV services outside the area was unknown and may have resulted in an under-estimate of coverage with PMTCT services, although data from sero7 indicated that the proportion attending ANC services outside the ward was fairly small (~10%), and this information was factored into coverage estimates. A few women may have attended private services within the ward, but these facilities did not offer PMTCT services until 2013 and so are unlikely to have affected the estimates.

The sample size was limited by the numbers of HIV-positive pregnant women eligible for inclusion in the analyses, and the numbers within some categories of risk factors investigated were small (e.g. for knowledge variables). Although there was strong statistical evidence for an independent association between some factors and PMTCT service outcomes, there may have been insufficient power to detect smaller effects for some variables (e.g. having any children who had died, or knowing someone taking ART), particularly in the multivariate analyses.

The qualitative study was conducted within a relatively short time-frame due to funding requirements and balancing time with that for quantitative work. Observations in the clinic could only be carried out over a few months during the fieldwork period, while it would have been optimal to observe on-goings in the clinic over a much longer time frame. Although health workers were used to my presence in the clinics for visits related to other matters including quantitative data collection, observations over a longer time frame may have lessened my influence, as a white European, on normal proceedings in the clinics. In this way, nuances of interactions between patients and providers and other health systems barriers may have come to light.

My presence in the PLA activities may also have influenced the behaviour and dialogue of the participants, potentially intimidating some women. However, local fieldworkers

facilitated the discussions and the atmosphere during the PLA activities was generally lively. The use of local fieldworkers to conduct the PLAs and interviews had the primary advantage of overcoming language barriers. My absence from the qualitative interviews may also have been advantageous and less intimidating for women who were perhaps more likely to build a rapport with the local interviewer. Nonetheless, if I had been able to carry out the interviews and facilitate the group activities myself, I may have gained a deeper insight into the data, which may have been partially lost through the feedback and translation process. It is also possible that the participants may have been *more* likely to trust and disclose information to a foreigner who they perceive to be less connected to their community and therefore less likely to leak confidential information.

The time frame available also made the recruitment of male partners through snowball sampling more challenging; as few partners were referred for interview, and they were often unavailable due to work or travel, other methods to recruit male partners might have been attempted. For example, HIV-positive men attending the CTC could have been recruited, selecting those with partners who were also HIV-positive and who had been pregnant recently. However, as male IDI participants were not the main focus of the qualitative papers presented within this thesis, this was only a minor limitation. Ideally, transcripts and translations of each interview would have been processed and read before commencing the next interview, so that the ways in which interviewers conducted the discussions and probed for information could have been assessed more closely in real-time, providing the opportunity to give them more specific feedback. In this way, some of the challenges that interviewers faced with administering the vignette might have been picked up at an earlier stage. That said, regular debriefings served as a forum for feedback and discussion of emerging results or concerns, and enabled new probes to be added to explore emerging themes and areas of interest, or to suggest modifications to content.

Despite efforts to recruit a variety of respondents from different settings and to include service users and potential non-users, as well as the use of random sampling from cohort datasets for PLA participants, those who were not available or who chose not to participate in the research may also have been least likely to attend modern health services. Thus, the challenges that these women faced in accessing PMTCT services may not have been fully explored. However, the inclusion of PLAs to capture community-wide perceptions and experiences of using PMTCT or maternal and child health services, and the triangulation of information from different sources, strengthened the findings.

10.6 Dissemination

The findings contained in this thesis have already, or shortly will be, disseminated to health workers and community members in Kisesa, Magu district health authorities, PMTCT programme officials at the Ministry of Health and Social Welfare (MOHSW) and National AIDS Control Program (NACP) in Tanzania, other researchers, and PMTCT programme planners at Non-Governmental Organisations (NGO). I plan to travel to Tanzania in December 2014 to disseminate the findings locally.

10.6.1 Health workers and community members in Kisesa

I will communicate the results to health workers in Kisesa through face-to-face meetings at the facilities, together with the TAZAMA project clinician. A report summarising the findings and recommendations will also be prepared and provided. As some of the findings presented in the paper on patient-provider interactions highlighted issues with conduct of health workers, it will be important to communicate these findings but this will need to be done sensitively and constructively.

The PLA discussions provided a platform for discussion of barriers to the uptake of PMTCT services in Kisesa, so participants will already have had some exposure to key issues that arose. The main findings will be communicated to community members through village meetings, AIDS committee meetings, or the 'post-test club' for HIV-positive individuals in Kisesa, with the help of TAZAMA project staff, of Tanzanian social scientists, or of fieldworkers who were involved in the qualitative research.

10.6.2 Magu district and Tanzanian health authorities

A short report will be prepared for health officials at the district level, some of whom were themselves participants in the qualitative research. This report will also be shared with officials responsible for the national PMTCT programme at the Tanzanian MOHSW in Dar es Salaam, and other relevant individuals working for the NACP. Paper B on routine PMTCT data was co-authored by officials from the MOHSW, so they are already aware of findings and recommendations that relate to the collection and usage of routine PMTCT data in Tanzania. Meetings will also be scheduled with officials to discuss the results of the report, with the help of the TAZAMA project clinician and principal investigator. I plan to attend these meetings in December 2014 and will prepare off-prints of all the published papers, as well as hard copies of drafted papers that have been submitted, for the health officials.

10.6.3 Researchers - Academic publications and conferences

Some of the papers contained within this thesis have already been published in peer-reviewed journals with broad international readership in the fields of HIV and other health research in developing countries. In addition to the papers presented within this thesis, the following presentations were made at conferences in 2013-2014 (posters or slide sets are included in the appendix):

Appendix 12.1.1: Gourlay A, Zaba B, Mshana G, Wringe A, Birdthistle I, Urassa M et al. Barriers to the uptake of prevention of mother-to-child transmission (PMTCT) of HIV services in rural Tanzania: Oral presentation; Global Maternal Health conference, Arusha, Jan 2013.

- Provided an overview of barriers and facilitating factors that were uncovered in Kisesa through the broader qualitative study described in the methods (chapter 7). The analysis also investigated whether factors were emerging with changing PMTCT guidelines, as well as potential solutions to overcome barriers.

Appendix 12.1.2: Gourlay A, Birdthistle I, Wringe A, Mshana G, Mkwashapi D, Nsigaye R, et al. Challenges with male involvement in prevention of mother-to-child transmission of HIV services in rural Tanzania: views of fathers, mothers and providers: Oral presentation at the AIDS Impact conference, Barcelona, October 2013.

- Explored male involvement in PMTCT services in Kisesa using data from the qualitative study, including how (lack of) partner support was characterised, impacts on PMTCT service use, barriers to male involvement and how barriers might be overcome (as discussed in section 10.3 above).

Appendix 12.1.3: Gourlay A, Birdthistle I, Wringe A, Mshana G, Mkwashapi D, Urassa M. "We didn't understand each other": exploring the impact of patient-provider interactions on prevention of mother-to-child transmission of HIV service use in rural Tanzania: Poster presentation; AIDS Impact conference, Barcelona, October 2013.

- The precursor to the qualitative paper on patient-provider interactions (paper F) presented in this thesis.

Appendix 12.1.4: Gourlay A, Wringe A, Birdthistle I, Marston M, Mkwashapi D, Mshana G, et al. Knowledge of vertical transmission of HIV in the context of prevention of mother-to-child transmission of HIV services in rural Tanzania: a

mixed-methods approach: Poster presentation at the ICASA conference, Cape Town 2013.

- Included quantitative data from the sero-surveys (sero4, 5 and 6) on knowledge of MTCT of HIV among women in Kisesa, and qualitative data from PLA discussions around the same topic.

Appendix 12.1.5: Gourlay A, Wringe A, Todd J, Marston M, Cawley C, Clark B et al. Factors associated with community-level access to services to prevent mother-to-child transmission of HIV in rural Tanzania: Poster presentation at the 20th International AIDS Conference, Melbourne 2014

- The precursor to the two quantitative results papers presented within this thesis (papers C and D).

Plans for future publications in peer-reviewed journals include writing up the results of those unpublished conference outputs listed above. A paper on the impact of ART on fertility of women in Kisesa is also in the stages of preparation, for which I am the second author. This paper is being developed following a collaborative ALPHA network workshop held in 2013 on HIV and fertility. Lessons learned from data linkage work may also be presented at an INDEPTH (International Network for the Demographic Evaluation of Populations and Their Health) network conference.

Presentations will also be given to other researchers at LSHTM and NIMR in Tanzania (planned for December 2014), summarising the overall findings from the thesis.

10.6.4 PMTCT programme planners at NGOs

A policy brief was prepared in collaboration with the International AIDS Alliance to communicate the findings of the systematic review to PMTCT programme planners (appendix 12.6). This policy brief was sent to regional offices of the International AIDS Alliance, and distributed through other channels including the AIDS Alliance website, and the September 2013 edition of the 'STOPAIDS' newsletter to other NGOs (243).

10.6.5 Feedback to funders

Update reports have been provided on a regular basis to IeDEA to fulfil their reporting requirements to the National Institutes for Health, summarising the findings and listing publications. A summary report and presentation will be prepared for the LSHTM Dr Gordon Smith Travelling Scholarship award, focussing on the quantitative component of the work which was funded by the award.

10.6.6 Data sharing

The ANC clinic dataset will be securely archived with the regional data centre of the IeDEA Consortium, but will only be released beyond the data centre with the express permission of lead investigators on the project (LSHTM-based and TAZAMA project principal investigators, and myself). The qualitative dataset will also be available on request via the research data manager at LSHTM who will feed any such requests to me and the LSHTM-based principal investigator of the Kisesa cohort study. Transcripts will be thoroughly checked to ensure data are confidential. Transcripts which cannot be fully anonymised (e.g. interviews with health workers, given the small universe of health providers in the study area, and possibility of identifying individuals through references to their job roles throughout the interview) will be embargoed.

10.7 Conclusions

The collective findings within this thesis highlight the considerable barriers to uptake of PMTCT services which remain, and must be tackled, in order to successfully achieve the global vision for elimination of new paediatric HIV infections. Although considerable improvements have occurred in recent years, coverage with PMTCT services in this rural community in Tanzania falls well short of targets for universal access, leaving many infants at risk of HIV acquisition and mothers vulnerable to their own health complications.

Option B+ is likely to improve uptake of PMTCT services in Tanzania, although the potential positive impacts may be limited by barriers affecting access to and retention in PMTCT programmes and the impacts of these new guidelines will need to be closely monitored. Optimisation of routine PMTCT programme data is required to ensure that the performance of the programme can be accurately tracked, and that investments can be targeted to address the weakest elements of the programme and the most vulnerable groups of women and infants in terms of service access and retention.

Addressing health systems weaknesses may have the greatest impact on PMTCT service use in this setting. Although further decentralisation of PMTCT and ART services is likely to improve uptake, there are other more realistic goals that could have a more immediate impact in this setting and in other rural parts of Africa. These practical measures include ensuring a consistent stock of HIV test kits, ARV drugs, and delivery materials for the labour wards - of critical importance for a fully functioning PMTCT programme and sometimes overlooked - as well as enhancing the training and

supervision of health workers to improve the quality of patient-provider interactions. Packaging these strategies with others to address barriers at different levels, such as mutual support strategies and community-driven interventions to improve male involvement, should be the most effective, although shifting cultural norms around male involvement in reproductive and child health services is likely to take time. Enthusiasm around the implementation of new policies must not detract from efforts to mitigate other pre-existing or emerging new barriers to PMTCT service use and programme delivery. Reaching or approaching the imminent goal of zero new infections in children by 2015 will remain elusive unless decisive action is taken to address these barriers and target PMTCT interventions to the most vulnerable groups of women.

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12 Appendix

12.1 Conference presentations and posters

12.1.1 Global Maternal Health conference presentation slides

Barriers to uptake of prevention of mother-to-child transmission services in rural Tanzania: a qualitative study

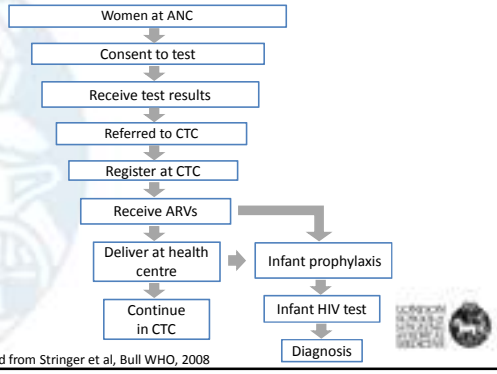
Annabelle Gourlay[1], Gerry Mshana[2], Alison Wringe[1], Mark Urassa[2], Denna Mkwashapi[2], Isolde Birdthistle[1], Basia Zaba[1]

[1] London School of Hygiene and Tropical Medicine
[2] National Institute of Medical Research, Mwanza

Background

- 84,000 HIV-positive pregnant women in Tanzania in 2009 (*World Health Organisation*)

"Cascade" of HIV+ pregnant women and HIV-exposed infants



Adapted from Stringer et al, Bull WHO, 2008

Background

- Many are unable to access PMTCT services
  - Uptake of ARVs for HIV-positive mothers and newborn was 24% in Magu district ANC surveillance (*Urassa et al, 2008*)
- Little qualitative research conducted recently in Tanzania on reasons for low uptake
- Rapidly evolving PMTCT guidelines
  - Initiation of ARVs from 14 weeks

	Option A	Option B	Option B+
Mother CD4 ≤350	Triple therapy for life	Triple therapy for life	Triple therapy for life
Mother CD4 >350	*Pregnancy*: AZT from week 14 *Labour*: NVP and AZT/3TC *Postpartum*: AZT/3TC	Triple therapy from week 14 until end of breastfeeding	
Infant	NVP from birth until end of breastfeeding	NVP or AZT from birth until age 4-6 weeks	NVP or AZT from birth until age 4-6 weeks

Adapted from UNAIDS, Programmatic Update: Use of anti-retroviral drugs for treating pregnant women and preventing HIV infection in infants, April 2012

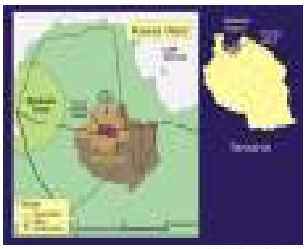
Aims and objectives

To determine:

- Barriers and facilitating factors to uptake of PMTCT services among HIV-infected women in a rural area of northwest Tanzania
- Challenges to delivering these services
- If new barriers and facilitating factors are emerging with changing PMTCT guidelines
- How barriers can be overcome

Context

- HIV cohort study since 1994
- Kisesa health centre (KHC) offers HIV care and treatment clinic (CTC) in trading centre (since 2008)
- 3 dispensaries offering ANC in rural villages
- Full PMTCT services since 2009



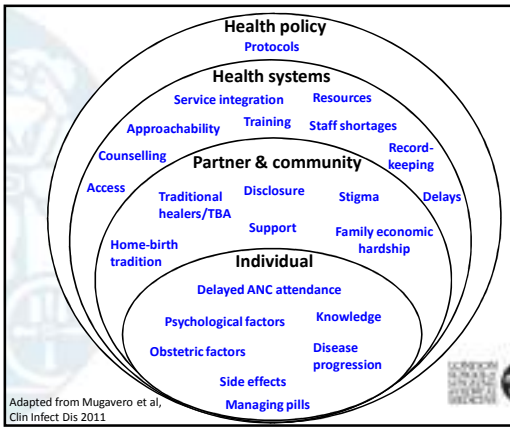
Methods

- Qualitative study conducted May-June 2012
- 6 Participatory Learning and Action (PLA) group activities
- 33 in-depth interviews (IDIs) using vignettes
  - 21 with mothers who gave birth recently (16 HIV+)
  - 3 with partners/ relatives of mothers completing IDIs
  - 9 with health workers/ officials involved in PMTCT
- Observations in KHC antenatal/ child clinic
- Framework analysis
- Ethical approval

'PMTCT journey' and barriers brainstorm

'Hanging fruits tree' of solutions

Results



Adapted from Mugavero et al, Clin Infect Dis 2011

Barriers considered most important by community and health providers

- Barriers considered most important by community:
  - Economic hardship
  - Distance from services
  - Lack/cost of clinic equipment
  - Fear of disclosure to partners/ lack of male support
  - Health worker insults
- Greatest challenges to health services delivery:
  - Lack of test kits or drugs
  - Integration of ANC with CTC
  - Lack of healthcare providers

"I think the very big challenge here, is the economic condition being bad. All things would be covered by that economic condition being good. Everything here starting ABC..it is money" (male PLA participant)

"You must go with those things [gloves, sheet] and if you don't have those things you must go with money... The lowest amount is starting at 10,000 shillings" (female PLA participant)

"Male involvement in the ANC clinic according to our culture is still a big problem" (male health official)

"That nurse who tests the blood was very rude...because sometimes she would tell you 'you are suffering from AIDS, you will give birth to a baby with diseases, , you will suffer' (HIV-positive mother)

"I think we have had a whole year without [testing] reagents...This situation is problematic, most of the mothers would like to know their condition but now it becomes a problem to get services (dispensary nurse)"

New barriers and facilitating factors with changing guidelines

- Barriers
  - Feeling healthy
  - Past actions affect adherence to next steps
  - Pill burden
  - Not aware of transmission during pregnancy
  - Refresher training for staff
  - Nurses managing treatments
- Facilitating factors
  - Desire to 'save the baby' and own health
  - Treatments easy to use

"Because she has given delivery at home it will be difficult for her even to take her baby to the clinic.... Because she didn't swallow those tablets...she will have the fear that 'obviously my baby that I have given birth to is also HIV affected'" (HIV-positive mother)

"You take one [tablet] from here and one from here...you swallow them in one go, although they don't tell you that this is for you and this is for the baby...I didn't know" (HIV-positive mother)

"These medicines can cause them [patients] adverse effects..we refer them back to Kiseso [health centre]... they change the medicines for them" (dispensary nurse)

"She will swallow those tablets in order to save herself ..to live and save her baby" (HIV-positive mother)

"They [drugs] haven't affected me. They [directions] were just easy" (HIV-positive mother)

Discussion

- New barriers emerging as PMTCT guidelines evolve, but long-standing health-systems and community issues remain
- Appropriate distribution of HIV test kits is a major and urgent issue, adequate stock and auditing of delivery tools would attract more women to deliver in facilities
- Enhanced counselling and education plus community support is critical to overcome psychological barriers

Discussion

- Male involvement could improve uptake of PMTCT services, but barriers and disclosure issues must be overcome
  - Priority for couples
  - Couples counselling and testing
  - Encourage general ANC attendance
  - Shift community norms through education 'from the village upwards' & peer encouragement

"I have also learned a little bit because I used to just let my wife go [to ANC], that 'just go and test, I am sure I am safe [not infected]'. I have learned because I have seen that we should be going together" (male PLA participant)

- Some women may not desire partner involvement so adequate support & alternatives needed

Suggested solutions and policy recommendations

Barrier or challenge	Solution
Economic hardship	Support new businesses, food aid
Lack of resources	Audits, accounts, communication
Distance from services	Accelerate decentralisation, health workers resident in villages, strengthen infrastructure, transport vouchers, train TBAs & midwives, proximity to facility near birth, medicine delivery
Health worker insults	Training, supervision, staff meetings & feedback
Integration of ANC & CTC	Full integration, referral forms, escorts, priority for referred, follow-up, new technology
Lack of trained staff	More frequent training, feedback, task shifting
Psychological barriers & knowledge	Peer & family support, enhanced counselling & education
Stigma	Education, sensitization, support groups & networks

Acknowledgements

- National Institutes of Health
- LSHTM Gordon Smith Scholarship
- National Institute of Medical Research
- Participants and staff involved in this study

12.1.2 AIDS Impact conference presentation slides

Challenges with male involvement in prevention of mother-to-child transmission of HIV services in rural Tanzania: views of fathers, mothers and providers

Annabelle Gourlay[1], Isolde Birdthistle[1], Alison Wringe[1], Gerry Mshana[2], Denna Mkwashapi[2] Ray Nsigaye[2], Mark Urassa[2], Basia Zaba[1]

[1] London School of Hygiene and Tropical Medicine
[2] National Institute of Medical Research, Mwanza

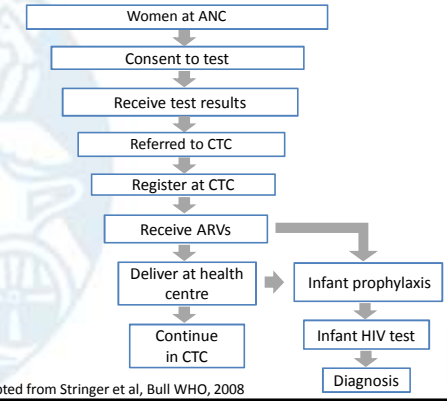
AIDS IMPACT CONFERENCE 2013

Background

- 12 million women (>15 years) living with HIV in sub-Saharan Africa in 2008[1]
- 260,000 new HIV infections among children globally in 2012[2]
- International commitments to eliminate paediatric HIV infections and preserve lives of mothers[3]
- Progress in coverage of PMTCT services but usage remains low[1,2]

References:
1.World Health Organisation, 2010. Towards universal access: scaling up priority HIV/AIDS interventions in the health sector
2.UNAIDS, 2013. Report on the Global AIDS epidemic, 2013
3.United Nations, 2011. Global Plan towards the elimination of new infections and keeping mothers alive 2011-2015

"Cascade" of HIV+ pregnant women and HIV-exposed infants



Adapted from Stringer et al, Bull WHO, 2008

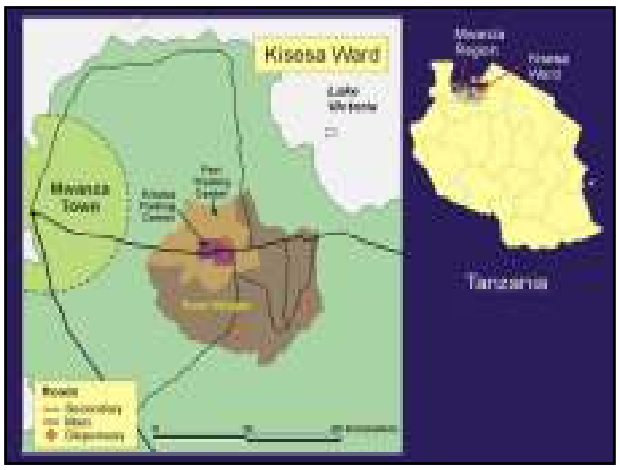
Background

- Involvement of male partners associated with increased PMTCT service use[1,2]
- Partner HIV testing encouraged in PMTCT HIV guidelines in sub-Saharan Africa
- Low levels of male involvement in PMTCT[1,2]
- Further research needed on implementation and effectiveness of this approach

References:
1.World Health Organisation, Male involvement in the prevention of mother-to-child transmission of HIV, 2012
2.Sherr and Croome, Involving fathers in prevention of mother to child transmission initiatives – what the evidence suggests; JIAS 2012, 15(suppl 2):17378

Aims and objectives

- To explore perceptions and experiences of male involvement in PMTCT services in rural Tanzania from the perspectives of fathers, mothers and health providers
  1. To what extent are male partners involved in PMTCT services in Kisesa?
  2. How is (lack of) partner support characterised?
  3. What are the impacts on PMTCT service use?
  4. What are the barriers to male involvement?
  5. How can these barriers be overcome?



Methods

- Qualitative study conducted May-June 2012
- 6 Participatory Learning and Action (PLA) group activities
  - 3 male, 3 female groups of 8-12 participants
- 33 in-depth interviews (IDIs)
  - 21 with women who gave birth recently (16 HIV+)
  - 3 with partners/ relatives of mothers completing IDIs
  - 9 with health workers/ officials involved in PMTCT
- Thematic analysis
- Ethical approval

'PMTCT journey' and barriers brainstorm

'Hanging fruits tree' of solutions

Results

Objective 1

Low male involvement in PMTCT services in Kisesa

"Male involvement in the ANC clinic according to our culture is still a big problem" (male health official)

"What happens in the society today, you can find that many men don't escort our wives to clinic" (male PLA participant)

"We advise mothers to come with their husbands to the clinic, but for now the situation in the village is that there are few men who agree to come..among ten men we can get only two who can accept" (female dispensary nurse)

"If you look at the men who come to the clinic you find there are very few men...most of us [women] are just going alone, the husband is not willing" (female PLA participant)

Objective 2

Lack of partner support typically characterised by refusal to test for HIV

- Partner refusal (or delay) to test was very common

"I was married. I was tested and found to have the virus. I told my husband to go for a test - he refused and deserted me here alone" (HIV-positive mother)

- Negative reactions to a woman's HIV-positive test results including disbelief, blame, scolding, violence, abandonment -> fear of disclosure to partners

"She fears to tell her husband [HIV positive result]. He will tell her that you are the one who has brought it.... she will be thinking 'maybe if I tell this man he will divorce me" (HIV-positive mother)

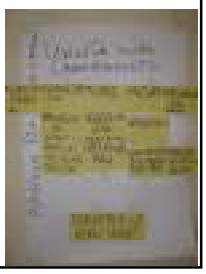
- Discouragement or controlling actions
- Lack of financial support

Objective 3

Lack of partner support seen as a major barrier to PMTCT service use

- Lack of partner support ranked as one of the greatest barriers to PMTCT service use by female PLA groups
- Recognised by male PLA groups but ranked lower
- Also noted by health workers to be a major challenge to delivering PMTCT services

"There are many challenges [providing PMTCT services]...the big one is that if you test a wife and see she is HIV-positive, the husband does not agree [to test]" (dispensary nurse)



Objective 3

Lack of partner support impacts adherence across the whole PMTCT service cascade

- Lack of partner support was thought to affect clinic attendance (ANC, delivery, child clinics), adherence to antiretroviral drugs, infant testing and feeding
  - Lack of financial assistance -> transport, clinic attendance issues, and difficulties following infant feeding advice were the most common impacts within personal stories
- In several cases, HIV-positive women overcame lack of partner support through assistance from relatives, friends or health workers

"I started thinking 'let me try to tell their father that maybe we should give them milk [cow's]' He said no…because you have a lot of [breast] milk…we will buy them just a little quantity…I have breastfed the babies since I gave birth until they reached the age of one year and ten months" (HIV-positive mother)

Objective 4

Barriers to male involvement in PMTCT services include individual, community and facility-based factors

Individual factors

-Fear of HIV testing & status disclosure

"There are men of that type: he doesn't tell his wife [HIV-positive status]….we see them…he fears, maybe his wife will say things" (male partner)

-Lack of understanding about sero-discordancy
-Denial
-Shame
-Work/ lack of time

Community factors

-Culture, social norms

"I was born here…I used to see my mother taking my young brothers and sisters to the clinic, I don't think my father escorted my mother to the clinic even on a single day - I think it is the culture we have inherited" (male PLA participant)

-HIV Stigma

Facility factors

-Infrastructure and regulations

"Infrastructure in RCH clinics here are not male friendly, just one chair for a woman" (male health official)

Objective 4

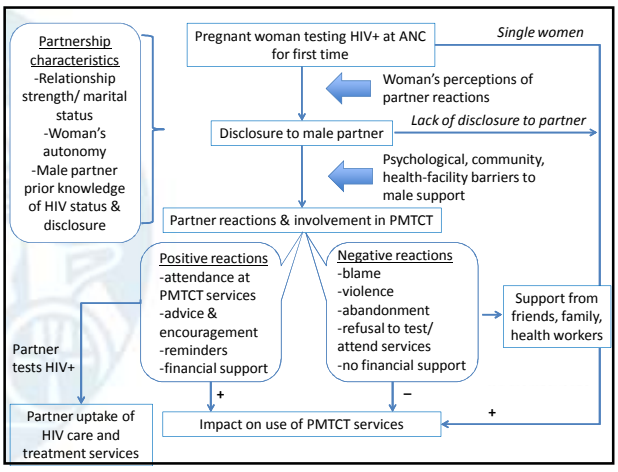
Low male involvement is not explained by negative perceptions of the PMTCT programme; involvement seen as important

- Positive community perception of the PMTCT programme
- Involvement of men in PMTCT/ HIV counselling and testing generally perceived as acceptable and important by men and pregnant women
  - Though many women had experienced or anticipated refusals
  - Some thought that relatives were more important
- Role for men throughout pregnancy, delivery and after birth
  - Encouragement and advice, shared decision making
  - Reminders (e.g. for taking ARV treatment, clinic appointments)
  - Financial assistance
  - Clinic attendance/ escorting and partner HIV testing
  - Delivery preparations

