The prevention of mother-to-child transmission of HIV programme in Eastern Uganda

Men's involvement in a changing HIV testing policy context

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To all the women and men who participated in the various studies contained in this thesis.

CONTRIBUTORS

LIST OF ORIGINAL PAPERS

This thesis is based on the following papers, which will be referred to in the text by the respective Roman numerals.

Paper I **Byamugisha R**, Tylleskär T, Kagawa MN, Onyango S, Karamagi CAS, Tumwine JK. Dramatic and sustained increase in HIV testing rates among antenatal attendees in Eastern Uganda after policy change from voluntary counselling and testing to routine counselling and testing for HIV: a retrospective analysis of hospital records, 2002-2009.
BMC Health Services Research 2010;**10**:290.

Paper II **Byamugisha R**, Tumwine JK, Ndeezi G, Karamagi CAS, Tylleskär T. Attitudes to HIV counselling and testing, and knowledge about prevention of mother to child transmission of HIV in eastern Uganda: a cross-sectional survey among antenatal attendees.
Journal of International AIDS Society 2010;**13**:52. *(Highly accessed)*

Paper III **Byamugisha R**, Tumwine JK, Semiyaga N, Tylleskär T. Determinants of male involvement in the prevention of mother-to-child transmission of HIV programme in Eastern Uganda: a cross-sectional survey.
Reproductive Health 2010;**7**:12. *(Highly accessed)*

Paper IV **Byamugisha R**, Åstrøm AN, Ndeezi G, Karamagi CAS, Tylleskär T, Tumwine JK. Male partner antenatal attendance and HIV testing in eastern Uganda: a randomized facility-based intervention trial.
Journal of International AIDS Society 2011;**14**:43. *(Highly accessed)*

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LIST OF ABBREVIATIONS

AIDS	Acquired immune deficiency syndrome
ANC	Antenatal care
ARV(s)	Antiretroviral drug(s)
CCR5	C-C chemokine receptor type 5
CDC	Centers for Disease Control and Prevention, USA
CRF	Case record form
CI	Confidence interval
CXCR4	C-X-C chemokine receptor type 4
DHO	District health officer
DNA	Deoxyribonucleic acid
FP	Family planning
GA	Gestational age
HC	Health centre
HIV	Human immunodeficiency virus
HSD	Health sub-district
HTLV-III	Human T-lymphotropic virus type III
IPT	Intermittent presumptive treatment of malaria (during pregnancy)
ITN	Insecticide-treated bed net
LAV	Lymphadenopathy-associated virus
MoLG	Ministry of Local Government
MTCT	Mother to child transmission of HIV
NRH	National referral hospital
PHP	Private health practitioner
PIH	Pregnancy induced hypertension
PITC	Provider-initiated testing and counselling
PMTCT	Prevention of mother to child transmission of HIV
PNFP	Private not-for-profit organisation
RNA	Ribonucleic acid
RRH	Regional referral hospital
TT	Tetanus Toxoid
TCMP	Traditional and complementary medicine practitioner
UNAIDS	Joint United Nations Programme on HIV/AIDS
VCT	Voluntary counselling and testing
VHT	Village health team
WHO	World Health Organisation

SUMMARY

Introduction: The prevention of mother-to-child transmission of HIV-1 (PMTCT) was launched in Uganda in early 2000 and in Mbale Regional Referral Hospital in Eastern Uganda in 2002. The initial challenges were the low antenatal HIV testing rates and low male partner involvement. The aim of this thesis was to explore determinants of women's and men's participation in the PMTCT programme in Eastern Uganda and find ways to improve male involvement.

Methods: The thesis contains four studies: (a) a retrospective analysis of routine data from hospital records on 54 429 new antenatal attendees and 469 male partners over a 7-year period; (b) a cross-sectional survey conducted in 2009 among 388 new antenatal attendees, who were tested for HIV; (c) a cross-sectional survey conducted in 2004 among 388 male partners of pregnant women attending antenatal care at Mbale hospital, and in addition, 5 key informant interviews and 8 focus group discussions; and (d) a double blind, randomized intervention trial to increase male participation using an invitation letter to the male partner as the intervention and an information leaflet to the partner as the control, conducted in 2009-10 among 1060 new antenatal attendees (530 in each arm) in the antenatal clinic at Mbale Hospital, with a follow-up period of four weeks. Descriptive statistics and logistic regression analyses were used to assess the study outcomes, content-thematic analysis of the qualitative data was done and intention to treat analysis was conducted to assess the primary outcome of the trial.

Results: There was a significant increase in HIV testing rates among the new antenatal attendees from 22% during the period of voluntary counselling and testing for HIV to 88% following the change in HIV testing policy to provider-initiated HIV testing and counselling (PITC). Our survey showed that PITC was highly acceptable to the pregnant women, increasing testing rates considerably and decreasing stigma. However, male partners HIV testing rates remained low. Our survey among male partners indicated that determinants of male partner participation in the PMTCT programme included social, cultural, and health system factors, and that the men had never been invited to the antenatal clinic. A simple and cheap intervention, such as a letter to the male partner, increased couple antenatal clinic attendance by 10 percentage points and the large majority of men attending the antenatal clinic accepted HIV testing. However, the two study arms had a similar effect.

Conclusions: PITC remarkably increased the HIV testing rates among the antenatal attendees and was highly acceptable to them and can therefore be actively promoted in antenatal clinics and possibly other clinical settings. Although cheap and underutilised, the use of an invitation letter addressed to the male partners of the ANC attendees increased male antenatal attendance and HIV testing. It should be promoted in antenatal clinics in Eastern Uganda where it has been shown to work and tried in other areas with low male antenatal attendance, both in Uganda and beyond.

1.0 INTRODUCTION

1.1 Background

The prevention of mother-to-child transmission (PMTCT) of HIV programme was launched in Mbale Regional Referral Hospital in May 2002. I was appointed by the hospital administration as the first coordinator of the programme to oversee its implementation within in the antenatal clinics at the hospital. One of my duties as a coordinator was to write monthly and quarterly reports about the programme, copies of which I forwarded to the Programme Manager of the PMTCT programme in the Ministry of Health headquarters, Kampala and the District Health Officer (DHO), Mbale. Anecdotal evidence showed that one of the challenges to implementation of the programme was the low male partner involvement. For example, some of the pregnant women who declined to test for HIV in the antenatal clinic reported that they needed to first seek for permission from their male partners, yet only few were accompanied by their spouses for antenatal care (ANC). This motivated me to conduct the studies on which this thesis is based. In the subsequent sections of the introduction, I present a brief history of HIV/AIDS and virological description; describe the HIV/AIDS situation (global and local) and the health system in Uganda; review literature on PMTCT and male involvement.

1.2 Brief history of HIV and AIDS

Acquired immunodeficiency syndrome (AIDS) cases were first reported in specific human populations in June 1981 in USA [1, 2] and the term AIDS was coined formally by Centers for Disease Control and Prevention (CDC) in 1982 [2, 3]. However, the causative agent for AIDS was discovered to be a retrovirus by researchers in France (referred to as lymphadenopathy-associated virus, LAV) in 1983 and in USA (known as human T-lymphotropic virus type III, HTLV-III) in 1984 respectively [4-6]. The retrovirus was accepted by the scientific community as the cause of AIDS in 1984 [7] and later renamed human immunodeficiency virus (HIV) by the International Committee on Taxonomy of viruses in 1986 [8, 9]. By 1985, AIDS cases had been reported from regions in Europe, Africa, South America, Asia

and Australia [10-15]. In addition, it was known that most of the HIV infections were acquired by sexual transmission, use of contaminated sharp instruments (e.g. needles), transfusion with infected blood or blood products and as a result mother-to-child transmission [10, 12, 15-18]. In Uganda, the first cases of AIDS (locally known as 'slim disease' due to extreme wasting and weight loss) were reported in 1982 in a small village on the shores of Lake Victoria in Rakai district, just north of the Tanzania border [19].

1.3 Brief virological description of HIV – structure, replication cycle and clinical progression

There are two known types of HIV: HIV-1 and HIV-2. HIV is transmitted through sexual intercourse, blood contact (transfusion or contaminated sharp objects) and from the mother to child (during pregnancy, delivery and breastfeeding period). HIV-1 is the predominant virus worldwide. HIV-2 is relatively uncommon, is concentrated in West Africa and seems to be less easily transmitted than HIV-1 [20, 21]; for instance it is almost never transmitted from the mother to the child [22, 23]. HIV-1 is related to simian immunodeficiency viruses (SIV) found in non-human primates (chimpanzees and gorillas) and HIV-2 is related to viruses found in monkeys (sooty mangabeys) [24, 25]. HIV-1 strains are of 4 groups: M (major or main), O (outlier), N (non-M and non-O) and P [26]. The M group accounts for most (over 90 %) of HIV-1 infections worldwide and is divided into at least 9 genetically distinct subtypes (or clades): A, B, C, D, G, F, H, J and K [27]. About 48 circulating recombinant forms (CRFs) between the subtypes have been described [28]; and subtype C accounts for about half (48%) of all HIV infections worldwide. The HIV-I subtypes found in sub-Saharan Africa are mainly A, C and D [28]. However in Uganda, the predominant subtypes are A and D [29-31], and compared with subtype A, subtype D is associated with more rapid disease progression [28, 32-35].

The HIV particle (virion) is about 0.4 microns in diameter, spherical in shape and its structure (figure 1) consists of:

(a) an outer viral envelope or membrane from which project some small spikes, formed from the proteins gp120 (cap) and gp41 (stem)

(b) a matrix made from protein p17

(c) a capsid (bullet-shaped viral core) made up of protein p24. Inside the capsid are: (i) two identical RNA strands (each of which has a complete copy of the virus's genes), and (ii) three enzymes (reverse transcriptase, integrase and protease) – required for HIV replication.

HIV has only nine genes; three of them (gag, pol and env) contain information needed to make structural proteins for new viral particles; the other six genes (nef, rev, tat, vif, vpr and vpu in HIV-1 or vpx in HIV-2) code for proteins which control the ability of HIV to infect a cell, replicate or cause disease.

Figure 1: Structure of HIV virion
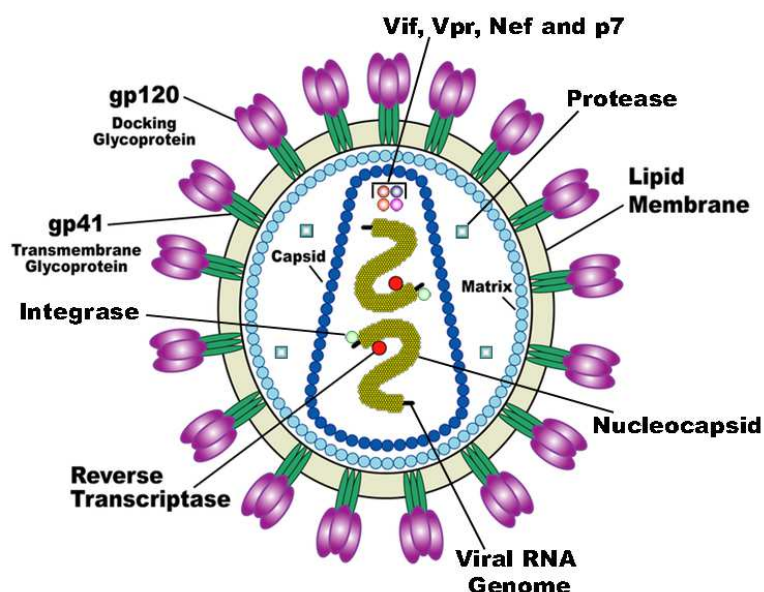Source: Adapted from: US National Institute of Health:
http://web.archive.org/web/20041119131214/http://www.niaid.nih.gov/factsheets/graphics/howhiv.jpg and http://upload.wikimedia.org/wikipedia/commons/6/63/HIV_Virion-en.png

The HIV-1 replication process begins when the virus particle gets into contact with a host cell that expresses CD4 (a glycoprotein on the surface of CD4[+] T-lymphocytes,

monocytes and dendritic cells). The spikes (gp120) on the viral envelope stick to CD4 and a co-receptor (chemokine receptor type 5 - CCR5 or chemokine receptor type 4 - CXCR4), and allow the viral envelope to fuse with the host cell membrane, and the contents of the HIV particle are released into the cell, leaving the envelope behind. Then the reverse transcriptase enzyme converts viral RNA (ribonucleic acid) into DNA (deoxyribonucleic acid) and this is transported into the cell's nucleus where it is integrated into human DNA by the integrase enzyme to form a provirus. The HIV provirus in the cell can remain dormant for a long time. Once the cell is activated, the provirus is converted into messenger RNA using human enzymes, transported outside the nucleus and acts as a blueprint for producing new HIV proteins and enzymes to form new viral particles. These immature viral particles are released from the cell and the protease enzyme chops up long strands of protein to form mature viral cores. The mature viral particles are capable of infecting a new cell and begin the process of replication all over again. HIV replicates only inside human cells.

When HIV enters the body, it infects and destroys a large number of $CD4^+$ T-lymphocytes, and replicates rapidly (figure 2). The CD4+ T-lymphocytes (helper T cells) are white blood cells vital for maintaining the function of the immune system in humans. The viral load (number of HIV copies) in the blood raises to a high level and the virus rapidly spreads throughout the body, seeding many organs, especially lymphoid organs (thymus, spleen, and lymph nodes) and gut-associated lymphoid tissues [36]. Because of the high viral load, the HIV infected individual is very infectious and the risk of HIV transmission is very high [37-39]. These high levels of the infectious virus in the blood persist for about 10-12 weeks [40]. During this acute phase of HIV infection, there is irreversible destruction of the reservoirs of the T helper cells. In addition, the virus may integrate in the resting T cells' genetic material and remain dormant for a long time. In this acute phase of HIV infection, about 50-70% of HIV infected people manifest flu-like symptoms. The more severe and numerous the symptoms are, the higher the likelihood of faster HIV disease progression [41, 42].

Consequently, the HIV levels in the blood are significantly reduced to a steady-state level (set point) and the CD^+ T cell counts, and for some people, the number of CD^+ T cells rises to the original levels [43]. If untreated, the HIV infection usually leads to a progressive decline in the CD4 cell count in the blood over a period of several years, leading to generalized failure of the immune system. The patients become more prone to life threatening opportunistic infections and are diagnosed with AIDS when the $CD4^+$ T cell count drops below 200 cells per cubic millimetre. Treatment of HIV infected patients with antiretroviral drugs suppresses HIV replication and often the viral load in the blood is reduced to undetectable levels (< 50 viral copies per ml of plasma using current assays) [44]. Consequently, the CD4 counts may be restored to healthier levels by the patients' homeostatic mechanisms. HIV infected persons can pass on the virus to others in their bodily fluids.
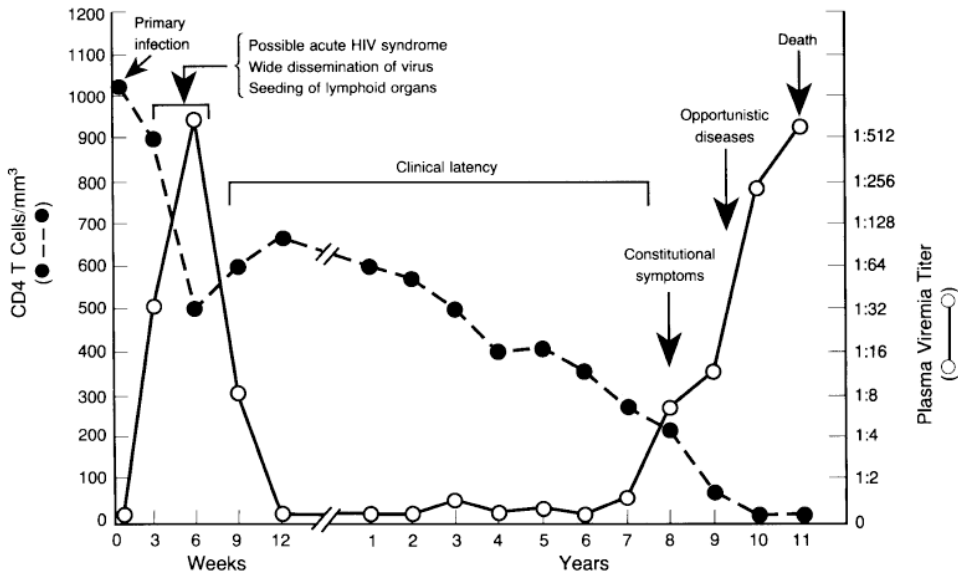
Figure 2: Typical Course of HIV-1 Infection. (Source: Pantaleo et al 1993) [45]

In the Ugandan population, the normal $CD4^+$ T cell count in adults is about 500-1450 $CD4^+$ T cells per cubic millimetre [46, 47]. Together with the viral load, the $CD4^+$ cell count is a surrogate marker of HIV disease progression. It is used to predict the time to initiate and monitor the effectiveness of antiretroviral therapy (ART) in HIV positive

patients [48-50]. The CD4$^+$ count and the viral load tests are not readily available in limited resource settings due to their high costs [51].