Objective 5

Couples HIV counselling and testing and educating men were widely suggested as ways of overcoming low male involvement

Strategies/ solutions	Suggested by
Couples counselling and HIV testing	Health workers and community members (men and women)
Education and sensitization of men towards attending ANC	Health workers, officials, and community members (men and women)
Invitation letters	Health workers
Priority for couples or men in queues	Health workers
Separate clinic for men	Health workers
Flexible attendance times	Health workers



Discussion

Discussion

- Male involvement is low in the PMTCT programme/ANC in Kisesa; particularly manifested in refusals to test for HIV, sparking negative reactions (e.g. blame, abandonment)
- Lack of male support is seen as having a major impact on uptake of PMTCT services by women and health workers, with impacts perceived/ experienced across the PMTCT service continuum. Men were aware of this issue, but may not realise the importance
- Lack of male involvement is determined by:
  - individual factors (e.g. fears of testing, perceptions of own health),
  - community-based factors (e.g. social norms, HIV stigma)
  - facility-based factors (e.g. facility regulations)

Discussion

- Education for men should address the possibility of sero-discordancy and benefit of testing for their own health, alongside the importance of their involvement in PMTCT for the benefit of the mother and infant's health
- Importance of receiving results together to avert blame, enhance understanding and facilitate access to counselling for fathers as well as mothers

  -> earlier and long-term involvement of men throughout pregnancy, delivery and post-partum

  -> approaches that do not rely solely on pregnant women inviting their partners

Discussion

- Solutions must be carefully implemented, taking care not to alienate single mothers or those whose partners remain uncooperative
- Shifting cultural norms around men's participation in maternal health may take a long time, and opportunities exist to capitalise on other sources of support such as relatives

Acknowledgements

- National Institutes of Health
- LSHTM Gordon Smith Scholarship
- National Institute of Medical Research Tanzania
- Participants and staff involved in this study

12.1.3 AIDS Impact conference poster

"We didn't understand each other": exploring the impact of patient-provider interactions on prevention of mother-to-child transmission of HIV service use in rural Tanzania

Gourlay, A.[1], Birdthistle, I.[1], Wringe, A.[1], Mshana G[2], Mkwashapi D.[2], Urassa M.[2]

1 London School of Hygiene & Tropical Medicine, UK; 2 National Institute for Medical Research, Mwanza, Tanzania

Introduction

- Patient-provider interactions are an important factor influencing uptake of prevention of mother-to-child transmission (PMTCT) of HIV services in sub-Saharan Africa[1], but the nature and role of such interactions have rarely been investigated in detail in this context
- The study aim was to explore how patient-provider interactions influence the use of PMTCT services in government facilities in a rural African setting

Methods

- Qualitative study conducted in 2012 in Kisesa, north-west Tanzania
- Full PMTCT services available from 2009 in Kisesa health centre (including HIV care and treatment) and 3 rural dispensaries (offering antenatal clinic)
- Participatory learning and action (PLA) activities (3 male; 3 female groups of 8-12 randomly selected participants, 'seeded' with 1-5 HIV-positive women[2]) (fig 1)
- In-depth interviews: 21 women who recently delivered (16 HIV-positive) (purposive sampling from PLAs & Kisesa health facilities); 3 partners/ relatives of HIV-positive mothers (snowball sampling); 9 health workers/ officials (purposively sampled)
- Observations in communal areas of Kisesa health centre antenatal and child clinic
- Data transcribed, translated from Kiswahili into English, then analysed with NVIVO 9 using a thematic approach. A patient-centred care framework was adapted and used to organise themes

Fig 1. PLA activity output

Results

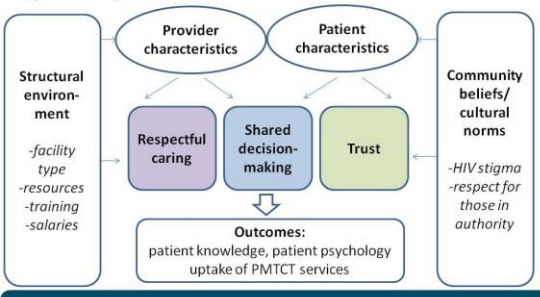
- Findings were broadly categorised under three key themes - respectful caring, shared decision-making and trust - shaped by structural and community factors and provider/ patient characteristics (fig 2)

Respectful caring

- Kind, helpful health workers sometimes described
- Receipt of services usually explained clients' perceptions of good care and service satisfaction
- Many accounts of scolding, not being attended by staff, or stigma/ discrimination of HIV-positive women →strong deterrents to service access/ re-use
- Delivery services particularly problematic, affecting HIV-positive and negative women
- Lack of supplies (e.g. gloves) and associated costs/ bribery exacerbated the issue, and frustrated staff

"I went to the health centre at the time of delivery...they asked me for that rubber sheet and I told them I didn't have anything. The nurse - I had a lot of problems to get her... I had to deliver on the floor" (HIV-negative mother)

Fig 2. Conceptual model



Shared decision-making

- Health workers had intricate knowledge of patients' personal situations (psychosocial counselling)
- A few examples of shared decision-making facilitating PMTCT service use (e.g. taking antiretroviral drugs)
- Limited pre HIV-test counselling impacted on women's understanding of option to decline HIV test
- Lapses in communication by health workers and lack of questioning by clients (power imbalance) also resulted in missed opportunities

R: "The nurse didn't tell me if I was supposed to wait or come back tomorrow [for HIV test results]...when I finished [testing] I left."
I: "So why didn't you ask about your results?"
R: "It is like that, we didn't understand each other" (HIV-positive mother)

Trust

- Fears of lack of staff confidentiality regarding HIV status, but no reports of actual breaches
- Lack of continuity of care or encountering unfamiliar staff (e.g. when referred) could cause anxiety among HIV-positive clients & service drop-outs

"One [client] can need only you to serve her. She can find you not present, and doesn't trust the other who is present. So she turns back" (Dispensary nurse)

Conclusions

- Patient-provider interactions play a pivotal role in HIV-positive women's access to and retention in PMTCT services. Strategies should focus on improving staff behaviour (including adherence to the ethics of care) and communication, while empowering patients to seek information
- Optimising relations between providers and patients within maternal health services may also improve uptake of services (e.g. skilled delivery) for all pregnant women regardless of HIV-status

References: (1) Gourlay A. et al. Journal of the International AIDS Society 2013, 16: 18588
(2) Busza J. et al. Sexually Transmitted Infections 2009; 85: 212-215

Contact: annabelle.gourlay@lshtm.ac.uk

12.1.4 ICASA poster

Knowledge of vertical transmission of HIV in the context of prevention of mother-to-child transmission of HIV services in rural Tanzania: a mixed methods approach

Gourlay A[1] Wringe A[1] Birdthistle I[1] Marston M[1] Mkwashapi D[2] Mshana G[2] Todd J[1] Urassa M[2] Zaba B[1]

[1] London School of Hygiene & Tropical Medicine, London [2] National Institute of Medical Research Mwanza, Tanzania

Introduction & study setting

Kisesa is a rural area in north-west Tanzania (Magu District, Mwanza region) with a population of ~30,0000; mostly subsistence farmers or traders of agricultural produce, with a low GDP

Poor knowledge of vertical HIV transmission was reported in Kisesa before Prevention of Mother-to-Child Transmission (PMTCT) of HIV services were implemented in 2009 [1]

Low uptake of PMTCT services reported during ANC surveillance across Magu district in 2008 [2]

The study objective was to examine trends in women's knowledge of vertical HIV transmission, and to explore misconceptions around vertical transmission, in a rural population in Tanzania (Kisesa)

Mixed Methods

Quantitative methods

3 HIV serological surveys conducted in Kisesa in 2003-4 (sero4), 2006-7 (sero5), 2010 (sero6):

- Consenting participants give blood for HIV research tests, & offered voluntary counselling & testing
- Structured questionnaires on socio-demographic characteristics, child-bearing & HIV knowledge

Analysis of trends in knowledge of HIV transmission by socio-demographic characteristics, using descriptive statistics (proportions) and logistic regression in Stata 12

- Outcome defined as % of participants mentioning, without prompting, vertical transmission as a way of transmitting HIV

Qualitative methods

Qualitative study conducted in Kisesa in 2012

- Participatory group discussions in Swahili with 3 male & 3 female groups of 8-12 randomly selected participants
- 1-5 purposively selected HIV-positive women "seeded" in each female group [3]

Discussions recorded, transcribed & translated into English. Thematic analysis conducted in NVIVO 9, using an inductive approach, guided by the research questions around knowledge

Results - Quantitative

Little change in women's (unprompted) knowledge of vertical HIV transmission, remaining low (7% sero6; 1% had not heard of HIV, another 8% did not know how HIV was transmitted) (fig 1)

Higher proportion of women mentioned HIV transmission by sharing personal items (40%), sex without a condom (29%), unsterile injections (23%) and blood transfusions (23%) (sero6)

Knowledge of vertical transmission similar in HIV-pos & HIV-neg women (all rounds p>0.2); <10% in HIV-pos women aged 15-49

Figure 1. Proportion of women mentioning vertical HIV transmission over time, by HIV-status and age

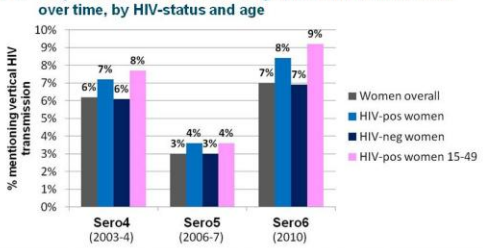


Table 1. Univariate and multivariate analysis of factors associated with knowledge of vertical transmission among women in sero6 (n=4868)

	N	% mentioning vertical HIV transmission	Crude OR [95%CI]	P†	Adjusted OR** [95%CI]	P†
Age (years)						
15-49	3954	8.0	0.98* [0.97-0.98]	<0.001	0.98 [0.97-0.99]	<0.001
>=50	909	2.5				
Educational level						
None	1827	3.4	1	<0.001	1	<0.001
Primary 1-4	314	8.9	2.8 [1.8-4.4]		2.6 [1.6-4.2]	
Primary 5-8	2201	8.8	2.8 [2.1-3.7]		2.3 [1.7-3.2]	
Secondary+	521	10.9	3.5 [2.4-5.1]		3.6 [2.4-5.6]	
Area of residence						
Rural villages	2963	7.0	1	0.8		
Roadside villages	1905	7.1	1.0 [0.8-1.3]			
Marital status						
Never married	1038	7.9	1	0.07	1	0.01
Currently married	2841	7.2	0.9 [0.7-1.2]		1.6 [1.1-2.3]	
Previously married	972	5.5	0.7 [0.5-1.0]		2.2 [1.3-3.6]	
Year of delivery						
Pre 2009/ no births	3577	6.1	1	<0.001	1	0.01
2009 or later	1263	9.4	1.6 [1.3-2.0]		1.4 [1.1-1.9]	
HIV status						
Negative	4494	6.9	1	0.3		
Positive	358	8.4	1.2 [0.8-1.8]			

*Age modelled as a continuous variable in the regression models
**Adjusted for age, education, marital status, year of delivery
† Likelihood ratio test

Knowledge of vertical transmission was higher among younger women, women with more education, ever married women, and women with recent births since 2009 (sero6) (table 1)

Results - Qualitative

Qualitative discussions confirmed quantitative results to some degree, by revealing confusion and misconceptions around vertical HIV transmission

- Disagreements about the possibility of vertical HIV transmission during pregnancy, with debates over whether the baby's and mother's blood mixes

"It is impossible [HIV transmission], because the baby is in its own place in the womb" (female PLA participant, trading centre)

- Several participants thought babies were infected in the womb during sexual intercourse with an HIV-infected man

In contrast, delivery and breastfeeding commonly mentioned as time points for vertical HIV transmission, and better understood

- Transmission during delivery mostly thought (correctly) to occur through lesions while giving birth, although cutting the umbilical cord sometimes seen (incorrectly) as the greatest potential risk, e.g. use of unsterile razor blades
- Transmission while breastfeeding believed (correctly) to be due to HIV in mother's milk, or biting by infant (occurs infrequently)

Conclusions

Knowledge of vertical HIV transmission remains disturbingly low in this setting, despite decentralisation of PMTCT services including opt-out HIV testing in antenatal clinics from early 2009

Misunderstandings and disbelief of HIV transmission during pregnancy have potential implications for pre-partum drug adherence and clinic attendance by HIV-positive pregnant women

Provider-led and community-based education regarding mother-to-child transmission, particularly among women of child-bearing age is urgently needed

References: [1] South A et al. BMC Public Health 2013; 13:802
[2] Urassa M et al. Abstract LBPE30 XVIII International AIDS Conference; 2010
[3] Buzsa J et al. STI 2009; 85: 212-215

Contact: annabelle.gourlay@lshtm.ac.uk

12.1.5 AIDS 2014 poster

Factors associated with community-level access to services to prevent mother-to-child transmission of HIV in rural Tanzania

Gourlay A.[1], Wringe A.[1], Todd J.[1] Marston M.[1], Cawley C.[1], Clark B.[1], Michael D.[2], Machemba R.[2], Reniers G.[1], Urassa M.[2], Zaba B.[1]
1 London School of Hygiene & Tropical Medicine, UK; 2 National Institute for Medical Research, Mwanza, Tanzania

Background

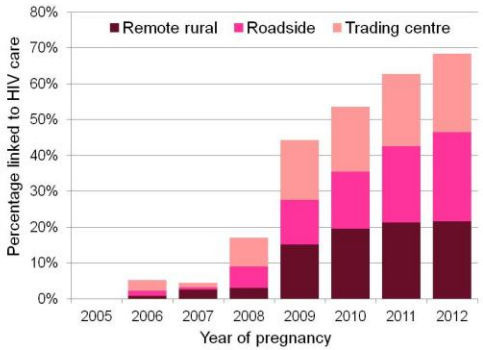
- Global targets set for eliminating mother-to-child transmission of HIV by 2015[1]
- This study aimed to identify factors associated with uptake of prevention of mother-to-child transmission (PMTCT) services among HIV-positive women in a community cohort in Kisesa, north-west Tanzania
- Kisesa is a rural area in Magu District, with a population of ~30,000; mostly subsistence farmers, with a low GDP; low uptake of PMTCT services was reported during ANC surveillance in Magu District in 2008[2]

Methods

- Kisesa cohort includes 28 rounds of demographic surveillance (DSS) & 7 HIV sero-surveys since 1994
  - Consenting participants give blood for HIV research tests, and are offered voluntary counselling & testing (VCT)
  - Structured questionnaires on socio-demographic characteristics, child-bearing & HIV knowledge
- PMTCT services offered in 4 antenatal clinics (ANC) in Kisesa since 2009; HIV care & treatment clinic (CTC) in the trading centre since 2008, with referrals for anti-retroviral treatment (ART) to city hospitals since 2005
- CTC records captured routinely in a national database; ANC/PMTCT registers from 2005-2012 double-entered
- Clinic records linked to cohort data via anonymised automated matching using personal attributes (e.g. name, age, sex, residence); ~80% of Kisesa-resident ANC and CTC records were linked to a DSS record
- Multivariable logistic regression to analyse factors associated with access to PMTCT and/or CTC ('HIV care') during pregnancy, random effects models used to allow for clustering of multiple pregnancies per woman

Results

Figure 1. Percentage of pregnancies to HIV-positive women that were linked to HIV care, by area of residence, over time



- Of 1497 pregnancies to HIV-positive women (n=849) residing in Kisesa between 2005-2012, 39% accessed PMTCT and/or CTC (29% of 849 women)

Table 1. Regression analysis of factors associated with access to HIV care (n=1497 pregnancies to HIV-positive women in Kisesa)

Factor	Categories	Number of pregnancies	Number (%) in HIV care		Crude OR	95% CI	P	Adjusted OR	95% CI	P
Age	<20	88	24	(27)	1		0.01	1		0.1
	20-29	749	289	(39)	1.9	1.1-3.3		2.2	0.9-5.6	
	30-39	576	239	(42)	2.3	1.3-4.0		2.9	1.1-7.8	
	40+	84	39	(46)	2.8	1.3-5.9		3.8	1.1-13.3	
Pregnancy year	2005-6	209	7	(3)	1		<0.001	1		<0.001
	2007-8	358	41	(12)	4.7	1.8-12.1		6.1	2.2-16.8	
	2009-10	412	203	(49)	85.5	29.8-245		82.3	27.6-245	
	2011-12	518	340	(66)	235	75.8-726		196	62.1-617	
Residence area	Remote rural	600	194	(32)	1		<0.001	1		0.01
	Roadside	434	194	(45)	1.8	1.3-2.4		1.7	1.1-2.7	
	Trading Centre	463	203	(44)	1.7	1.3-2.2		1.9	1.2-3.0	
Marital status	Currently married	1,079	435	(40)	1		0.03	1		0.009
	Never married	150	69	(46)	1.3	0.9-2.0		1.2	0.6-2.3	
	Previously married	267	87	(33)	0.7	0.5-1.0		0.5	0.3-0.8	
Gravidity	1	217	79	(36)	1		0.002	1		0.5
	2	275	99	(36)	1.0	0.7-1.5		0.7	0.4-1.3	
	3	305	105	(34)	1.0	0.7-1.5		0.6	0.3-1.2	
	4	238	100	(42)	1.5	1.0-2.4		0.6	0.3-1.2	
	>=5	462	208	(45)	1.8	1.2-2.8		0.8	0.4-1.5	
Duration of HIV-infection	<=2 years	466	74	(16)	1		<0.001	1		<0.001
	>2-4 years	511	269	(53)	2.7	1.4-5.1		7.8	4.7-12.9	
	>4 years	520	248	(48)	10.8	5.6-21.0		5.2	3.1-8.6	

- Uptake of HIV care during pregnancy increased over time, reaching 68% for pregnancies in 2012, with a steep increase in 2009 when the PMTCT program was fully implemented in the study area (Figure 1)
- Factors associated with better access to HIV care included: residence in roadside areas and trading centre versus remote rural areas (p=0.01), longer duration of HIV infection (p<0.001), and pregnancy in later calendar year (p<0.001); separated and widowed women were less likely to access HIV care compared to those currently married (p=0.009) (Table 1)
- An analysis restricted to those attending sero-surveys revealed some evidence in the crude analysis that having VCT before pregnancy (p<0.001), higher levels of education (p=0.03), and knowledge of HIV transmission modes (p=0.001) were associated with better access to care (data not presented)

Discussion

- An encouraging upward trend in access to HIV care for pregnant HIV-positive women is evident since implementation of the PMTCT program in the study area, although disparities in access to care by area persist
- Strategies to improve PMTCT service access may include further decentralisation of HIV services, and support for separated or widowed women. Promotion of VCT and implementation of Option B+ (immediate initiation of life-long ART for pregnant HIV-positive women) may improve women's enrolment in HIV programs by increasing testing and diagnosis rates, and attracting them into care and treatment earlier in their infection

References: (1) UNAIDS. Global Plan Towards the Elimination of New HIV Infections Among Children by 2015 and Keeping Their Mothers Alive 2011-2015
(2) Urassa M. et al. Abstract LBPE30 XVIII International AIDS Conference; 2010

Contact: annabelle.gourlay@lshtm.ac.uk or basia.zaba@lshtm.ac.uk

This study was funded through the East Africa IeDEA Consortium by the US National Institutes of Health - the Eunice Kennedy Shriver National Institute Of Child Health & Human Development (NICHD) and the National Institute Of Allergy And Infectious Diseases (NIAID). grant award 3U01AI069911-06S2.
HIV sero-surveillance & cohort activities carried out by the TATAMA project were funded by the Global Fund To Fight AIDS, Tuberculosis & Malaria. Grant number TNZ-911-G14-S

12.2 Ethical clearance certificates

12.2.1 Kisesa cohort activities

LSHTM approval

London School of Hygiene & Tropical Medicine
Keppel Street, London WC1E 7HT
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LONDON SCHOOL of HYGIENE &TROPICAL MEDICINE

Observational / Interventions Research Ethics Committee

Jim Todd
DPH / EPH
LSHTM

21 January 2014

Dear Mr. Todd,

Study Title: **Analysis of the Sero 7 data from Kisesa Open HIV cohort**

LSHTM ethics ref: **7191**

Thank you for your application of 7 January 2014 for the above research, which has now been considered by the Observational Committee.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

Conditions of the favourable opinion

Approval is dependent on local ethical approval having been received, where relevant.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document Type	File Name	Date	Version
Protocol / Proposal	Final2.zip	7/1/2014	1

After ethical review

Any subsequent changes to the application must be submitted to the Committee via an Amendment form onthe online application website. All studies are also required to notify the ethics committee of any serious adverse events which occur during the project via an AdverseEvent form on the online application website. At the end of the study, please notify the committee via anEnd of Study form on the online application website.

Yours sincerely,

[redacted]

Professor John DH Porter
Chair

ethics@lshtm.ac.uk
http://www.lshtm.ac.uk/ethics/

Improving health worldwide

Tanzanian approval

THE UNITED REPUBLIC OF
TANZANIA

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NIMR/HQ/R.8a/Vol. IX/1489

Ministry of Health and Social Welfare
P.O. Box 9083
Dar es Salaam
Tel: 255 22 2120262-7
Fax: 255 22 2110986

04th March, 2013

Mr. Mark S. Urassa
NIMR- Mwanza
P. O. Box 1462
MWANZA
TANZANIA

CLEARANCE CERTIFICATE FOR CONDUCTING MEDICAL RESEARCH IN TANZANIA

This is to certify that the research entitled: Monitoring HIV prevalence and incidence in an observational HIV cohort in Magu District, Mwanza region (Urassa M. S. *et al*), has been granted ethical clearance to be conducted in Mwanza, Tanzania.

The Principal Investigator of the study must ensure that the following conditions are fulfilled:

1. Progress report is submitted to the Ministry of Health and the National Institute for Medical Research, Regional and District Medical Officers after every six months.
2. Permission to publish the results is obtained from National Institute for Medical Research.
3. Copies of final publications are made available to the Ministry of Health & Social Welfare and the National Institute for Medical Research.
4. Any researcher, who contravenes or fails to comply with these conditions, shall be guilty of an offence and shall be liable on conviction to a fine. NIMR Act No. 23 of 1979, PART III Section 10(2).
5. Approval is for one year: 04th March, 2013 to 03rd March, 2014.

Name: Dr Mwelecele N Malecela

Signature [redacted]
CHAIRPERSON
MEDICAL RESEARCH
COORDINATING COMMITTEE

Name: Dr Donan Mmbando

Signature [redacted]
ACTING CHIEF MEDICAL OFFICER
MINISTRY OF HEALTH, SOCIAL WELFARE

CC: RMO
DMO

12.2.2 Data linkage project

LSHTM approval (original application)

LONDON SCHOOL OF HYGIENE
& TROPICAL MEDICINE

ETHICS COMMITTEE

APPROVAL FORM
Application number: **A266 5567**

Name of Principal Investigator	**Basia Zaba**
Faculty	**Epidemiology and Population Health**
Head of Faculty	**Professor Laura Rodrigues**

Title: **Monitoring the uptake of HIV voluntary counselling and testing (VCT) in Tanzania' to include PMTCT services.**

Amendments to this application have been approved by the Ethics Committee.

Chair of the Committee [redacted]

Date .....01 August 2011.....

Approval is dependent on local ethical approval having been received.

Any subsequent changes to the application must be re-submitted to the Committee.

LSHTM approval (amendment to original application)

London School of Hygiene & Tropical Medicine
Keppel Street, London WC1E 7HT
United Kingdom
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Observational / Interventions Research Ethics Committee

Basia Zaba
DPH / EPH
LSHTM

6 January 2014

Dear Professor Zaba,

Study Title:	**Monitoring the uptake of HIV voluntary counselling and testing (VCT) in Tanzania**
LSHTM ethics ref:	**5567**
LSHTM amend no:	**A483**

Thank you for your application of 4 December 2013 for the amendment above to the existing ethically approved study and submitting revised documentation. The amendment application has been considered by the Observational Committee.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above amendment to research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Conditions of the favourable opinion

Approval is dependent on local ethical approval for the amendment having been received, where relevant.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	Version	Date
LSHTM amendment application	n/a	02/12/2013

After ethical review

Any further changes to the application must be submitted to the Committee via an Amendment form on the online application website. The Principal Investigator is reminded that all studies are also required to notify the ethics committee of any serious adverse events which occur during the project via an Adverse Event form on the online application website. At the end of the study, please notify the committee via an End of Study form on the online application website.

Yours sincerely,

Professor John DH Porter
Chair
ethics@lshtm.ac.uk
http://www.lshtm.ac.uk/ethics/

Tanzanian approval (original application)

THE UNITED REPUBLIC OF TANZANIA

National Institute for Medical Research
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NIMR/HQ/R.8a/Vol. IX/1304

08th March 2012

Dr Alison Wringe
London School of Hygiene and Tropical Medicine
Keppel Street, London WC1E 7HT, UK
C/O Mark S Urassa
NIMR Mwanza
P O Box 1462,
MWANZA

CLEARANCE CERTIFICATE FOR CONDUCTING MEDICAL RESEARCH IN TANZANIA

This is to certify that the research entitled: Monitoring access to HIV Voluntary Counseling and Testing (VCT) and HIV Care and Treatment Clinic (CTC) services in Kisesa, Magu district, Tanzania (Wringe A *et al)*, whose Local Investigator is Mr Mark Urassa, NIMR Mwanza, has been granted ethics clearance to be conducted in Tanzania.

The Principal Investigator of the study must ensure that the following conditions are fulfilled:

1. Progress report is submitted to the Ministry of Health and the National Institute for Medical Research, Regional and District Medical Officers after every six months.
2. Permission to publish the results is obtained from National Institute for Medical Research.
3. Copies of final publications are made available to the Ministry of Health & Social Welfare and the National Institute for Medical Research.
4. Any researcher, who contravenes or fails to comply with these conditions, shall be guilty of an offence and shall be liable on conviction to a fine. NIMR Act No. 23 of 1979, PART III Section 10(2).
5. Approval is for one year: 08th March 2012 to 07th March 2013.

Name: Dr Mwelecele N Malecela

Signatur [redacted] ,

CHAIRPERSON
MEDICAL RESEARCH
COORDINATING COMMITTEE

Name: Dr Donan Mmbando

Signature [redacted]

ACTING CHIEF MEDICAL OFFICER
MINISTRY OF HEALTH, SOCIAL WELFARE

CC: RMO
DMO

Tanzanian approval (amendment to original application)

THE UNITED REPUBLIC OF
TANZANIA

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NIMR/HQ/R.8c/Vol. I/ 307

Ministry of Health and Social Welfare
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Tel: 255 22 2120262-7
Fax: 255 22 2110986

15th April 2014

Mr Mark Urassa
NIMR Mwanza
P O Box 1462
MWANZA

APPROVAL FOR PROTOCOL AMENDMENT

This letter is to confirm that your application for Amendment 01 on the study entitled: Monitoring Access to HIV voluntary Counseling and Testing (VCT) and HIV Care and Treatment Clinic Services in Kisesa, Magu Mwanza, Tanzania. Ref. NIMR/HQ/R.8a/Vol. IX/356, dated 15 December 2009, has been granted ethics clearance to be conducted in Tanzania

The Principal Investigator of the study must ensure that the approval is for the following amendments:

1. To add a PHD student Anabelle Gourlay, at the London School of Hygiene and Tropical Medicine, To work with Data Managers in Organizing Collection of the PMTCT Registers from the Clinics, advice on Data Edit Checks, work on Validation of the Linked datasets, and lead the PMTCT and ART linked Data Analysis
2. To link the Kisesa Clinic and Cohort Datasets to include a development Phase in which Data Management Team and researchers will optimize the algorithms used to carry out the linkage

Other condition for approval is as per original approval.
Approval is up to 15th December 2014

Name: Dr Mwelecele Malecela

Signature
CHAIRPERSON
RESEARCH
COORDNATING COMMITTEE

Name: Dr Donan Mmbando

Signature
CHIEF MEDICAL OFFICER MEDICAL
MINISTRY OF HEALTH & SOCIAL WELFARE

12.2.3 Qualitative work

LSHTM approval

LONDON SCHOOL OF HYGIENE & TROPICAL MEDICINE

ETHICS COMMITTEE

APPROVAL FORM
Application number: **6005**

Name of Principal Investigator	**Basia Zaba**
Faculty	**Epidemiology and Population Health**
Head of Faculty	**Professor Laura Rodrigues**

Title: **Improving uptake of PMTCT services among HIV-infected women in rural Tanzania**

This application is approved by the Committee.

Chair of the Ethics Committee [redacted]

Date .....02 August 2011 .....

Approval is dependent on local ethical approval having been received.

Any subsequent changes to the application must be submitted to the Committee via an E2 amendment form.

Tanzanian approval

LAKE ZONE INSTITUTIONAL REVIEW BOARD
(LZIRB)

National Institute for Medical Research
Mwanza Medical Research Centre
P.O. Box 1462, Mwanza
Tel: +255 28 2541935, Fax: +255 28 2500654
e-mail: mwanza@nimr.or.tz

MR/53/100/24 **26th June 2012**

Mr Mark Urassa
P.O. Box 1462
Mwanza

CLEARANCE CERTIFICATE FOR CONDUCTING MEDICAL RESEARCH

This is to certify that the research entitled: Understanding uptake of PMTCT services among HIV-infected women in rural Tanzania (Gourlay A *et al*) whose local Investigator is Mr Mark Urassa NIMR Mwanza, has been granted ethics clearance by LZIRB .

The Principal Investigator (PI) of the study must ensure that the following conditions are fulfilled:

1. **Progress report is submitted to the Ministry of Health and Mwanza Medical Research Centre, Regional and District Medical Officers after every six months.**
2. **Permission to publish the results is obtained from NIMR Headquarters.**
3. **Copies of final publications are made available to the Ministry of Health & Social Welfare Mwanza Medical Research Centre and the National Institute for Medical Research Headquarters.**
4. **Any researcher, who contravenes or fails to comply with these conditions, shall be guilty of an offence and shall be liable on conviction to a fine - NIMR Act No. 23 of 1979, PART III Section 10(2).**
5. **Approval is for this study, any other changes should be communicated to the committee for approval.**
6. **Approval is for one year: 26th June 2012 to 25th June 2013.**
7. **Since the study involves foreign collaborators, you are also directed to apply for National Ethics Clearance from NIMR Headquarters.**

Name: Fr Alphonse Twimann'ye **Name: Mr Mansuet Temu**

Signature: [redacted] **Signature** [redacted]
Vice Chairperson LZIRB **Secretary**

cc: Regional Medical Officer
District Medical Officer

12.3 Systematic review tools

12.3.1 Systematic review search terms

Search terms used in Medline database search

1. (PMTCT or mother-to-child transmission or MTCT or vertical transmission).mp. [mp=protocol supplementary concept, rare disease supplementary concept, title, original title, abstract, name of substance word, subject heading word, unique identifier]

2. Infectious Disease Transmission, Vertical/

3. (HIV or human immunodeficiency virus or AIDS or Acquired Immune Deficiency Syndrome or Acquired Immunodeficiency Syndrome).mp. [mp=protocol supplementary concept, rare disease supplementary concept, title, original title, abstract, name of substance word, subject heading word, unique identifier]

4. exp HIV/

5. (ART or ARV* or HAART or antiretroviral* or anti-retroviral* or prophylaxis or prophylactic or nevirapine or zidovudine or lamivudine or NVP or AZT or 3TC or HIV treatment*).mp. [mp=protocol supplementary concept, rare disease supplementary concept, title, original title, abstract, name of substance word, subject heading word, unique identifier]

6. exp Antiviral Agents/ or exp Antiretroviral Therapy, Highly Active/

7. (barrier* or obstacle* or hindrance or hinder or hurdle or impediment* or impede* or block* or bottleneck* or adhere* or non-adheren* or nonadheren* or constrain* or uptake or take-up or access* or participat* or attend*).mp. [mp=protocol supplementary concept, rare disease supplementary concept, title, original title, abstract, name of substance word, subject heading word, unique identifier]

8. 5 or 6

9. 1 or 2

10. 3 or 4

11. exp "Africa South of the Sahara"/

12. (Senegal or gambia or guinea or sierra leone or Liberia or cote d-ivoire or Burkina faso or Ghana or togo or benin or niger or Nigeria or Cameroon or gabon or congo or angola or Namibia or Lesotho or Swaziland or Botswana or Zimbabwe or Mozambique or Malawi or Zambia or Tanzania or Kenya or Uganda or Rwanda or Burundi or Ethiopia or Somalia or Djibouti or Eritrea or sudan or central africa or south* africa or east africa or west africa or sub-saharan africa).mp. [mp=protocol supplementary concept, rare disease supplementary concept, title, original title, abstract, name of substance word, subject heading word, unique identifier]

13. 11 or 12

14. exp Health Services Accessibility/

15. exp Attitude to Health/

16. 7 or 14 or 15

17. 8 and 9 and 10 and 13 and 16

18. limit 17 to (english language and humans and yr="2000 -Current")

Search terms used in Embase database search

1. (barrier* or obstacle* or hindrance or hinder or hurdle or impediment* or impede* or block* or bottleneck* or adhere* or non-adheren* or nonadheren* or constrain* or uptake or take-up or access* or participat* or attend*).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword]

2. exp attitude to health/

3. exp health care utilization/ or exp health care access/

4. (PMTCT or mother-to-child transmission or MTCT or vertical transmission).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword]

5. exp vertical transmission/

6. (HIV or human immunodeficiency virus or AIDS or Acquired Immune Deficiency Syndrome or Acquired Immunodeficiency Syndrome).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword]

7. exp Human immunodeficiency virus infection/

8. exp Human immunodeficiency virus/

9. (ART or ARV* or HAART or antiretroviral* or anti-retroviral* or prophylaxis or prophylactic or nevirapine or zidovudine or lamivudine or NVP or AZT or 3TC or HIV treatment*).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword]

10. exp highly active antiretroviral therapy/ or exp antiretrovirus agent/

11. exp antiviral therapy/

12. exp "Africa south of the Sahara"/

13. (Senegal or gambia or guinea or sierra leone or Liberia or cote d-ivoire or Burkina faso or Ghana or togo or benin or niger or Nigeria or Cameroon or gabon or congo or angola or Namibia or Lesotho or Swaziland or Botswana or Zimbabwe or Mozambique or Malawi or Zambia or Tanzania or Kenya or Uganda or Rwanda or Burundi or Ethiopia or Somalia or Djibouti or Eritrea or sudan or south* africa or sub-saharan Africa or east africa or west africa or central africa).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword]

14. 1 or 2 or 3

15. 4 or 5

16. 6 or 7 or 8

17. 9 or 10 or 11

18. 12 or 13

19. 14 and 15 and 16 and 17 and 18

20. limit 19 to (human and english language and yr="2000 -Current")

Search terms used in Global Health database search

1. social barriers/

2. (barrier* or obstacle* or hindrance or hinder or hurdle or impediment* or impede* or block* or bottleneck* or adhere* or non-adheren* or nonadheren* or constrain* or uptake or take-up or access* or participat* or attend*).mp. [mp=abstract, title, original title, broad terms, heading words]

3. 1 or 2

4. exp vertical transmission/

5. (PMTCT or mother-to-child transmission or MTCT or vertical transmission).mp. [mp=abstract, title, original title, broad terms, heading words]

6. 4 or 5

7. exp human immunodeficiency viruses/

8. exp hiv infections/

9. (HIV or human immunodeficiency virus or AIDS or Acquired Immune Deficiency Syndrome or Acquired Immunodeficiency Syndrome).mp. [mp=abstract, title, original title, broad terms, heading words]

10. 7 or 8 or 9

11. exp antiviral agents/

12. exp highly active antiretroviral therapy/

13. (ART or ARV* or HAART or antiretroviral* or anti-retroviral* or prophylaxis or prophylactic or nevirapine or zidovudine or lamivudine or NVP or AZT or 3TC or HIV treatment*).mp. [mp=abstract, title, original title, broad terms, heading words]

14. 11 or 12 or 13

15. (Senegal or gambia or guinea or sierra leone or Liberia or cote d-ivoire or Burkina faso or Ghana or togo or benin or niger or Nigeria or Cameroon or gabon or congo or angola or Namibia or Lesotho or Swaziland or Botswana or Zimbabwe or Mozambique or Malawi or Zambia or Tanzania or Kenya or Uganda or Rwanda or Burundi or Ethiopia or Somalia or Djibouti or Eritrea or sudan or south* africa or sub-saharan Africa or east africa or west africa or central africa).mp. [mp=abstract, title, original title, broad terms, heading words]

16. exp "africa south of sahara"/

17. 15 or 16

18. 3 and 6 and 10 and 14 and 17

19. limit 18 to (english language and yr="2000 -Current")

Search terms used in Web of Science database search

7 #1 AND #6 AND Language=(English)
Databases=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH Timespan=2000-01-01 - 2012-09-12
Lemmatization=On

6 #2 AND #3 AND #4 AND #5 AND Language=(English)
Databases=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH Timespan=2000-01-01 - 2012-09-12
Lemmatization=On

5 TS=(barrier* OR obstacle* OR hindrance OR hinder OR hurdle OR impediment* OR impede* OR block* OR bottleneck* OR adhere* OR "non-adheren*" OR nonadheren* OR constrain* OR uptake OR access* OR participat* OR attend*) AND Language=(English)
Databases=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH Timespan=2000-01-01 - 2012-09-12
Lemmatization=On

4 TS=(PMTCT or "mother-to-child transmission" or MTCT or "vertical transmission") AND Language=(English)
Databases=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH Timespan=2000-01-01 - 2012-09-12
Lemmatization=On

3 TS=(ART OR ARV* OR HAART OR antiretroviral* OR "anti-retroviral*" OR prophylaxis OR prophylactic OR nevirapine OR zidovudine OR lamivudine OR NVP OR AZT OR 3TC OR "HIV treatment*") AND Language=(English)
Databases=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH Timespan=2000-01-01 - 2012-09-12
Lemmatization=On

2 TS=(HIV OR "human immunodeficiency virus" OR AIDS OR "Acquired Immune Deficiency Syndrome" OR "Acquired Immunodeficiency Syndrome") AND Language=(English)
Databases=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH Timespan=2000-01-01 - 2012-09-12
Lemmatization=On

1 TS=(Senegal OR gambia OR guinea OR sierra leone OR Liberia OR cote d-ivoire OR Burkina faso OR Ghana OR togo OR benin OR niger OR Nigeria OR Cameroon OR gabon OR congo OR angola OR Namibia OR Lesotho OR Swaziland OR Botswana OR Zimbabwe OR Mozambique OR Malawi OR Zambia OR Tanzania OR Kenya OR Uganda OR Rwanda OR Burundi OR Ethiopia OR Somalia OR Djibouti OR Eritrea OR sudan OR "south* africa" OR "sub-saharan Africa" OR "east africa" OR "west africa" OR "central africa") AND Language=(English)
Databases=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH Timespan=2000-01-01 - 2012-09-12
Lemmatization=On

12.3.2 Quality appraisal of qualitative research included in the review

	Study number																							
	1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**37**	**38**	**39**	**40**	**41**	**42**	**43**	**44**
AIMS																								
Are the aims clear?	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Did the authors state why the research was important*?	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Is the qualitative methodology and design appropriate for the aims (justified by the researcher)?	1	1	0	0	1	1	0	1	0	1	0	1	0	1	1	0	0	0	0	1	0	0	1	0
SAMPLING AND RECRUITMENT																								
Is there an explanation of how the participants were selected?	1	1	1	1	1	1	1	1	1	1	1	0	1	1	1	1	0	1	0	1	1	0	1	1
Did the authors justify the selection/choice of participants?	0	1	0	1	0	0	1	1	1	1	1	1	0	1	1	1	0	0	0	0	0	0	1	0
Is the degree of participation mentioned and any reasons for non-participation discussed?	1	0	1	0	1	0	1	0	0	0	1	0	1	1	0	0	0	1	0	0	1	0	0	0
DATA COLLECTION																								
Is it clear how data were collected / are the methods explicit? (*eg. including use of topic guide?*)	1	1	1	1	1	1	1	1	1	1	1	0	1	1	1	1	0	1	0	1	0	1	1	1
Is the form of data clear? (*ie were the data transcribed verbatim; eg tape recordings/ transcriptions, video, notes etc*)	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	0	1	1	0	1	1	0
Did the authors discuss saturation of data?	1	0	0	0	0	0	1	0	1	0	0	1	1	0	0	0	1	0	0	0	0	0	0	0
REFLEXIVITY (RECOGNITION OF RESEARCHER BIAS)																								
Did the researcher critically examine their own role and potential bias during the study?	1	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0
ETHICS																								
Are ethical issues discussed (eg consent / anonymity)?	1	0	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	0	1	1	0	1	0	1
Was the study approved by an ethics committee?	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	0	1	0	0	1	0	1	1	1
DATA ANALYSIS																								
Is there a detailed description of the analysis process?	1	1	1	0	1	1	1	1	1	1	0	1	1	1	1	1	0	0	0	1	0	0	1	0
Is it clear how categories/themes and concepts were derived?	1	1	1	0	1	1	1	0	1	0	0	1	1	1	1	1	0	0	0	1	0	0	1	0
Are quotes presented to support the findings?	1	1	1	0	1	1	1	1	1	1	1	1	1	1	1	1	1	0	0	1	1	0	1	0
Was the analysis conducted (coding/themes) by more than one assessor?	0	0	1	0	1	1	0	0	1	0	0	0	1	0	0	1	0	0	0	1	0	0	0	0
TOTAL SCORE	**14**	**11**	**12**	**8**	**13**	**12**	**13**	**11**	**13**	**11**	**10**	**11**	**13**	**14**	**12**	**11**	**7**	**5**	**4**	**12**	**5**	**6**	**11**	**6**
Second appraiser total score				**9**		**13**		**9**				**12**									**5**			**3**
Agreed final decision								**I**																

1 indicates 'yes', 0 indicates 'no' or absence of/ unclear information on the topic

* 'Important' was considered to mean "pragmatically and theoretically useful and advanced the current knowledge base" [19]

25% of the studies that included qualitative research were double-appraised by an independent researcher. Studies scoring less than 10 were excluded in the sensitivity analysis, therefore an agreed final score was only discussed where the first and second marker scores differed to the extent that they would affect the study's inclusion (I) or exclusion (E) in the sensitivity analysis.

12.3.3 Quality appraisal of quantitative research included in the review

	Study number																							
	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	39	42	44
AIMS																							
1. Are the research aims clear? (focused in terms of research question/hypothesis, population studied, outcome, and risk factors or intervention of interest?)	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
2. Did the authors state why the research was important?	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
3. Is the methodology & design appropriate to answer the research question(s)? (regardless of whether justified by authors)	1	1	1	1	1	1	1	1	1	1	0	1	1	1	1	1	1	1	1	1	1	1	1
SAMPLING & RECRUITMENT																							
4. Are the sampling methods explained?	1	1	1	1	1	1	0	1	0	1	1	1	1	1	0	1	0	1	1	1	1	1	1
5. Is the degree of participation mentioned and adequate, e.g., >70%?	1	0	1	0	1	1	0	1	0	1	1	1	1	0	0	0	0	1	0	1	0	1	1
6. Is the sample size adequate and justified with a sample /power calculation? (Consider confidence intervals and p values where no power calculation)	1	1	1	0	1	1	0	1	1	0	0	0	0	1	0	1	1	1	1	1	0	0	1
7. Is the sample representative of a defined population? [For case-control: do cases represent the defined population of cases, and do controls represent population from which cases were drawn?]	1	1	1	0	1	1	0	1	1	1	0	1	0	1	0	0	1	1	0	1	0	1	1
DATA COLLECTION																							
8. Was exposure measured accurately to minimize bias (reporting, recording, recall bias)?*	1	1	1	0	0	1	0	1	1	1	1	1	1	1	1	1	1	1	0	1	1	1	1
9. Was outcome defined and measured accurately to minimize bias?**	1	0	1	1	0	0	0	1	0	1	0	1	1	1	0	0	0	1	1	1	1	1	1
10. Were potential confounders identified and incorporated in design (via questionnaire, stratification, randomization?)	1	1	0	1	0	1	1	1	1	1	1	0	1	1	1	1	1	0	1	1	1	0	1
11. For cohort & trials: Was follow-up complete enough? (i.e., long enough and unlikely to introduce bias? For case-control & cross-sectional: do authors address issues of temporal sequence either in study design or limitations?)	1	1	0	1	0	0	1	1	0	0	1	1	1	1	0	0	1	1	0	1	1	0	1
ETHICS																							
12. Are ethical issues discussed? (eg consent, confidentiality and anonymity)	0	1	0	1	1	1	1	1	1	1	1	1	1	0	1	1	0	0	1	1	1	0	1
13. Was the study approved by an ethics committee?	0	1	0	1	0	0	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
DATA ANALYSIS																							
14. Is there a detailed description of analytical methods?	1	1	1	1	0	1	0	1	1	1	1	1	1	1	1	1	0	1	1	1	1	1	1
15. Is the analysis appropriate to the design & data?	1	1	1	1	1	1	0	1	1	1	0	1	1	1	1	1	1	1	1	1	1	1	1
16. Have reasonable efforts been made to address confounding/ residual confounding?	1	1	0	1	0	1	0	1	1	0	1	0	1	0	1	1	1	0	1	1	1	0	1
17. Do the results appear reliable? (i.e. not due to chance, power or bias, & to what extent do authors discuss this?)	1	0	0	1	1	0	0	1	0	0	0	1	0	1	0	0	1	1	1	1	1	0	1
TOTAL SCORE (out of 17)	**15**	**14**	**11**	**13**	**10**	**13**	**7**	**17**	**12**	**13**	**11**	**14**	**14**	**14**	**10**	**12**	**12**	**14**	**13**	**17**	**14**	**11**	**17**
Second appraiser total score		**11**			**11**		**12**		**11**			**12**						**10**	**16**				
Agreed final decision (include/ exclude)							**E**																

1 indicates 'yes', 0 indicates 'no' or absence of/ unclear information on the topic

*Consider for trials: was allocation to intervention status blinded and randomized if appropriate? For risk factor analyses (multiple exposures): Measured in objective way using a structured questionnaire/ form? Reliance on recall by participants & recall period? Were interviewers/ recorders aware of study aims?

**Consider if a reliable system was used to detect all cases? Same system used for cases & controls / all intervention arms? For other designs: Measured in objective way on a dedicated form? Reliance on recall by participants & recall period? Were those recording outcome aware of study aims?

30% of the quantitative studies were double-appraised by an independent researcher. Studies scoring less than 10 were excluded in the sensitivity analysis, therefore an agreed final score was only discussed where the first and second marker scores differed to the extent that they would affect the study's inclusion (I) or exclusion (E) in the sensitivity analysis.

12.4 Fieldwork tools

12.4.1 DSS 27 survey questionnaire

DSS27 Questionnaire Record: Header

Question	Question Label	Scope of Question affect	Skips	Valid Values (Codes)	Visible to Interviewer
Qn0	Batch number [DSS Round suffix, Village, and sub Village]	Each household			No
Qn1	Form number [Village, Sub Village, Balozi, Household number]	Each Household			No
Qn2	Balozi	Each household		1 - 9	Yes, Only When registaring New Household.
Qn3	Interviewer code	Each Household		30459; 30847;30556; 30362; 30944; 30265; 30168; 31041; 31138	Yes
Qn4	Date of previous interview	Each Household			No
Qn5	Interview Start Date [Day, Month, Year, Hour, Minute, Second]	Each Household			No
Qn6	Interview End Date [Day, Month, Year, Hour, Minute, Second]	Each Household			No
Qn7	Dynamic Interview Start Date [Day, Month, Year, Hour, Minute, Second]	Each household			No
Qn8	Dynamic Interview End Date [Day, Month, Year, Hour, Minute, Second]	Each household			No
Qn9	Max Household Number	Each Household			No
Qn10	Max Line Number	Each Household			No
Qn11	New household this round?	Each Household		Y - Yes; N - No	No
Qn12	Ever Lived In kisesa	Each household		Y - Yes; N - No	Yes
Qn13	GPS Status	Each Household		Y - GPS coordinates taken; N - GPS coordinates not taken	No
Qn14	Latitude	Each Household			No
Qn15	Longitude	Each			No

Question	Question Label	Scope of Question affect	Skips	Valid Values (Codes)	Visible to Interviewer
		Household			
Qn16	Altitude	Each Household			No
Qn17	GPS Work Status	Each Household		800 - Coordinates already taken; 801 - Take GPS coordinates now; 802 - Remind me to take GPS coordinates; 803 - Postpone taking GPS coordinates	No
Qn18	Take pictures	Each Household			No
Qn19	Entire household moved	Each Household	If Qn19 = N, Move to Qn23	Y - Yes; N - No	Yes
Qn20	Date of move [Day, Month, Year]	Recent Dissolved Household			Yes
Qn21	Where moved to	Recent Dissolved Household		See Code Sheet below	Yes
Qn22	Reason for move	Recent Dissolved Household	If Qn19 = Y, Move to Qn23	See Code Sheet	Yes
Qn23	Observation Code	Each Household	If Qn19 = Y, Save Partial and Exit Case	54 - Interview started 55 - Interview Completed; 56 - Interview Partial completed; 57: Household Refuse Interview; 58 - No body at moment	Yes
Qn24	Line number of respondent	All		1 - 120	Yes
Qn25	Balozi Name	Each household			Yes
Qn26	Is there any Disability Person	Each household		Y - Yes; N - No	Yes
Qn27	Line Number of head of Household	Each Household		1 - 120	Yes

DSS27 Questionnaire Record: All members, new and previously existing

Question	Question Label	Scope of Question affect	Skips	Valid Values (Codes)	Visible to Interviewer
Qn28	Line Number	All		1 - 120	No

Question	Question Label	Scope of Question affect	Skips	Valid Values (Codes)	Visible to Interviewer
Qn29	First Name	All			Yes
Qn30	Second Name	All			Yes
Qn31	Sex	All		M – Male ; F – Female	Yes
Qn32	Date of Birth [Day, Month, Year]	All			Yes
Qn33	Current Status	All		1 - Alive; 2 - Dead; 3 - Moved; 4 - Returned (Alive); 5 - Still Away; 6 - Moved (Died); 7 - Returned (Died); 9 - Unknown	Yes
Qn34	Member status	New and Returning members only	If Computeage(Qn32)>17 Move to Qn43	B - Birth; N - New resident; R - Returning resident	Yes
Qn35	Mother status	Age: 0 - 17		D - Dead; R - Resident in kisesa; E Live somewhere else Out side Kisesa; X Don't know	Yes
Qn36	Mother line number	Age: 0 - 17		1 - 120	Yes
Qn37	Mother Names	Age: 0 - 17			
Qn38	Father status	Age: 0 - 17		D - Dead; R - Resident in kisesa; E Live somewhere else Out side Kisesa; X Don't know	Yes
Qn39	Father line number	Age: 0 - 17		1 - 120	Yes
Qn40	Father Names	Age: 0 - 17			
Qn41	Does Child Have Under Five Clinic Card?	Age: 0 -7	If Computeage(Qn32)>7 Move to Qn43	1 - Yes; 2 – No; 3 – Yes, Can't Find it Now	Yes
Qn42	Under Five Clinic Card	Age: 0 - 7	If Computeage(Qn32)>7 Move to Qn43		
Qn43	Still Alive	All	If Qn43=Y, Move to Qn45	Y - Yes; N - No	No
Qn44	Date of Death [Month, Year]	Recent Dead			Yes
Qn45	Resident or Visitor	New and Returning members only	If Not Qn34 IN (R,N,B) Move to Qn53	R - Resident; V - Visitor	Yes
Qn46	Arrival Date [Day, Month, Year]	New and Returning members only			Yes
Qn47	Reason for Arrival	New and Returning members only			Yes
Qn48	Arrived from	New and Returning members only			Yes
Qn49	Returning resident?	New and Returning members only		Y - Yes; N - No	No

Question	Question Label	Scope of Question affect	Skips	Valid Values (Codes)	Visible to Interviewer
Qn50	Have You Ever Lived In Kisesa?	New and Returning members only		Y - Yes; N - No	Yes
Qn51	Has Tazama member Card	New and Returning members only		Y - Yes; N - No	Yes
Qn52	Tazama Member CardID	New and Returning members only		AbidanceID	Yes
Qn53	Still live here?	All	If Qn53=Y, Move to Qn57	Y - Yes; N - No	No
Qn54	Date of Move [Month, Year]	Recent Moved			Yes
Qn55	Where move to	Recent Moved		See code Sheet Below	Yes
Qn56	Reason for move	Recent Moved	If Qn53 = N, Move to Qn95	See code Sheet Below	Yes
Qn57	Slept here last night	All	If Computeage(Qn32)<15 Move to Qn79	Y - Yes; N - No	Yes
Qn58	Marital status	Age: 15+		N - (No) Never Married; FM - First marriage Monogamy; FP - First Marriage polygamy; RM - Remarried monogamy; RP - Remarried Polygamy; S - separated, Divorced; W - Widow/Widower	Yes
Qn59	Spouse line number	Age: 15+		1 - 120	Yes
Qn60	Where is the Spouse	Age: 15+	If(Qn31=F); Move to Qn63	See code Sheet Below	Yes
Qn61	Second wife line number	Age: 15+		1 - 120	Yes
Qn62	Where is the second wife	Age: 15+	If(Qn31=M); Move to Qn79	See code Sheet Below	Yes
Qn63	Pregnant now?	Females: Age: 15 - 49	If Computeage(Qn32)<15; Move to Qn79; Or If Computeage(Qn32)>49 Move to Qn88	Y - Yes; N - No	Yes
Qn64	Did she give birth Last Dss	Females: Age: 15 - 49			Yes
Qn65	Do you have any ANC Cards	Females: Age: 15 - 49		1 - Yes; 2 – No; 3 - DK (Do not know); 4 – Yes, Can't Find it/Them Now	Yes
Qn66	How Many ANC cards She Kept	Females: Age: 15 - 49			Yes
Qn67	ANC Card Number01	Females: Age: 15 - 49			Yes

Question	Question Label	Scope of Question affect	Skips	Valid Values (Codes)	Visible to Interviewer
Qn68	Clinic Name _ Card 1	Females: Age: 15 - 49		1 - Igekemaja; 4 - Kisesa; 6 - Ihayabuyaga; 7 - Welamasonga; 9 - Others	Yes
Qn69	First Visit Date_ Card 1	Females: Age: 15 - 49			Yes
Qn70	Expected Date Of Delivery _Card 1	Females: Age: 15 - 49			Yes
Qn71	ANC Card Number02	Females: Age: 15 - 49			Yes
Qn72	Clinic Name _ Card 2	Females: Age: 15 - 49		1 - Igekemaja; 4 - Kisesa; 6 - Ihayabuyaga; 7 - Welamasonga; 9 - Others	Yes
Qn73	First Visit Date_ Card 2	Females: Age: 15 - 49			Yes
Qn74	Expected Date Of Delivery _Card 2	Females: Age: 15 - 49			Yes
Qn75	ANC Card Number03	Females: Age: 15 - 49			Yes
Qn76	Clinic Name _ Card 3	Females: Age: 15 - 49		1 - Igekemaja; 4 - Kisesa; 6 - Ihayabuyaga; 7 - Welamasonga; 9 - Others	Yes
Qn77	First Visit Date_ Card 3	Females: Age: 15 - 49			Yes
Qn78	Expected Date Of Delivery _Card 3	Females: Age: 15 - 49			Yes
Qn79	Still at school?	Age: 5 - 25	If Computeage(Qn32)>25 Move to Qn88	Y - Yes; N - No	Yes
Qn80	School type and year he/she is in	Age: 5 - 25			Yes
Qn81	New this round?	All	If(Qn81=N & Qn82<>Null), Move to Qn88	Y - Yes; N - No	No
Qn82	Status last round	Only existing member		I - Ishi; F - Fariki; S - Siju; H - Hama; V - Very Dead	No
Qn83	Estimated Age	New members only			Yes
Qn84	Resurrected?	Dead		Y - Yes; N - No	No
Qn85	Picture Status	All Residency		Y - Yes; N - No	No
Qn86	Picture Timestamp	All Residency			No
Qn87	Picture Work Status	All Residency			No
Qn88	Is This Person With Disability	Age: 5+	If(Qn26 <> Y & Qn88 <>Y) Move to 95	Y - Yes; N - No	Yes

Question	Question Label	Scope of Question affect	Skips	Valid Values (Codes)	Visible to Interviewer
Qn89	Do you have Difficulty Seeing, even if wearing glasses?	Age: 5+	If Q22 =N and Computeage(Qn32)<5; Move to 95	No - no difficulty; Yes - Some difficulty; Yes - a lot of difficulty; Cannot do at all	Yes
Qn90	Do you have Difficulty hearing, even if using a hearing aid?	Age: 5+		1 - No difficulty; 2 - Yes Some difficulty; 3 - Yes a lot of difficulty; 4 - Cannot do at all	Yes
Qn91	Do you have Difficulty walking or climbing steps?	Age: 5+		1 - No difficulty; 2 - Yes Some difficulty; 3 - Yes a lot of difficulty; 4 - Cannot do at all	Yes
Qn92	Do you have Difficulty remembering or Concentrating?	Age: 5+		1 - No difficulty; 2 - Yes Some difficulty; 3 - Yes a lot of difficulty; 4 - Cannot do at all	Yes
Qn93	Do you have Difficulty (With self care such as) washing all over or dressing?	Age: 5+		1 - No difficulty; 2 - Yes Some difficulty; 3 - Yes a lot of difficulty; 4 - Cannot do at all	Yes
Qn94	Using your usual (customary) language, Do you have Difficulty Communicating, for example understanding or being understood?	Age: 5+		1 - No difficulty; 2 - Yes Some difficulty; 3 - Yes a lot of difficulty; 4 - Cannot do at all	Yes
Qn95	Line Number	All			No

12.4.2 Sero-survey questionnaire (sero 6)

Registration and consent sheet

Sero6 link number

1234567

Today's Date ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
Day Month Year

Informed consent for general survey participation

		Please print names	staff ID code
r1	Name of person reading information sheet	....	⌊_⌋⌊_⌋⌊_⌋⌊_⌋⌊_⌋⌊_⌋
r2	Who will sign informed consent?	***circle response*** Respondent 1 Witness 2	**Respondent → ic1**
r3	Name of witness for informed consent	....	⌊_⌋⌊_⌋⌊_⌋⌊_⌋⌊_⌋⌊_⌋

Read first side of information sheet down to first consent question, sign next to yes or no box:

ic1	Do you agree to register at the clinic and answer questions in our survey?	***circle response*** Yes 1 No 2	Signature .....