1.4 The global burden of HIV

Globally, the size of the HIV epidemic appears to have stabilized and the number of new HIV infections has been declining since the late 1990s with the scale up of antiretroviral therapy [52]. A recent UNAIDS (Joint United Nations Programme on HIV/AIDS) report showed that the HIV incidence has fallen in 33 countries world-wide, 22 of them in the sub-Saharan region [53]. However, sub-Saharan Africa still bears the brunt of the global HIV disease burden. In 2010, sub-Saharan Africa, a region with about 12% of the global population, accounted for about 70% of all new HIV infections and about 68% of all people living with HIV [53]. In sub-Saharan Africa, women of reproductive age (15-49 years) represent about 59% of the people living with HIV [53]. While paediatric HIV has been virtually eliminated in high-income countries through effective prevention of mother to child HIV transmission (PMTCT) interventions [54, 55], it remains of public health concern in low-income and middle-income countries [52, 56]. For example, an estimated 1000 children (under 15 years of age) contract HIV infection daily worldwide. Most of these children (over 90%) acquire it through mother to child transmission (MTCT) and more than 90% of this MTCT of HIV occurs in sub-Saharan Africa [52], largely because of the low coverage with PMTCT interventions. Worldwide, an estimated 2 million children are living with HIV-1 infection [52].

WHO/UNAIDS classify HIV epidemics into 4 types based on HIV prevalence and major mode of transmission : (1) low-level epidemic where HIV prevalence has not exceeded 5% in any defined sub-population, (2) concentrated epidemic where the HIV prevalence is above 5% in at least one defined sub-population but is below 1% in pregnant women, (3) generalized epidemic where the HIV prevalence is 1-15% in pregnant women, and (4) hyper-endemic epidemic where the HIV prevalence exceeds 15% in the adult population [57].

1.5 HIV situation in Uganda

The HIV epidemic in Uganda is mature and generalized [58], with heterosexual contact as the main mode of transmission, and it is still a major public health problem. The overall national adult (15-49 years) HIV prevalence rate was 7.3% in 2011 and 0.6% in children [59, 60]. There are about 1.2 million people living with HIV-1 (PLWH) in Uganda and about 150,000 of them are children [52]. Annually, approximately 120,000 new HIV infections occur countrywide; about 76% are acquired through sexual transmission while MTCT contributes about 22% [60, 61]. Uganda's HIV epidemic has evolved over time since the first reports of AIDS cases in 1982. According to reports from the Ministry of Health, the national HIV prevalence rate among antenatal attendees peaked in the early1990s and dropped from 18 % (25-30% in some urban antenatal care sites) to about 6% (14% in urban sites) in 2002, and it has since stabilised between 6.4 and 7.3%, figure 3 [58, 60, 62-64].

Trends in HIV Prevalence among Women and Men age 15-49, Uganda

■ 2004-05 UAIS ■ 2011 UAIS

	Total 15-49	Women 15-49	Men 15-49
2004-05 UAIS	6.4	7.5	5.0
2011 UAIS	7.3	8.3	6.1
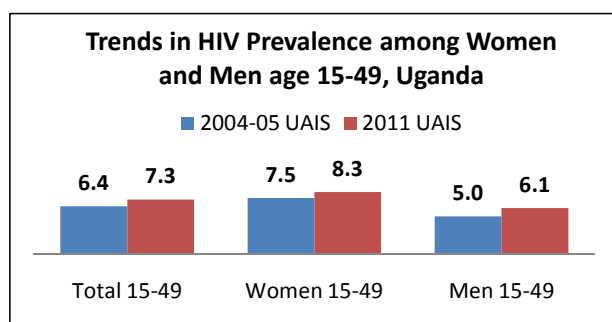
Figure 3: HIV prevalence among Ugandan adults aged 15-49 years.
Source: Uganda Ministry of health press release – key results of the 2011 Uganda AIDS indicator survey [65].
http://www.tasouganda.org/attachments/292_UAIS%20Press%20Release%20-%20jUNE%202012-2.doc

The HIV prevalence decline has been debated. One contributing element was the high mortality of the AIDS victims. The local history in Uganda also emphasises the early public mobilisation by Uganda's AIDS control programme that led to positive changes in sexual behaviour and contributed to the decline in HIV prevalence [66-70].

However, with the availability of some free antiretroviral drugs (ARVs), there appears to have been a shift towards more risky sexual behaviours [71].

A recent study of modes of HIV transmission (MoT) revealed that 43% of all the new HIV infections in Uganda occurred in discordant sequentially monogamous couples and 46% are among people reporting multiple partnerships. In addition, there has been a shift in the concentration of HIV epidemic from younger to older people with highest HIV prevalence for men being among the 40-44 years age group and for women it is highest among the 35-39 age group, figure 4 [58, 59, 61].
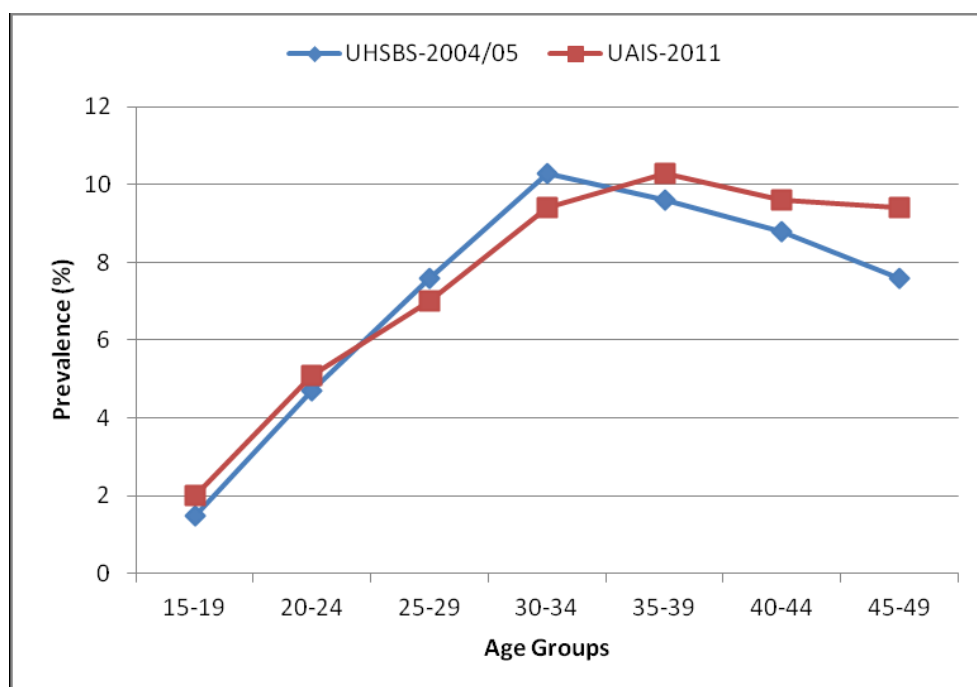
Figure 4: HIV prevalence in Uganda by age groups, 2004-2011 [60].

A recent report from the Ministry of Health documents that overall, the HIV prevalence is generally higher among women (8.3 %) than men (6.1%). In addition, for both sexes, the prevalence is lowest among those aged 15-19 years [72, 60]. The HIV discordance among couples is high (ranges from 30 to 50%) [73-75]. The prevalence of HIV infections also varies by marital status. It is lowest

among those who have never married and highest among those who are widowed or divorced/ separated [72].

UGANDA
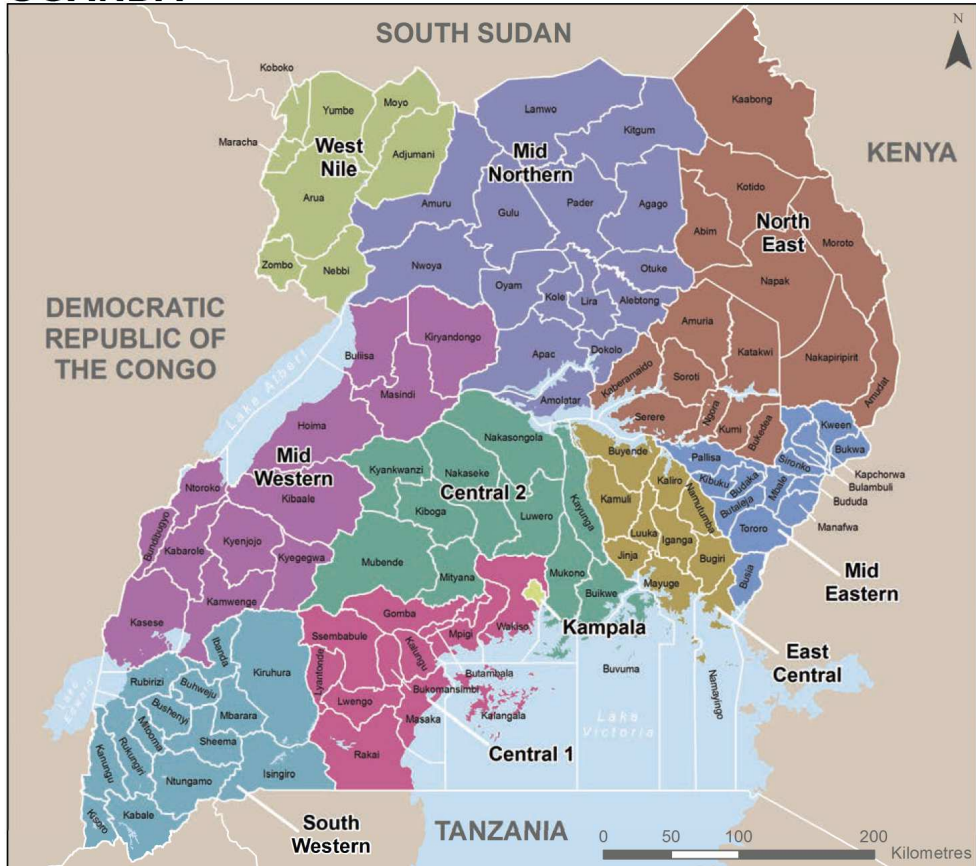
Figure 5: Uganda with the regions and districts (2011).
Source: Uganda AIDS indicator survey 2011 - final report [72]

Available evidence indicates that HIV prevalence rates in Uganda also vary by region, place of residence and socio-economic status [72, 60]. In the nine regions of Uganda (figure 5), the HIV prevalence is highest in the central I region (10.6%) and lowest in mid-eastern region (4.1%). Over the past 6 years, there has been a slight decrease in the number of people living with HIV on only three regions of Uganda, namely Kampala, East Central and Mid Eastern (figure 6). Overall, women have a higher HIV-1 prevalence than men in all regions of Uganda. The HIV prevalence is higher among people who reside in urban areas than those in rural areas

in Uganda. This urban-rural difference is much stronger for women than for men [58, 59].
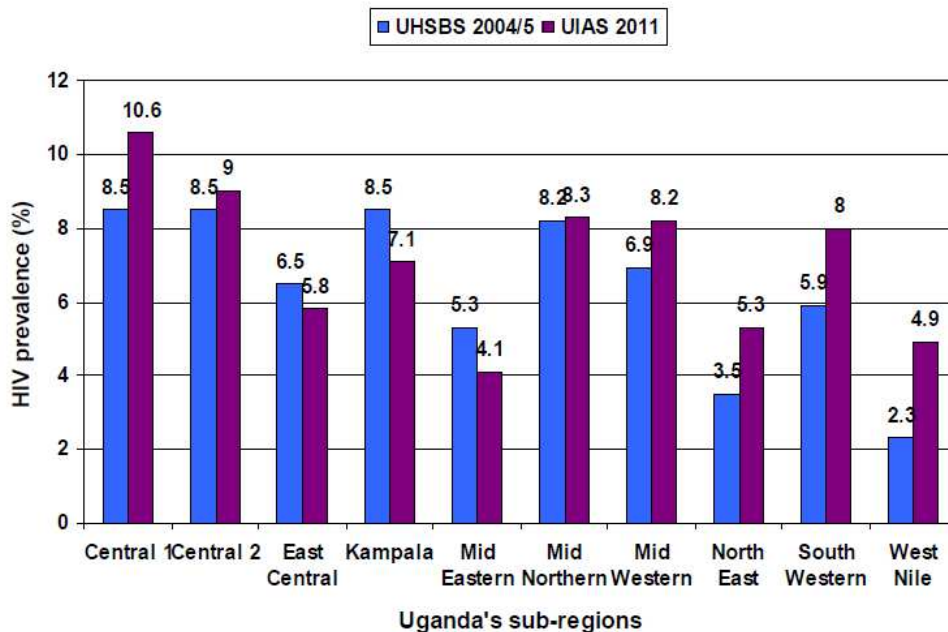
Figure 6: HIV prevalence among age groups 15-49 years by Uganda's sub-regions. From: (a) Moving towards universal access: National HIV and AIDS strategic plan 2007/2008 to 2011/2012, (b) Ministry of Health final report of results of the 2011 Uganda AIDS Indicator Survey [72, 76].

Findings from the 2006 Uganda Demographic and Health Survey showed that wealth and poverty can increase HIV risk and vulnerability independently [77]. The HIV prevalence is higher among those gainfully employed than those who are not and there is a gradual increase in the HIV disease burden with the wealth quintile [61]. According to the recent Uganda AIDS indicator survey report, the HIV prevalence among adults in the lowest wealth quintile is below the national average. However, HIV infection rates among those in the fourth and fifth quintiles are above the national prevalence level [59, 60].

Empirical evidence from Uganda shows that the higher the education level a person has, the lower the risk of being HIV positive [59, 78]. For example, a recent study among six universities in Uganda revealed that the overall HIV prevalence among the

university students is 1.2%, a figure much lower than the average national HIV prevalence of 6.7% among adults [79]. A recent report from the Uganda AIDS Commission indicates that the HIV prevalence is highest among the "most-at-risks populations"; these include female sex workers (FSW) and their partners, motorcycle taxi drivers (commonly known as "boda-boda" riders), workers in large commercial plantations, the fishing communities and men having sex with men (MSM) [60].

Compared to the overall HIV prevalence of 8.3% in Ugandan women [72], the prevalence among FSW in Kampala was higher at 37%, though it increased with age from 29% in those aged 25 years or less to 48% among those aged 35 years or more [80]. Findings from Hladik's study among MSM have revealed an HIV prevalence of 13.7% which is higher than overall prevalence rate of 5.6% in Ugandan men in general [59, 81]. A recent publication reported a high prevalence of HIV among Uganda's fishing community of 29% though it was higher in women (34%) than men (24%) [82]. The factors driving the HIV epidemic in Uganda are summarised in table 1.

Table 1: Factors driving the HIV epidemic in Uganda.

Risk factors for HIV transmission	Contextual factors of the HIV epidemic
- Multiple partners - Discordance and non-disclosure - Lack of condom use - Transactional sex - Cross-generational sex - Presence of sexual transmitted diseases (STIs) especially HSV-2 - Intact foreskin - Alcohol and illicit drug use - Behavioural disinhibition due to antiretroviral therapy (ART)	- Socio-cultural factors - Wealth and poverty - Low status of women and girls - Human rights, stigma and discrimination - Inequity and access to prevention, care and treatment

Source: Uganda modes of HIV transmission study [58].

1.6 Health system in Uganda

The Ministry of Health provides leadership for the health sector and some of its functions include: policy formulation and policy dialogue with development partners,

setting standards and quality assurance, capacity development and technical support supervision, monitoring and evaluation of the overall health sector performance, and soliciting funding and budgeting. However, the health services are provided by both the public and private sectors, each contributing about 50% to health care delivery. The private sector includes: (a) private not for profit organisations (PNFPs) and these are mainly faith-based, (b) private health practitioners (PHPs), and (c) the traditional and complementary medicine practitioners (TCMPs) [83, 84].

The national health system consists of: (a) the district health system (communities, village health teams (VHTs), health centres (HCs) II, III and IV, and general hospitals) and (b) regional and national referral hospitals (figure 7). Currently, there are 13 regional referral hospitals (RRHs) and 2 national referral hospitals (NRHs), namely Butabika hospital for psychiatric care and Mulago hospital for general care, both situated in the capital, Kampala city [85]. The national referral hospitals are the highest level of the health system pyramid. The RRHs and NRHs are semi-autonomous and are answerable to the Ministry of Health headquarters. Currently, there are about 143 hospitals in Uganda (66 public hospitals, 61 PNFP and 16 PHP hospitals [85]. Ideally, all hospitals are supposed to provide technical back up for referral and support functions to lower level health facilities [83]. The village health teams, sometimes referred to as health centre I (HC I), are the lowest level of the health system and work as a link between the community and the health facilities; there is no physical infrastructure at this level. The district health system is further sub-divided into health sub-districts (HSDs), with the referral facility of each HSD being either a HC IV or general hospital [84]. The districts health services are managed by the Ministry of Local Government (MoLG) through the local district governments.