If ic1 is NO stop here, attach all stickers to back of form so they cannot be used elsewhere.

Informed consent for HIV tests: sign to confirm yes or no response

ic2	Do you agree to provide us with a blood spot for our HIV research tests and for us to store the blood spot for further tests, without telling you the result?	***circle response*** Yes 1 No 2	Signature .....
ic3	Do you want to have a VCT test for HIV so you can find out your HIV status today? If no, sign, fill r4 and then go to r11	***circle response*** Yes 1 No 2	Signature .....
ic4	If yes, can we store the VCT blood sample to carry out further research tests in the future, for which you will not receive individual results?	***circle response*** Yes 1 No 2	Signature .....

Which sections of the sero-survey clinic did the person visit?

	Section	Write your staff ID code below if this person visits your section		
r4	Identification desk	⌊_⌋⌊_⌋⌊_⌋⌊_⌋⌊_⌋⌊_⌋		
r5	Questionnaire hut	⌊_⌋⌊_⌋⌊_⌋⌊_⌋⌊_⌋⌊_⌋	**r5a**	QC ⌊_⌋⌊_⌋⌊_⌋⌊_⌋⌊_⌋⌊_⌋
r6	DBS research sample	⌊_⌋⌊_⌋⌊_⌋⌊_⌋⌊_⌋⌊_⌋	do not go here if ic2 is **No**	
r7	Clinician consultation	⌊_⌋⌊_⌋⌊_⌋⌊_⌋⌊_⌋⌊_⌋		
r8	Laboratory diagnostics	⌊_⌋⌊_⌋⌊_⌋⌊_⌋⌊_⌋⌊_⌋		
r9	Drug dispensary	⌊_⌋⌊_⌋⌊_⌋⌊_⌋⌊_⌋⌊_⌋		
r10	VCT counsellor	⌊_⌋⌊_⌋⌊_⌋⌊_⌋⌊_⌋⌊_⌋	do not go here if ic3 is **No**	

Identification form

r11	***Ask:*** What name do you use now?	....		
r12	***Ask:*** What name have you used before now (if different)?	....		
r13	***Check:*** Was the person recognised by the village enumerator or other helper?	Yes 1 No 2	Yes - put staff code of helper No - put 0000	⌊__⌋⌊__⌋⌊__⌋⌊__⌋
r14	***Ask:*** Have you got a sero survey invitation slip?	Yes 1 No 2	**no → r20**	

Take their invitation slip so you can check the following

r15	***Check:*** Does sex of person match sex on the invitation slip?	Yes 1 No 2	
r16	***Check:*** Does age of person approximately match age on the invitation slip?	Yes 1 No 2	
r17	Copy the name written on the invitation slip	....	
r18	***Think carefully*** Is the person using the correct invitation slip?	Yes 1 No 2	**no → r20**
r19	Copy the DSS link number only from ***correct*** invitation slip	⌊__⌋⌊__⌋⌊__⌋⌊__⌋⌊__⌋	**→ r35**

If invitation slip is correct put one of the sero6 linking stickers on it
If invitation slip is wrong put the slip in the wrong invitation box

Identify those with wrong invitation or no invitation by consulting clinic register

	Current residence	**name**	**DSS code**
r20	Village		⌊__⌋
r21	Subvillage		⌊__⌋⌊__⌋
r22	Balozi (if known)		⌊__⌋⌊__⌋
r23	Can you find this person in the clinic register?	Yes 1 No 2	**no → r25**
r24	Copy down the DSS link number if it is in the register	⌊__⌋⌊__⌋⌊__⌋⌊__⌋⌊__⌋	**→ r35**

Check if this person currently lives in a household that is in the clinic register

r25	Do you know the name of any other invited person from same household? ***Write NONE if no-one else invited***	....	
r26	Was the household found in the clinic register?	Yes 1 No 2	**no → r28**
r27	Write down the household DSS number	⌊__⌋ ⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋	
r28	Fill new member DSS visit request form	⌊__⌋⌊__⌋⌊__⌋⌊__⌋⌊__⌋⌊__⌋ DSS visit request form no.	
r29	Were you previously resident in a different household in Kisesa ward?	Yes 1 No 2	**no → r38**

Consult clinic register for place of previous residence

	Previous residence	**name**	**DSS code**
r30	Village		⌊__⌋
r31	Subvillage		⌊__⌋⌊__⌋
r32	Balozi (if known)		⌊__⌋⌊__⌋
r33	Can you find the previous residence in the clinic register?	Yes 1 No 2	**no → r38**
r34	Write down the DSS link number if shown for previous residence	⌊__⌋⌊__⌋⌊__⌋⌊__⌋⌊__⌋⌊__⌋⌊__⌋	

Check past sero-survey attendance for those with clinic register entry

r35	Is the person's old study number available from invitation slip or clinic register entry?	Yes 1 No 2	**no → r38**
r36	Copy old study number from invitation slip or clinic register	⌊__⌋⌊__⌋⌊__⌋⌊__⌋⌊__⌋⌊__⌋⌊__⌋⌊__⌋	
r37	***Ask:*** Have you ever attended a sero survey before this one?	Yes 1 No 2	**yes → q1**

If person answers no, they have never been to sero-survey before, probe carefully and check that you have found the correct line in the clinic register.

Make any corrections necessary above in RED ink, remember to cross out incorrect study number on this form if there is no study number for this person in the register.

If past sero-survey number not available from invitation slip or clinic register entry

r38	***Ask:*** Have you ever attended a sero survey before this one?	Yes 1 No 2	**no → q1**
r39	***Ask:*** Were you old enough to be interviewed last time you came to a sero survey?	Yes 1 No 2	**no → q1**
r40	***Ask:*** Were you resident in Kisesa last time you came to a sero survey?	Yes 1 No 2	**no → q1**

Consult clinic register for village of residence at latest sero-survey

	Residence at last sero survey attended	**Name**	**DSS code**
r41	Village		⌊__⌋
r42	Subvillage		⌊__|__⌋
r43	Balozi (if known)		⌊__|__⌋
r44	***Check:*** Is the person's previous residence in the clinic register?	Yes 1 No 2	**no → q1**
r45	Write down the DSS link number for previous residence if one is shown.	⌊__|__|__|__|__|__|__|__⌋	
r46	Is the old study number shown in clinic register?	Yes 1 No 2	**no → q1**
r47	Copy old study number from clinic register	⌊__|__|__|__|__|__|__|__|__⌋	

Label page

This label for invitation slip	∗123456789∗ **1234567**
This label for DSS visit request form	∗123456789∗ **1234567**
This label for DBS submission form	∗123456789∗ **1234567**
This label for clinician diagnosis record	∗123456789∗ **1234567**
This label for pharmacy dispensing record	∗123456789∗ **1234567**
This label for VCT attendance record	∗123456789∗ **1234567**
This label for green VCT to CTC referral form	∗123456789∗ **1234567**
This label for plasma submission form	∗123456789∗ **1234567**
This is a spare label	∗123456789∗ **1234567**

Stickers supplied by NIMR lab

Put DBS lab sticker here	
Put plasma lab sticker here	
Sero Link Number	∗123456789∗

This blank page represents reverse side of label page

Main questionnaire

Note to interviewers: q1 to q5 filled at identification desk before going to interview hut

q1	Sex **(circle one)**	Male 1 Female 2	
q2	Date of birth **(write 99 if day or month not known, 9999 if year not known)**	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ dd mm yyyy	
q3	Age or approximate age **(refer to calendar of events if needed)**	⌊_⌋⌊_⌋ years	
q4	Height	⌊_⌋⌊_⌋⌊_⌋ cms	
q5	Weight	⌊_⌋⌊_⌋⌊_⌋ kgs	

Private interview starts here **Education & literacy**

q6	Can you read? **(circle one)**	Yes 1 No 2	
q7	Can you write?	Yes 1 No 2	
q8	Have you had a formal education?	Yes 1 No 2	**no → q10**
q9	How many years of education did you have?	**number of years completed at each level**	
q9a	Primary	⌊_⌋⌊_⌋ years	
q9b	Secondary	⌊_⌋⌊_⌋ years	
q9c	College	⌊_⌋⌊_⌋ years	
q9d	University	⌊_⌋⌊_⌋ years	
q9e	Adult institute	⌊_⌋⌊_⌋ years	
q9f	Religious education	⌊_⌋⌊_⌋ years	
q9g	Other (specify below)	⌊_⌋⌊_⌋ years	
q9h		.....	

Economic activity

q10	Do you perform any work that helps you or your household earn money?	**Circle only one response**	
	Yes	1	
	No, I am still a student	2	for all "No, …" responses → **q13**
	No, I just look after the house	3	
	No, I am too ill to work	4	
	No, I am too old to work	5	
	No, other reason (specify below)	6	
q10a		.....	

q11	What is the main way in which you earn money?	**Circle only one response**
	Farming	01
	Tending livestock	02
	Small business	03
	Large business	04
	Professional	05
	Driver	06
	Skilled manual worker	07
	Unskilled labourer	08
	Fishing	09
	Bar Work	10
	Other (specify below)	11
q11a		.....

q12	In which other ways do you earn money? ***Do not read out the list below, but after each response ask if there are other ways***	**Write 01 for the way mentioned first, 02 for the second, etc. When respondent runs out of answers write 00 in all unused lines**
q12a	Farming	⌊__⌋⌊__⌋
q12b	Tending livestock	⌊__⌋⌊__⌋
q12c	Small business	⌊__⌋⌊__⌋
q12d	Large business	⌊__⌋⌊__⌋
q12e	Professional	⌊__⌋⌊__⌋
q12f	Driver	⌊__⌋⌊__⌋
q12g	Skilled manual worker	⌊__⌋⌊__⌋
q12h	Unskilled labourer	⌊__⌋⌊__⌋
q12i	Fishing	⌊__⌋⌊__⌋
q12j	Bar Work	⌊__⌋⌊__⌋
q12k	Other (specify below)	⌊__⌋⌊__⌋
q12l		.....

Religion and Ethnicity

q13	What is your ethnic group?	**Circle only one response**
	Sukuma	1
	Other (specify below)	2
q13a		.....
q14	What is your religion?	**Circle only one response**
	Muslim	1
	Catholic	2
	Other established Christian	3
	Other evangelical Christian	4
	Traditional	5
	None	6
	Other (specify below)	7
q14a		.....

Residence and mobility

q15	Were you born in the village that you now live in?	Yes 1 No 2	**yes → q19**
q16	Have you lived in this same village for 1 year or more?	Yes 1 No 2	**no → q16b**
q16a	How many years have you lived in this village?	⌊__⌋⌊__⌋ years	**→ q17**
q16b	How many months have you lived in this village?	⌊__⌋⌊__⌋ months	
q17	Where did you live before moving here?	**Circle only one response**	
	Other part of Kisesa ward	1	
	Another part of Magu district	2	
	Mwanza city	3	
	Another part of Mwanza region	4	
	Another part of Tanzania	5	
	Another country	6	
q18	What type of place was it?	**Circle only one response**	
	Rural – remote	1	
	Rural – on main road	2	
	Urban	3	

Condom knowledge

q19	Have you ever heard of condoms?	Yes 1 No 2	**no →q22**
q20	Is it possible to get condoms in this village?	Yes 1 No 2 DK 9	**no or DK → q22**
q21	Where can you get condoms in this village? ***Do not read out the list, but after each response ask if there are other places***	**Write 1 for place mentioned first, 2 for the second, etc. If respondent doesn't know any, or any more places, write 0 in all unused lines**	
q21a	Village dispensary	⌊__⌋	
q21b	Family planning clinic	⌊__⌋	
q21c	Pharmacy	⌊__⌋	
q21d	Shop	⌊__⌋	
q21e	Community distribution scheme	⌊__⌋	
q21f	TANESA / TAZAMA / PSI	⌊__⌋	
q21g	Other (specify below)	⌊__⌋	
q21h		.....	

Family planning

q22	Have you ever heard about family planning?	Yes 1 No 2	**no → r29**
q23	What was the source of your information? ***Do not read out the list, but after each response ask if there were other sources***	**Write 1 for source mentioned first, 2 for the second, etc. When respondent runs out of answers write 0 in all unused lines**	
q23a	Radio	⌊__⌋	
q23b	Television	⌊__⌋	
q23c	Posters	⌊__⌋	
q23d	Newspapers / Magazines	⌊__⌋	
q23e	Health facility	⌊__⌋	
q23f	TANESA / UMATI	⌊__⌋	
q23g	Family member or friend	⌊__⌋	
q23h	Other (specify below)	⌊__⌋	
q23i		.....	

q24	Have you ever used family planning ?	Yes 1 No 2	**no → q28**
q25	Which methods did you use? ***Do not read out the list, but after each response ask if there were other methods***	**Write 01 for method mentioned first, 02 for the second, etc. When respondent runs out of answers write 00 in all unused lines**	
q25a	Pills	⌊__⌋⌊__⌋	
q25b	IUD/loop	⌊__⌋⌊__⌋	
q25c	Injection	⌊__⌋⌊__⌋	
q25d	Female condom or cap	⌊__⌋⌊__⌋	
q25e	Male condom	⌊__⌋⌊__⌋	
q25f	Female sterilisation	⌊__⌋⌊__⌋	
q25g	Male sterilisation / vasectomy	⌊__⌋⌊__⌋	
q25h	Norplant	⌊__⌋⌊__⌋	
q25i	Abstinence	⌊__⌋⌊__⌋	
q25j	Calendar / rhythm	⌊__⌋⌊__⌋	
q25k	Traditional methods	⌊__⌋⌊__⌋	
q25l	Other (specify below)	⌊__⌋⌊__⌋	
q25m		.....	

q26	Are you currently using family planning?	Yes 1 No 2	**no → q28**
q27	Which is the main method that you use now?	**Circle only one response**	
	Pills	01	
	IUD/loop	02	
	Injection	03	
	Female condom or cap	04	
	Male condom	05	
	Female sterilisation	06	
	Male sterilisation / vasectomy	07	
	Norplant	08	
	Abstinence	09	
	Calendar / rhythm	10	
	Traditional methods	11	
	Other (specify below)	12	
q27a		.....	
q28	Do you intend to use family planning in the future?	Yes 1 No 2 DK 9	

Pregnancy and childbirth

q29	***Checkq1 and q3 : is this person a woman aged 15-49?***	Yes 1 No 2	**no → q42**

q30	Have you ever been pregnant?	Yes 1 No 2	**no → q42**
q31	Have you ever given birth?	Yes 1 No 2	**no → q37**

		write 00 if none in q32a to q32f	
q32	How many of your own biological children:	**Boys**	**Girls**
	live with you in your home?	**q32a** ⌊_⌋⌊_⌋	**q32b** ⌊_⌋⌊_⌋
	live somewhere else?	**q32c** ⌊_⌋⌊_⌋	**q32d** ⌊_⌋⌊_⌋
	have died?	**q32e** ⌊_⌋⌊_⌋	**q32f** ⌊_⌋⌊_⌋

Check: add together responses to q32a, q32b, q32c, q32d, q32e and q32f and enter at q33

q33	***Say:*** I want to check, altogether you have given birth to ⌊_⌋⌊_⌋ children?

If mother disagrees with your total estimate check responses to q32a, q32b, q32c, q32d, q32e and q32f and check your addition.

If total children = 01 → q35

q34	Do all your children have the same father?	Yes 1	No 2
q35	When did you last give birth? **(write 99 if day or month not known, 9999 if year not known)**	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ d d m m y y y y	
q36	Is your last born child still alive?	Yes 1	No 2
q37	Did you attend an Ante Natal Clinic (ANC) during your last pregnancy?	Yes 1 No 2	**no → q39**
q38	Which blood tests did you have at any ANC you attended during your last pregnancy?	**Ask about each one in turn**	
q38a	HIV test for PMTCT	Yes 1 No 2 DK 9	
q38b	Syphilis test	Yes 1 No 2 DK 9	
q38c	Test for anaemia	Yes 1 No 2 DK 9	
q38d	Other blood test (specify below)	Yes 1 No 2	
q38e		.....	

q39	Are you pregnant now?	Yes 1 No 2 DK 9
q40	How many of your pregnancies have ended in a still birth? (write 99 if not known)	⌊_⌋⌊_⌋ number
q41	How many pregnancies have you had in which you lost a baby before it was fully formed? (write 99 if not known)	⌊_⌋⌊_⌋ number

Current marriage or cohabitation: men and women

q42	What is your current marital status?	**Circle only one response**
	Never married or been in cohabiting union	1 never married → **q51**
	Monogamously married or cohabiting	2
	Polygamously married or cohabiting	3
	Widowed	4
	Separated or divorced	5
q43	If polygamously married, how many co-wives are there in this marriage? (including person being interviewed, if woman)	⌊_⌋⌊_⌋ number

First marriage or cohabitation

q44	How old were you when you first married or lived with a sexual partner? (write 99 if not known)	⌊_⌋⌊_⌋ years old	
q45	Are you still married to or living with that same person?	Yes 1 No 2	**if yes,** → **q51**
q46	Is that first spouse / partner still alive?	Alive 1 Dead 2 DK 9	**if alive or DK** → **q49**
q47	Were you living together when he/she died?	Yes 1 No 2	
q48	Did he / she die in Kisesa ward?	Yes 1 No 2	→ **q51**
q49	Did you live together in Kisesa ward?	Yes 1 No 2	**if no,** → **q51**
q50	Does he / she still live in Kisesa ward?	Yes 1 No 2 DK 9	

First sex

q51	How old were you when you first had sex? (never = 99, don't know = 88, when married = 77)	⌊_⌋⌊_⌋ years	**if 99** → **q57**
q52	Why did you have sex at that time?	**Circle only one response**	
	I got married	1	
	I wanted to have sex	2	
	I was tricked into having sex	3	
	I had sex because I needed money	4	
	I was forced to have sex	5	
	Can't remember, too long ago	6	
	Other (specify below)	7	
q52a		.....	
q53	Did you use a condom when you first had sex? (if can't remember code don't know)	Yes 1 No 2 DK 9	

All sexual partners: ***probe carefully and explain all partners must be reported, including spouses and partners who died long ago***

q54	How many different sexual partners altogether in your whole lifetime? (including spouse(s), regular & casual partners)	⌊_⌋⌊_⌋	
q55	How many different sexual partners altogether in the last 12 months? (including spouse(s), regular & casual partners)	⌊_⌋⌊_⌋	**if 00** → **q57**

ALL SEXUAL PARTNERS IN LAST 12 MONTHS

		A) FIRST, MOST RECENT PARTNER		B) SECOND PARTNER		C) THIRD PARTNER	
pp1	How would you describe your relationship to this person? *Circle only one*	Spouse or cohabiting partner Regular partner Casual partner Other friend or visitor	1 2 3 4	Spouse or cohabiting partner Regular partner Casual partner Other friend or visitor	1 2 3 4	Spouse or cohabiting partner Regular partner Casual partner Other friend or visitor	1 2 3 4
pp2	Do you live in the same house as this partner?	Yes 1 No 2	**yes → pp4**	Yes 1 No 2	**yes → pp4**	Yes 1 No 2	**yes → pp4**
pp3	Where does this partner live now? *Circle only one*	Other part of Kisesa ward Another part of Magu district Mwanza city Another part of Mwanza region Another part of Tanzania Another country Dead Don’t know	1 2 3 4 5 6 7 8	Other part of Kisesa ward Another part of Magu district Mwanza city Another part of Mwanza region Another part of Tanzania Another country Dead Don’t know	1 2 3 4 5 6 7 8	Other part of Kisesa ward Another part of Magu district Mwanza city Another part of Mwanza region Another part of Tanzania Another country Dead Don’t know	1 2 3 4 5 6 7 8
pp4	Is this partner older or younger than you? *Circle only one*	more than 10 years older around 5 years older about same age around 5 years younger more than 10 years younger	1 2 3 4 5	more than 10 years older around 5 years older about same age around 5 years younger more than 10 years younger	1 2 3 4 5	more than 10 years older around 5 years older about same age around 5 years younger more than 10 years younger	1 2 3 4 5

Last sex with this partner

pp5	When did you last have sex with this partner? *One line each partner*	last week 1 → last month 2 → last year 3 →	How many times:	in last week? └┘ in last month? └┴┘ in last year? └┴┴┘	last week 1 → last month 2 → last year 3 →	How many times:	in last week? └┘ in last month? └┴┘ in last year? └┴┴┘	last week 1 → last month 2 → last year 3 →	How many times:	in last week? └┘ in last month? └┴┘ in last year? └┴┴┘
pp6	Did you use a condom last time you had sex?	Yes 1 No 2			Yes 1 No 2			Yes 1 No 2		
pp7	Had either you or your partner drunk alcohol last time you had sex?	Yes 1 No 2			Yes 1 No 2			Yes 1 No 2		
pp8	Do you think in the future you will have sex with this partner again?	Yes 1 No 2			Yes 1 No 2			Yes 1 No 2		

Most recent partners continued

		A) FIRST, MOST RECENT PARTNER		B) SECOND PARTNER		C) THIRD PARTNER	
	Check: is this spouse or regular partner ?	→ **pp10**		→ **pp10**		→ **pp10**	
	Check: is pp5 how many times > 01 ?	→ **pp10**		→ **pp10**		→ **pp10**	
pp9	Was this the only time you ever had sex with this partner?	Yes 1 No 2	**yes → pp13**	Yes 1 No 2	**yes → pp13**	Yes 1 No 2	**yes → pp13**
pp10	How frequently did you use a condom with this partner? ***Circle only one***	Always 1 Most of the time / often 2 Occasionally 3 Only at the start of the relationship 4 Never 5 Don't know 6		Always 1 Most of the time / often 2 Occasionally 3 Only at the start of the relationship 4 Never 5 Don't know 6		Always 1 Most of the time / often 2 Occasionally 3 Only at the start of the relationship 4 Never 5 Don't know 6	

First sex with this partner

pp11	When did you first have sex with this partner? ***Circle only one***	last week 1 last month 2 last year 3 more than a year ago 4		last week 1 last month 2 last year 3 more than a year ago 4		last week 1 last month 2 last year 3 more than a year ago 4	
pp12	Did you use a condom first time you had sex with this partner?	Yes 1 No 2 DK 9		Yes 1 No 2 DK 9		Yes 1 No 2 DK 9	
pp13	Before you first had sex with this partner how long had you known him/her? ***Circle only one***	less than a week 1 less than a month 2 less than a year 3 more than a year 4		less than a week 1 less than a month 2 less than a year 3 more than a year 4		less than a week 1 less than a month 2 less than a year 3 more than a year 4	

Next partner

pp14	Did you have sex with anyone else in the last 12 months?	Yes 1 No 2	→ **pp1 for second partner** → **q56 end of partner columns**	Yes 1 No 2	→ **pp1 for third partner** → **q56 end of partner columns**	Yes 1 No 2	→ **pp1 for fourth partner** → **q56 end of partner columns**

ALL SEXUAL PARTNERS IN LAST 12 MONTHS

		D) FOURTH PARTNER		E) FIFTH PARTNER		F) SIXTH PARTNER	
pp1	How would you describe your relationship to this person?	Spouse or cohabiting partner	1	Spouse or cohabiting partner	1	Spouse or cohabiting partner	1
		Regular partner	2	Regular partner	2	Regular partner	2
		Casual partner	3	Casual partner	3	Casual partner	3
	Circle only one	Other friend or visitor	4	Other friend or visitor	4	Other friend or visitor	4
pp2	Do you live in the same house as this partner?	Yes 1 No 2	**yes → pp4**	Yes 1 No 2	**yes → pp4**	Yes 1 No 2	**yes → pp4**
pp3	Where does this partner live now?	Other part of Kisesa ward	1	Other part of Kisesa ward	1	Other part of Kisesa ward	1
		Another part of Magu district	2	Another part of Magu district	2	Another part of Magu district	2
	Circle only one	Mwanza city	3	Mwanza city	3	Mwanza city	3
		Another part of Mwanza region	4	Another part of Mwanza region	4	Another part of Mwanza region	4
		Another part of Tanzania	5	Another part of Tanzania	5	Another part of Tanzania	5
		Another country	6	Another country	6	Another country	6
		Dead	7	Dead	7	Dead	7
		Don’t know	8	Don’t know	8	Don’t know	8
pp4	Is this partner older or younger than you?	more than 10 years older	1	more than 10 years older	1	more than 10 years older	1
		around 5 years older	2	around 5 years older	2	around 5 years older	2
	Circle only one	about same age	3	about same age	3	about same age	3
		around 5 years younger	4	around 5 years younger	4	around 5 years younger	4
		more than 10 years younger	5	more than 10 years younger	5	more than 10 years younger	5

Last sex with this partner

pp5	When did you last have sex with this partner?	last week 1 →	How many times:	in last week? └┘	last week 1 →	How many times:	in last week? └┘	last week 1 →	How many times:	in last week? └┘
		last month 2 →		in last month? └┴┘	last month 2 →		in last month? └┴┘	last month 2 →		in last month? └┴┘
	One line each partner	last year 3 →		in last year? └┴┴┘	last year 3 →		in last year? └┴┴┘	last year 3 →		in last year? └┴┴┘
pp6	Did you use a condom last time you had sex?	Yes 1	No 2		Yes 1	No 2		Yes 1	No 2	
pp7	Had either you or your partner drunk alcohol last time you had sex?	Yes 1	No 2		Yes 1	No 2		Yes 1	No 2	
pp8	Do you think in the future you will have sex with this partner again?	Yes 1	No 2		Yes 1	No 2		Yes 1	No 2	

More distant partners continued

		D) FOURTH PARTNER		E) FIFTH PARTNER		F) SIXTH PARTNER	
	Check: is this spouse or regular partner ?	→ **pp10**		→ **pp10**		→ **pp10**	
	Check: is pp5 how many times > 01 ?	→ **pp10**		→ **pp10**		→ **pp10**	
pp9	Was this the only time you ever had sex with this partner?	Yes 1 No 2	**yes → pp13**	Yes 1 No 2	**yes → pp13**	Yes 1 No 2	**yes → pp13**
pp10	How frequently did you use a condom with this partner? ***Circle only one***	Always 1 Most of the time / often 2 Occasionally 3 Only at the start of the relationship 4 Never 5 Don't know 6		Always 1 Most of the time / often 2 Occasionally 3 Only at the start of the relationship 4 Never 5 Don't know 6		Always 1 Most of the time / often 2 Occasionally 3 Only at the start of the relationship 4 Never 5 Don't know 6	

First sex with this partner

pp11	When did you first have sex with this partner? ***Circle only one***	last week 1 last month 2 last year 3 more than a year ago 4		last week 1 last month 2 last year 3 more than a year ago 4		last week 1 last month 2 last year 3 more than a year ago 4	
pp12	Did you use a condom first time you had sex with this partner?	Yes 1 No 2 DK 9		Yes 1 No 2 DK 9		Yes 1 No 2 DK 9	
pp13	Before you first had sex with this partner how long had you known him/her? ***Circle only one***	less than a week 1 less than a month 2 less than a year 3 more than a year 4		less than a week 1 less than a month 2 less than a year 3 more than a year 4		less than a week 1 less than a month 2 less than a year 3 more than a year 4	

Next partner

pp14	Did you have sex with anyone else in the last 12 months?	Yes 1 No 2	→ **pp1 for fifth partner** → **q56 end of partner columns**	Yes 1 No 2	→ **pp1 for sixth partner** → **q56 end of partner columns**	Yes 1 No 2	→ **q56 end of partner columns**

Check: Is the number of partner columns filled less than number of partners in last 12 months reported in q55 (or Less than 6 if q55 is 6 or more)?
If less, say: I just need to make sure, and repeat question pp14 on last partner column.
If respondent remembers another partner in last 12 months continue with partner loops

Even if there is an inconsistency, do not ask respondent to change their answer to q55 partners in last 12 months, but report on consistency here (without asking respondent).

q56	Summary of partner reporting consistency:	**Circle only one response**
	Number of columns agrees with partners last year	1
	Number of columns greater than partners last year	2
	Number of columns less than partners last year	3
	Number of columns less than partners last year because more than 6 partners last year	4

Partner loops finished → q58

If no sexual partners last 12 months

q57	Why did you abstain from sex in the last 12 months?	**Circle only one response**
	No spouse or other sexual partner	01
	Previous spouse or partner died	02
	Quarrelled with spouse or partner	03
	Divorced from previous spouse	04
	Spouse / partner travelled away from home	05
	I travelled away from home	06
	Spouse / partner was too sick	07
	I was too sick	08
	We are abstaining after birth of a child	09
	Spouse /partner is afraid of HIV	10
	I am afraid of HIV	11
	Other (specify below)	12
q57a		.....

Other risk factors

q58	Have you had a blood transfusion in the last 5 years?	Yes 1 No 2	
q59	How many injections did you get in last 12 months? (write 99 if not known)	⌊__⌋⌊__⌋ number	
q60	Have you had body incisions during the last 5 years?	Yes 1 No 2	**women → q63**
q61	Have you been circumcised ?	Yes 1 No 2	**no → q63**
q62	How old were you when you were circumcised? (write 99 if not known)	⌊__⌋⌊__⌋ years	

Knowledge of sexually transmitted infections

q63	Have you ever heard about sexually transmitted infections?	Yes 1 No 2	**no → q65**
q64	What are the signs of sexually transmitted infections? ***Do not read out list, but after each response ask if there are other signs***	**Write 1 for sign mentioned first, 2 for the second, etc. When respondent runs out of answers write 0 in all unused lines**	
q64a	Discharge or bleeding from genitals	⌊__⌋	
q64b	Genital ulcers, swelling or irritation	⌊__⌋	
q64c	Difficulty in urinating	⌊__⌋	
q64d	Painful intercourse	⌊__⌋	
q64e	Pain in uterus	⌊__⌋	
q64f	Don't know any signs	⌊__⌋	
q64g	Other (specify below)	⌊__⌋	
q64h		.....	

Symptoms of sexually transmitted infections

q65	Have you had painful urination at any time in last 12 months?	Yes 1	No 2
q66	Have you urinated blood at any time in last 12 months?	Yes 1	No 2
q67	Have you had a genital discharge in last 12 months?	Yes 1	No 2
q68	Have you got genital ulcers or swelling in last 12 months?	Yes 1	No 2
	If q65 to q68 all answered No	**→ q71**	
q69	Do you still have any of these symptoms now?	Yes 1	No 2

q70	What action did you take? ***Do not read out list, but after each response ask what else they did***	**Write 1 for action mentioned first, 2 for the second, etc. When respondent runs out of answers write 0 in all unused lines**
q70a	Treated at government health facility	⌊__⌋
q70b	Treated at private health facility	⌊__⌋
q70c	Self medication with pharmacy drugs	⌊__⌋
q70d	Self medication with herbs	⌊__⌋
q70e	Consulted traditional healer	⌊__⌋
q70f	Got drugs from TANESA / TAZAMA / TUMAINI	⌊__⌋
q70g	No action taken	⌊__⌋
q70h	Other (specify below)	⌊__⌋
q70i		.....

Knowledge about HIV

q71	Have you ever heard / read about HIV, the virus which causes AIDS?	Yes 1 No 2	**no → q102**
q72	What was the source of your information? ***Do not read out list, but after each response ask if there were other sources***	**Write 01 for source mentioned first, 02 for the second, etc. When respondent runs out of answers write 00 in all unused lines**	
q72a	Radio	⌊__⌋⌊__⌋	
q72b	Television / Video / Cinema	⌊__⌋⌊__⌋	
q72c	Posters	⌊__⌋⌊__⌋	
q72d	Magazines / Booklets	⌊__⌋⌊__⌋	
q72e	Meetings / Campaigns (including TANESA)	⌊__⌋⌊__⌋	
q72f	At school / from peer counsellors	⌊__⌋⌊__⌋	
q72g	Church / Mosque	⌊__⌋⌊__⌋	
q72h	Health facility workers	⌊__⌋⌊__⌋	
q72i	Home based care / Village health worker	⌊__⌋⌊__⌋	
q72j	Family or friend	⌊__⌋⌊__⌋	
q72k	Other (specify below)	⌊__⌋⌊__⌋	
q72l		.....	

q73	Do you know how HIV/AIDS is transmitted?	Yes 1 No 2	**no → q75**
q74	Mention all the ways that you know ***Do not read out list, but after each response ask if there are other ways***	**Write 1 for way mentioned first, 2 for the second, etc. When respondent runs out of answers write 0 in all unused lines**	
q74a	Having sex with a casual / high risk partner	⌊__⌋	
q74b	Having sex without a condom	⌊__⌋	
q74c	Unsafe blood transfusion	⌊__⌋	
q74d	Unsterile injections	⌊__⌋	
q74e	Mother to child transmission	⌊__⌋	
q74f	Incisions on the body	⌊__⌋	
q74g	Sharing personal items	⌊__⌋	
q74h	Other (specify below)	⌊__⌋	
q74i		.....	

q75	Is it possible for a healthy looking person to have HIV/AIDS?	Yes 1	No 2	DK 9
q76	Can AIDS be transmitted by mosquito bites?	Yes 1	No 2	DK 9
q77	Can AIDS be transmitted by sharing cups and plates?	Yes 1	No 2	DK 9
q78	Can AIDS be transmitted by kissing?	Yes 1	No 2	DK 9

Stigma and personal experience of HIV

q79	Where does HIV transmission mainly take place? ***Do not read out list, but after each response ask if there are other places***	**Write 1 for place mentioned first, 2 for the second, etc. If respondent doesn't know any or any more write 0 in all unused lines**
q79a	Wedding and funeral parties	⌊__⌋
q79b	Pombe shops	⌊__⌋
q79c	Bars and guest houses	⌊__⌋
q79d	Discos / Ngoma dances	⌊__⌋
q79e	At hospitals	⌊__⌋
q79f	At markets	⌊__⌋
q79g	Hair salons	⌊__⌋
q79h	Other (specify below)	⌊__⌋
q79i		.....

q80	What kinds of people are responsible for transmitting HIV? ***Do not read out list, but after each response ask if there are others***	**Write 01 for people mentioned first, 02 for the second, etc. If respondent doesn't know any or any more, write 00 in all unused lines**
q80a	Bar workers / Food vendors	⌊__⌋⌊__⌋
q80b	Students / Young people	⌊__⌋⌊__⌋
q80c	People who travel a lot	⌊__⌋⌊__⌋
q80d	Widows and widowers	⌊__⌋⌊__⌋
q80e	Refugees and homeless people	⌊__⌋⌊__⌋
q80f	Drunks &/or drug users	⌊__⌋⌊__⌋
q80g	Teachers and village leaders	⌊__⌋⌊__⌋
q80h	Health workers and hospital workers	⌊__⌋⌊__⌋
q80i	Homosexuals	⌊__⌋⌊__⌋
q80j	Anyone can transmit it	⌊__⌋⌊__⌋
q80k	Other (specify below)	⌊__⌋⌊__⌋
q80l		.....

q81	Among your relatives is anyone infected with HIV?	Yes 1	No 2	DK 9
q82	Have any of your relatives died of AIDS?	Yes 1	No 2	DK 9
q83	Is anyone in this village infected with HIV?	Yes 1	No 2	DK 9
q84	Has anyone in this village died of AIDS?	Yes 1	No 2	DK 9

Need for services

q85	What services are needed to help HIV infected people? ***Do not read out list, but after each response ask if there are others***	**Write 1 for those mentioned first, 2 for the second, etc. If respondent doesn't know any or any more write 0 in all unused lines**
q85a	Drugs to treat HIV	⌊__⌋
q85b	Drugs to treat other infections	⌊__⌋
q85c	Home based care during serious illness	⌊__⌋
q85d	Help to get food	⌊__⌋
q85e	Help to take care of their children	⌊__⌋
q85f	Other (specify below)	⌊__⌋
q85g		.....

q86	What services are needed to prevent new HIV infections? ***Do not read out list, but after each response ask if there are others***	**Write 1 for those mentioned first, 2 for the second, etc. If respondent doesn't know any or any more, write 0 in all unused lines**
q86a	Education & information	⌊__⌋
q86b	Condom provision	⌊__⌋
q86c	Rules to enforce good behaviour	⌊__⌋
q86d	PMTCT in ANC clinics	⌊__⌋
q86e	Clean syringes at health centres & dispensaries	⌊__⌋
q86f	Other (specify below)	⌊__⌋
q86g		**.....**

Experience of VCT

q87	Have you ever had VCT ?	Yes 1	No 2	**no → q99**
q88	When did you last use any of these VCT services?	**Ask about each**		
q88a	Sero survey VCT note: sero5 was in 2006	At sero5 1	At earlier sero-survey 2	Never 3
q88b	Kisesa health centre VCT	Last year 1	More than a year ago 2	Never 3
q88c	ANGAZA	Last year 1	More than a year ago 2	Never 3
q88d	At ANC clinic	Last year 1	More than a year ago 2	Never 3
q88e	Mobile VCT service	Last year 1	More than a year ago 2	Never 3
q88f	Other (specify below)	Last year 1	More than a year ago 2	Never 3
q88g		**.....**		

q89	Did you receive pre-test counselling at your last VCT?	Yes 1	No 2
q90	Did you find out your test results after your last VCT?	Yes 1	No 2
q91	Did you receive post-test counselling after your last VCT?	Yes 1	No 2

q92	Did you tell anyone about your test result?	Yes 1 No 2	**no → q94**
q93	Who did you tell? ***Do not read out list, but after each response ask if there were other people***	**Write 1 for person mentioned first, 2 for the second, etc. When respondent runs out of answers write 0 in all unused lines**	
q93a	Spouse / partner	⌊__⌋	
q93b	Parent	⌊__⌋	
q93c	Other relative	⌊__⌋	
q93d	Friend	⌊__⌋	
q93e	Home Based Care Worker	⌊__⌋	
q93f	Other (specify below)	⌊__⌋	
q93g		**……**	

q94	Would you recommend a friend to have VCT?	Yes 1	No 2	DK 9
q95	Was your VCT counsellor kind and understanding?	Yes 1	No 2	
q96	Was the VCT interview embarrassing or difficult?	Yes 1	No 2	
q97	Can VCT counsellors be trusted to keep results secret?	Yes 1	No 2	DK 9
q98	If a person is seen going into a VCT centre do people assume he/she is infected?	Yes 1	No 2	DK 9

Knowledge about ART

q99	Is anyone you know taking drugs for HIV infection?	Yes 1	No 2	DK 9
q100	Are drugs for HIV infection available at the following places?	**Ask about each one**		
q100a	Village dispensary	Yes 1	No 2	DK 9
q100b	Kisesa Health Centre	Yes 1	No 2	DK 9
q100c	Magu district hospital	Yes 1	No 2	DK 9
q100d	Sekou Toure regional hospital	Yes 1	No 2	DK 9
q100e	Bugando referral hospital	Yes 1	No 2	DK 9

q101	Are the following statements about drugs for HIV treatment true or false	**Ask about each one**		
q101a	Drugs can only slow down HIV illness, not stop it	True 1	False 2	DK 9
q101b	ART drugs are very dangerous and can kill people	True 1	False 2	DK 9
q101c	ART drugs have to be used for life	True 1	False 2	DK 9
q101d	ART drugs are available free of charge in Tanzania	True 1	False 2	DK 9
q101e	Everyone who is infected with HIV needs drugs	True 1	False 2	DK 9

Use of health services

q102	In the last 12 months, how many times have you used the following services	**write number for each, 00 if none**
q102a	Hospital in patient	⌊__⌋⌊__⌋ times
q102b	Hospital clinic outpatient	⌊__⌋⌊__⌋ times
q102c	Health centre / dispensary	⌊__⌋⌊__⌋ times
q102d	ANC or MCH or vaccination clinic	⌊__⌋⌊__⌋ times
q102e	Visit from Home Based Care Worker	⌊__⌋⌊__⌋ times
q102f	Private pharmacy	⌊__⌋⌊__⌋ times
q102g	Traditional healer	⌊__⌋⌊__⌋ times

If zero for each of q102a to q102g→ q107

q103	Did you have expenses when you used these services?	Yes 1	No 2	**no → q87**
q104	What kind of expenses have you had? ***Do not read out list, but after each response ask if there were others***	**Write 1 for those mentioned first, 2 for the second, etc. When respondent runs out of answers write 0 in all unused lines**		
q104a	Paid for meals / bed in hospital	⌊__⌋		
q104b	Paid for transport	⌊__⌋		
q104c	Paid to see doctor / nurse	⌊__⌋		
q104d	Paid for drugs	⌊__⌋		
q104e	Gave gifts to service provider	⌊__⌋		
q104f	Gave gifts to helper	⌊__⌋		

q105	Did you get help from anyone with these expenses?	Yes 1 No 2	**no → q107**
q106	What kind of help did you get? ***Do not read out list, but after each response ask if there were others***	**Write 1 for help mentioned first, 2 for the second, etc. When respondent runs out of answers write 0 in all unused lines**	
q106a	Family and friends helped	|__|	
q106b	I got a loan	|__|	
q106c	The service provider lowered the cost	|__|	
q106d	TUMAINI / TAZAMA / TANESA helped	|__|	
q106e	I got district health insurance	|__|	
q106f	Other (specify below)	|__|	
q106g		....	

Home based care

q107	Have you ever heard of home based care for people who are too sick to leave home?	Yes 1 No 2	**No → end interview**
q108	Has your village ever had home based care workers / volunteers?	Yes 1 No 2 DK 9	**No or DK → q110**
q109	Who organised this service? ***Do not read out list, but after each response ask if there were others***	**Write 1 for organiser mentioned first, 2 for second, etc. When respondent runs out of answers write 0 in all unused lines**	
q109a	TUNAJALI / TUMAINI	|__|	
q109b	TAZAMA / TANESA / NIMR	|__|	
q109c	HUPEMEF	|__|	
q109d	Other (specify below)	|__|	
q109e		....	

q110	Do people welcome home based care workers to visit them in their house?	Yes 1	No 2	DK 9
q111	Do home based care workers help with household tasks?	Yes 1	No 2	DK 9
q112	Do home based care workers provide medicines?	Yes 1	No 2	DK 9
q113	Do home based care workers give advice about going to clinics and hospitals?	Yes 1	No 2	DK 9

THANK PARTICIPANT FOR THEIR TIME AND PATIENCE

notes about interview

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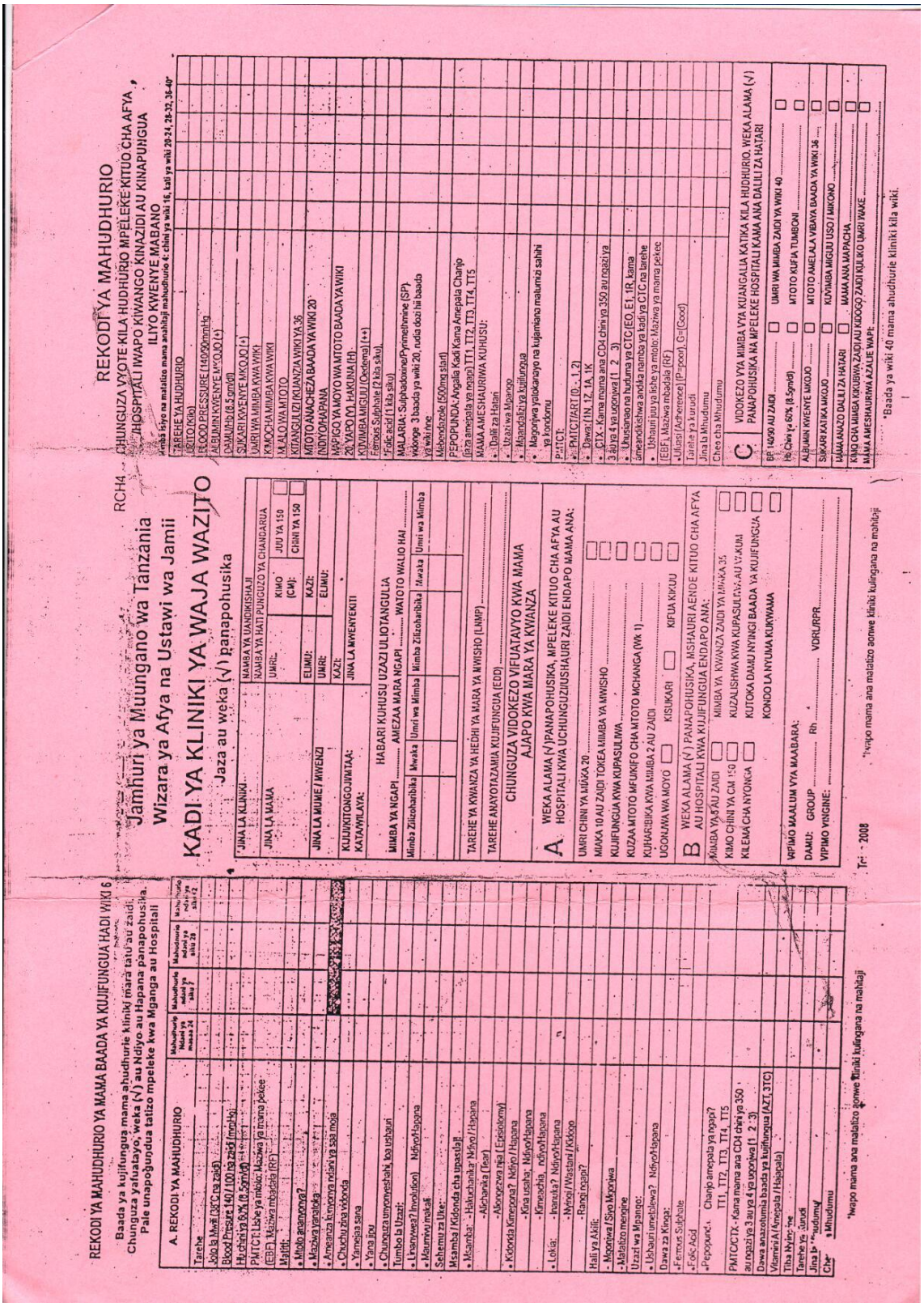
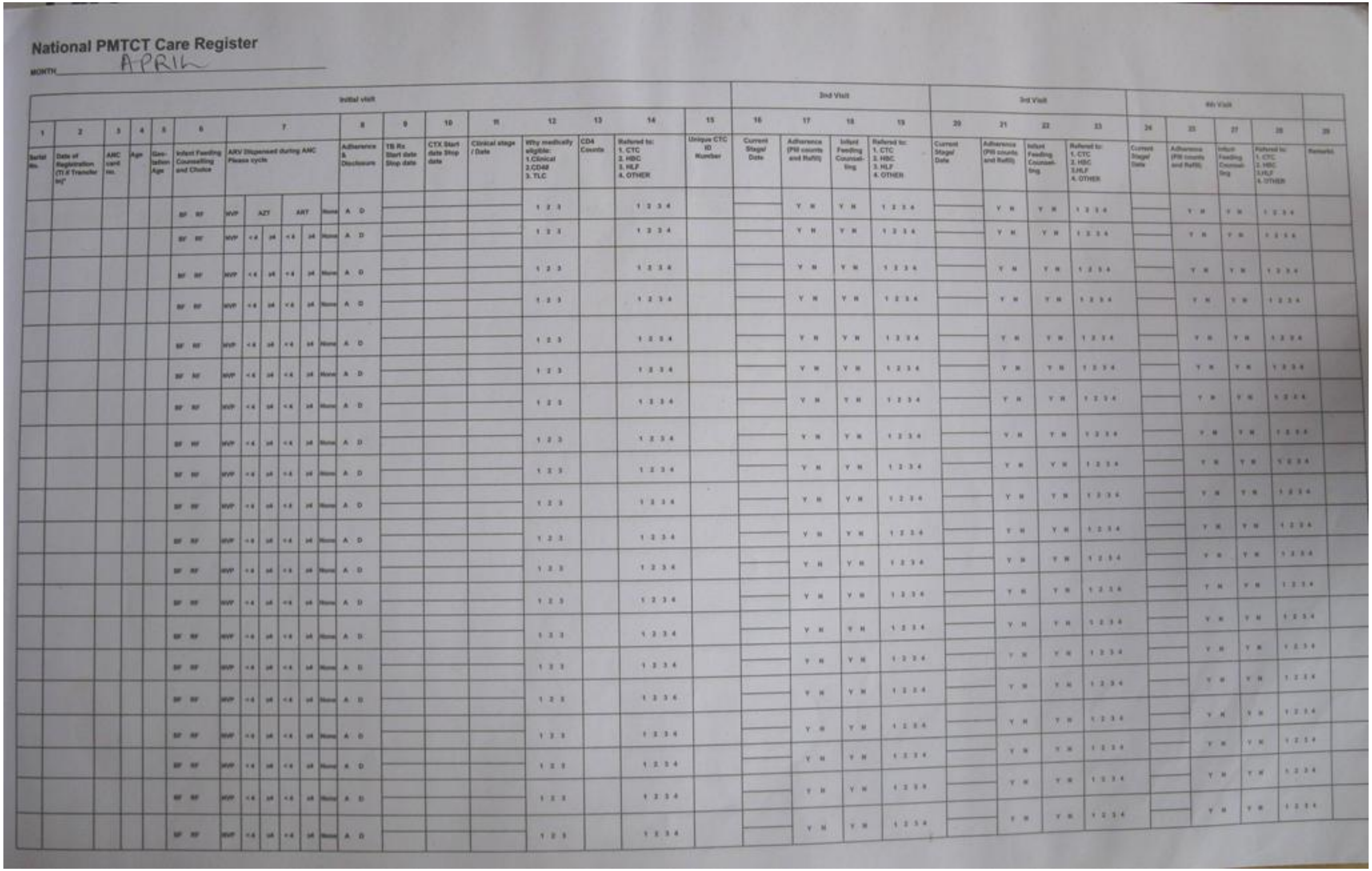
12.4.3 ANC card example



12.4.4 PMTCT register page example



National PMTCT Care Register

MONTH APRIL

Initial visit															2nd Visit				3rd Visit				4th Visit				
1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	27	28	29
Serial No.	Date of Registration (TI if Transfer In)*	ANC card no.	Age	Gestation Age	Infant Feeding Counselling and Choice	ARV Dispensed during ANC Please cycle	Adherence & Disclosure	TB Rx Start date Stop date	CTX Start date Stop date	Clinical stage / Date	Why medically eligible: 1.Clinical 2.CD4# 3.TLC	CD4 Counts	Referred to: 1. CTC 2. HBC 3. HLF 4. OTHER	Unique CTC ID Number	Current Stage/ Date	Adherence (Pill counts and Refill)	Infant Feeding Counsel-ling	Referred to: 1. CTC 2. HBC 3. HLF 4. OTHER	Current Stage/ Date	Adherence (Pill counts and Refill)	Infant Feeding Counsel-ling	Referred to: 1. CTC 2. HBC 3.HLF 4. OTHER	Current Stage/ Date	Adherence (Pill counts and Refill)	Infant Feeding Counsel-ling	Referred to: 1. CTC 2. HBC 3.HLF 4. OTHER	Remarks
					BF RF	NVP AZT ART None	A D				1 2 3		1 2 3 4			Y N	Y N	1 2 3 4		Y N	Y N	1 2 3 4		Y N	Y N	1 2 3 4	
					BF RF	NVP <4 ≥4 <4 ≥4 None	A D				1 2 3		1 2 3 4			Y N	Y N	1 2 3 4		Y N	Y N	1 2 3 4		Y N	Y N	1 2 3 4	
					BF RF	NVP <4 ≥4 <4 ≥4 None	A D				1 2 3		1 2 3 4			Y N	Y N	1 2 3 4		Y N	Y N	1 2 3 4		Y N	Y N	1 2 3 4	
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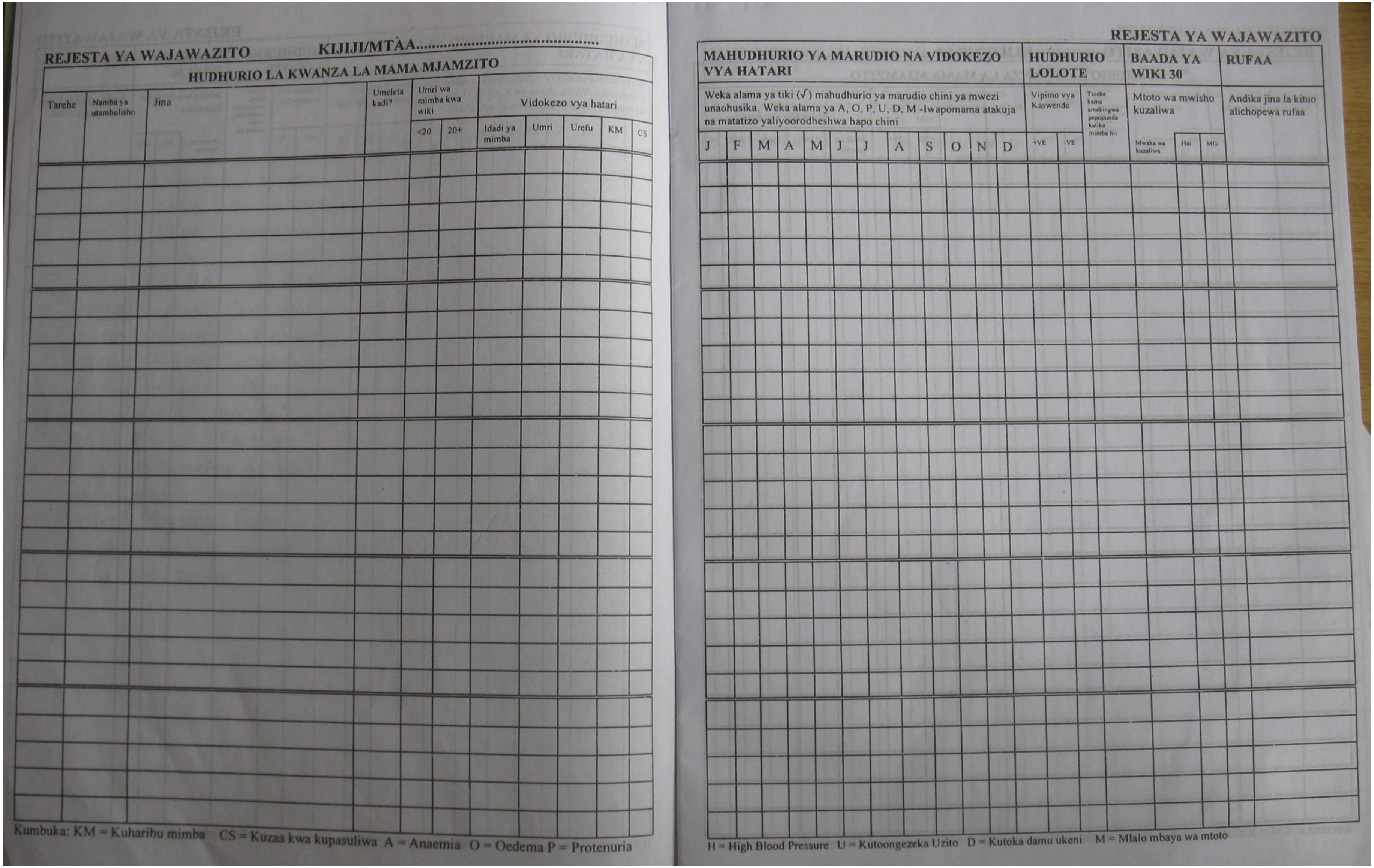
12.4.5 General ANC register page example



REJESTA YA WAJAWAZITO KIJIJI/MTAA...