The health services offered at each level of the health system are summarised in table 2. Many (about 70%) households in Uganda live within 5 kilometres of a health facility; however, utilization of the facilities is limited due to poor infrastructure, inadequate supply of medicines and other materials with frequent stock-outs, and

shortage and low motivation of the health personnel [84]. The referral system from lower to higher levels of the health system is poor and it is common for patients to present to regional or national referral hospitals for treatment without any referral from lower level health facilities.
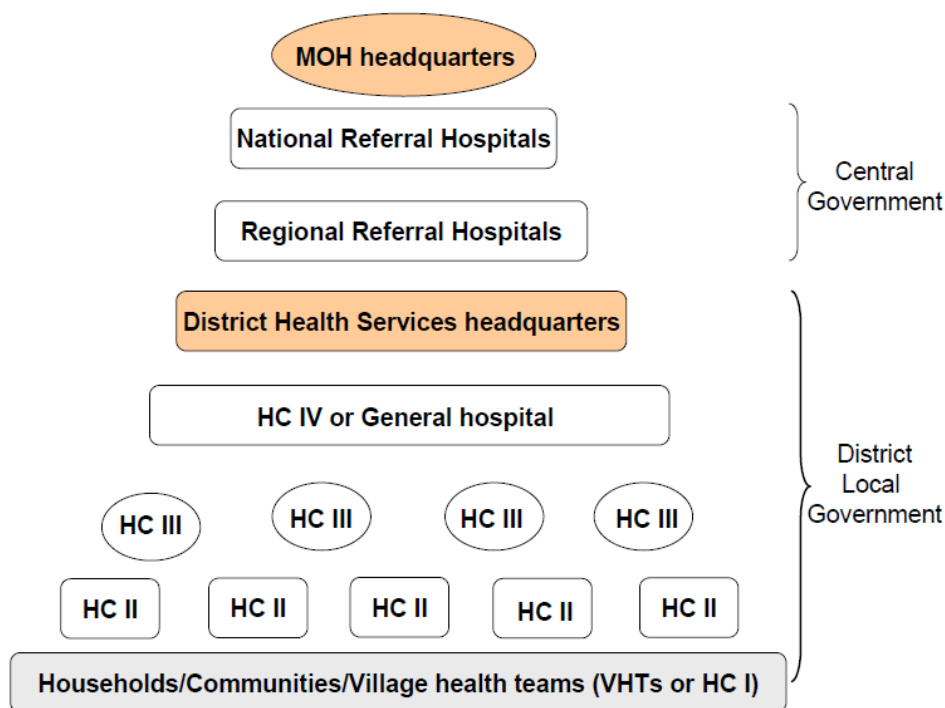
Figure 7: The Uganda national health system.
(Source: Health Strategic Plan II, 2005/6-2009/10, MOH; 2005) [86]

1.7 Antenatal care

Antenatal care (ANC) is the care given to a pregnant woman by a skilled health provider between conception and onset of labour. A skilled provider is a trained health professional that is proficient in skills required: (a) to manage a normal (uncomplicated) pregnancy, childbirth and immediate postnatal period, and (b) to identify and manage and refer complications in a woman and newborn [87, 88]. Therefore, a skilled provider includes: a nurse/midwife, medical assistant/clinical officer and a doctor. The aim of ANC is to improve pregnancy outcome, and to ensure the health of the mother and the foetus. It involves: (1) monitoring the health status of the mother and the foetus,

Table 2: Health services offered at each level of the health system in Uganda

Type of health facility	Location	Standard population per facility	Current population served	Services provided per health facility level
Health centre (HC) I	Village level	1 000		• Community mobilization for health interventions such immunization, malaria control, sanitation. • Health education, promoting health seeking behaviour • Community-based management of common childhood illnesses including malaria, diarrhoea, pneumonia • Referral
HC II	Parish	5 000	15 000	• Outpatient care, antenatal care, immunization and outreach services.
HC III	Sub-county	20 000	90 000	• All services provided at HC II, maternity care, general ward, laboratory services. • First referrals cover for the sub-county, support supervision for HC II and community.
HC IV	County	100 000	190 000	• All services provided at HC III, wards, theatre (surgical and obstetrical emergency care), blood transfusion. • Second level referral services for the health sub-district (HSD)
General Hospital	District	500 000	260 000	All services provided at HC IV; more wards, more life-saving medical, surgical and obstetric emergency care X-ray services Second level referral services for HSD
Regional Referral Hospital	Regional level	3 Million	2.3 Million	• All services provided at general hospital • Specialist services such psychiatry, ear, nose and throat (ENT), radiology and ultrasonography, pathology, orthopaedics, ophthalmology, higher level surgical, medical and obstetric/gynaecological, and paediatric services • Teaching and research • Tertiary level referral services
National Referral Hospital	National level (capital city)	10 million	33 million	• Comprehensive specialist services and care • Teaching and research, in addition to services provided by general and referral hospitals • Tertiary level referral services

Adapted from: Health Sector Strategic and Investment Plan (HSSIP) 2010-2015 (MOH 2010); The second National Health Policy (NHP II) (MOH 2010); 2011 Statistical Abstract (UBOS 2011) [84, 89, 90]

(2) providing the appropriate medical and psychosocial interventions and support, and (3) health promotion and helping the woman make a birth plan. ANC services are offered from HC IIs up to Mulago National Referral Hospital (Table 2).

As per World Health Organization guidelines [91, 92], the Uganda Ministry of Health recommends 4 routine visits of goal-oriented (focused) antenatal care for women with low-risk (normal) pregnancies [77, 93]. Focused ANC refers to ANC provided by skilled health staff or providers that emphasizes individualised, woman-centred care; quality versus quantity of visits; and evidence-based, goal-directed actions. It ensures that the pregnant woman gets adequate care from the time pregnancy is diagnosed to time of delivery. The ANC services offered to the woman depend on the timing and duration of pregnancy. Ideally, in an uncomplicated pregnancy, the woman should come for her first ANC visit in the first trimester; the second visit, in the second trimester; the third and fourth visits, in the third trimester. The goals for and the timing of the routine ANC visits for women with uncomplicated pregnancies are presented in table 3.

The Ministry of Health recommends that if a pregnant woman comes for her first antenatal visit later than the first trimester, the health provider should combine and attend to the preceding goals. At all the ANC visits, the woman's blood pressure (BP) and weight should be checked, the symphysio-fundal height and foetal heart activity be measured, and the identified problems be addressed. The woman should be encouraged to bring her partner to at least one antenatal visit [93].

Overall, in Uganda, most women (about 95%) attend one antenatal visit [94, 95], however, less than half of all women (about 47%) attend four or more visits. Most women (about 84%) get ANC from nurses/midwives but only 9% of the pregnant women receive ANC from a doctor. In addition, the urban women are two times more likely than rural women to get ANC from a doctor (15% compared with 8%) [77]. Though most women receive ANC from a skilled health provider (doctor, nurse/midwife, medical assistant/clinical officer or nursing aide), only about 57% of the pregnant women deliver in a health facility. Overall, about 59% of the deliveries are assisted by a skilled health provider [96].

Table 3: Timing and goals of the recommended antenatal care (ANC) visits and the services offered to women with normal pregnancies (adapted from: Uganda Clinical Guidelines 2010 [93]).

Antenatal care visit	Antenatal care services offered
First visit (a) Gestational age (GA): - 10-20 weeks (b) Goals of ANC visit: - Risk assessment - Health education - Plan for delivery	History taking: - history (medical, surgical, obstetric/gynaecological) - social and family history - current pregnancy Examination: - complete physical examination and obstetric examination Laboratory investigations: - blood for haemoglobin (Hb) estimation, ABO and Rhesus grouping, RPR (syphilis), routine counselling and testing for HIV - urine for albumin, glucose - other tests – as appropriate for the individual patient Health promotion: - address any problems - draw up a delivery plan and involve husband in ANC - educate on danger signs of pregnancy and future family planning - educate and counsel on PMTCT of HIV, malaria prevention and use of insecticide treated nets (ITNs) - educate on adequate nutrition and hygiene, infant feeding/ breastfeeding, breast care, avoidance of smoking and alcohol - discuss sexual activity during pregnancy, dual protection for FP (family planning) /HIV, and avoidance of smoking and alcohol. Management: - treat incidental ailments - give haematinics (ferrous sulphate & folic acid), tetanus toxoid (TT)
Second visit (a) Gestational age: - 20-28 weeks (b) Goals of ANC visit: - Action on abnormal laboratory results - Ensure TT vaccination - Exclude multiple pregnancy and anaemia - Assess for signs of pregnancy induced hypertension (PIH) - Check foetal growth	History taking: - history of any symptoms or problems, like vaginal bleeding, drainage of liquor etc. - date of first foetal movements Examination: - as for 1st antenatal visit - weight: amount and pattern of weight change Laboratory investigations: - as for first antenatal visit Health promotion: - advise the woman how to recognize and promptly report any problems for timely appropriate treatment (e.g. vaginal bleeding, draining of liquor, blurred vision etc.) - dual protection for FP/HIV Management: - give TT, haematinics, mebendazole and first dose of IPT (intermittent presumptive treatment of malaria) - treat incidental ailments
Third visit (a) Gestational age: - 28-36 weeks (b) Goals of ANC visit: - Exclude anaemia - Assess for signs of PIH - Check foetal growth - Review delivery plan	History taking, laboratory investigations, examination: - as for 2nd antenatal visit Health promotion - as for antenatal visit - discuss labour signs (including early rupture of membranes) - review delivery plan - dual protection for FP/HIV Management: - give haematinics and second dose of IPT
Fourth visit (a) GA: above 36 weeks (b) Goals of ANC visit: - As for 3rd visit - Exclude abnormal lie	History taking, laboratory investigations, examination, health promotion: - as for 3rd antenatal visit

1.8 Mother-to-child transmission of HIV

In absence of any HIV prevention measures, the estimated risk of mother-to-child transmission (MTCT) of HIV is 5-10% during pregnancy, 10-20% during labour and delivery, and 5-20% through breastfeeding [97]. Hence, the rates of MTCT range from about 15 to 30% among non-breastfeeding HIV-infected women compared with rates of about 25 to 45% in breastfeeding populations in low-income countries [97]. The factors associated with MTCT of HIV include maternal and obstetric factors, and infant feeding methods (table 4) [98, 99].

1.9 Prevention of mother to child transmission of HIV (PMTCT) programme

The PMTCT programmes were launched in several high HIV prevalence countries in the late 1990s, following the initial reports of efficacious antiretroviral (ARV) regimens [100-103]. However, the World Health Organization (WHO) issued the first guidelines for the use of ARV drugs for PMTCT and recommendations for infant feeding options for HIV infected mothers in resource-limited settings in 2000 [104]. The WHO guidelines help the national ministries of health in the selection and provision of antiretroviral therapy (ART) and ARV prophylaxis for the women and their infants taking into account the local health system context. These guidelines have been updated several times since then to incorporate new empirical evidence. The current guidelines on PMTCT and infant feeding practices were released by WHO in 2010 [105].

The strategy for PMTCT is a United Nations (UN) comprehensive, four-pronged strategy that encompasses HIV-related prevention, care and treatment, and support needs of the pregnant women, the mothers, their children and their families [106]. The four prongs are:

1) Prevention of HIV infection among women and their partners
2) Prevention of unintended pregnancies among HIV infected women
3) Prevention of HIV transmission from HIV-infected women to their infants
4) Provision of treatment, care and support for HIV-infected mothers, their children and families

Table 4: Risk factors associated with mother-to-child transmission of HIV

Risk factor	Possible mechanism of infection MTCT
Maternal Health	
Advanced HIV disease	High viral load and low CD4 T cells
Primary HIV infection	High viral load, lack of immune response
No maternal ARV treatment	High viral load
Obstetric factors	
Vaginal delivery	Exposure to HIV-infected genital secretions
Episiotomies and vaginal tears	Exposure to HIV-infected blood
Instrumental deliveries	Exposure of breached infant skin to secretions containing HIV
Chorionic villus biopsy or amniocentesis	Increased risk of placental microtransfusion
Fetal electrode monitoring	Breach in infant skin and exposure to infected secretions
Prolonged rupture of fetal membranes	Prolonged exposure to HIV-infected secretions
Chorioamnionitis	Ascending infection
Low birth weight	Impaired fetal or placental membranes
Prematurity	Impaired fetal or placental membranes
Maternal co-infection	
Malaria (placental malaria)	Increased viral load, disruption in placental architecture
HSV-2	Increased plasma viral load, increased shedding of HIV in genital secretions, genital ulcers
Other STIs	Genital ulcerations and exposure to HIV-infected blood or genital secretions
Infant feeding	
Breast-feeding	Mastitis, cell-free and cell-associated virus
Mixed feeding	Contaminated formula or water used in preparing formula may cause gastroenteritis leading to microtrauma to infant's bowel and provides entry to HIV virus
Miscellaneous factors	
Infant–mother HLA concordance	HLA molecules on the surface of HIV-infected maternal cells are recognized as 'self' by cytotoxic T-lymphocytes or NK cells of the infant and are, therefore, less likely to be destroyed
Maternal HLA homozygosity	Increased viral load
Presence of CCR5 delta 32 mutation in T-cell	Decreased susceptibility to HIV infection

ARV, antiretroviral; HLA, human leukocyte antigen; HSV-2, herpes simplex virus type 2; MTCT, mother-to-child transmission; NK, natural killer; STIs, sexually transmitted infections. Adapted/modified from Paintsil E et al, 2009 and Lehman D et al, 2007 [98, 99].

The prevention of mother-to-child transmission of HIV-1 (PMTCT) programme was launched in Uganda in the early 2000. In Mbale Regional Referral Hospital in Eastern Uganda it was launched in 2002. The programme was scaled up to almost all districts

of Uganda by the end of 2004 as a comprehensive, four-pronged strategy [107]. The availability of PMTCT services in Uganda varies by level of health facility. By the end of 2009, about 87% of the hospitals, 93% of HC IVs, 73% of HC IIIs and 21% of HC IIIs in Uganda were offering PMTCT services [61]. The Uganda Ministry of Health released the first PMTCT guidelines in 2002 with single dose nevirapine (for women during labour and for babies within 72 hours after birth) as the main drug [108]. The other recommended drug was zidovudine but was used in a few sites only and HIV positive mothers were advised to use replacement feeding for their babies. However, the Ministry of Health (MOH) revised the PMTCT guidelines in 2006 according to recommendations by WHO and UNAIDS [107]. The recommended antiretroviral drug for eligible women was Combivir[®] (zidovudine 300 mg/lamivudine 150 mg) – given twice a day from 32 weeks of pregnancy till delivery, boosted by single dose nevirapine (200 mg) at onset of labour, and then continue with Combivir[®] for a week after delivery. The babies were recommended to receive a single dose of nevirapine (2 mg/kg body weight) within 72 hours after birth and zidovudine (4 mg/kg body weight) twice a day for one week. The recommended infant feeding option for HIV positive mothers was exclusive breastfeeding for 3-6 months. However, exclusive replacement feeding could be used if it was acceptable, feasible, affordable, safe and sustainable (AFASS) [107]. Currently, Uganda is scaling up the use of option B-plus which involves giving pregnant, HIV positive women Highly Active Antiretroviral Therapy (HAART) from 14 weeks of pregnancy for life irrespective of the CD4 count [109].

The work in this thesis focuses on mainly the first and third prongs. Within the PMTCT programme, a continuum of PMTCT services is offered. The services include critical antenatal, intrapartum and postnatal services to the mothers and their infants. In the antenatal clinic, pregnant women and their male partners are counselled about and tested for HIV. The women who are found to be HIV negative are encouraged to adopt measures to reduce the risk of contracting HIV and other sexually transmitted infections during pregnancy and lactation. This requires the support of their male partners. Hence male partner involvement in ANC and the PMTCT programme is encouraged and promoted by the health care providers. The pregnant women who are

found to be living with HIV are offered a set of sequential measures or interventions [110], namely:

(a) Clinical (WHO clinical staging; table 5) assessment and CD4$^+$ count estimation to determine the eligibility of mothers for treatment

(b) ART for eligible mothers for their own health or antiretroviral prophylaxis for both the mothers and their infants to prevent MTCT

(c) Safe obstetric practices

(d) Counselling and support for HIV infected pregnant women on feeding options for infants.

Pregnant women who have clinical HIV disease stage 3 or 4 and those with a CD+ count below 350 cells/ml are eligible for highly active antiretroviral therapy (HAART). Those living with HIV but are either disease stage 1 or 2 and have a CD+ count above 350 cells are eligible for antiretroviral prophylaxis to prevent MTCT [105]. The success of the PMTCT programmes is dependent on the proper implementation and utilization of the four-pronged strategy. MTCT has been markedly reduced in high-income countries but is still a threat to child survival in resource limited settings [52].