HUDHURIO LA KWANZA LA MAMA MJAMZITO

Tarehe	Namba ya utambulisho	Jina	Umeleta kadi?	Umri wa mimba kwa wiki		Vidokezo vya hatari				
				<20	20+	Idadi ya mimba	Umri	Urefu	KM	CS

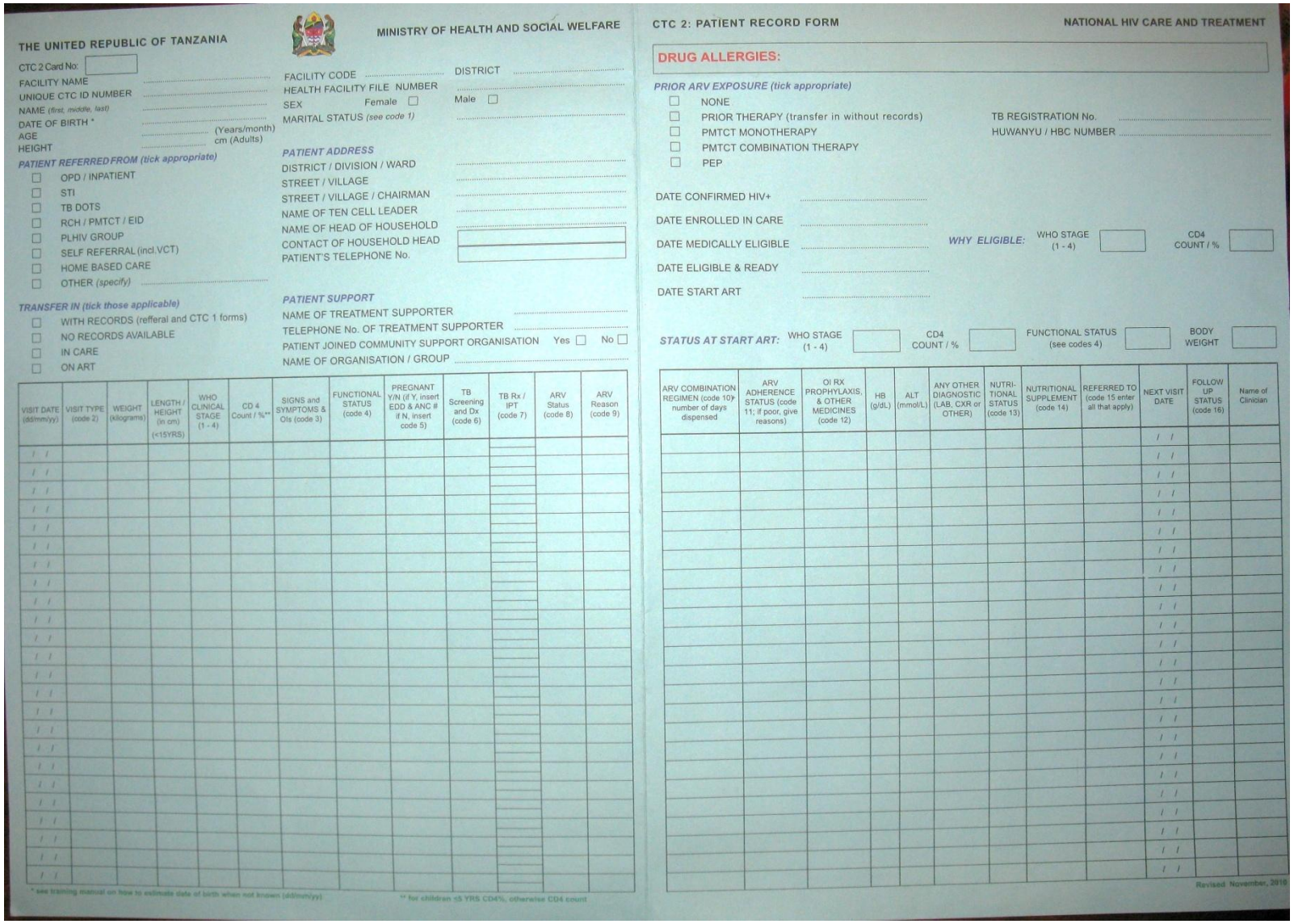
Kumbuka: KM = Kuharibu mimba CS = Kuzaa kwa kupasuliwa A = Anaemia O = Oedema P = Protenuria

REJESTA YA WAJAWAZITO

MAHUDHURIO YA MARUDIO NA VIDOKEZO VYA HATARI												HUDHURIO LOLOTE			BAADA YA WIKI 30			RUFAA
Weka alama ya tiki (√) mahudhurio ya marudio chini ya mwezi unaohusika. Weka alama ya A, O, P, U, D, M -Iwapomama atakuja na matatizo yaliyoorodheshwa hapo chini												Vipimo vya Kaswende		Tarehe kama amekingwa pepopunda katika mimba hii	Mtoto wa mwisho kuzaliwa			Andika jina la kituo alichopewa rufaa
J	F	M	A	M	J	J	A	S	O	N	D	+VE	-VE		Mwaka wa kuzaliwa	Hai	Mfu	

H = High Blood Pressure U = Kutoongezeka Uzito D = Kutoka damu ukeni M = Mlalo mbaya wa mtoto

12.4.6 CTC2 form



THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH AND SOCIAL WELFARE

CTC 2 Card No: ☐
FACILITY NAME ....
UNIQUE CTC ID NUMBER ....
NAME *(first, middle, last)* ....
DATE OF BIRTH * ....
AGE .... (Years/month)
HEIGHT .... cm (Adults)

FACILITY CODE .... DISTRICT ....
HEALTH FACILITY FILE NUMBER ....
SEX Female ☐ Male ☐
MARITAL STATUS *(see code 1)* ....

PATIENT REFERRED FROM (tick appropriate)

- ☐ OPD / INPATIENT
- ☐ STI
- ☐ TB DOTS
- ☐ RCH / PMTCT / EID
- ☐ PLHIV GROUP
- ☐ SELF REFERRAL (incl.VCT)
- ☐ HOME BASED CARE
- ☐ OTHER *(specify)* ....

TRANSFER IN (tick those applicable)

- ☐ WITH RECORDS (refferal and CTC 1 forms)
- ☐ NO RECORDS AVAILABLE
- ☐ IN CARE
- ☐ ON ART

PATIENT ADDRESS

DISTRICT / DIVISION / WARD ....
STREET / VILLAGE ....
STREET / VILLAGE / CHAIRMAN ....
NAME OF TEN CELL LEADER ....
NAME OF HEAD OF HOUSEHOLD ....
CONTACT OF HOUSEHOLD HEAD ☐
PATIENT'S TELEPHONE No. ☐

PATIENT SUPPORT

NAME OF TREATMENT SUPPORTER ....
TELEPHONE No. OF TREATMENT SUPPORTER ....
PATIENT JOINED COMMUNITY SUPPORT ORGANISATION Yes ☐ No ☐
NAME OF ORGANISATION / GROUP ....

VISIT DATE (dd/mm/yy)	VISIT TYPE (code 2)	WEIGHT (kilograms)	LENGTH / HEIGHT (in cm) (<15YRS)	WHO CLINICAL STAGE (1 - 4)	CD 4 Count / %**	SIGNS and SYMPTOMS & OIs (code 3)	FUNCTIONAL STATUS (code 4)	PREGNANT Y/N (if Y, insert EDD & ANC # if N, insert code 5)	TB Screening and Dx (code 6)	TB Rx / IPT (code 7)	ARV Status (code 8)	ARV Reason (code 9)
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* see training manual on how to estimate date of birth when not known (dd/mm/yy)

** for children ≤5 YRS CD4%, otherwise CD4 count

CTC 2: PATIENT RECORD FORM

NATIONAL HIV CARE AND TREATMENT

DRUG ALLERGIES:

PRIOR ARV EXPOSURE (tick appropriate)

- ☐ NONE
- ☐ PRIOR THERAPY (transfer in without records)
- ☐ PMTCT MONOTHERAPY
- ☐ PMTCT COMBINATION THERAPY
- ☐ PEP

TB REGISTRATION No. ....
HUWANYU / HBC NUMBER ....

DATE CONFIRMED HIV+ ....
DATE ENROLLED IN CARE ....
DATE MEDICALLY ELIGIBLE ....
DATE ELIGIBLE & READY ....
DATE START ART ....

WHY ELIGIBLE: WHO STAGE (1 - 4) ☐ CD4 COUNT / % ☐

STATUS AT START ART: WHO STAGE (1 - 4) ☐ CD4 COUNT / % ☐ FUNCTIONAL STATUS (see codes 4) ☐ BODY WEIGHT ☐

ARV COMBINATION REGIMEN (code 10) number of days dispensed	ARV ADHERENCE STATUS (code 11; if poor, give reasons)	OI RX PROPHYLAXIS, & OTHER MEDICINES (code 12)	HB (g/dL)	ALT (mmol/L)	ANY OTHER DIAGNOSTIC (LAB, CXR or OTHER)	NUTRI-TIONAL STATUS (code 13)	NUTRITIONAL SUPPLEMENT (code 14)	REFERRED TO (code 15 enter all that apply)	NEXT VISIT DATE	FOLLOW UP STATUS (code 16)	Name of Clinician
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Revised November, 2010

12.4.7 Protocol for PLA activities

Facilitators and note-takers should be aware of the following objectives of the PLA activities for this study:

- To identify barriers and facilitating factors to the uptake of PMTCT services
- To identify strategies to reduce barriers to accessing PMTCT services
- To explore the acceptability of enhanced counselling sessions with male partners/ female relatives
- Raise awareness and encourage support for PMTCT and ART services
- Recruitment of HIV+ women and HIV- (who have delivered recently) from the community for IDIs by way of seeded focus groups
- Development of 'vignettes' for IDI guides and refining all the tools for the remaining activities

WELCOME AND THANK THE PARTICIPANTS

READ OUT THE INFORMATION SHEET AND TAKE INFORMED CONSENT (VERBAL)

CONDUCT ICE BREAKER ACTIVITY

START THE PLA ACTIVITIES BELOW

- **Knowledge section about the PMTCT programme [1-1.5 hour]**

<u>Brainstorm</u>
Resources: Flip charts
Method: Brainstorming as a group
Output: Tape recording of discussions

Explain that we are going to begin by thinking about and discussing a few questions about HIV transmission. Emphasize to participants that we want to get the views of everyone, that there are no right and wrong answers and that we respect everyone's opinion.

TURN ON TAPE RECORDER
Q1. If an HIV-positive woman becomes pregnant, is it possible/ likely for her to pass the virus to her baby?
Probes: When could this happen? (during pregnancy? delivery? after birth?)
What do others in the community say/think about this? (ie not just their own personal opinions)

Q2. Are there any ways to *<u>prevent</u>* (or reduce the chances of) an HIV-positive woman who becomes pregnant from passing the virus to her baby?
Probes: Any treatments? What kind? If so, when are these given/taken, who gives them?
Other ways? (Feeding practices? Other medical interventions? Traditional methods or practices?)
During pregnancy? Delivery? Breastfeeding?

Q3. What do you know about/ have you heard about the PMTCT programme?
Probes: Good things? Bad things? (about the services/programme)
What do other people in the community say? (ie not just their own personal opinions)
Where did they hear about this/ what is the source of this information? (eg what type of people (no names are needed), what places?)

What services does it include?
Who does it include? (Women? Infants? Men?)
Where can people go to receive these services? (In Kisesa ward? Outside of Kisesa?)
Get the overall consensus from the group about the feeling in the community regarding the PMTCT programme (Very/a little positive? Very Negative/ a little negative?)
After each question ask: *Anything else anyone thinks/would like to say about this?*

TURN OFF TAPE RECORDER AFTER DISCUSSION

- Clarify/tell participants that ARV treatments (given during pregnancy and delivery to the mother, and after birth to the baby) are available that can be used to reduce the possibility of an HIV-positive woman transmitting HIV to her child (this is the main intervention). Appropriate infant feeding practices are also a way to reduce the chances (exclusive breastfeeding, or exclusive formula/replacement feeding for the first 6 months if acceptable, feasible, affordable, sustainable and safe, but choice of these methods depend on the situation for each woman).
- (Note: Only if someone mentions caesarian section surgery, tell them that this can also be a way to reduce the chances of passing HIV during delivery, but that these procedures are not routinely conducted/recommended in the national guidelines for PMTCT in Tanzania because the risks are considered to outweigh the benefits)

- Conclude this activity by saying that we are now going to discuss the services/steps of the PMTCT programme in more depth in the next activity.

PMTCT 'journey'
Resources: Flip charts, pre-prepared cards with symbols for the different services/steps
Method: Group discussion & cards to be arranged in correct order of service flow on flip-chart paper
Physical outputs: PMTCT journey pathways on flip-chart paper; photographs; tape recordings of group discussions

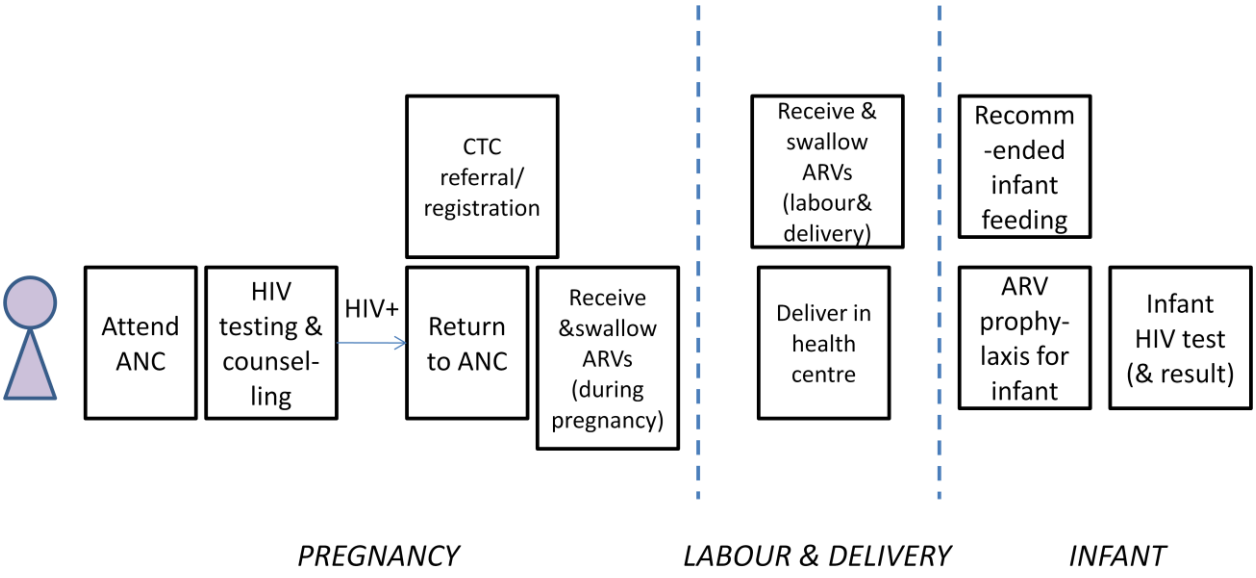
Draw a woman on the left side of the flipchart (give imaginary name). Explain that the woman becomes pregnant. Explain that we are going to think through her journey of realising she is HIV-positive to accessing subsequent services for PMTCT. Firstly we are going to think through her journey if she is able to participate in the /whole PMTCT programme with all the steps/services that are available/recommended. (If participants say that she will not use these services the facilitator can say that we will think about what happens in real-life in the next activity)

TURN ON TAPE-RECORDER
Discussion: Summarise any PMTCT services that were correctly mentioned in the previous brainstorming question (produce/lay out on the floor pre-prepared cards for any services that were correctly identified already, and clarify what these symbols mean), but then start the group(s) off by asking them to think from the beginning of when she becomes pregnant (she does not necessarily know her HIV-status) through to what happens when she gives birth, and what should happen in the first few weeks after the baby is born. Ask them to try to think of any steps in the process that they might have missed using probes for example:
Can you think what would happen when she gives birth? What would happen when the baby is born?
Lay down the cards as they are identified (in no specific order). Clarify what 'service' the card/symbol represents. The group(s) should be encouraged to think of the path but should include all the cards/ steps below, so explain and lay out any remaining cards that they have not been able to identify.

TURN OFF TAPE RECORDER

Give the group the full set of pre-prepared cards and ask them to arrange them in the order that they think they would happen. Tell the participants again that this is not a test, and that there are some different possible pathways, that the programme is quite complicated and everyone's ideas are valued.

- Going to ANC
- HIV testing and counselling, receiving HIV positive results
- Referral to/ registration at the ART clinic*
- Returning to ANC for more ANC appointments*
- Receiving and taking/swallowing ARV prophylaxis (ANC) or ART for her own health (ART clinic)*
- Labour and delivery (in a health facility, more ARV prophylaxis given)*
- Infant ARV prophylaxis after birth*
- Infant HIV testing
- Infant feeding advice; Adopting recommended infant feeding practices



The facilitator can go around the groups and probe: *what should happen while she is pregnant? during labour and delivery? just after/a few weeks after the child is born? Where?*

Notes (for the facilitator if questions are asked, you do not need to read all this information to the participants):
-The pathway may also include the alternative route that the woman already knows her HIV-status and is even registered at the ART clinic, but becomes pregnant. She would then be referred to the ANC for her pregnancy management
-Disclosure to partner/others might be mentioned as a step after HIV testing
-Registration at the ART clinic or ART for her own health will include CD4 count testing for eligibility for starting ART
-Referral to/ registration at the ART clinic and returning for ANC appointments could go the other way round
-HIV testing and counselling is 'provider initiated'/'opt-out' (the nurse/counsellor will conduct the test unless the woman declines to be tested – she can tell the nurse she does not want to be tested)
-ARV prophylaxis (AZT) is given to the mother from 14 or 28 weeks of pregnancy, during labour and delivery, and for a few days after delivery

-Infant ARV prophylaxis is usually given for 1 to 4 weeks after birth
-Infant HIV testing – The blood ('blood spot' from a finger or heel prick) will usually be taken by a PMTCT nurse in the health centre then sent to the referral hospital (Bugando) for conducting the test, then the results will be received back to Kisesa health centre. The first infant HIV test should be conducted between 1 month - 2 months old. Testing may also done later but it is important to make a diagnosis as early as possible so that if the baby is diagnosed with HIV then it can be referred to the ART clinic to start receiving more ARV treatment to stop it from becoming sick.

PHOTOGRAPH THE PATHWAYS PRODUCED BY THE GROUP (before the cards are rearranged)

TURN ON THE TAPE-RECORDER
Ask the group to explain their pathway/ why they ordered the cards as they chose to. If any parts of the pathway are in the wrong order, probe *is there anything else that might happen between these steps? Or, can you think of anywhere else in the journey this step would come?)* Finally, the facilitator can explain the 'correct' pathway and move around the cards into the correct sequence.
TURN OFF THE TAPE RECORDER

Conclude this activity by providing some summary information about PMTCT services:

- Free basic maternity care, delivery services, and child clinics are offered to pregnant women at Kisesa health centre, village dispensaries and regional hospitals (Bugando Medical Centre and ST Hospital).
- HIV testing and counselling is also offered by the antenatal clinics at these sites. Voluntary HIV testing and counselling is also available at the VCT clinic in Kisesa health centre for all men and women in the community.
- The Tanzanian government provides free HIV medication to HIV-infected pregnant women and their newborn babies, to prevent the virus from being passed from the mother to her baby. This programme, known as the prevention of mother-to-child transmission (PMTCT) programme, also includes counselling, advice and support. It is available at Kisesa health centre, village dispensaries and regional hospitals (Bugando Medical Centre and ST Hospital).
- Pregnant women who find out that they are infected with HIV, and their babies, are also able to enrol into the HIV care and treatment programme at Kisesa health centre (or regional hospitals). Antiretroviral treatment (ART) is available free of charge to all HIV-infected individuals: they will be able to start treatment as soon as the HIV disease reaches a dangerous point. (Full HIV care and treatment services are not yet available in the village dispensaries)

SODA BREAK

Storyline and role play to develop vignettes [1 hour]

Resources: Flip-chart paper and marker pens, props for role-plays
Methods: Character and storyline generation (group discussion) then role-playing
Physical outputs: PMTCT journey map illustrating which services/steps the woman actually participated in during the story; Flip-chart of the summary of characters to be used for role-plays; Tape recording of the characters, storyline and final discussion; Facilitator notes of the main barriers and facilitating factors mentioned in the final discussion (to be brought to the following day's activities on barriers and solutions)

Facilitator will guide the group to develop characters and a storyline about a woman (same one that we just thought about in the PMTCT journey activity) who discovers she is

HIV-positive at ANC and the extent to which she is able to/chooses to participate in the PMTCT programme. Explain that the story begins when she is diagnosed with HIV at the ANC, and ends a few weeks after the baby is born (show them on the PMTCT journey map). During this activity the facilitator will draw a web diagram of the characters developed for the story, and also update the PMTCT journey map with arrows representing the choices the woman makes in their story, based on the discussion of the group.

TURN ON TAPE-RECORDER

Developing **characters** that would be important in this woman's pregnancy / relevant in this woman's story:[15 minutes]
Probes/guidance for the group
Who is important in the woman's pregnancy/delivery?
Where does she live?
Who would be involved in her pregnancy management/ decisions/ seeking services?
Who would she confide in, if anyone?
Think of health workers, male partners, mothers-in-law, children, other relatives, friends etc

Developing the **storyline**: [15 minutes]
The group can discuss their story together in a group, with help from the facilitator as needed: The facilitator can ask the participants to think through each step listed on the 'PMTCT journey' (lay out the PMTCT journey pathways/diagrams for the group to see)and ask:
What are the most likely decisions she would make at each step? What would be most likely to happen in real life? Why?
(for example, does she go back for more ANC appointments, does she swallow the ARV medicines she is given (none/some/all of them)? Does she deliver in the health centre? etc)
What are the difficulties that she would face? Think about family/community issues and health services
Who else (which other characters would be involved at each step?)
How would these other people be involved? How would they affect the HIV+ woman's own actions?
Where would different parts of the story take place? (clinic, at home, at someone else's house etc)
What is the most likely ending of the story? / What would be most likely to happen in real life? Why?
TURN OFF TAPE RECORDER

Role-play [10 minutes to act the play]
After the storyline is created the group will role-play/act the the story. Ensure relationships with partners and the community are acted out. Tell the groups that their role-play should not last more than 10 minutes. The facilitator/ note taker should include notes about body language and behaviours, not just the storylines.

TURN ON TAPE-RECORDER:
Discussion of role plays with the groups afterwards [20 minutes]
Probes for discussion:
Does this story reflect what actually happens in real life?
Are the ways the characters behaved similar to what actually happens real life?
What difficulties did the woman face?
How about for the other characters (family/male partners) in the process? Did they face any difficulties in supporting the woman or being involved?

Was there enough/a lack of support from other characters?

TURN OFF TAPE RECORDER

DAY 2 ACTIVITIES

WELCOME BACK AND THANK THE PARTICIPANTS

-
- **Barriers to using services: 1hr [30-40 mins brainstorming plus 20-30 mins ranking]**

Resources: Cards (blank), tape, flip chart paper (in case items cannot be stuck to the wall), output from PMTCT journey activity
Methods: Brainstorm of barriers; represented on cards; ranking barriers on the wall
Outputs: Photograph of cards on the 'wall of challenges', facilitator notes of discussion, tape-recording of discussions

TURN ON TAPE RECORDER
Brainstorm and carding:
The facilitator will remind participants/summarise about the discussions that they had yesterday regarding the role-plays and the difficulties/barriers that they identified for the person in the story in accessing PMTCT services. They will also show participants the PMTCT journey pathway that was created the previous day.

Facilitators will then ask participants to reflect again about the storyline and the role-plays from the previous day, and to look at the pathway of services in the PMTCT 'journey' and think about all possible reasons that might have made it difficult for the woman to participate in every aspect of the PMTCT programme (discuss barriers along each step of the way and barriers that affect all of the steps). Each new barrier suggested by a participant should be drawn or written on a card, and cards will be laid out on the PMTCT journey diagram at the appropriate step.

Probes:
(Referring to the PMTCT journey map), what are the difficulties that the woman would face at this step? What blocks her journey? What helps her on her way?
How and why does each barrier prevent women from using PMTCT services/this step? (try to get participants to consider social/community issues, issues for the woman herself, as well as any issues about the health facilities themselves)
Probe for and encourage discussion around support structures: involvement/ lack of involvement of partners or relatives, and barriers for partners/relatives in being able to provide this support
Probe for barriers to taking/swallowing ARVs (not just receiving ARVs) during pregnancy and during labour and delivery

PHOTOGRAPH THE PMTCT JOURNEY WITH THE BARRIERS CARDS LAID OUT (before moving them onto the wall)

Ranking exercise: **'Wall of challenges'**
The facilitator will explain that the 'barrier' cards they have made now represent bricks. They are going to build a 'wall of challenges' with these bricks, thinking about how important each barrier is in terms of the woman being able to participate in PMTCT services (how high on the wall of challenges it comes).
The most important barriers should be placed at the top of the wall while the least relevant or significant barriers should be placed at the bottom of the wall. If possible the

facilitators should actually tape the cards to a flipchart page stuck on the wall in the room.
Probes:
Where should we tape this brick? Is it an important barrier so we should tape it high up the wall? Or is it less important so that we should tape it lower down the wall? Why? Does everyone agree that it should go here?

TURN OFF TAPE-RECORDER
TAKE A PHOTOGRAPH OF THE WALL AT THE END OF THE ACTIVITY

SODA BREAK

Solutions: 1 hour

Low hanging fruits tree
Resources: Flip-chart paper, coloured markers, pre-prepared blank fruit shaped cards
Methods: "low hanging fruits tree" with initial brainstorm of possible solutions to barriers, with solutions drawn on fruit shaped cards, then arranged on the tree with the most feasible solutions on the lower branches)
Physical Outputs: picture of tree with attached cards representing possible solutions, photograph, tape recording of discussion

Facilitator will explain the aim of the session: to identify solutions to each of the barriers that have been discussed, and which of these possible solutions will be hardest and which will be easiest to achieve/implement. Focus firstly on the main/most important barriers identified in the previous wall of challenges activity.

TURN ON TAPE-RECORDER
Start with a brainstorm/discussion of solutions for each barrier discussed in the previous activity. The group can be broken into 2 groups to think and discuss among themselves solutions to different sets of barriers. Someone from each group can be asked explain their solutions, and the facilitator will lead a discussion of each solution with the whole group. Facilitator can then write the solutions on fruit-shaped cards. Label the back of the fruit cards with the barrier that the solution refers to. Encourage the group to think about possible ways that other family/partners/friends/community could be involved, not only changes to health facilities and services.
Probes:
How would this idea help to overcome (jump over) the barrier on the wall?
What do others in the group think about this possible solution? Is it a good idea? Could it help to improve uptake of PMTCT services? Can anyone think of anything else similar/other alternatives that might work?
Who would be involved?
Could some of these barriers be overcome if male partners/ female relatives participated (more) in the programme? Why/why not? How about if the women attended some counselling sessions with male partners or a female relative?
How about more/ increased quality of counselling?

After solution brainstorming, the facilitator will explain the hanging tree activity: the group will arrange these potential solutions on the tree, where the lowest branches and 'lowest hanging fruit' are the easiest to pick and represent solutions that are the easiest to implement, while the highest fruits are the hardest to pick and implement. First ask the participants to draw a tree with different level branches (high and low), then ask them to arrange the fruits on the tree. (Participants may also choose to put the fruits in the middle of the tree). Tell them to draw the tree big.
Probes:
What things would get in the way of carrying out these 'solutions'? Why?

Tell the group they can rearrange the fruits if they wish to after these discussions.

TURN OFF TAPE RECORDER
TAKE A PHOTOGRAPH OF THE FINAL TREE PICTURE

LABEL ALL DIAGRAMS

CONCLUSION:
-Participants can contact Raymond Nsigaye in private if they have any questions about ART/PMTCT. Any other difficult questions should be noted so that information can be fed back to the community using TAZAMA leaflets.
-Manage expectations: Thank participants for all their ideas and say that we will do our best to try to consider all the suggestions, however we cannot promise that all the changes that they suggested can be implemented

12.4.8 IDI discussion guide with mothers who delivered recently

Objectives

**1.To identify barriers and facilitating factors to the uptake of PMTCT services*

**2.To explore personal experiences of the PMTCT programme*

**3.To explore the acceptability of PMTCT counselling sessions with male partners or female relatives of HIV+ pregnant women*

READ THE INFORMATION SHEET AND TAKE INFORMED CONSENT (WRITTEN OR VERBAL)

1. Personal circumstances

Firstly I am interested to know a little about your family and household:

-Where do you live?

-Who do you live with?

-Probe: partner? – married? How long have you been with this partner?

-How many children do you have? How old are they?

2. Vignette/short story

I'd now like to tell you a story about a pregnant woman called [Flora] and her experiences her experiences in trying to access antenatal clinic (ANC), delivery and infant health services. I will tell you part of the story, then I would like you to help me complete the story. *(Change the name of the woman in the story if necessary so that it does not resemble the name of the participant)*

Flora, lives in a remote village in Welamasonga, she is 27 years old. She is married to Paulo and she has 3 children. She becomes pregnant and after a few months decides to attend an antenatal clinic by herself. At the ANC she receives a test for HIV. The nurse tells her that she is HIV-positive but explains that there are medicines that she can take to save the baby from being infected with HIV. She also tells Flora that it is important that she delivers the baby in the health centre so that it can also receive medicine to reduce the chances of it being infected. She gives the woman the medicines to take during her pregnancy, and also tells her to persuade her husband to come for an HIV test. She also discusses options for feeding the infant, and advises Flora to breastfeed the child for 6 months without any replacement food/formula. The nurse explained all this information very quickly.

What do you think happens next? Please think for Flora, as a woman in your community, and imagine what she would be thinking and feeling at this time.

Why?

What would she be thinking?

What difficulties would she face?

Does she tell anyone the result of her test?

Is that what would happen in real life? Why?

In the next part of the story, Flora goes home to her husband and tells him the result of her HIV test, and what the nurse advised her. He is angry and denies her status because he believes he is clean/not infected, and questions whether she has had other partners. Flora decided to disclose her status to her sister and get her support, but she decides not tell to any of her other relatives about what happened.

Do you think Flora would go back to the clinic for more ANC appointments?
Why/ why not?
What would she be thinking?
What difficulties would she face?
Would anyone go with her? Who?
Is that what would happen in real life? Why?

Do you think Flora would be able to/decide to take the treatments during her pregnancy? Why/ why not?
What would she be thinking?
What would make it difficult for her to take them?
Is that what would happen in real life? Why?
What might encourage her/would make it easier for her to take them?
Do you think she understands or believes why she has to take them?

Where do you think Flora will give birth to her child? Why?
At a health centre? Which one? At Home? Traditional birth attendant?
Would anyone go with her? Who?
What would she be thinking?
What difficulties would she face?
Is that what could happen in real life?

Do you think she would be able to swallow the HIV medicines during labour and delivery? Why / why not?
What would she be thinking?
What difficulties would she face?
Is that what could happen in real life?

I'll now tell you the next part of the story:
Unfortunately Flora didn't manage to take the medicines during her pregnancy because she feared the reaction of her husband. She gave birth at home because she was unable to get the support of her husband for the transport fare and to buy gloves and other items which might be needed for when she arrives at the delivery ward. She also fears the suspicion of her relatives who might escort her to the delivery ward: they might see her swallowing the HIV medication during labour pain, and she might have to wash her own clothes/sheets after delivery.

Do you think Flora will be able to take the baby back to the clinic for ARVs in the first few days after it is born? Why?

What would she be thinking?
What difficulties would she face?
Is that what could happen in real life?
If she goes, would anyone else go with her? Could someone else take the baby?

Will she be able to take the baby to a clinic to be tested for HIV after one month? Why/ why not?
What would she be thinking?
What difficulties would she face?
Is that what could happen in real life?
If she goes, would anyone else go with her? Could someone else take the baby?

Will she be able to follow the advice about breastfeeding? Why/ why not?
What would she be thinking?
What difficulties would she face?
Is that what could happen in real life?

Does Flora's story reflect what can happen in real life? Why?

3. Personal experiences with the ANC/maternal and child health programme

Interviewers should trace a woman's journey from becoming pregnant, awareness of HIV status (negative or positive), through labour and delivery, and care for the infant in the first 1-2 months. Discuss any difficulties experienced at each stage: encourage them to think of personal problems they may have faced, difficulties with their partners/family/community, and difficulties at the health centres.

Now I would like to talk to you about your experiences of antenatal clinic services during your most recent pregnancy and any difficulties you faced, or things that encouraged you, during this time. I'd like to remind you that you do not have to answer any questions that you do not want to.

First ANC appointment and HCT experience

During your most recent pregnancy, did you attend ANC somewhere?
Probes: When was this? *(Clarify the year of her last/most recent pregnancy)*
Where? How many times?

[IF SHE DID NOT ATTEND ANC]:
Why not?
Who made the decision?
What other care or advice did you receive during pregnancy?
Did you ever attend ANC in the past?

Can you tell me about your past experiences of ANC?

(For the next questions, if she did not attend ANC in her most recent pregnancy, ask her to think of another time she attended ANC in the past, or move on to talk about her labour and delivery)

Can you tell me what happened when you went for your *first* ANC appointment during this (most recent) pregnancy?

Probes:

Did anyone go with you (who?)

How did the staff treat you? *(Check gender/sex of the staff)*

How long did you have to wait at the clinic?

What services did you receive?

HIV testing?

-Were you expecting the test?

-Did the staff explain why you were recommended to take the test?

-How did you feel about having the test?

-Did you feel you had a choice to take the test/could decline the test? Why?

-Did you take the test? Why/why not?

Can you tell me about any advice or counselling that you received?

-How long did it last roughly?

-What advice/information were you given?

-What did you think about this advice? Was it enough?

-Was it given somewhere private or not?

-Was the counsellor/nurse supportive or not?

Medicines given?

-What kind? / What for?

[Note: If participant does not wish to discuss details of their result/diagnosis they DO NOT have to, but try to probe about any information and advice they were given in terms of their pregnancy/ delivery, information about the PMTCT programme. If she discloses her HIV-positive status, clarify if she already knew her status before coming to the ANC/ receiving the HIV test at ANC]

[ASK ONLY TO WOMEN WHO WERE DIAGNOSED <u>HIV+</u>]:

What happened after you first received your positive test results, and went back home? Please describe what happened in those first few days, how you reacted, and if you told anyone.

Probes:

How did you feel?

Did you tell anyone? Who? Why?

How did they react? Have you told other people since this time? Why/ why not?

(Note: For women who already knew their status clarify if they have disclosed to anyone)

After your first ANC appointment (in your most recent pregnancy), did you go back to a health centre/dispensary for more ANC appointments during this pregnancy? Why?

Probes:

Same or different health centre?

What encouraged you to go back?

Any difficulties you had in going back?

Can you tell me more about what happened at these next ANC appointments you attended?

Probes:

Did anyone go with you?

Any new information/advice given?

How did the staff treat you?

Any medicines they gave you? What kind/ what for?

[ASK TO HIV+ WOMEN ONLY] Taking ARVs

Can I clarify, during your pregnancy, were you given ARV (HIV) medicines to take (to stop the virus passing to the baby or for your own health?)

Who gave you the medicines (a doctor/an ANC nurse?)?

Where (ANC or HIV/ART clinic)?

When (at what stage of pregnancy)?

Did you receive any treatments (or other care) for your health (for HIV) from anywhere/ anyone else, other than a health centre/hospital/dispensary? (*eg traditional methods*)

Please tell me about what the nurse/doctor told you when you were given these medicines, and what you were thinking at this time.

What advice/information did the health worker give?

Was the information clear or not? Easy or difficult to understand?

Was the conversation somewhere private, or not?

Some people can experience difficulties in being able to take these HIV medicines. Can you tell me what happened after you were given these medicines? Please tell me about if you were able to swallow/take these medicines and any difficulties you may have experienced.

What made it difficult to take them?

What helped you to take them?

How did the medicines make you feel?

Were the instructions for taking it easy/difficult to understand?

How many times per day did you have to take these pills?

How easy/difficult was it remembering to take them?

When did you start taking them? (During pregnancy/labour?)
When did you stop taking them? (During pregnancy/labour/delivery/after delivery?)
Did you tell anyone that you were taking these ARV medicines?
Did they help you? How?

[ASK TO HIV+ WOMEN ONLY] HIV care and treatment centre (CTC)

Can I clarify, after you received your positive HIV test result, did you ever go to the HIV care and treatment centre? Why/ why not?
When did you first go? (During pregnancy? Sometime after?)
What made it difficult/encouraged you to go there?
Did anyone go with you?

[ASK IF SHE SAYS SHE ATTENDED CTC]

Please tell me about your experience when you arrived for the first time at the CTC
How were you feeling?
Waiting times?
How did the staff treat you?
This time, or on another/later visit to CTC:
Did you have any tests for readiness to start HIV treatment? (CD4)
Did the doctor explain these results?
Did the doctor discuss ARV treatment with you? What did (s)he tell you?
Were the discussions easy or difficult for you to understand?
Clarify if the woman started ARV treatment for her own health

[ASK IF SHE SAYS SHE ATTENDED CTC]

Are you still attending the CTC? Please tell me about any difficulties you have had in continuing at the CTC
(*If not attending any longer)* why did you stop going there?

[ASK TO ALL WOMEN] Labour and Delivery

Thinking about this (your most recent) pregnancy, can you tell me about any plans you made for what would happen during your labour/ delivery?
[if the woman is still pregnant discuss future plans for labour and delivery instead]
Did you decide where you would go?
Had the counsellor/nurse given you any advice of where you should deliver?
Did you decide what would happen if there were any complications with the labour?
Did you discuss/ make these plans with anyone? Who? Who made the final decisions?

Can you tell me what happened when you went into labour?
When did it happen? (night time/day time? Earlier/later than expected?)
Where did you go? Why?
Was this your own choice/preference? If not, who made the decision?
Any complications?

Who was with you during labour/delivery?
How was the care you were given?
How did people (health workers/relatives) help you, if at all?
Comfort and privacy?

[ASK TO HIV+ WOMEN ONLY]:
Were you given any HIV (ARV) medication to take during labour or delivery?
Were you able to swallow it? Please tell me about any difficulties you experienced in taking it

[ASK TO ALL WOMEN] Infant care services
[if the woman has not yet given birth/is still pregnant, skip the rest of this section]

Can you tell me what happened in the first few days after your baby was born? Please tell me about any treatments, services or other care your baby received, and if there were any difficulties for you or the baby at this time.
How was the health of your baby?
How was your own health?
Did your baby receive any treatments? Who gave these?
[*If the woman had a home birth:*]
Did you/somebody take your baby to a health centre/somewhere else to receive care or treatment? Where? Who took the baby? When? Why/ why not?
Any difficulties you experienced? What encouraged you to go there?

[ASK TO HIV+ WOMEN ONLY] **Did your baby receive an HIV test? Can you tell me about this? Please describe any difficulties you experienced in taking the baby for the test and getting the test results**
Who did the test?
Where did they do this test?
How did you go there?
Experienced any difficulties in going there/ when you got there?
How were you feeling about your baby receiving an HIV test?
Did you get the test results? Any difficulties in getting them? How were you feeling?

Can you tell me about how you were feeding your child in the first few months after it was born, and any difficulties you had with this?

4. Overall perceptions & suggestions for possible improvements to services

Overall, thinking about your pregnancy/delivery/care of your baby that we have discussed today what were the biggest difficulties for you? Why?

Overall, what do you think of the care/services you received during your pregnancy? Were you able to get/do everything you wanted during this time? Why?
In the health-facilities attended? At home? TBAs (if attended)?
In terms of family/partner/community support? How have they helped you, if at all?
Did you have any other sources of support? (Church/religious leaders, community groups?) How have they helped you?

If you became pregnant again in the future, would you go to a health centre to receive any of these pregnancy/delivery/infant services? Why/why not?
Is there anything that would make it easier for you in future?
Would it be helpful or more difficult for you in the future if you received some counselling sessions together with your partner or a female relative/friend? Why?
Which person would be best?
Do you think they would want/be able to be involved/help?
Are there any other ways they could they help? How?

Is there anything else you would like to tell me about your experiences/ thoughts about your pregnancy/delivery, any difficulties you had, or about the services you received?

Thank and finish interview

INVITATION FOR MALE PARTNER/FEMALE RELATIVE TO INTERVIEW:
We would like to conduct personal interviews with some male partners of HIV+ women who have disclosed their status, to understand more about how they are/can be involved in the PMTCT services. Would you be willing for us to contact your partner for an interview?
IF YES FILL IN DETAILS BELOW
IF NO,
Would you be willing for us to contact a female relative of yours who may have helped you during your pregnancy for an interview?

IF YES TO EITHER PARTNER OR RELATIVE RECORD THE FOLLOWING INFORMATION

NAME	Village/sub-village	Household head	Phone number

12.4.9 IDI discussion guide with partners/relatives of HIV+ women

Objectives

**1.To identify barriers and facilitating factors to the uptake of PMTCT services*

**2.To explore personal experiences of providing support to women in the PMTCT programme (where disclosure has taken place)*

**3.To explore attitudes towards PMTCT counselling sessions with male partners or female relatives of HIV+ pregnant women*

READ THE INFORMATION SHEET AND TAKE INFORMED CONSENT (WRITTEN OR VERBAL)

1.Personal circumstances

Firstly I am interested to know a little about your family and household:

-Where do you live?

-Who do you live with?

-Probe: partner? – married? How long have you been with this partner?

-How many children do you have? How old are they?

2.Involvement in pregnancy, delivery and HIV care

Now I would like to talk about your [wife/partner/relative's] last pregnancy and the ways in which you may have helped her during this time.

Can you tell me about the story of what happened during your [wife/partner/relative's] most recent pregnancy/delivery, from the time that she first realised she was pregnant, until a few months after the child was born? Please tell me about how you or any other people were involved with helping or assisting them during this time, and about any health care services she visited.

Probes:

-How were you/others involved or how did you/others assist her, if at all, during:

- -ANC attendance
- -coping with the results of the HIV test? (at this time or earlier, if she was already diagnosed HIV+)
- -taking ARV medicines, or any other treatments
- -attending the HIV clinic (CTC)
- -labour and delivery
  - -planning for the labour/delivery
  - -during the event (when she was in labour/delivered the child)
- -care of the infant
  - -ARVs for the infant (administering or collecting treatment for the baby)
  - -taking the baby to the health centre
  - -taking the baby for an HIV test / for the test results?
  - -feeding the infant
- -attendance of any other services (eg traditional healers)

-Who were the other people involved?
-Who made the decisions about:
-attending the health centre?
-where she delivered?
-services/caring for the infant?
-What difficulties did your [wife/partner/relative] experience? Why?
-Did you/others experience any difficulties in trying to help her? (During pregnancy? Delivery? Care of the infant?) What difficulties? Why?

[Ask if the respondent attended clinic services with the woman:]
Can you tell me more about your own experiences in attending the clinic with your partner/relative?
-How long did you have to wait at the clinic?
-How did you feel, and what were you thinking while attending the clinic with her?
-How did the staff treat you?
-What services did you receive/ attend? What did you think about these?
-Were you given any advice/information/counselling? What did you think about this?

3. Vignette/short story

I'd now like to tell you a story about a pregnant woman called [Flora] and her experiences her experiences in trying to access antenatal clinic (ANC), delivery and infant health services. I will tell you part of the story, then I would like you to help me complete the story. *(Change the name of the woman in the story if necessary so that it does not resemble the name of the participant)*

Flora, lives in a remote village in Welamasonga, she is 27 years old. She is married to Paulo and she has 3 children. She becomes pregnant and after a few months decides to attend an antenatal clinic by herself. At the ANC she receives a test for HIV. The nurse tells her that she is HIV-positive but explains that there are medicines that she can take to save the baby from being infected with HIV. She also tells Flora that it is important that she delivers the baby in the health centre so that it can also receive medicine to reduce the chances of it being infected. She gives the woman the medicines to take during her pregnancy, and also tells her to persuade her husband to come for an HIV test. She also discusses options for feeding the infant, and advises Flora to breastfeed the child for 6 months without any replacement food/formula. The nurse explained all this information very quickly.

What do you think happens next? Please think for Flora, as a woman in your community, and imagine what she would be thinking and feeling at this time.
Why?
What would she be thinking?
What difficulties would she face?
Does she tell anyone the result of her test?

Is that what would happen in real life? Why?

In the next part of the story, Flora goes home to her husband and tells him the result of her HIV test, and what the nurse advised her. He is angry and denies her status because he believes he is clean/not infected, and questions whether she has had other partners. Flora decided to disclose her status to her sister and get her support, but she decides not tell to any of her other relatives about what happened.

Do you think Flora would go back to the clinic for more ANC appointments?
Why/ why not?
What would she be thinking?
What difficulties would she face?
Would anyone go with her? Who?
Is that what would happen in real life? Why?

Do you think Flora would be able to/decide to take the treatments during her pregnancy? Why/ why not?
What would she be thinking?
What would make it difficult for her to take them?
Is that what would happen in real life? Why?
What might encourage her/would make it easier for her to take them?
Do you think she understands or believes why she has to take them?

Where do you think Flora will give birth to her child? Why?
At a health centre? Which one? At Home? Traditional birth attendant?
Would anyone go with her? Who?
What would she be thinking?
What difficulties would she face?
Is that what could happen in real life?

Do you think she would be able to swallow the HIV medicines during labour and delivery? Why / why not?
What would she be thinking?
What difficulties would she face?
Is that what could happen in real life?

Unfortunately Flora didn't manage to take the medicines during her pregnancy because she feared the reaction of her husband. She gave birth at home because she was unable to get the support of her husband for the transport fare and to buy gloves and other items which might be needed for when she arrives at the delivery ward. She also fears the suspicion of her relatives who might escort her to the delivery ward: they might see her swallowing the HIV medication during labour pain, and she might have to wash her own clothes/sheets after delivery.

Do you think Flora will be able to take the baby back to the clinic for ARVs in the first few days after it is born? Why?
What would she be thinking?
What difficulties would she face?
Is that what could happen in real life?
If she goes, would anyone else go with her? Could someone else take the baby?

Will she be able to take the baby to a clinic to be tested for HIV after one month? Why/ why not?
What would she be thinking?
What difficulties would she face?
Is that what could happen in real life?
If she goes, would anyone else go with her? Could someone else take the baby?

Will she be able to follow the advice about breastfeeding? Why/ why not?
What would she be thinking?
What difficulties would she face?
Is that what could happen in real life?

Does Flora's story reflect what can happen in real life? Why?

Solutions/possible improvements to PMTCT services

Thinking about the difficulties for your [wife/partner/relative] that you told me about today, can you think of any other possible ways these difficulties could be overcome?

Thinking about any of the difficulties that *you* faced yourself during this time, can you think of any possible ways these difficulties could be overcome?

Do you think it would be helpful for partners and relatives or friends to be more involved in maternal health / PMTCT services? Why? How could they help?
-Would *you* like to be more involved? Why?
-Attending (more) counselling sessions together with the women?

Is there anything else you would like to tell me about your [partner/wife/relative's] experiences, or your own experiences, of PMTCT services?

Thank and finish interview

12.4.10 IDIs with health workers and health officials

Objectives

*1.To obtain detailed information about the PMTCT programme and its evolution

*2.To understand, from a health provider's perspective, what are the perceived barriers and facilitating factors to the uptake of PMTCT services for HIV-infected pregnant women

*3.To identify the challenges faced by health workers and health officials in delivering PMTCT services and linking women to the HIV care and treatment programme

*4.To identify strategies to reduce barriers to accessing PMTCT/ HIV care services and to overcome the challenges faced by health workers and officials (including exploration of the acceptability of enhanced counselling sessions with male partners/ female relatives of HIV-infected pregnant women)

[Note: Some health workers may not be aware of all aspects of the PMTCT programme or its history, so the interviewer may have to focus on the aspects that they are most familiar with, although they can still gauge perceptions about other less familiar aspects]

Warm up: job role of the health worker/official

Firstly I am interested to understand more about your role.

Can you describe your role in relation to the PMTCT programme?

Probes:

When did you start working here?

What are you in charge of/responsible for? Who else is involved at the district level in organisation of PMTCT services? Relation vs District RCH coordinator?

Evolution of the PMTCT programme and main features

Now I am interested to understand more about the evolution of the PMTCT programme in the district.

Can you explain to me the history of the PMTCT programme in the district, when it started and how it has changed over time?

Probes: When did it start?

What changes have taken place? Why?

Changes in national protocols/guidelines? If YES, how are these changes communicated to you? Who from? Is there any new training provided at such a time?

Have there been any local improvements to procedures, or to the clinics and service infrastructure?

Changes in availability of resources /treatments?

How are PMTCT services organised in this district?
Probes: In which facilities in the district does this take place? (*all* dispensaries?)

Who is in charge of the programmes at each of these facilities? Who manages them?

What PMTCT services are offered at the different levels – tertiary hospitals down to dispensaries? (ARV prophylaxis in all dispensaries for example?)

How are the services integrated between different facilities? between services within facilities? for eg RCH and HIV services or CTC and ANC services)

Is there any training provision for PMTCT staff in the district? Can you tell me about that?

What do you think are the best things/strengths about the PMTCT programme? (*If they have difficulty answering ask them the best thing about their own job)*

What do you think are the worst things/weaknesses about the PMTCT programme? (*or if they have difficulty answering ask them the most challenging/worst thing about their own job)*

Barriers to receiving and delivering PMTCT services

When/at which step of the PMTCT programme are women/infants most likely to drop-out? Why? (*Probe for drop-outs at each step of the PMTCT programme*: *attending ANC, HIV testing, mother ARVs, linkage to care and treatment, delivery in health centre, baby receiving ARV prophylaxis, infant HIV testing, adhering to recommended breastfeeding practices).*

What do you think are the main barriers to/difficulties for women participating in PMTCT services? Why? *Explore general barriers and any specific barriers in terms of each step of the PMTCT programme (attending ANC, HIV testing, ARVs/linkage to care and treatment, delivery in health centre, baby receiving ARV prophylaxis, infant HIV testing, adhering to recommended breastfeeding practices) Encourage them to think not only in terms of health-systems access but also social barriers)*

What are the biggest challenges that you find in being able to deliver PMTCT services?

At each level of service (eg dispensaries-tertiary hospitals)?

Any specific steps of the PMTCT programme= biggest challenges?

Are there any challenges/difficulties with

resource/supply issues eg test kits/drugs,

provision of ARVs

- *-current protocols for supply of ARVs (pregnant women and infants)*
- *-challenges with changing guidelines*
- *-changes over time at the district level in PMTCT ARV uptake for positive women/infants*

clinic infrastructure,

clinic layout and confidentiality,

record keeping/documentation issues and performance measurement/management

- *-feedback to local health centres?*

volume of patients, staff and or time constraints,

training (poor/lack of?), service accessibility for clients including costs,

service integration issues

- *-mother and child service linkage?*
- *-RCH-CTC service linkage?*

-dispensary/health centre/hospital service linkage (eg HIV testing for infants)

issues with home-deliveries

-follow up of mothers and infants after home births?

Infant services

-receipt of results?

women who present at the health centre for the first time during labour – HIV testing?

Possible solutions

Can you think of any ways the challenges in implementing PMTCT services/difficulties for women in using PMTCT services could be overcome? (*summarise the main difficulties discussed*) *(Encourage them to consider strategies to address the social as well as health-systems issues discussed)*

Probes:
Improvements to services (local/district+) level? How would these help you/health workers? How would these help women/clients? Which of these improvements would be the most important/have the most impact?

Potential for further involvement of male partners or family members? Are women advised to bring partners (or other relatives or friends?) to any ANC/HIV testing/PMTCT/ART appointments? Do they come? What are the biggest barriers to this? How could male partners or other family members be more involved in the PMTCT programme?

Tell me your opinion about provision of couple counselling sessions (or joint sessions with another relative) as part of the PMTCT programme? Could they help increase the number of women who participate in PMTCT services? In your opinion how realistic/practical is this strategy? In pairs, or individually? How could it be promoted/ encouraged?

Do you have any other ideas at all that we have not yet discussed, or anything else about the PMTCT programme that you would like to tell me?

Thank and close.

12.4.11 Structured clinic observations tool

Objectives:

*Facilitate a deeper understanding of the ANC/PMTCT programme (for background knowledge of how the programme operates in real life setting, rather than national guidelines on how it should happen)

*Contribute to an understanding of health-systems barriers to uptake of ANC and PMTCT services.

*Triangulation with the other qualitative data sources: interviews with health workers and mothers are likely to be influenced by social desirability biases and masking of true actions, hence this observational work will provide an important alternative data source to investigate these biases

Guidance for what to write in the fieldwork diary

Name of observer:

Date: dd/mm/yyyy

Time observation started:

Time observation completed:

Location of the observation:

Comments (including)

- the approximate number of clients at the time in the area of the clinic being observed

-the atmosphere

- the behaviour of the staff and clients and interactions between them

- procedures for registering or dealing with clients when they arrive or leave

-privacy and confidentiality

-time women spend waiting for services

12.4.12 PLA invitation slip

Introduce yourself and read the following outline of the study:

NIMR is carrying out a study with women and men in the community about access to maternal health and PMTCT services in Kisesa. We would like to know the views of women and men about these services, so that we can understand the challenges that pregnant women face in accessing these services, or the challenges for relatives, partners and friends trying to support women in their pregnancy. This study will be very important in helping to improve these services.

Social scientists from NIMR will be conducting activities in same sex groups on [*date*] **and the next day** at [*location*]. The activities will last for a few hours on each day (2-3) and we will have discussions as a group, exchanging information and trying to identify potential solutions to overcome any identified challenges to accessing maternity services. The discussion will be kept confidential by the researchers, but no one will have to share any personal experiences or discuss sensitive topics. NIMR will also pay the travel costs (5000 TZS) to the activity location, once the activity is finished.

Would you like to participate in this activity?

If yes, arrange appointment details with the participant and record the details in the activity diary/log-book. Only recruit the participant if they are able to participate on BOTH days. If no, thank and finish invitation visit.

Appointment date:
Appointment time:
Appointment location:

Thank you! If you have any questions about the activity, you can contact [name of fieldworker] on [phone number].

_____ _____

Signature of Witness (Interviewer) Date

12.4.13 PLA participation sheet

Participant number	First name	Last name	Village	ATTENDED PLA (Y/N)	Agrees to be contacted again for interview (Y/N)	Interview date/time if applicable	Phone number (if acceptable to participant)
1							
2							
3							
4							
5							
6							
7							
8							
9							
10							
11							
12							

12.4.14 IDI invitation slip

Read the following outline of the study:

NIMR is carrying out a study about access to maternal health and prevention of mother-to-child transmission services in Kisesa. They would like to know the views of women and men about these services, so that they can understand the challenges that they face in accessing these services, and the challenges for relatives, partners and friends in trying to support women during their pregnancy. This study will be very important in helping to improve access to these services.

Social scientists from NIMR (of the same sex as the participant) will be conducting private interviews during the next few weeks. The interviews will last for approximately 1.5 hours and will be kept completely confidential. NIMR will also pay the travel costs to the interview location, when the interview is finished.

Would you like to participate in this study?

If yes, arrange appointment details with the participant and record the interview details in the interview log-sheet. Cut off the bottom half of this paper and give it to the participant. If no, thank and finish invitation visit.

Appointment date and time:

Appointment location:

Thank you! If you have any questions about the interview or need to re-arrange the date/time, you can contact Raymond Nsigaye on [phone number].

_____ _____

Signature of Witness Date

12.4.15 Example of informed consent sheet for IDIs

Informed Consent Information Sheet

(English version to be translated into Kiswahili or Sukuma)
Interviews with HIV-infected and HIV-negative women

(This information sheet and informed consent explanation is read out to all people participating in the in-depth interviews for the barriers to uptake of PMTCT study, with opportunities for them to ask questions and provide verbal consent or sign the appropriate part of the cover sheet).

Thank the participant for his/her time and introduce yourself.