Table 5: WHO clinical staging of HIV/AIDS for adults and adolescents

Primary HIV infection
    Asymptomatic
    Acute retroviral syndrome

Clinical stage 1
    Asymptomatic
    Persistent generalized lymphadenopathy (PGL)

Clinical stage 2
    Moderate unexplained weight loss (<10% of presumed or measured body weight)
    Recurrent respiratory tract infections (RTIs, sinusitis, bronchitis, otitis media, pharyngitis)
    Herpes zoster
    Angular cheilitis
    Recurrent oral ulcerations
    Papular pruritic eruptions
    Seborrhoeic dermatitis
    Fungal nail infections of fingers

Clinical stage 3
Conditions where a presumptive diagnosis can be made on the basis of clinical signs or simple investigations
    Severe weight loss (>10% of presumed or measured body weight)
    Unexplained chronic diarrhoea for longer than one month

Unexplained persistent fever (intermittent or constant for longer than one month)
Oral candidiasis
Oral hairy leukoplakia
Pulmonary tuberculosis (TB) diagnosed in last two years
Severe presumed bacterial infections (e.g. pneumonia, empyema, pyomyositis, bone or joint infection, meningitis, bacteraemia)
Acute necrotizing ulcerative stomatitis, gingivitis or periodontitis
Conditions where confirmatory diagnostic testing is necessary
Unexplained anaemia (< 8 g/dl), and or neutropenia (<500/mm3) and or thrombocytopenia (<50 000/ mm3) for more than one month

Clinical stage 4
Conditions where a presumptive diagnosis can be made on the basis of clinical signs or simple investigations
HIV wasting syndrome
Pneumocystis pneumonia
Recurrent severe or radiological bacterial pneumonia
Chronic herpes simplex infection (orolabial, genital or anorectal of more than 1 month)
Oesophageal candidiasis
Extrapulmonary TB
Kaposi's sarcoma
Central nervous system (CNS) toxoplasmosis
HIV encephalopathy
Conditions where confirmatory diagnostic testing is necessary
Extrapulmonary cryptococcosis including meningitis
Disseminated non-tuberculous mycobacteria infection
Progressive multifocal leukoencephalopathy (PML)
Candida of trachea, bronchi or lungs
Cryptosporidiosis
Isosporiasis
Visceral herpes simplex infection
Cytomegalovirus (CMV) infection (an organ other than liver, spleen or lymph nodes)
Any disseminated mycosis (e.g. histoplasmosis, coccidiomycosis, penicilliosis)
Recurrent non-typhoidal salmonella septicaemia
Lymphoma (cerebral or B cell non-Hodgkin)
Invasive cervical carcinoma
Visceral leishmaniasis

Source: WHO clinical staging of HIV/AIDS and HIV/AIDS case definitions for surveillance [111]

HIV counselling and testing

HIV counselling and testing is the entry point to treatment, care and support for people living with HIV [112]. HIV counselling has been defined as a confidential dialogue between a client and a trained counsellor whose objective is to help the client make informed, personal decisions related to HIV/AIDS and cope with the psychological stress of the HIV test results [113]. There are two types of counselling according to the site where the HIV counselling is offered, namely:

 (a) Clinic-based counselling (in health facility)

(b) Community-based counselling (in a village or urban neighbourhood)

Counselling is often offered to clients before HIV testing (pre-test counselling) and after an HIV test (post-test counselling). Pre-test counselling is a prerequisite for obtaining an informed consent from a client who is offered an HIV test [113, 114] and helps dispel myths, rumours and misinformation about HIV, and prepares the client psychologically for the HIV tests and its results [113]. Depending on the HIV test results, post-test counselling offers the counsellor an opportunity to discuss with the client HIV prevention methods, emphasize the need for a repeat test within 1-2 months because of the possibility of a "window period" and help the client adopt or sustain safer sexual practice if HIV negative. For those found to be living with HIV, the counsellor can provide emotional support on how to cope and accept their HIV status with a positive attitude, and provide the relevant referral information for treatment, care and support services [113]. Hence HIV counselling plays a vital role in HIV prevention, care and treatment efforts. For example, empirical evidence has showed that clients who received counselling were more likely to change their behaviour positively and adopt safer sexual practices, hence the decreased transmission of HIV and other sexual transmitted infections (STIs) [115, 116].

For the PMTCT programmes, HIV counselling and testing was first recommended in 1985 by the Centers for Disease Control and Prevention [117]. When the PMTCT programme was launched in Uganda in 2000, HIV counselling and testing were provided in the antenatal clinics using voluntary counselling and testing (VCT) model, also known as client-initiated or opt-in approach [108]. The antenatal attendees were offered the HIV test only if they requested for it and given individual pre- and post-test counselling. Anecdotal evidence showed low HIV testing rates in antenatal clinics under VCT model. However, in 2006, the HIV counselling and testing policy was changed from VCT to provider-initiated testing and counselling (PITC) model, also known as opt-out or routine counselling and testing approach [107]. In this model, group pre-test counselling/education and routine offer of the HIV test are provided to all the antenatal attendees but the client can decline the HIV test (opt-out) if she/he desires. A recent WHO report has documented that about 63% of all pregnant women

in Uganda accepted to be tested for HIV in 2010 compared to 18% in 2005 (under VCT model)[118]. Similarly, a 2010 report from the Uganda AIDS Commission documented that over 90% of the ANC attendees in Uganda were counselled and tested for HIV [61]. A sequential HIV testing algorithm, with same day results, including 3 rapid tests is used on a single blood sample. The rapid tests are: Determine HIV 1/2 assay for screening, STAT-PAK HIV I/2 dipstick assay as a second test and Uni-Gold Recombigen HIV test as a "tie-breaker" [107].

1.10 Male partner involvement in ANC/PMTCT

A recent (2010) UNAIDS report highlights the importance of engaging men in the global HIV/AIDS response [52]. Male partner involvement in the PMTCT programme is vital since in many contexts men are the decision makers in most of the reproductive health issues of their spouses [119, 120]. However, men's antenatal attendance and their participation in the PMTCT programme are still low [121-123]. The underlying factors include the perception that antenatal clinics are not "male-friendly" [124, 125], the fact that men are invited to participate [126], HIV-associated stigma [127, 128], men's misconception that the HIV status of their partners is a proxy of theirs [129, 130] and the belief that antenatal care is a woman's activity[124, 125, 130-133]. Recent reviews have revealed that the determinants of male partner involvement in the PMTCT programme include health system, societal/cultural and individual (male or female) factors [134, 135].

Male involvement in the PMTCT programme increases the use of PMTCT interventions [136, 137]. It is associated with reduced risk of MTCT and a lower HIV-associated infant mortality [138]. It may facilitate HIV sero-status disclosure among couples [139]. It may also enhance communication between couples about HIV and facilitate positive behavioural change such use of condoms and limiting sexual partners [129].

1.11 Rationale and focus of the studies

HIV/AIDS is a public health problem and MTCT of HIV is the major cause of paediatric HIV. In Uganda, MTCT contributes about 22% of the new HIV infections that occur annually countrywide [60, 61]. Although the PMTCT programme has been implemented in Uganda for over 10 years, its performance is still inadequate to meet the national goal of eliminating HIV in children [61]. While many of the PMTCT intervention strategies require involvement of men, in actual practice they hardly participate or support the women in PMTCT of HIV. Antenatal clinics are the entry points to the PMTCT programme and yet anecdotal evidence shows that in Uganda few men accompany their spouses to attend antenatal care. Since men are the decision makers in most family matters, engaging men is a critical component of the PMTCT programme [140, 141]. Provider-initiated testing and counselling (PITC) for HIV was launched in the PMTCT programme in Uganda in 2006 in order to increase the testing rates among the antenatal attendees, although it had been practiced in high incomes countries since the late 1980s [142, 143]. However, antenatal HIV testing rates among the male partners have remained low despite the change in HIV testing policy. In addition, there is neither a standard operational definition of what "male involvement" entails nor standardized instruments to measure it. Within this context, the focus of the each of the four papers included in this thesis is described the following section.

Paper I documents the performance of the PMTCT programme over a 7-year period and the effect of the change in HIV testing policy on HIV testing rates among antenatal attendees in Mbale Regional Referral Hospital. In *Paper II*, we explore the attitudes of the pregnant women to PITC for HIV and their knowledge about the PMTCT programme. *Paper IIII* documents the factors that either facilitate or hinder men's participation in the PMTCT programme and reports some suggestions that could increase male involvement in the programme. It also documents the level of male partner involvement in the PMTCT programme in Eastern Uganda. In paper IV, we report findings from a randomized facility-based intervention trial we tested of the suggestions from paper III. The intervention was an invitation letter delivered to

spouses of new antenatal attendees and the control group received an information leaflet about antenatal care in general.

2.0 STUDY AIM AND OBJECTIVES

2.1 Aim

The overall objective of this research was to explore factors that determine women's and male partners' participation in the programme for prevention of mother-to-child transmission of HIV (PMTCT) in Eastern Uganda, and to identify an intervention to increase male partner participation and examine its effect on male partner participation in the PMTCT programme.

2.2 Specific objectives

1. To describe the past performance of the PMTCT programme at Mbale Regional Referral Hospital with particular reference to lessons learnt in changing from voluntary counselling and testing (VCT) to routine counselling and testing (RCT) for HIV in the antenatal clinic (Paper I).

2. To evaluate the attitudes of pregnant women to routine HIV counselling and testing, and their knowledge about feeding options in the PMTCT programme to HIV infected women (Paper II).

3. To determine level of male participation in the PMTCT programme and identify the factors associated with this participation, and suggest ways in which it could be increased (Paper III).

4. To assess the effect of a written letter to spouses of antenatal attendees attending their first antenatal visit, on couple antenatal attendance and partner acceptance of HIV testing at the subsequent antenatal visit (Paper IV).

3.0 SUBJECTS AND METHODS

3.1 Study area and geographical description

Uganda is a landlocked country in Eastern Africa, situated astride the Equator west of Kenya, east of Democratic Republic of Congo and covering an area of approximately 241 600 square kilometres. It also borders the Republic of South Sudan in the north, and Rwanda and Tanzania in the south (figure 8). Its terrain is mostly a plateau around 1 100 metres above sea level with a rim of rift valley mountains. It has a tropical climate, generally rainy (around 700-2000 mm/year) with two dry seasons and average temperature of 24 degrees centigrade (range: 16-31^{0}C) [95].

Figure 8: Map of Uganda
Source: http://goafrica.about.com/library/bl.mapfacts.uganda.htm

It has an estimated population of 34 million with an annual growth rate of 3.2 percent, one of the highest growth rates in the world [95]. The population is therefore very young, in fact more than half of Uganda's population is below 15 years of age (52%) [95, 144].

Uganda is a low income country and has a Gross Domestic Product (GDP) per capita of about $ 550 (US dollars) and 25% of the population lives below the poverty line [95, 145]. The Uganda government spends about 9% of the government's total budget on health, inadequate in relation to the 2001 Abuja Declaration target of at least 15%

[85]. Although there has been some improvement in the health service delivery, the health indicators are still poor (table 6).

Table 6: Selected socio-demographic and health indicators for Uganda

Indicator	2010/2011
Population (total)	34 million inhabitants
Life expectancy	54 years
Total fertility rate	6.2 children/woman
Maternal mortality ratio	310 per 100 000 live births
Infant mortality rate	54 per 1 000 live births
Population growth	3.2% per year
Adult literacy rate - overall (aged 15 years and above)	73%
Population living below poverty, below US$ 1	25%

Sources: 2012 Statistical abstract [95], Uganda poverty status report 2012 [145] and Trends in maternal mortality: 1990-2010 [146], 2011 Uganda Demographic and Health Survey (2011 UDHS) - preliminary report [94], The State of the World's Children 2012 [147], The state of the world population 2011[148].

The studies included in this thesis were conducted in Mbale district (figure 8), one of the 111 districts in Uganda as of July 2010 [149]. Mbale is situated at the foothills of Mt Elgon in Eastern Uganda, just north of the Equator. The district was larger in 2002 (Table 7) and had a population of about 721 240 people [150]. After being divided, the district had a population of 429,000 inhabitants (2011 estimate) [90]. The population are mainly subsistence farmers. Like the rest of Uganda, most of the population is rural. The main language spoken in the district is *Lugisu*, also known as *Lumasaba*. The literacy rate among males was 75 % and 60 % in females [95]. Mbale district is administratively divided into Bungokho County (rural) and a municipality (urban). Mbale town is the main administrative and commercial centre in Eastern Uganda and had an estimated population of 92 000 inhabitants in 2011 [95].

Mbale Regional Referral Hospital, commonly known as Mbale hospital, is located in Mbale municipality, approximately 240 kilometres north-east of Kampala City by road. It is a regional referral hospital for the districts in eastern Uganda, which include: Budaka, Bududa, Bukedea, Bukwo, Bulambuli, Busia, Butaleja, Kapchorwa, Kibuku, Kumi, Kween, Manafwa, Mbale, Pallisa, Sironko, Tororo [95]. Mbale Regional Referral Hospital serves an estimated population of 3.5 million people. It is a public

health facility funded by the Uganda government (Ministry of Health) and the general care is free. The hospital has a bed capacity of 380 and also serves as a teaching hospital for clinical paramedical trainees (clinical officer trainees) and interns (junior house-officers). Antenatal services, including routine HIV counselling and testing, are offered daily, except for weekends and the average attendance is 50 to 60 pregnant women per day.

Table 7: Mbale district's area and estimated population before and after 2007

	Surface area	Counties (subdivisions)	Population
Before 2007	About 1 370 square kilometres (km^2)	Bubulo Bungokho Manjiya Mbale Municipality	- 718 240 inhabitants (2002 Census)
After 2007	About 470 square kilometres	Bungokho Mbale Municipality	- 428,800 inhabitants (2011 mid-year estimate)

Sources: The 2002 Uganda Population and Housing Census, Population Dynamics (UBOS 2006); 2010 Statistical Abstract released (UBOS 2010); 2011 Statistical Abstract (UBOS 2011).
The former counties of Bubulo and Manjiya are now the districts of Manafwa and Bududa, respectively [90, 151, 152].

3.2 Study designs and study population

The study designs for the studies in this thesis included a retrospective (secondary) analysis of data from hospital records about the prevention of mother-to-child transmission of HIV (PMTCT) programme in Mbale regional Referral Hospital (Paper I), two cross-sectional surveys (Papers II & III) and a randomised intervention trial (Paper IV). The study participants were antenatal attendees (Papers I, II & IV) and/or their male partners (Papers I-IV) except for the key informants who were health care providers (3 men and 2 women) and the men that participated in the focus group discussions (Paper III). We used purposive sampling during recruitment of the key informants and the focus groups' participants (Paper III), convenience sampling for the cross-sectional surveys (Papers II & III) and simple random sampling was employed in the intervention trial (paper IV). Table 8 summaries the study designs and study populations, and types of data analyses used in the 4 papers in this thesis.

Table 8: Overview of the study designs, study population and types of analyses of data in the 4 papers in this thesis.

Paper	Study design	Study population	Data analysis	Study period
I	Retrospective data analysis	54 429 new antenatal attendees 469 male partners	- Descriptive statistics	May 2002 to April 2009
II	Cross-sectional survey	388 new antenatal attendees	- Descriptive statistics - Multivariate logistic regression	August to October 2009
III	Cross-sectional survey	388 male partners antenatal attendees 5 key informants (3 male & 2 females) 76 men – in 8 focus group discussions	- Descriptive statistics - Multivariate logistic regression - Content-thematic analysis of transcripts of key informant interviews & focus group discussions	July to August 2004
IV	Randomised intervention trial	600 antenatal attendees (290 intervention & 310 non-intervention groups)	Descriptive statistics Multivariate logistic regression	October 2009 to February 2010

In paper I, a retrospective analysis of routine data from all hospital records on HIV counselling and testing of 54 429 antenatal attendees and 469 male partners was carried out. Descriptive statistics were used to describe the performance of the PMTCT programme at Mbale hospital over a 7-year period. In paper II, 388 new antenatal attendees, who accepted routine HIV counselling and testing in the antenatal clinic, were consecutively enrolled in the cross-sectional survey from August to October 2009. Descriptive statistics and logistic regression analyses were done to assess the women's attitudes to routine HIV counselling and testing, and their knowledge about feeding options in the PMTCT programme to HIV infected women.

Paper III reports a cross-sectional survey conducted over a 2-month period among 388 male partners of women attending antenatal care at Mbale hospital. In addition, 5 key

informants (3 males and 2 females) were interviewed, and 8 focus group discussions were conducted with a total of 76 men. Descriptive statistics were used to determine level of male participation in the PMTCT programme in Eastern Uganda; multivariate logistic regression analysis was used to identify the factors associated with male partner participation; and content-thematic analysis of the qualitative data carried out to identify barriers to male partner participation in the PMTCT programme and suggest ways how it could be increased.

In paper IV, a randomized, parallel group, hospital-based intervention trial was performed among 1060 new antenatal attendees to evaluate the effect of a written letter addressed to their spouses on couple antenatal attendance and male partner acceptance of HIV testing at the subsequent antenatal visit from October 2009 to February 2010. The study was conducted in an antenatal clinic at Mbale Regional Referral Hospital, Mbale District in eastern Uganda. The intervention comprised an invitation letter delivered to the spouses of new antenatal attendees, while the control group received an information letter, a leaflet, concerning antenatal care. The randomization code was computer-generated by an independent statistician using a random sequence generator at RANDOM.ORG website. At enrolment into the study, the research assistants randomly assigned 1 060 eligible new antenatal attendees to the two parallel groups (intervention and non-intervention) with an allocation ratio of 1:1. The respondents, the health staff in the antenatal clinic and the research assistants were masked to group assignments and to letter allocation to the groups.

3.3 Data collection methods and data management
In order to address the research questions stated in the objectives of this thesis, data were collected using mainly quantitative methods (papers I – IV), however, in paper III some qualitative techniques were also used. In paper I, data were obtained from copies of Mbale hospital's monthly PMTCT programme reports submitted by the PMTCT coordinator to the national PMTCT programme manager in the Ministry of Health. We also got data from the *VCT* and *HIV Registers*, the *Enrolment Registers* and *Antenatal Summary Registers* in the antenatal clinic and the *Delivery Summary*

Registers in the maternity ward covering a seven-year period of the PMTCT programme at Mbale Regional Referral Hospital. We also used the registers to verify the information in the PMTCT monthly reports. The data were extracted using a standardized data extraction form and entered into a Microsoft Excel sheet by the principal investigator.

In papers II, III and IV, the data were collected by research assistants (social scientists) who were knowledgeable in the local language and interview techniques, and had been trained about the objectives of the studies. They interviewed the respondents using pre-tested structured questionnaires after obtaining written consent. The principal investigator checked filled questionnaires for completeness at the end of each day. Double-entry of the data was done by data-entry clerks using EpiData version 3.1. The data were validated by the principal investigator by checking for any errors in the EpiData file and exported to SPSS for analysis. In addition, for the qualitative part of the study in paper III, key informant interviews were conducted by the principal investigator with 5 senior health managers and 8 focus group discussions (FGDs) were conducted by two research assistants using an interview guide. The principal investigator participated in 4 FGDs as an observer. All the focus group discussions were tape-recorded. Data were transcribed by the research assistants and validated by the principal investigator (by listening to all the tape-recordings) before analysis.

3.4 Sample size, study outcomes and statistical analysis
In paper I, the sample size included all the antenatal attendees and their male partners who attended the antenatal clinic at Mbale hospital during a 7-year period (from May 2002 to April 2009). The main outcomes were the proportion of pregnant women and their male partners who were (a) counselled for HIV and (b) tested for HIV, and (c) were found to be HIV positive.

For the cross-sectional survey in paper II, the sample size calculated using OpenEpi, version 2.3.1 (open source calculator software for epidemiologic statistics): http://www.openepi.com/OE2.3/Menu/OpenEpiMenu.htm, based on the following

assumptions: (a) a two-sided level of significance of 5% (95% confidence interval), (b) 80% power and (c) a 50% prevalence of positive attitude to routine HIV counselling and testing (RCT) among antenatal attendees. It was calculated to be 384 new antenatal attendees. The main outcome variable was the proportion of new antenatal attendees who had a positive attitude to RCT. In paper III, the sample size of the cross-sectional survey was calculated based on an estimated proportion of male involvement (defined as men accompanying their spouses to the antenatal clinic) in the population of 10% and a 5% level of significance. It was estimated to be 422 men. The main outcome variable was the level of male involvement in the PMTCT programme. For the randomized intervention trial (paper IV), the sample size calculation was based on the assumptions that antenatal couple attendance would increase from about 4.5% (without intervention) to 9% (with intervention) with 80% power and 95% confidence intervals. It was estimated to 1060 new antenatal attendees (530 in each group). The primary outcome measure was the proportion of pregnant women who attended antenatal care with their male partners at their subsequent ANC visit at Mbale hospital during a follow-up period of four weeks. The secondary outcome measure was the proportion of male partners that were tested for HIV in the antenatal clinic.

Microsoft Excel and SPSS for windows (version 13 and PASW Statistics 18) were used for analyses. We used descriptive statistics to examine demographic characteristics of participants and the main outcome measures (papers I-IV). As a measure of the level of male involvement in the PMTCT programme, a male involvement index was constructed from 6 variables with equal weight using principal component analysis (paper III). The Pearson chi-square test and the student's t-test were used to compare selected indicators for the PMTCT programme before and after HIV testing policy change (paper I); and also to compare the participants socio-demographic characteristics between the intervention and non-intervention groups (paper IV). Multicollinearity among the independent variables and outliers were checked. Binary logistic regression analyses were conducted to identify the factors associated with (a) positive attitude to routine antenatal HIV counselling and testing,

(b) male partner participation in the PMTCT programme (paper III) and (c) couple antenatal attendance and male partner antenatal HIV testing (paper IV).

3.5 Ethical considerations

Ethical approval to conduct the studies was obtained from the Research and Ethics Committee of the School of Medicine, Makerere University College of Health Sciences; the Uganda National Council of Science and Technology, and the Mbale Regional Referral Hospital. Written informed consent was obtained from all the participants in the studies (papers II, III and IV).

4.0 SUMMARY OF RESULTS

4.1 PAPER I: Increase in HIV testing rates among antenatal attendees after policy change from voluntary counselling and testing to routine counselling and testing for HIV

This paper describes the trends in antenatal HIV testing rates among pregnant women and their male partners at Mbale hospital during the first seven years of the prevention of mother-to-child transmission of HIV (PMTCT) programme. Overall, a total of 54429 new antenatal attendees visited the antenatal clinic. Many of them (78.6%) were counselled, a half of them (51.6%) were tested for HIV and some (6.1%) were HIV positive. Of all the new attendees, only 469 (0.9%) were accompanied by their male partners. All the men were counselled, most of them (97.9%) accepted HIV testing and some of them (8.7%) tested HIV positive.

Two approaches of HIV counselling and testing were used in the antenatal clinic. The voluntary counselling and testing for HIV (VCT) approach was offered from May 2002 to May 2006. However, there was a change in the Uganda national HIV testing policy in June 2006 to provider-initiated testing and counselling (PITC), also known as routine counselling and testing, to date. Our study showed that there was a significant increase in HIV testing rates among new antenatal attendees from 22.0% (6570/29834) during the VCT period (May 2002 to May 2006) to 87.6% (21538/24595) in the PITC period (June 2006 to April 2009). Similarly, because more women were tested, more HIV-infected women (n = 1147) were identified in the antenatal clinic during the PITC period compared to 566 women in the VCT period (p = 0.012). Although the HIV testing rates among the male partners who accompanied their spouses to the antenatal clinic increased from 87.5% in the VCT period to 100% in the PITC period (p = 0.010), the increase in the proportion of HIV-infected male partners identified from 21% (VCT period) to 25% in PITC period was not statistically significant (p = 0.103). However, the absolute numbers of the male partners tested for HIV in the antenatal clinic remained very low despite the policy change in HIV testing.

4.2 PAPER II: Attitudes to HIV counselling and testing, and knowledge about prevention of mother to child transmission

Of the 388 pregnant women enrolled in the study, two-thirds were living in the rural areas and had a median age of 24 years (range 15-46 years). Most of them were Bagisu (64%), had no salaried employment (87%) and had had less than 11 years of education, that is incomplete secondary education or less (74%). Their male partners were older (median age 30 years; range, 18-72 years) and a half of them had completed secondary school education.

All the pregnant women were given pre-test HIV counselling and many of them (86.3%) rated highly the pre-test counselling they had received. The new ANC attendees were more likely to have a positive attitude to pre-test counselling for HIV if they were residing in an urban area (Odds Ratio, OR: 3.0, 95% Confidence interval, CI: 1.4-6.6); having three or more pregnancies (OR: 3.0, 95% CI: 1.4-6.8); were among the least poor (OR: 1.9, 95% CI: 1.0-3.7); and were young (15 to 24 years of age) (OR: 2.5, 95% CI: 1.1-5.4). Almost all the women (99.5%, 386/388) attending their first antenatal visit at Mbale regional Referral hospital tested for HIV and 382 (98.5%) received same-day HIV test results. The majority of the new ANC attendees (98.5%) had a positive attitude to routine antenatal HIV testing. In addition, more than half of the women (54%) sought their male partners' permission to test for HIV.

Our study also showed that many of the women (more than 60%) knew that mother-to-child transmission (MTCT) of HIV could occur during pregnancy, delivery and through breastfeeding, and also knew MTCT of HIV could be prevented. About 63% of them knew that the risk of MTCT of HIV could be reduced if an HIV-infected mother exclusively breast-fed her baby for six months. The new antenatal attendees were likely to have knowledge of exclusive breastfeeding as an infant feeding option for an HIV-infected mother if they had completed secondary school (OR: 2.5, 95% CI: 1.3-4.9); were non-Bagisu by ethnicity (OR: 1.7, 95% CI: 1.0-2.7); and had three or more pregnancies (OR: 2.5, 95% CI: 1.4-4.5).

4.3 PAPER III: Determinants of male involvement in the prevention of mother-to-child transmission of HIV programme

In the cross-sectional survey, there were 387 male partners of new antenatal attendees with a median age of 32 years (inter-quartile range, IQR, of 28 to 37 years) and had a median period of education of 7 years (range 0 to 18 years). In addition, 76 men who participated in the focus group discussions had a median age of 34 years (IQR: 24-44 years). Few of the male partners (4.7%) had attended the antenatal clinic with their spouses, however the majority (97%) had provided financial support to their spouses to attend ANC. The level of male involvement in the PMTCT programme was low; only twenty-six percent of the respondents had a high male involvement index.

In logistic regression analysis, the factors associated with a high male involvement index were: male partners' level of education, occupation and fear of disclosure of HIV results to wife. Men who had attained secondary education were two times more likely to have a high male involvement index (OR: 1.9, 95% CI: 1.1-3.3). However, those whose occupation were drivers or motocycle (locally known as *Bodaboda*) cyclists (OR: 0.3, 95% CI: 0.1 0.9) and those who had fear to disclose their HIV results to their wives (OR: 0.4, 95% CI: 0.2-0.7) were likely to have a low male involvement index. In addition, the male partners who were professionals by occupation (OR: 5.4, 95% CI: 1.7-17) were aware about antenatal clinic (ANC) services (OR: 3.1, 95% CI:1.2-9.2); knew their women's ANC appointment dates (OR: 8.6, 95% CI: 1.0-72); and were willing to go with their spouses for HIV testing (OR: 3.6, 95% 95% CI: 1.1-12), were more likely to accompany their wives' to the antenatal clinic on their scheduled visits. This study also showed that barriers to male partner involvement in the PMTCT programme included health system, socio-economic and cultural factors. The male partners' suggestions for increasing male participation in ANC and PMTCT activities hinged mainly around improvements in the health system. However, another suggestion by the men was that the midwives should formally invite them to attend the antenatal clinic using the antenatal cards of their wives. We decided to test this idea which we did in paper 4.

4.4 PAPER IV: Male partner antenatal attendance and acceptance of HIV testing

In this facility-based intervention trial, a total of 1060 pregnant women attending their first antenatal visit to Mbale Regional Referral Hospital were enrolled and randomly assigned to the intervention and non-intervention groups (530 women in each group). During the follow-up period, 290 women in the intervention group and 310 in the non-intervention group attended the scheduled antenatal clinic visits. The median age of the pregnant women was 24 years in both the intervention (IQR: 20-28 years) and non-intervention (IQR: 21-29 years) groups. A total of 86 women in intervention group and 75 women in the non-intervention group attended the antenatal clinic with their male partners. The median age of the male partners was 30 years in both the intervention group (IQR: 26-38 years) and non-intervention group (IQR: 26-35 years) respectively. The socio-demographic characteristics of participants in the two arms of the trial were similar.

Analysis by intention-to-treat demonstrated that male partner antenatal attendance (couple antenatal attendance) was 16.2% (86/530) in the intervention group and 14.2% (75/530) in the non-intervention group; partner attendance in the two trial arms was similar (OR = 1.2; 95% , CI: 0.8 to 1.6). Similarly, the majority of the male partners (95% in the intervention group and 91% in the non-intervention group) accepted HIV testing. However, in logistic regression analysis, there was no statistically significant difference between the intervention and non-intervention groups with respect to male partner antenatal HIV testing (OR = 1.6; 95% CI: 0.4 to 6.8). Surprisingly the male participation increased by 10% compared to what it was before the trial (5%) by simply inviting the spouses.

All the female antenatal attendees who participated in the trial accepted antenatal HIV testing and 25 of them (11 in the intervention and 14 in the control group) tested positive for HIV. Significantly, many of the male partners of these HIV positive pregnant women (84 %; 21/25) were not tested for HIV in the antenatal clinic (10 men did not attend the clinic; 11 men attended but declined to be tested).

5.0 DISCUSSION

The overall objective of the studies included in this thesis was to explore factors that determine women's and male partners' participation in the PMTCT programme) in Eastern Uganda, and to identify an intervention to increase male partner participation and examine its effect on male partner participation in the PMTCT programme. The studies were: (a) a retrospective analysis of data from a single site (Mbale Regional Referral Hospital) in Eastern Uganda on coverage of antenatal care attendees (and their partners) with HIV testing, over a seven-year period, which included a switch in policy from an opt-in to an opt-out approach in HIV testing (Paper I), (b) two cross-sectional surveys (Papers II & III) and (c) a randomised, hospital-based intervention trial (Paper IV).

This chapter will discuss the methodological issues, the findings and the overall conclusions that we can draw from this thesis.

5.1 Methodological considerations

The strengths and limitations of the papers included in this thesis are summarized in table 9 under two methodological characteristics, namely: (a) internal validity including precision, and (b) external validity. The internal validity of a study refers to the ability of a study to provide an unbiased estimate of what it sets out to measure [153, 154]. Internal validity depends on the study design used, how the study is conducted and how the data is analysed, and is a requirement for external validity. Precision refers to relative lack of random error (chance) [153]. Bias (systematic error), confounding and chance weaken the internal validity of a study [154]. External validity (generalizability) refers to the degree to which the findings from a study may be extrapolated or generalised to populations or groups that did not participate in the study [153, 154].

Table 9: Summary of strengths and limitations of the four studies as reported in papers I-IV.

Methodological characteristics	Paper I	Paper II	Paper III	Paper IV
Relating to internal validity				
Sample size	Large	Adequate	Adequate	Reduced
Precision of estimates of major findings	High	High Narrow CIs[a]	High Narrow CIs	High Narrow CIs
Study subjects - enrolment	All new ANC[b] attendees	Consecutively; new ANC attendees	Consecutively; male partners of ANC attendees	Randomly; new ANC attendees
- attrition/refusals - potential for selection bias	None minimal	None minimal	Few refusals minimal	High attrition minimal
Ways to minimize information bias	Verifying data accuracy for various registers	- training of data collectors - pre-testing data collection instruments - daily de-briefs with research assistants - PI in antenatal clinic daily - regular data quality controls	- training of data collectors - pre-testing data collection instruments - daily de-briefs with research assistants - PI in field daily - regular data quality controls	- training of data collectors - pre-testing data collection instruments - daily de-briefs with research assistants - PI in antenatal clinic daily - regular data quality controls -blinding
Ways to minimize random error	- Double data entry - Data cleaning - use of statistics	- Double data entry - Data cleaning - use of statistics	- Double data entry - Data cleaning - use of statistics	- Double data entry - Data cleaning - use of statistics
Ways to minimize confounding		Multiple logistic regression	Multiple logistic regression	- Randomization - Intention to treat analysis
Relating to external validity Study design	Retrospective records review	Cross-sectional survey	Cross-sectional survey	Randomized, facility-based intervention trial
Generalizability	ANC attendees and/or their male partners	New ANC attendees	Male partners	ANC attendees and/or their male partners

[a]CIs: Confidence intervals, [b]ANC: antenatal care

Paper I

Our study was a retrospective analysis of routinely collected data in the antenatal clinics and the maternity wards at Mbale Regional Referral Hospital about the PMTCT programme and compared two different time periods, 4 years of voluntary counselling and testing for HIV, followed by 3 years of routine counselling and testing for HIV. The strengths of this study were: (a) the large study population of new antenatal attendees, (b) the study was cheap and easy to conduct because the data was already collected in a standardised way over the 7-year study period permitting comparisons of trends in HIV counselling and testing over time.

The study had some limitations. Some of the data in the *Antenatal* and *Delivery Summary Registers* was incomplete. Efforts were made to validate the accuracy and completeness of data in the summary registers by comparing the daily client records in the various registers in the antenatal clinic and maternity units. However, the main focus of our study was on trends in antenatal HIV counselling and testing rates among pregnant women and their male partners at Mbale hospital, indicators where complete data were available. Hence risk of information bias was most likely minimal. Information bias, also called misclassification, occurs when there are errors in the information collected about or from the study subjects and impacts on the internal validity of the findings of the study [154, 155]. In comparison to the number of women (new ANC attendees), very few men (male partners) accessed the PMTCT services. It is possible that the small number of the men may have affected the validity (both internal and external) of our findings on male partners in the study. The policy change in HIV testing strategy was implemented in 2006, a period during which free ARVs had become more available. This may be a potential confounder. It is possible the ANC attendees were more likely to accept the HIV test since they could access the required ARVs more easily than before in case of need. The above limitations notwithstanding, we consider our findings to be valid since none of the weaknesses could question our conclusions.