Give participants a brief overview of the study:

- NIMR is carrying out a study about the ANC and PMTCT programme; in particular the barriers women might face, in accessing these services.
- NIMR can use this information to think of ways in which these barriers may be overcome, in order to improve the programmes and improve access to PMTCT services for HIV-infected pregnant women.
- It is important for us to hear about the different experiences, concerns, and suggestions of some women who have attended the Kisesa antenatal clinic (ANC), or been referred for/enrolled into the HIV care and treatment programme, as well as some women who did not use these services.
- Although we will do our best, we cannot guarantee that we will be able to cover all the needs that are identified by study participants.

If you have any questions about the information that I have given you, or about any aspect of the study, then please feel free to ask me and I'll try to clarify the information for you.

Do you have any questions?

If you have additional questions regarding the study after the discussion, you can speak with me or contact the VCT counsellors, or the fieldworker in your village that can then get in touch with [name of social scientists at NIMR] (Phone: xx).

This interview will take about 1 hour, and NIMR will compensate you for the travel costs to the interview location. It will be kept completely confidential within the study. Codes, for example "participant 3", will be used for identification so we will not record your name anywhere. All the professionals involved have been trained and are fully committed to keep this information confidential. We would, however, like to tape record this interview to help with our documentation. Only researchers at NIMR will hear this tape.

Do I have permission to record our conversation? *Turn on tape recorder if permission given*

(If permission to record is not given, skip the next paragraph, and instead read the attached "Consent Form" to the interviewee and sign it as a witness).

In this interview, I am going to ask you for some personal information about your experiences at the ANC and ART clinic, or your perceptions about these clinics and services if you have not used them. Some of the questions may bring up issues or emotions that are upsetting or difficult for you, but I will try to offer counselling and answer your questions throughout our conversation. You do not have to answer any questions that you do not want to, and you can ask to stop the interview at any time.

Have you understood the information that has been read to you? Do you have any questions about what I have explained?
Do you agree to continue with this interview?

Consent Form

(English version to be translated into Kiswahili or Sukuma)

(To be filled if permission to record the interview is not given and verbal consent is not obtained. Read this to the interviewee and sign it as a witness).

I would like to talk to you about your experiences of / perceptions about participating in the PMTCT programme.

This interview will take about 1 hour. Though I will be taking notes, all the information will be kept completely confidential. We will be using codes, for example "participant 3", to identify you, so your name will not be recorded anywhere. All the professionals involved in the project have been trained and are fully committed to keep information confidential.

In this interview, I am going to ask you for some personal information about your experiences at the ANC and CTC, or your perceptions about these clinics and services if you have not used them. Some of the questions may bring up issues or emotions that are upsetting or difficult for you, but I will try to offer counselling and answer your questions throughout our conversation.

You do not have to answer any questions that you do not want to, and you can ask to stop the interview at any time.

Have you understood the information that has been read to you? Yes ☐ No ☐

Do you have any question about what I have just explained?

Do you agree to participate in this interview? Yes ☐ No ☐

_____ _____

Signature of participant Date

_____ _____

Signature of Witness (Interviewer) Date

12.5 Parameters for the CTC algorithm

The CTC algorithm referred to in this thesis was based on ‘Version 1’ of the ‘VCT’ algorithm described in the following document

TAZAMA VCT Auto-Matcher

Introduction

1) This is a brief description of the stored procedure that implements the matching of the VCT data to the DSS data. There are two stored procedures that implement the matching, and they differ in the way that the individual component scores are computed and combined.
2) Unless stated otherwise, all tables and stored procedures mentioned in this document are located in the SQL Server database KisesaVCT.

Matching Algorithms

Input Data

1) For both versions of the algorithm the inputs are the same and are the VCT data, and the DSS data to which it is to be matched. The DSS data is taken from AbidanceTable, augmented by the Village, Sub Village, and Ten Cell Leader names from GeoUnitsTable. The following cases are excluded from the DSS input data:
    - The geography represented by the GeoUnitID is missing or invalid
    - The first name is missing
    - The second name is missing
    - The sex is missing or invalid
2) The VCT data is taken from three sources:
    - The table valued function [dbo].[tfn_VCTNumberV001_00] that contains encrypted VCT data;
    - the join of the tables [dbo].[VCTIdenifiers] and [dbo].[VCTLog];
    - the table [PostedData].[dbo].[VCTLOGFE_1_01]
3) Where sex is missing from the VCT data it is estimated by using the gender probabilities of the names found in the table [dbo].[NameSexProb], provided that the probability found in the table exceeds 0.85.
4)

Output Data

1) Data about the matches are stored in the output table VCT_PossibleMatches by version V1 of the algorithm, and in VCT_PossibleMatches_V3 by version V3 of the algorithm. Apart from the column SourceIdentifier that occurs in the version V3 output, both tables have the same structure, given in Table 1 below. The primary key of the table is indicated by underlining the names of the columns of the key.
2) The column labeled 'SourceIdentifier' is obtained by concatenating the following columns of the tables used to construct the input VCT data, and separating them by semi-colons ';':
    - A constant:
        - 1 if the input was from [dbo].[tfn_VCTNumberV001_00]
        - 2 if the input was from [dbo].[VCTIdenifiers] and [dbo].[VCTLog]
        - 3 if the input was from [PostedData].[dbo].[VCTLOGFE_1_01]

- The VCT number
- If the input was from [dbo].[VCTIdenifiers] and [dbo].[VCTLog]
    - The RID of the input row from [dbo].[VCTIdenifiers]
    - The RID of the input row from [dbo].[VCTLog]
- If the input was from [PostedData].[dbo].[VCTLOGFE_1_01], the VRID of the input row.

3) The scheme such as this has turned out to be necessary due to the appearance of duplicate VCT numbers in the input data, leading to insertion failures in the output tables VCT_ PossibleMatches and VCT_ PossibleMatches_V3 as these originally had (VCTNumber, AbidanceID, MatchRoutine) as a multi-column primary key.

Name	Type	Description
VCTNumber	Int	The VCT number of the person being matched.
AbidanceId	Int	The Abidance ID of the person against whom the match is being made.
TotalScore	Float	The total score for the match
FirstNameRawScore	Float	The raw score of the first name match
SecondNameRawScore	Float	The raw score of the matching of trhe second names
GenderRawScore	Float	The raw gender matching score
AgeRawScore	Float	The raw age matching score
VillageRawScore	Float	The raw village name matching score
SubVillageRawScore	Float	The raw subvillage name matching score
TenCellLeaderRawScore	Float	The raw ten cell leader matching score
FirstNameScore	Float	The final first name matching score
SecondNameScore	Float	The final second name matching score
GenderScore	Float	The final gender matching score
AgeScore	Float	The final age matchig score
VillageScore	Float	The final village name matching score
SubVillageScore	Float	The final sub village name matching score
TenCellLeaderScore	Float	The final ten cell leader name matching score
VCTFirstNameFreq	Float	The relative frequency of the first name in the VCT data
VCTLastNameFreq	Float	The relative frequency of the last name in the VCT data
VCTFullNameFreq	Float	The relative frequency of the full name (first name followed by last name) in the VCT data.
DSSFirstNameFreq	Float	The relative frequency of the first name in the DSS data
DSSLastNameFreq	Float	The relative frequency of the last name in the DSS

Name	Type	Description
		data
DSSFullNameFreq	Float	The relative frequency of the full name (first name followwed by last name) in the DSS data
MatchRoutine	Text	The name given to the parameter set that was used in the run of the algorithm
Verified	Int	Always zero. Used by other routines.
SourceIdentifier	Text	An identifier used to distinguish between input rows that have the same VCTNumber

Table 1: Output Table Columns

Method

1) The present implementation of the matching algorithm is based on the following variables taken from the VCT data (the *source*) variables: first name, second name, gender, year of birth, village name, subvillage name, and ten-cell leader name, and a similar set of variables taken from the DSS data (the *target*): first name, second name, gender, year of birth, village name, sub-village name, and ten-cell leader name. For each pair of variables, one from the source and the other being the corresponding variable from the target, a score is computed and these are then summed to give a total score for the pair of records. A match is declared if the total score exceeds a pre-set threshold, which is passed as an input parameter to the routine. When a match is declared information about the match is written to the output table.
2) In addition to the total score exceeding the threshold, constraints have been placed on some of the individual scores and these must also be satisfied before the source and target are declared to be matched.
3) The similarity Sim(Name1, Name2) between two names, Name1 and Name2 is given by the function

   1 – Levenstein(Name1, Name2)/Max(length(Name1), length(Name2))

   where:

   Levenstein(Name1, Name2) is the Levenstein distance between Name1 and Name2. The Levenstein distance between two words is the minimum number of single-character edits (insertion, deletion, substitution) required to change one word into the other

   This similarity function lies in the range 0 to 1 inclusive, is 0 if the names are totally dissimilar and 1 if the names are identical.

First Name Score

Raw Score

1) This is the similarity of the first name of the source and the first name of the target:

   Sim(VCT First Name, DSS First Name),

Final Score – Version 1

1) This is a cubic polynomial in the raw first name score, R:

$$(a_{13}*R^3+a_{12}*R^2+a_{11}*R+a_{10})*w_1$$

where a_{10}, a_{11}, a_{12}, a_{13} , and w_1 are constants whose values are given in the appendix.

Final Score – Version 3

1) This is given by the non-linear function:

$$\lfloor R/c_1 \rfloor *g_1+f_1$$

where R is the raw score, c_1 (the cutoff), g_1 (the gap), and f_1 (the offset) are constants whose values are given in the appendix.

2) The effect of the floor function, $\lfloor \ \rfloor$ is to turn the final score, as a function of the raw score R, into a series of discrete steps with a constant value between each step.

Second Name Score

Raw Score

1) This is the maximum of the similarities of the second name of the source and the first and second names of the target:

Max(Sim(VCT Second Name, DSS First Name), Sim(VCT Second Name, DSS Second Name))

2) The constraint on the second name score is that it must exceed 0.6

Final Score – Version 1

1) This is a cubic polynomial in the raw second name score, R:

$$(a_{23}*R^3+a_{22}*R^2+a_{21}*R+a_{20})*w_2$$

where a_{20}, a_{21}, a_{22}, a_{23} and w_2 are constants whose values are given in the appendix.

Final Score – Version 3

1) This is given by the non-linear function:

$$\lfloor R/c_2 \rfloor *g_2+f_2$$

where R is the raw score, c_2 (the cutoff), g_2 (the gap), and f_2 (the offset) are constants whose values are given in the appendix.

2) The effect of the floor function, $\lfloor \ \rfloor$ is to turn the final score, as a function of the raw score R, into a series of discrete steps with a constant value between each step.s

Gender Score

Raw Score – Version 1

1) This is given by the formula:
   - 5 if DSS Gender = VCT Gender
   - -5 otherwise.

Final Score – Version 1

1) This is simply the weighted value of the raw score:

   $R * w_{13}$

   where w_{13} is the gender weight whose value is given in the appendix.

Raw Score – Version 3

1) This is given by the formula:
   - 1 if DSS Gender = VCT Gender
   - 0 otherwise

Final Score – Version 3

1) This is given by the formula:
   - $5 * w_{23}$ if DSS Gender = VCT Gender
   - $-5 * w_{23}$ otherwise

   where w_{23} is the gender weight whose value is given in the appendix

Year of Birth Score

Raw Score

1) The year of birth raw score is given by the absolute value of the difference between the two ages:

   |VCT Year of Birth – DSS Year of Birth|

2) The constraint on Year of Birth is that the source and target must not differ by more than 10 years, i.e.

   |VCT Year of Birth – DSS Year of Birth| ≤ 10

Final Score – Version 1

1) This is given by the formula:

   $(-e^{R * b_{11}} + b_{12}) * b_{13}$

   where R is the Year of Birth raw score, and b_{11}, b_{12}, and b_{13} are constants whose

values are given in the appendix.

Final Score – Version 3

1) This is given by the formula:

$$(-R^{b_{21}} * b_{22} + b_{23}) * b_{24}$$

where R is the Year of Birth score, and b_{21}, b_{22}, b_{23}, and b_{24} are constants whose values are given in the appendix.

Village Score

Raw Score

1) The village raw score is the similarity between the VCT village name and the DSS village name:
   Sim(VCT Village Name, DSS Village Name).
2) There are no additional constraints on the village raw score.

Final Score – Version 1

1) This is simply the weighted village raw score
   $R * v_1$
   where R is the raw village score and v_1 (the village weight) is a constant whose value is given in the appendix.

Final Score – Version 3

1) This is given by the non-linear function:

$$\lfloor R/c_3 \rfloor * g_3 + f_3$$

where R is the village raw score, and c_3 (the cutoff), g_3 (the gap), and f_3 (the offset) are constants whose values are given in the appendix.

1) The effect of the floor function, $\lfloor \ \rfloor$ is to turn the final score, as a function of the village raw score R, into a series of discrete steps with a constant value between each step.

Subvillage Score

Raw Score

1) The subvillage raw score is the similarity between the VCT subvillage name and the DSS subvillage name:
   Sim(VCT Subvillage Name, DSS Subvillage Name).
2) There are no additional constraints on the subvillage raw score.

Final Score – Version 1

1) This is simply the weighted subvillage raw score

$$R * v_2$$

where R is the raw subvillage score and v_2 (the subvillage weight) is a constant whose value is given in the appendix.

Final Score – Version 3

1) This is given by the non-linear function:

$$\lfloor R/c_4 \rfloor * g_4 + f_4$$

where R is the subvillage raw score, and c_4 (the cutoff), g_4 (the gap), and f_4 (the offset) are constants whose values are given in the appendix.

2) The effect of the floor function, $\lfloor \rfloor$ is to turn the final score, as a function of the subvillage raw score R, into a series of discrete steps with a constant value between each step.

Ten-Cell Leader Score

Raw Score

1) The ten-cell leader raw score is the similarity between the VCT ten-cell leader name and the DSS ten-cell leader name:

   Sim(VCT Ten-cell Leader Name, DSS Ten-cell Leader Name).

2) There are no additional constraints on the ten-cell leader raw score.

Final Score – Version 1

1) This is simply the weighted ten-cell leader raw score

$$R * v_3$$

where R is the raw ten-cell leader score and v_3 (the ten-cell leader weight) is a constant whose value is given in the appendix.

Final Score – Version 3

1) This is simply the weighted ten-cell leader raw score

$$R * v_4$$

where R is the raw ten-cell leader score and v_4 (the ten-cell leader weight) is a constant whose value is given in the appendix.

Appendix

Values of the Constants

Version 1

	Parameter Name	Value	Notes
a_{10}	Name0Order1	-3	First Name Parameters
a_{11}	Name1Order1	-0.6	
a_{12}	Name2Order1	4.0	
a_{13}	Name3Order1	8.0	
w_1	FirstNameWt	3.217200725477540000E+119	
a_{20}	Name0Order2	-3	Second Name Parameters
a_{21}	Name0Order2	-0.6	
a_{22}	Name0Order2	4.0	
a_{23}	Name0Order2	8.0	
w_2	SecondNameWt	1.785129198009530000E+119	
w_{13}	GenderWt	2.11E+118	Gender Parameter
b_{11}	Age3rdExpondent	0.6	Year of Birth Parameter
b_{12}		1.28402541669000	
b_{13}	AgeWt	1.524010308350720000E+116	
v_1	VillageWt	0	Village Parameter
v_2	SubVillageWt	3.34E+119	Subvillage Parameter
v_3	TenCellLeaderWt	0	TenCell Parameter

Version 3

	Parameter Name	Value	Notes
c_1	NameCutOff1	0.6	First Name Parameters
g_1	NameGap1	100	
f_1	NameOffset1	40	
c_2	NameCutOff2	0.6	Second Name Parameters
g_2	NameGap2	60	
f_2	NameOffset2	10	
w_{23}	GenderWt	1	Gender Parameter
b_{21}	AgePower	5	Year of Birth Parameters
b_{22}	AgeCurve	0.1	
b_{23}	AgeOffset	250	
b_{24}	AgeWt	1	
c_3	VillageCutOff2	0.6	Village Parameters
g_3	VillageGap2	60	
f_3	VillageOffset2	15	
c_4	SubVillageCutOff2	0.6	Subvillage Parameters
g_4	SubVillageGap2	60	
f_4	SubVillageOffset2	15	
v_4	TenCellLeaderWt	0	TenCell Parameter

12.6 Systematic review policy brief

International HIV/AIDS Alliance

Together to end AIDS

Programmatic and policy brief

Addressing low uptake of antiretroviral drugs for prevention of mother-to-child transmission of HIV in sub-Saharan Africa

Key messages

- Provision of antiretroviral (ARV) drugs to HIV-infected mothers and their newborn babies is a critical component of prevention of mother-to-child transmission (PMTCT) of HIV, and is key to changing the trajectory of the HIV epidemic in sub-Saharan Africa.
- Uptake of ARV drugs for PMTCT remains unacceptably low in many countries across sub-Saharan Africa.

The main challenges faced by HIV-infected mothers and health care providers in accessing or delivering ARV drugs for PMTCT include:

- HIV stigma, which leads pregnant women to fear disclosing their HIV status to their partners and relatives. As a result, most women have limited partner and peer support to help them take ARV drugs appropriately
- inadequate numbers of health care providers and poor accessibility of HIV services
- the psychological impact of an HIV-positive diagnosis, which can delay or prevent uptake of services
- poor knowledge of HIV transmission and antiretroviral therapy (ART).

PMTCT programmes need to overcome these challenges through solutions that engage communities and by investments in strengthening health systems.

A mother at Kojja-Mukono Health Clinic, Uganda, where there is a PMTCT programme © Nell Freeman for the Alliance

Background

PMTCT programmes were introduced to sub-Saharan Africa over ten years ago with the aim of reducing new childhood HIV infections. PMTCT programmes comprise four different aspects that focus on:

1. preventing HIV infection among women of childbearing age;
2. preventing unintended pregnancies among women living with HIV;
3. preventing HIV transmission from infected mothers to their babies; and
4. lifelong care and treatment for these women and their families.

A key element of the third programme 'prong' is the provision of ARV drugs to the mother and child. This medical intervention can reduce the chance of HIV transmission from mother to child from 15–45% (in the absence of treatment) to less than 5%.

Global guidelines for PMTCT have evolved rapidly and now encourage initiation of ARV drugs for PMTCT earlier in pregnancy, including starting women on lifelong combination ART for their own health when diagnosed during pregnancy. However, over ten years on since the introduction of PMTCT programmes to the region, and despite international commitments to eliminate new infections in children, the numbers of women and infants accessing and using these lifesaving treatments within the context of PMTCT programmes remains well below target in most sub-Saharan African countries.

The purpose of this brief is to highlight key reasons for this poor access to, and low uptake and use of, ARV drugs for PMTCT, based on a systematic literature review, and to make recommendations for how these challenges can be overcome. The brief will be relevant to policymakers, programme planners, clinicians and research scientists working in the field of HIV and maternal and child health.

How the research was conducted

The research was a systematic review of published studies that looked at factors impeding or facilitating the use of ARV drugs for PMTCT. A total of 44 studies from sub-Saharan Africa were analysed, conducted between 2000 and 2012. Some of these studies incorporated the perspectives of mothers, other community members and health care providers on the main barriers to using ARVs in PMTCT.

Where the evidence comes from

Cameroon, Côte d'Ivoire, Ethiopia, Kenya, Lesotho, Malawi, Rwanda, South Africa, Tanzania, Uganda, Zambia, Zimbabwe

Serah has been living with HIV for many years and thought she could have no more children. When she learned about PMTCT she had her second son who she is breastfeeding exclusively. Nairobi, Kenya © Nell Freeman for the Alliance

The main findings from the research

Research showed that factors impeding or facilitating the uptake of ARV drugs for PMTCT exist at a number of levels: individual, family and community, and health systems (see Figure 1).

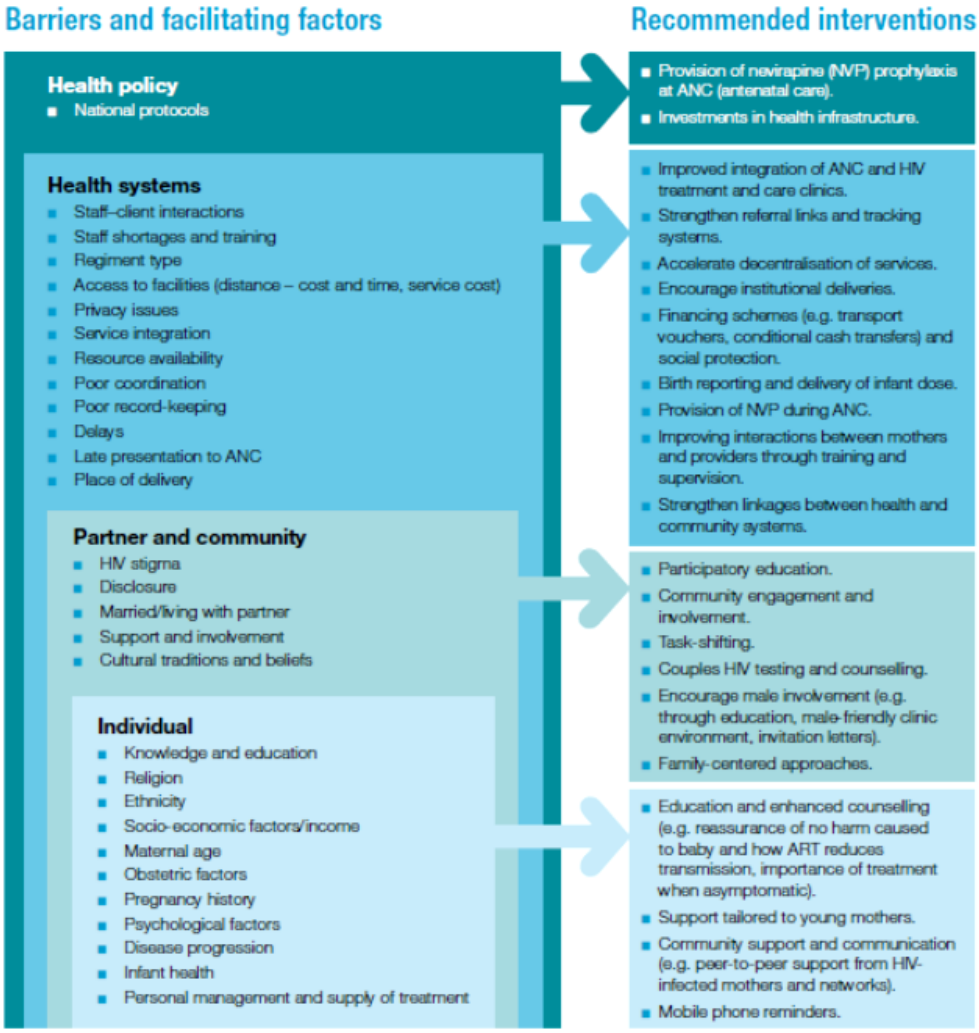
At the individual level, psychological difficulties following an HIV diagnosis, such as shock, denial of disease, depression, or fear of handling side effects and a lifelong commitment to treatment, were common among mothers and hindered uptake. Poor knowledge of HIV transmission and ART, together with a limited formal education, was also associated with low uptake among mothers. For example, women were sometimes sceptical about the effectiveness of ART for PMTCT, or believed the drugs could harm their unborn child. Lack of visible symptoms of HIV infection could also have contributed to poor uptake of treatment by pregnant women.

Family and community-level barriers most frequently identified in the review were stigma regarding HIV status and fear of status disclosure to partners and family members. These factors deterred women from attending HIV/PMTCT clinics to receive ARV drugs for themselves and their infants, or from starting or continuing to take the treatment prescribed. Lack of partner support was also a major hindrance, and women anticipated or experienced negative reactions from partners, including violence and separation after sharing their HIV test results. Although male partners were often invited for HIV testing, they frequently refused. However, some women did receive support from partners and others, and this was an important positive factor in improving uptake of PMTCT ARV drugs. Cultural traditions such as preferences for traditional healers and traditional birth attendants, especially among elders, were also common community-level factors limiting attendance at modern facilities and use of ARV drugs.

Basic health systems issues, including distance to health clinics and associated travel costs, and staffing issues, were also key barriers to attendance at antenatal and ART clinics, limiting the opportunity to receive ARV drugs. Service accessibility issues (alongside cultural traditions) also influenced the place of delivery for many women, with home births presenting a barrier to receiving maternal and infant ARV drugs. Delayed first antenatal care attendance was identified as a problem affecting timely access to ARV drugs during pregnancy. Staffing issues included a shortage of health care providers, particularly those with sufficient training, and poor behaviour among staff, including scolding or discriminating against HIV-positive clients. However, health care providers also assisted women in persevering with their treatment. Resource issues, such as stock-outs of ARV drugs or HIV test kits, were also reported in some settings, where they seriously impaired the functioning of the PMTCT programme. Poor referral links and tracking systems hampered linkage between antenatal and ART services, while better integration of these services was generally found to improve linkage.

In conclusion, basic health systems issues of staffing and service accessibility, together with community-level factors such as stigma and fear of disclosure to partners and others, emerged consistently over time and across different settings in sub-Saharan Africa. This suggests that little progress has been made in addressing these long-standing challenges.

Figure 1. Factors impeding or facilitating uptake of ARVs for prevention of mother-to-child transmission and recommended interventions at each level



What can be done to address these barriers

Based on our findings, a number of recommendations can help to overcome these barriers and improve the uptake of ARV drugs for PMTCT.

Recommendations

Recommendations for policymakers

- Further investment in health infrastructure and resources should be made, while continuing to accelerate service decentralisation, particularly to rural locations.
- Ensuring adequate stock and distribution of commodities, including HIV test kits and ARV drugs, is critical.
- Provision of enough sufficiently trained staff is essential. Regular formal training courses for staff and task-shifting should be considered where feasible.

Recommendations for community-based organisations implementing PMTCT programmes

Community-based organisations should design programmes that engage communities and implement solutions tailored to the setting, including:

- sensitisation and participatory education for community members, particularly mothers, men, elders and community leaders, to reduce stigma and improve disclosure and knowledge of HIV transmission and ART
- addressing preferences for traditional healers and birth attendants by promoting antenatal care and institutional and assisted delivery
- strategies to improve male participation in PMTCT programmes, including couple counselling when desired by women; for example, invitation letters to male partners or 'male-friendly' clinics with flexible opening times
- involving other family members in PMTCT services, particularly for single women or women who do not wish to involve their partner but want extra support
- improving counselling and support to women living with HIV and their partners, other family members and peers. Counselling messages should include reassurance that ARV drugs will not harm the baby, and simple explanations of how the drugs work to reduce transmission of the virus, as well as reinforcing the importance of continuing to take medication even if physical symptoms decrease. Careful distribution of any printed educational information is needed to ensure confidentiality is not breached
- providing transport services by members of the community, transport and service vouchers, and conditional cash transfers to overcome financial barriers and access issues.

Recommendations for PMTCT programmes in health facilities

- Clinicians or other health care providers in charge of health facilities should set up structures for supervising and mentoring staff, provide on-job training and toolkits, and establish procedures for improving performance and staff–client interaction.
- The physical layout of services within clinics should be optimised to ensure privacy for clients.
- Improving integration of services, referrals and linkage to other support, together with systems for tracking patients, can help linkage between antenatal and HIV care and treatment services.

Recommendations for researchers

- Further research is needed on barriers to PMTCT ARV use in key, and as yet unreached, vulnerable populations such as sex workers.
- Rigorous implementation/evaluation of research is needed on how to optimise men's involvement in PMTCT programmes, including from the perspective of men themselves.

Amon Banda and his daughter Taonga at the Bwafwano Community Community Care Association clinic, Zambia. His wife Mwenzi has had two children at the clinic within the PMTCT programme © The Alliance

> I went with Mwenzi to the clinic, I always go. I want to know and care that my child will be born safely.
>
> ***Amon Banda, Zambia***

www.aidsalliance.org

About the International HIV/AIDS Alliance

We are an innovative alliance of nationally-based, independent, civil society organisations united by our vision of a world without AIDS.

We are committed to joint action, working with communities through local, national and global action on HIV, health and human rights.

Our actions are guided by our values: the lives of all human beings are of equal value, and everyone has the right to access the HIV information and services they need for a healthy life.

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Reference and full article: Barriers and facilitating factors to the uptake of antiretroviral drugs for prevention of mother-to-child transmission of HIV in sub-Saharan Africa: a systematic review. *J Int AIDS Soc.* 2013 Jul 19;16(1):18588. doi: 10.7448/IAS.16.1.18588. Review.

12.7 Evidence of retention of copyright

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