Papers II and III

The methods in papers II and III were similar to each other and we handle them together. They were cross-sectional surveys and the sample size calculation for each study was done prior to conducting the survey. The sample size in both studies was adequate and the precision was high. One of the strengths of paper III study was that we interviewed the men themselves directly rather than getting the information about men indirectly by interviewing their spouses. The other strength was the use of both quantitative and qualitative methods during data collection. The qualitative findings helped to explain the quantitative findings by answering the question on what factors influenced men's participation in the PMTCT activities.

Both studies had potential limitations. Being cross-sectional surveys, causality could not be inferred from our findings [155-157]. The participants in both studies were enrolled consecutively and not randomly. This may have introduced a selection bias, thus undermining the internal validity. However, since about 95% of pregnant women in Uganda attend at least one antenatal visit [94, 95], the effect of possible selection bias on our study findings is minimal. We collected the data in both studies using experienced, trained research assistants (males and females) and pre-tested questionnaires. Completeness of questionnaires was checked regularly. Therefore potential information bias is likely to have been limited. The new antenatal attendees were not asked about their HIV status in order to assure confidentiality and minimize information bias. We attempted to reduce social desirability bias by using data collectors who were not health staff, conducted the interviews in a private environment and appealed to the participants to give honest answers to the questions in the questionnaire. In paper III study, we determined the level of male involvement using an ad hoc male involvement index. It is possible this may have introduced some measurement bias. As far we are aware, there is no established instrument to determine the level of male participation in the PMTCT programme. To ensure good consistency of the data in the qualitative part in this study, a combination of note-taking and tape-recording (verbatim) of the focus group discussions and the in-depth interviews was used. Double entry of data and data cleaning were done before data analysis, and

during data analysis, interactions were checked for and confounding adjusted for using multiple logistic regression technique. With the high number of participants studied, the confidence intervals of our results are narrow and our study findings are unlikely to be due to chance. Therefore, we consider the internal validity of our findings in the two studies to be high.

The studies were conducted in Mbale district in eastern Uganda. Even though the study participants were from rural and urban areas they may not be representative of the whole population of Uganda. Therefore, our study findings may not be extrapolated to the rest of the population nationwide and it is not possible to generalize our findings to other sub-Saharan Africa countries, more so where the level of maturation of the HIV epidemic is different from that in Uganda. For the qualitative part of paper III study, the transferability of our findings to other populations beyond our study area may be limited.

Paper IV

A randomised controlled trial gives strong evidence for the effectiveness of an intervention [158, 159]. It also enables us to control for known and unknown confounding factors. This design – a parallel group, randomised health facility-based intervention – was appropriate for the study objective, that is: to evaluate the effect of a written invitation letter to the spouses of the new antenatal attendees on antenatal couple attendance and male partner acceptance of HIV testing.

The baseline demographic characteristics of the study participants in this trial show that randomisation worked well and that the outcome variable (couple antenatal attendance) may not have been affected by participant assignment bias. Health staff and research assistants were blinded. It is assumed that randomisation and blinding dealt with known and unknown confounders in both arms of the trial [159]. However, the respondents were not blinded, which is impossible in behavioural interventions. It is possible that there could have been contamination between the two trial arms if the participants shared the information about the interventions. The main limitation of the trial was arguably the high loss to follow-up rate of approximately 40%, negatively

impacting on the precision (internal validity) of our findings, reducing the power (from 80% to 30%) of the trial to detect real differences between the arms and introducing the potential of a differential loss to follow-up. There are several possible explanations for the high rate of loss to follow-up. First, we had a short follow-up period (coming back within 4 weeks). Second, women with low risk pregnancies may have decided to continue getting their antenatal care at lower level health facilities closer to home. Third, some may have come to the hospital in order to get a hospital antenatal card and access HIV counselling and testing services but thereafter continued attending antenatal clinics elsewhere or to be able to deliver in the hospital in case of problems. Fourth, due to financial constraints, some women may have failed to come back for their return ANC visits as scheduled.

Another strength was that being both a principal investigator for the trial and a clinician in the hospital, I intentionally did not directly participate in administering intervention to the trial participants in order to avoid the Hawthorne effect [153, 160, 161] on the internal validity of the trial.

Behavioural interventions are inherently contextual and therefore it is difficult to know if the intervention will work as in our case in other places without trying. We consider that it is likely to have a similar impact in populations that are similar or close to the one in the trial area.

5.2 Discussion of findings

Paper I and II: Provider-initiated testing and counselling
At the time we carried out and published studies I and II, provider-initiated testing and counselling (PITC) was still under debate and mainly questioned from a human rights perspective, whether it was correct to push for HIV counselling and testing [162-166]. Our Paper I demonstrated a dramatic increase in the testing rates in the new antenatal attendees in the antenatal clinic. Paper II showed that almost all the participants were positive to PITC; the main reasons being that it considerably decreased stigma related

to the testing and the need to ask the husband for permission to be tested. Now (2013), a couple of years down the line, there is an overwhelming number of different studies in different settings, basically showing the same thing as our papers I and II: that PITC is highly acceptable to the women, that it increases testing considerably and that it decreases stigma [167, 168] and a recent review article supports our findings [169].

One issue remains, however, as PITC did not lead to a similar increment in the male partner testing rates. This has led to an increase in the inequity in access to HIV testing between the sexes. We therefore went on to paper III and IV to see how this inequity in access to HIV testing between the antenatal attendees and their male partners could be reduced.

PAPER III and IV: Male partner involvement in PMTCT
The study Paper III showed that determinants of male participation in the PMTCT programme included social, economic, cultural and health system factors, and male partner involvement in the PMTCT programme was low**.** The intervention study in paper IV showed that the use of a letter addressed to male partners increased couple antenatal clinic attendance from 5% to 15% and most of the male partners accepted the HIV test. However, the outcome in the two study arms was similar. Other studies support our findings [138, 170]. We tried to remove some of the health system factors and had an encouraging effect in light of the fact that the letter did not change the social, economic or cultural factors.

Why was the outcome in the two arms so similar?
This study used a simple, cheap intervention (a letter) that was easy to administer. In the Mbale Regional Referral Hospital with its 10 000 new ANC attendees annually the cost of this intervention is 200 USD per year (not counting the extra workload). The effect was encouraging and should be tried in programmatic fashion in several other places. As mentioned above, behavioural interventions are inherently contextual and it is difficult to predict if it will work as well in other places without trying. It could be subjected to regular monitoring and evaluation and with more resources, the follow-up

period could be increased and the intervention could be introduced in a step-wise manner.

So far, we have not found any similar study being carried out, neither as a trial nor as a programmatic intervention. It seems like the potential found in a single sheet letter to the partner in increasing the male participation has not been fully utilised and in this sense our findings are underutilised. More lobbying among strong stakeholders and programme organisers is needed.

We know that a number of social, economic, cultural and health system factors are hindering the male partners to come forward for HIV testing. We tried to remove some of the health system factors and had an encouraging effect in light of the fact that the letter did not change the social, economic or cultural factors.

Other ways than a letter to the partner to reduce the gender inequity in access to testing that have been proposed are: couple counselling [171], community sensitisation to mobilise men [170], use of male peer counsellors , and HIV testing in other environments [172] such as: community based testing [173, 174] workplace testing, home-based testing [175, 176] and hot spot testing. Most likely, a combination of efforts will have a larger impact.

6.0 CONCLUSION

PITC remarkably increased the HIV testing rates among the antenatal attendees and was highly acceptable to the antenatal attendees and can therefore be actively promoted in antenatal clinics and possibly other clinical settings.

Although cheap and underutilised, the use of an invitation letter addressed to the male partners of the ANC attendees increased male antenatal attendance and HIV testing. It should be promoted in antenatal clinics in Eastern Uganda where it has been shown to work and tried in other areas with low male antenatal attendance, both in Uganda and beyond.

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Dramatic and sustained increase in HIV-testing rates among antenatal attendees in Eastern Uganda after a policy change from voluntary counselling and testing to routine counselling and testing for HIV: a retrospective analysis of hospital records, 2002-2009

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Abstract

Background: The burden of mother-to-child transmission of HIV in Uganda is high. The aim of this paper is to describe the experience of the first 7 years of the prevention of mother- to- child transmission of HIV (PMTCT) programme in Mbale Regional Hospital, Eastern Uganda, with particular reference to the lessons learnt in changing from voluntary counselling and testing (VCT) to routine counselling and testing (RCT) for HIV testing in antenatal services.

Methods: The study was a retrospective analysis of the PMTCT records of Mbale Regional Referral Hospital, Uganda, from May 2002 to April 2009. The data on HIV testing of pregnant women and their male partners was extracted from the reports and registers using a standardized data extraction form, and data was analysed using descriptive statistics. Permission to conduct the study was obtained from School of Medicine, Makerere University College of Health Sciences; Uganda National Council of Science and Technology, and Mbale Hospital.

Results: A total of 54 429 new antenatal (ANC) attendees and 469 male-partners accessed antenatal services at Mbale Regional Referral Hospital. There was a sustained, significant increase in HIV testing among new ANC attendees from 22% during the VCT period to 88% during the RCT period ($p = 0.002$), while among male partners, HIV testing increased from 88% to 100% ($p = 0.010$) However, the overall number of male partners who tested for HIV remained very low despite the change from VCT to RCT approach in HIV testing.

Conclusions: Routine offer of antenatal HIV testing dramatically increased HIV testing in pregnant women and their partners in Uganda. Our findings call for further strengthening of the policy for routine HIV testing in antenatal clinics. Our study also showed that male partner HIV testing in antenatal clinics is low and this area needs further work through research and innovative interventions in order to improve male partner involvement.

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\Background

Over the last decade, large efforts have been used to prevent mother-to-child transmission (MTCT) of HIV in Sub-Saharan Africa. The prevention of mother-to-child transmission of HIV (PMTCT) programme has evolved over the past decade and currently comprises of HIV counselling, HIV-testing, infant feeding counselling, and antiretroviral prophylaxis.

In Uganda, the burden of mother-to-child transmission of HIV in Uganda is high because of the large number of deliveries (1.3 million deliveries per year), almost universal breastfeeding [1] and the high [6.0%] antenatal HIV prevalence [2,3]. This implies that about 78 000 of the women who deliver annually are living with HIV. Hence without any interventions for PMTCT, about 30% of these women would pass the virus to their babies. This translates to about 23 400 infected children every year, at least half of would be prevented if there were a nation-wide PMTCT programme. The national PMTCT programme was launched as a pilot intervention in 8 hospitals in the year 2000, and was integrated into existing antenatal care services. The Government of Uganda in collaboration with UNAIDS, UNICEF and other partners scaled up the PMTCT programme to all districts by December 2004. The programme was introduced as a client-initiated approach where antenatal care clients were encouraged to undergo counselling and testing for HIV if they so wished. This approach is also known as 'opt-in' or voluntary counselling and testing (VCT).

The prevention of mother-to-child transmission of HIV package consisted of interventions designed to reduce the risk of HIV transmission during pregnancy, labour, delivery and during the postnatal period. The comprehensive PMTCT package comprises of the following:

 • VCT that is integrated within the antenatal clinic services
 • Quality antenatal, intra-natal and postnatal care services as well as follow-up support for both the mother and baby
 • Antiretroviral (ARV) drugs for HIV-positive mothers and their babies
 • Counselling and support on optimal infant and young child feeding
 • Promotion of family and community support including the involvement of male partners and spouses

The ARV prophylaxis regimen was a single dose of *Nevirapine (NVP)* 200 milligrams (mg) to the mother at onset of labour, and a single of *NVP* (2 mg/kilogram [kg] body weight), to the baby within 72 hours of birth.

The infant feeding options to HIV infected mothers were either breastfeeding only for 3 months with abrupt weaning or replacement feeding if it was affordable, feasible, acceptable sustainable and safe (AFASS). By December 2005, the PMTCT programme was providing HIV counselling to about 35% and HIV testing to about 20% of all pregnant women in the country. Only 15% of the pregnant women living with HIV in the country were identified and about 10% of them accessed prophylactic antiretroviral drugs for PMTCT [4]

Following CDC and UNAIDS/WHO recommendations [5,6], there was a change in strategy in the year 2006. The provider-initiated approach that routinely tests all antenatal attendees for HIV was introduced in the PMTCT programme in Uganda in 2006. This approach is also known as 'opt-out' or routine counselling and testing (RCT). Concurrently, new guidelines on the use of ARV prophylaxis for PMTCT were issued. The ARV regimen included: *Zidovudine (AZT, ZDV)* 300 mg given to the mother orally plus *Lamivudine (3TC)* 150 mg twice a day starting from 32 weeks through out labour and boosted by a single dose of *NVP* 200 mg at onset of labour. Then she continues with *AZT plus 3TC* twice a day for one week after delivery. The baby receives a single dose of *NVP* syrup (2 mg/kg body weight) within 72 hours of birth and *AZT* syrup (4 mg/kg body weight, twice a day for seven days. The HIV-infected mothers were recommended to either exclusively breastfeed for 6 months instead of 3 months or give replacement feeds if affordable, feasible, acceptable sustainable and safe.

In Uganda, about 94% of the women attend the antenatal clinic at least once during pregnancy but less than half (47%) of them receive 4 or more visits for antenatal care. Only about 17% of the women make their first antenatal visit in the first three months of pregnancy. However, a high proportion (41%) of women makes their first antenatal care (ANC) visit in the fourth or fifth months of pregnancy. The median gestational age at the first visit is 5.5 months, when the opportunity may have passed to diagnose problems early, provide treatment, and prevent further complications. About 41% of women deliver in a health facility and about 58% deliver at home [7]. The aim of this paper is to describe the experience of the past 7 years of the PMTCT programme in Mbale Regional Hospital, Eastern Uganda, with particular reference to the lessons learnt in changing from the VCT to the RCT strategy for HIV testing and counselling in antenatal services.

Methods

The study was conducted at Mbale Regional Referral Hospital in Mbale district, Eastern Uganda. It was a retrospective analysis of data from hospital records on HIV

counselling and testing of antenatal attendees in the hospital covering a seven year period (May 2002 to April 2009). The hospital is located in Mbale town approximately 240 kilometres North-East of Kampala city by road. The district had a population of over 720 000 in the year 2002, with an annual population growth rate of 2.5%. Like the rest of Uganda, 92% of the people live in the rural areas and are predominantly *Bagisu* or *Bamasaba*. The main language is *Lumasaba* and the main economic activity is subsistence farming. The literacy rate was 64% for men and 49% for women [8]. In 2003, the HIV prevalence was reported to be 5.6% [9]. The PMTCT services are offered at Mbale Regional Referral Hospital, Bufumbo Health Centre IV and some of health centre III units in the district. It is a regional referral hospital for 11 districts in Eastern Uganda and serves an estimated population of 1.9 million people. The hospital has a bed capacity of 380 and serves approximately 6 000-9 000 new antenatal attendees per year. The antenatal care services are provided daily except weekends. The average attendance is 50-60 pregnant women per day, including those who come for ANC return visits. The HIV testing policy is communicated to women attending ANC by either nurses/midwives or lay counsellors during the health talk given in the morning after the mothers' registration exercise in the clinic. All the health workers involved in the PMTCT programme underwent a basic two-week course on counselling for PMTCT and a one-week course on infant and young child feeding counselling, though some of them are now fully-trained professional counsellors. They also received a one-week refresher course on updates about HIV counselling and testing before the introduction of RCT in June 2006. Initially the counsellors offered one-to-one pre and post-test counselling, since the number of clients accessing the PMTCT services was low. However, as the number of antenatal attendees undergoing VCT increased, pre-testing counselling was given to small groups of about 5 clients (from January 2003) but individual post-test counselling was maintained. The pregnant women were encouraged to come for HIV testing with their partners but very few men showed up for VCT. However since introduction of RCT in June 2006, the service-providers give pre-test group counselling to large groups of ANC attendees, but offer one-to-one post-test counselling to the women. Couples who come for RCT are seen first before attending to the mothers who come alone as one way of encouraging couple attendance.

HIV testing is done on-site by the health staff in the antenatal clinic who have received a five-day training on HIV tests using rapid HIV testing kits. All the other routine antenatal tests are performed by the laboratory staff in the hospital's main laboratory nearby. A sequential HIV testing algorithm, with same day results, including three rapid tests is used on one blood sample: *Determine HIV 1/2 assay (Abbott Laboratories, Abbott Park, IL, USA)* for first screening; *STAT-PAK HIV 1/2 DIPSTICK assay (Chembio Diagnostic Systems Inc.)* as a second test and *Uni-Gold (Trinity Biotech, Wicklow, Ireland)* as a "tie-breaker". The ANC attendees are classified as uninfected if *Determine* is negative and as HIV-infected if both *Determine* and *STAT-PAK* tests are positive. Discordant *Determine* and *STAT-PAK* blood samples are tested using the *Uni-Gold* test. The HIV test result is reported as positive if the *Uni-Gold* test is positive or as negative if both *STAT-PAK* and *Uni-Gold* tests are negative. Since 2006 ANC attendees who test HIV-positive undergo CD4 cell count before being given appropriate treatment according to the national PMTCT guidelines [10].

Several registers are used to monitor and evaluate the performance of the PMTCT programme. The *VCT and HIV Register* is used during counselling and testing for HIV to collect data from all women who are counselled. The *Enrolment Register* is used to collect information from HIV positive mothers at the time of getting the antiretroviral drugs (accessed free of charge in the antenatal clinic or the labour ward). The *Delivery and Birth Register* is used to collect information from all HIV-positive women who have been enrolled on the programme, at the time when they are in labour and immediately after they have delivered. The *Follow-up Register* is used to collect data during the postnatal period and beyond while the mother and baby are being followed up till the bay is at least eighteen months of age. In addition, there are two summary registers, namely the *Antenatal Summary Register* and the *Delivery Summary Register*, for monthly antenatal activities as well as activities related to labour and delivery. Every month, the PMTCT coordinator in the hospital compiles a report about the PMTCT activities in the hospital, a copy of which is sent to the National PMTCT programme manager in the Ministry of Health headquarters.

We analysed the monthly PMTCT programme reports, the *VCT and HIV Registers, the Enrolment Registers and the Antenatal Summary Registers* in the antenatal clinic, and the *Delivery Summary Registers and HIV registers* in the maternity ward at Mbale Regional Referral Hospital covering a seven-year period (May 2002-April 2009). The data was extracted using a standardized data extraction form, and entered into an excel sheet. The variables of interest were: total number of new antenatal attendees per year, number of ANC attendees counselled about HIV, number of ANC attendees who underwent HIV-testing and number of ANC attendees who obtained a positive HIV-test result. The other variables were: number of male partners

counselled for HIV, number tested for HIV and number of those who obtained a positive HIV-test result, number HIV-infected mothers and their infants who received ARV prophylaxis for PMTCT. The total number of new attendees and male partners who accessed the ANC and PMTCT services, and the total number of HIV-positive women and their infants that accessed ARV drugs (ARVs) was computed annually. The percentages of the ANC attendees or their male partners who were counselled and tested for HIV and of those who tested HIV-positive were calculated. The few pregnant women who knew that they were HIV positive at their first antenatal visit were recorded in the *VCT and HIV Registers* as having been counselled about HIV and infant feeding options, and we included them in the analysis among the total number HIV-positive ANC attendees. The *Student's t-test* was used to compare some selected indicators for PMTCT in the hospital before and after the policy change in antenatal HIV-testing approach. A *p*-value of < 0.05 was considered statistically significant.

Ethical clearance to conduct the study was obtained from the Research and Ethics Committee of the School of Medicine, Makerere University College of Health Sciences; the Uganda National Council of Science and Technology; and the National PMTCT programme, Ministry of Health, Uganda. Permission to use the hospital records was obtained from the Mbale Regional Referral Hospital administration through the local institutional review board.

Results

Overall results of HIV testing

From May 2002 to April 2009, a total of 54 429 new ANC attendees and 469 male-partners accessed antenatal services at Mbale Regional Referral Hospital. Of all the new ANC attendees, 42 754 (78.6%) were counselled about HIV, 28 108 (51.6%) were tested for HIV and 1713 (6.1%) of those tested received an HIV-positive result. During the same period, a total of 469 male partners received HIV counselling while 459 (97.9%) of them were tested for HIV and 40 (8.7%) of those tested were HIV positive.

Trends of HIV testing in pregnant women

From May 2002 to May 2006 (VCT period), 6 570 (22.0%) out of 29 834 new ANC attendees were tested for HIV as compared to 21 538 (87.6%) out of 24 595 new ANC attendees who were tested during the RCT period from June 2006 to April 2009 (*p* = 0.002), with a corresponding increase in numbers of HIV-infected women identified antenatally (n = 1147, 5.3% sero-prevalence as compared with 566, 8.6% sero-prevalence in the VCT period, *p* = 0.012), Figure 1 and table 1.

During the period of May 2002 to April 2003, a total of 6 298 pregnant mothers attended their first antenatal visits. Of these, 1 903 (30%) were counselled and 209 (3%) were tested for HIV. A steady increase in pregnant mothers accepting voluntary counselling and testing (VCT) for HIV was observed during the first three years of the PMTCT programme, Figure 2 and table 2. From May 2004 to April 2005, out of 7 982 new ANC attendees, 3 546 (44%) accepted HIV testing. However in the following year (May 2005 - April 2006), 1 915 (22.9%) out of 8 358 pregnant mothers were tested for HIV though 5 811 (73%) new ANC attendees had been counselled.

In the first year after the policy change from VCT to RCT, there was a dramatic increase in the number of mothers who were tested for HIV. Out of 7 286 new ANC attendees, 6 393 (79%) of them were tested for HIV. The number of mothers accepting an HIV-test rose to 95% (7 792 mothers out of 8 245) in the period from May 2008 to April 2009, table 2. The increase in coverage of antenatal HIV testing among the pregnant women led to a corresponding significant increase in the use of PMTCT interventions, table 1.

Trends of HIV testing in men

During the VCT period, out of 80 male partners that accompanied their spouses to the antenatal clinic, 70 (87.5%) of them were tested for HIV compared with 389 male partners (100%) who escorted their spouses for antenatal care and accepted HIV testing (*p* = 0.010), with a corresponding increase in the numbers of HIV-infected male partners identified in the RCT period (n = 25, 6.4% sero-prevalence as compared with 15, 21.4% sero-prevalence in the VCT period, *p* = 0.103), table 1 and table 3. In comparison with the new ANC attendees, the number of male partners who underwent counselling and testing for HIV at the antenatal clinic in Mbale Regional Referral Hospital remained very low despite the change from VCT to RCT approach in HIV testing, table 1 and 3.

Discussion

Our study showed that the policy change from VCT to RCT dramatically increased the number of mothers tested for HIV. This change was sustained over the 3 years of observation. These findings are similar to those reported elsewhere in Africa [11]. In rural Malawi, the number of pregnant women who accepted HIV-testing increased from 78.7% to 98.8% after changing from VCT to RCT testing approach for HIV[12]. A study from an urban area in Zimbabwe found that 99.9% of the ANC attendees underwent HIV-testing during the first 6 months of routine HIV-testing compared to 65% of the women during the last 6 months of opt-in testing
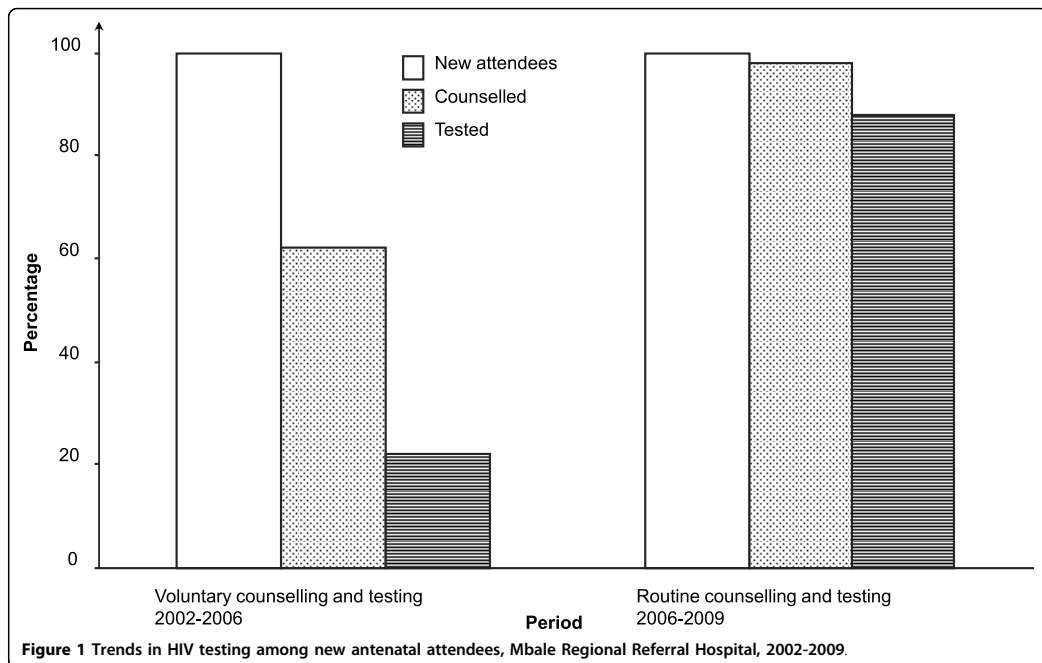
Figure 1 Trends in HIV testing among new antenatal attendees, Mbale Regional Referral Hospital, 2002-2009.

Table 1 Selected indicators of prevention of mother-to-child HIV transmission at Mbale Regional Referral Hospital, 2002-2009

Indicator	Voluntary HIV testing period n (%)	Routine HIV testing period n (%)	P-value (two-tailed)
New ANC attendees			
Booked for ANC	29834	24595	-
Counselled for HIV	18583 (62.3)	24171 (98.3)	0.042*
Tested for HIV	6570 (22.0)	21538 (87.6)	0.002*
HIV positive	566 (8.6)	1147 (5.3)	0.012*
Male Partners of the ANC attendees[a]			
Counselled for HIV	80 (100)	389 (100)	0.012*
Tested for HIV	70 (87.5)	389 (100)	0.010*
HIV positive	15 (21.4)	25 (6.4)	0.112
HIV- infected pregnant women			
Used ARVs for PMTCT[b]	316 (55.8)	885 (77.2)	0.015*
Delivered in hospital	172 (30.4)	464 (40.5)	0.042*
Infants given ARVs for PMTCT[c]	184 (32.5)	451 (39.3)	0.050

* Statistically significant *p*-value of the independent-samples *t*-test at the 0.05 level.

[a] All male partners who accompanied their spouses for the antenatal care visit were counselled about HIV.

[b] During the VCT period the HIV- infected women and their infants received single dose *Nevirapine (sdNVP)*, but in the RCT period the mothers received a combination regimen of *Zidovudine (ZDV, AZT)* and *Lamivudine (3TC)* from 32 weeks plus *sdNVP* at onset of labour. The infants received *sdNVP* syrup and *ZDV* syrup for one week. Women were started on HAART after 14 weeks gestation if they had a CD4 count of < 350 or WHO disease stage 3 or 4 clinically.

[c] Some babies were brought to hospital for the ARVs within 72 hours of birth outside the hospital and some babies born in the hospital missed getting ARVs when out of stock.

Figure 2 Trend of HIV counselling, testing and sero-positivity among new antenatal attendees, Mbale Regional Referral Hospital, 2002-2009.
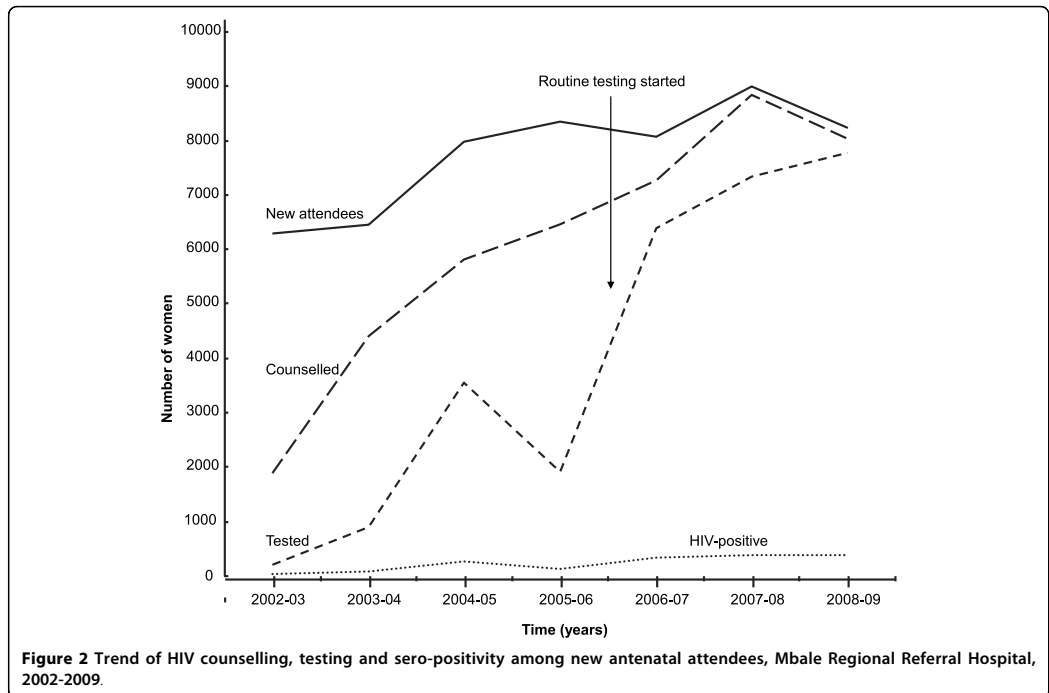
[13]. A study conducted in Botswana demonstrated an increase in HIV testing rate from 75% in the last 3 months of VCT period to 91% in the first 4 months of RCT period [6].

The high proportion of routine HIV-testing in our study could be attributed to several factors. The new ANC attendees were less fearful of accepting HIV-testing because the opt-out approach was perceived by their partners and families as "standard of care" given to all pregnant women in the antenatal clinic. In addition, the availability of rapid HIV-testing in the clinic and the giving of same-day HIV test results may have contributed to the high proportion of HIV-testing. The refresher

courses given to the ANC providers/counsellors with the launch of RCT in June 2006 may have equipped them with improved HIV counselling and testing skills, and thus may have had a positive impact on the testing during the RCT period. Our study has also shown that the high coverage of antenatal HIV-testing after policy change significantly identified more HIV-infected pregnant women who easily accessed the free antiretroviral drugs (ARVs) in the antenatal clinic and the maternity ward. A similar finding was reported in study in Zimbabwe [13].

During the first 3 years of the VCT period (May 2002 - April 2005), there was a substantial increase in HIV

Table 2 Antenatal HIV counselling and testing among new attendees at Mbale Regional Referral Hospital, 2002-2009

Period	HIV testing Approach	New ANC attendees N	Counselled n (%)	Tested n (%)	HIV-positive n (%)
May 02 - April 03	VCT	6 298	1 903 (30.2)	209 (3.3)	45 (21.5)
May 03 - April 04	VCT	6 468	4 407 (68.1)	900 (13.9)	101 (11.2)
May 04 - April 05	VCT	7 982	5 811 (72.8)	3 546 (44.4)	288 (8.1)
May 05 - April 06	VCT	8 358	6 462 (77.3)	1 915 (22.9)	132 (6.9)
May 06 - April 07	RCT	8 079	7 286 (90.2)	6 393 (**79.1**)	356 (5.6)
May 07 - April 08	RCT	8 999	8 851 (98.4)	7 353 (**81.7**)	387 (5.3)
May 08 - April 09	RCT	8 245	8 034 (97.4)	7 792 (**94.5**)	404 (5.2)

Table 3 Male partners counselled and tested for HIV at Mbale Regional Referral Hospital, 2002-2009

Period	HIV testing approach	Male partners[a] counselled N	Male partners tested n (%)	Male partners HIV-positive n (%)
May 02 - April 03	VCT	8	7 (87.5)	3 (42.9)
May 03 - April 04	VCT	6	6 (100)	1 (16.7)
May 04 - April 05	VCT	32	28 (87.5)	8 (28.6)
May 05 - April 06	VCT	34	29 (85.3)	3 (10.3)
May 06 - April 07	RCT	103	103 (100)	11 (10.7)
May 07 - April 08	RCT	92	92 (100)	9 (9.8)
May 08 - April 09	RCT	194	194 (100)	5 (2.6)

[a] All male partners who accompanied their spouses for antenatal care were counselled (100%) and most of them were tested for HIV in the antenatal clinic.

testing among the antenatal attendees from 3.3% to 44%, but testing coverage halved in the following year (May 2005/April 2006). This decline was largely due to inadequate supplies of HIV-test kits and sundries during that period and the HIV-test tests were completely out of stock in the months of April and May 2006, Figure 2. During those two months about 1400 new attendees visited the antenatal clinic but could not be offered HIV-testing services, leading to missed opportunities as has been documented elsewhere [14-16].

The apparent higher prevalence of HIV in the VCT period is likely to be attributed to selection bias. It is probable that the ANC attendees who perceived themselves to be at higher risk of HIV infection were the ones that most likely opted to test for HIV voluntarily. Coupled with the small number of pregnant women that were tested for HIV, this may partly explain the higher prevalence of HIV during the VCT period. The shift from one-to-one pre-test counselling to group pre-test counselling seems not to have impacted on the testing rates since there was a substantial increase in antenatal HIV-testing rates from 14% to 44% in the periods May 2003/April 2004 and May 2004/April 2005 respectively.

Our study showed that the number of male partners who tested for HIV at the antenatal clinic was low (below 5%) compared to the total number of the ANC attendees despite the change from "opt-in" to "opt-out" approach in HIV-testing. Poor male partner involvement in PMTCT programme has been documented elsewhere in Africa, and studies in Tanzania, Kenya and Zambia [17,7] have reported HIV testing rates among male partners of 9% to 16%. Male partner involvement is essential for improving PMTCT outcomes [17-19]. Thus the low rate of HIV-testing among the male partners remains a major challenge to the PMTCT programme in Uganda. Overall, 98% of the male partners of the new ANC attendees were tested for HIV. During the "opt-in" period, 88% of the male partners accepted HIV testing while 100% accepted HIV testing in the "opt-out"

period. Although the number of male partners in our study was small, the opt-out approach appears to increase male partner testing for HIV.

The study revealed that the average prevalence of HIV among the new ANC attendees over the 7-year study period was 6.1%. Similarly, HIV prevalence rates of 6.0% and 5.9% have been reported by Musinguzi et al and the Uganda Demographic and Health Survey respectively [2,3]

Our study had a number of limitations. It was a retrospective analysis of routinely collected data in the antenatal clinic and made comparisons between two different time periods. Accordingly, the study may have suffered from selection bias arising from differential selection of the participants, and from confounding due to inability to measure and control for potential confounders concurrently. For example, it was not possible to measure and control for other possible factors like media influence that may have contributed to the increase in HIV testing that was observed in the study. The change in HIV testing from VCT to RCT coincided with a period of wide availability of free ARVs especially for treatment. This may have been a potential confounder since the ANC attendees knew they could easily access the required ARVs in case they were found to be HIV positive. It is also possible that the policy change in HIV testing strategy may have introduced some measurement bias but this is likely to have been minimal. In addition, there was missing data and limited demographic data in the records that may also have impacted on the study findings. Finally, the small number of male partners who accessed the PMTCT services may also have affected the validity of the data on male partners in the study.

Conclusions

Despite these limitations, our study documented a dramatic and sustained increase in antenatal HIV testing among pregnant women and their partners in Mbale, Eastern Uganda following the change from VCT to

RCT. Our findings call for further strengthening of the policy for routine HIV testing in antenatal clinics. Our study also showed that male partner HIV testing in antenatal clinics is low and this area needs further work through research and innovative interventions in order to improve male partner involvement.

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Authors' contributions
RB participated in the conception, design, and implementation of the study, statistical analysis, interpretation and drafting of the manuscript. CASK participated in statistical analysis and interpretation, and the drafting on the manuscript. TT participated in the conception and design of the study, interpretation and drafting the manuscript. MK participated in study conception, design and drafting of the manuscript. SO participated in interpretation and drafting of the manuscript. JKT participated in the study conception, design, statistical analysis, interpretation and drafting of the manuscript. All authors read and approved the final manuscript.

Competing interests
The authors declare that they have no competing interests.

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II

RESEARCH

Attitudes to routine HIV counselling and testing, and knowledge about prevention of mother to child transmission of HIV in eastern Uganda: a cross-sectional survey among antenatal attendees

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Abstract

Background: HIV testing rates have exceeded 90% among the pregnant women at Mbale Regional Referral Hospital in Mbale District, eastern Uganda, since the introduction of routine antenatal counselling and testing for HIV in June 2006. However, no documented information was available about opinions of pregnant women in eastern Uganda about this HIV testing approach. We therefore conducted a study to assess attitudes of antenatal attendees towards routine HIV counselling and testing at Mbale Hospital. We also assessed their knowledge about mother to child transmission of HIV and infant feeding options for HIV-infected mothers.

Methods: The study was a cross-sectional survey of 388 women, who were attending the antenatal clinic for the first time with their current pregnancy at Mbale Regional Referral Hospital from August to October 2009. Data were collected using a pre-tested questionnaire and analysed using descriptive statistics and logistic regression. Permission to conduct the study was obtained from the Makerere University College of Health Sciences, the Uganda National Council of Science and Technology, and Mbale Hospital.

Results: The majority of the antenatal attendees (98.5%, 382/388) had positive attitudes towards routine HIV counselling and testing, and many of them (more than 60%) had correct knowledge of how mother to child transmission of HIV could occur during pregnancy, labour and through breastfeeding, and ways of preventing it. After adjusting for independent variables, having completed secondary school (odds ratio: 2.5, 95% confidence interval: 1.3-4.9), having three or more pregnancies (OR: 2.5, 95% CI: 1.4-4.5) and belonging to a non-Bagisu ethnic group (OR: 1.7, 95% CI: 1.0-2.7) were associated with more knowledge of exclusive breastfeeding as one of the measures for prevention of mother to child transmission of HIV. Out of 388 antenatal attendees, 386 (99.5%) tested for HIV and 382 (98.5%) received same-day HIV test results.

Conclusions: Routine offer of antenatal HIV counselling and testing is largely acceptable to the pregnant women in eastern Uganda and has enabled most of them to know their HIV status as part of the prevention of mother to child transmission of HIV package of services. Our findings call for further strengthening and scaling up of this HIV testing approach in many more antenatal clinics countrywide in order to maximize its potential benefits to the population.

Background

HIV counselling and testing is pivotal to HIV prevention, care and treatment programmes as knowing one's HIV status is a precursor to accessing the appropriate care and treatment services. However, data from surveys conducted in 12 high-prevalence countries in sub-Saharan Africa show that only 12% of men and 10% of women know their HIV status [1]. Uganda has an estimated adult HIV prevalence rate of 6.7%, and only 15% of adults are aware of their HIV status [2]. It is

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estimated that in 2008, mother to child transmission of HIV accounted for 15% of new HIV infections in Uganda [3,4].

Routine antenatal counselling and testing for HIV, also known as provider-initiated testing or an "opt-out" approach, involves testing all antenatal attendees for HIV, apart from those who decline the test (i.e., those who opt out). This is the standard of care in Scandinavia and other high-income countries [5-10]. In a bid to increase HIV testing rates, routine antenatal HIV counselling and testing was successfully introduced in the HIV prevention programmes of several countries in sub-Saharan countries [11-15] in line with Centers for Disease Control and Prevention (CDC) and Joint United Nations Programme on HIV/AIDS (UNAIDS) and World Health Organization (WHO) recommendations [16,17].

In Uganda, the policy change from antenatal voluntary HIV counselling and testing (VCT), also known as the client-initiated or "opt-in" approach (where clients are encouraged to undergo counselling and testing for HIV if they so wish) to routine HIV counselling and testing (RCT) was integrated into the prevention of mother to child transmission (PMTCT) of HIV programme in 2006 [18]. As a result, there has been a sustained increase in HIV testing rates to more than 90% among the pregnant women at Mbale Regional Referral Hospital since June 2006 [19]. We conducted our study to assess: (a) attitudes towards routine HIV testing among the new antenatal attendees in the hospital; and (b) their knowledge about mother to child transmission of HIV and infant feeding options for HIV-infected mothers.

Methods

The study site was Mbale Regional Referral Hospital, located in the town of Mbale, approximately 240 kilometres north-east of the city of Kampala by road, in Mbale District. The district has a population of about 410,600 (2010 estimate) [20] and an annual population growth rate of 2.5%, according to the 2002 national census. The majority (92%) of the people in this district live in the rural areas. They are predominantly Bagisu or Bamasaba people. The main language is Lumasaba and the main economic activity is subsistence farming. The literacy rate is 64% for men and 49% for women [21]. In 2003, HIV prevalence was reported to be 5.6% [22].

The hospital in Mbale is a regional referral hospital for 11 districts in eastern Uganda and serves an estimated population of 1.9 million people. The hospital has a bed capacity of 380 and serves 6000 to 9000 new antenatal attendees per year. Antenatal care services (ANC) are provided daily, except for weekends. The average attendance is 50 to 60 pregnant women per day, including those who come for ANC return visits.

The prevention of mother to child transmission (PMTCT) of HIV programme was launched at the hospital in May 2002 as an integrated service in the antenatal care services. The PMTCT programme was introduced as a voluntary counselling and testing (VCT) for HIV approach. In line with CDC and UNAIDS/WHO recommendations [16,17], the Uganda Ministry of Health issued new guidelines for HIV counselling and testing of pregnant women in September 2005 [23] and a revised edition of Policy Guidelines for Prevention of Mother to Child Transmission of HIV in August 2006 [18]. VCT was replaced by routine counselling and testing (RCT) in Mbale Regional Referral Hospital in June 2006.

Currently, service providers give pre-test group counselling to groups of ANC attendees. The counsellors in the antenatal clinic first attend to couples who come for RCT when the clinic opens in the morning before attending to the mothers who have come alone: this is one way of encouraging couple attendance. Routine HIV testing is done with the client's knowledge and verbal consent. Mothers are free to decline (opt out of) HIV testing if they so wish without fear of any retribution from the clinic staff.

According to national guidelines, a sequential HIV testing algorithm, with same-day results, including three rapid tests is used on one blood sample: Determine HIV 1/2 assay (Abbott Laboratories, Abbott Park, IL, USA) for first screening; STAT-PAK HIV 1/2 dipstick assay (Chembio Diagnostic Systems Inc.) as a second test and Uni-Gold Recombigen HIV (Trinity Biotech, Wicklow, Ireland) as a "tie-breaker". An ANC attendee is classified as uninfected if Determine is negative and as HIV-infected if both Determine and STAT-PAK tests are positive. Discordant Determine and STAT-PAK blood samples are tested using the Uni-Gold test. The HIV test result is reported as positive if the Uni-Gold test is positive, or as negative if both STAT-PAK and Uni-Gold tests are negative. Since 2006, ANC attendees who test HIV positive undergo CD4 cell count tests before being given appropriate treatment according to the national PMTCT guidelines [18].

A cross-sectional survey was conducted among 388 new antenatal attendees in the antenatal clinic at Mbale Regional Referral Hospital from August to October 2009. The targeted study population were all antenatal attendees who were visiting the hospital for the first time within the current pregnancy. Women, who were very sick, requiring urgent medical attention, were excluded from the study. Women attending ANC for the first time were identified at reception, and tracked through RCT for HIV and through routine antenatal assessment. All those who were confirmed as having undergone RCT for HIV were consecutively identified and approached for inclusion in the

study after giving written informed consent for exit interviews about their attitudes regarding RCT until the required sample size was obtained.

The sample size was calculated using the computer programme, OpenEpi, version 2, open source calculator (open source software for epidemiologic statistics: http://www.openepi.com/SampleSize/SSCohort.htm), based on the following assumptions: (a) a two-sided confidence level or interval of 95% (level of significance of 5%); and (b) a 50% prevalence of positive attitudes about RCT among the antenatal attendees.

A standardized, pre-tested questionnaire was administered in either English or Lumasaba by five trained research assistants. The questionnaire was adapted from a pilot project on routine HIV testing in Botswana [14] and had 50 items. The structured interview covered topics concerning the participant's and her partner's education, occupation, religion, ethnic group, number of pregnancies, household assets, opinions and experiences about routine HIV counselling and HIV testing in the antenatal clinic, and knowledge about mother to child transmission of HIV and infant feeding options for HIV-infected mothers. Exclusive breastfeeding (EBF) was defined in this study as feeding an infant with only breast milk and nothing else, even water, apart from prescribed medicines or vitamins. During group counselling sessions in the antenatal clinic, counsellors discussed the lactational amenorrhea that occurs as a result of EBF.

The research assistants were knowledgeable in the local language and interview techniques, and had received training about the study objectives and methods. The principal investigator checked filled questionnaires for completeness at the end of each day. Data-entry clerks entered data, using EpiData version 3.1; the principal investigator undertook validation of data, checking for any errors in the data in EpiData file. We exported the data file to PASW Statistics 18 (formerly SPSS) for analysis.

Ethical clearance to conduct the study was obtained from the Research and Ethics Committee of the School of Medicine, Makerere University College of Health Sciences, and the Uganda National Council of Science and Technology. Permission to conduct the study in the antenatal clinic was also obtained from the Mbale Regional Referral Hospital administration through the local institutional review board.

The main outcome measure was a positive attitude of pregnant women to routine counselling and testing for HIV. The secondary outcome was participants' knowledge about mother to child transmission of HIV and infant feeding options for HIV-infected mothers. We used descriptive statistics to examine the demographic characteristics of the participants and their experiences with and attitudes towards RCT. The participants were grouped into socio-economic quintiles based on a proxy wealth index using principal component factor analysis [24]. Housing characteristics and assets, including radio, hurricane lamp, television set, mobile phone, bicycle, motorcycle, motor vehicle, refrigerator, sofa and cupboard, were included in the model.

Prior to performing the principal component analysis, the suitability of the data for factor analysis was assessed. The correlation matrix showed some coefficients of 0.3 and above. The Kaiser-Meyer-Oklin of Sampling Adequacy value was 0.808, exceeding the value of ≥ 0.6 recommended for this test to demonstrate that factors are inter-correlated, and the Barlett's test of Sphericity was significant (p = 0.000), supporting the factorability of the correlation matrix [25]. The quintiles were based on the first principal component, a recognized method to provide a good proxy for household wealth [26,27]. Participants were asked, "Nowadays in this clinic, all mothers are tested for HIV unless they say no. What do you think about this system?" Responses included "very bad", "bad", "fair", "good" and "very good". The responses, "good" and "very good", were taken as positive attitudes towards routine HIV testing.

Bivariate analysis was performed between knowledge about exclusive breastfeeding as an infant feeding option by HIV-infected mothers as the dependent variable and each independent (predictor) variable. Bivariate analysis was also performed between each independent variable and the following dependent variables: positive attitude to pre- and post-test HIV counselling and to HIV testing; and having sought male partner permission to test for HIV. Multicollinearity among the independent variables and outliers were checked for.

Age as a possible confounder and all variables that were significant at the level of p < 0.2 in binary analysis were retained in the multivariate regression model. All p-values were two-tailed at a significance level of 5%. The goodness-of-fit test (Omnibus Tests of Model Coefficients) of the final model for knowledge about exclusive breastfeeding was significant [Chi-square statistic (χ^2) = 28.249, degrees of freedom (df) = 7, p = 0.000] and the Hosmer and Lemeshow goodness-of-fit test was not significant (χ^2 = 5.866, df = 8, p = 0.662) as indicators of model appropriateness. The final models for positive attitude to pre-test and post-test counselling, HIV testing and having sought male partner permission for HIV tests yielded Hosmer and Lemeshow goodness-of-fit test results that were not significant (p-value > 0.05).

Results

Socio-demographic characteristics

Of the 388 new antenatal attendees enrolled in the study, about two-thirds were living in rural villages, and they had

Table 1 Predictors of knowledge of exclusive breastfeeding among 388 new antenatal attendees, Mbale, Uganda; logistic regression results

Participants' characteristics	Number, n (%)	Exclusive breastfeeding knowledge	
		Unadjusted OR (95% CI)	Adjusted OR (95% CI)
Age groups (years)			
15-24	220 (56.7)	1.0	1.0
25 or more	168 (43.3)	1.1 (0.7-1.7)	1.5 (0.8-2.5)
Place of residence			
Rural	252 (64.9)	1.0	
Urban	136 (35.1)	1.5 (0.9-2.3)	1.4 (0.9-2.3)
Marital status			
Single/divorced/separated	35 (9.0)	1.0	
Married/cohabiting	353 (91.0)	1.4 (0.7-2.8)	
Occupation			
Not getting a salary	337 (86.9)	1.0	1.0
Salaried	51 (13.1)	2.6 (1.2-5.6)	1.9 (0.8-4.5)
Education level			
None or incomplete primary	134 (34.5)	1.0	1.0
Completed primary	152 (39.2)	1.5 (0.9-2.4)	1.6 (1.0-2.7)
Completed secondary or more	102 (26.3)	2.5 (1.4-4.5)	**2.5 (1.3-4.9)**
Religion			
Christian	234 (60.3)	1.0	
Muslim	154 (39.7)	1.2 (0.8-1-9)	
Number of pregnancies			
1-2	201 (51.8)	1.0	1.0
3 or more	187 (48.2)	1.5 (1.0-2.3)	**2.5 (1.4-4.5)**
Socio-economic status			
Poorest (quintiles: 4th, 5th)	159 (41.0)	1.0	
Least poor (quintiles: 1st-3rd)	229 (59)	1.3 (0.8-1.9)	
Ethnic group			
Bagisu	247 (63.7)	1.0	1.0
Non-Bagisu	141 (36.3)	1.6 (1.0-2.5)	**1.7 (1.0-2.7)**
Tested for HIV today [a]			
No	2 (0.5)		
Yes	386 (99.5)		
Received same-day HIV test results			
No	6 (1.5)	1.0	
Yes	282 (98.5)	1.9 (0.4-9.8)	

I. [a]No unadjusted odds ratio was calculated since one of the cells had less than 5 cases.

II. P-value (P) < 0.05 was statistically significant.

III. The goodness-of-fit test (Omnibus Tests of Model Coefficients) of the final model was significant [Chi-square statistic (χ^2) = 28.249, degrees of freedom (df) = 7, p = 0.000] and the Hosmer and Lemeshow goodness-of-fit test was not significant [χ^2 = 5.866, df = 8, p = 0.662] as indicators of model appropriateness.

a median age of 24 years (range 15-46 years, Table 1). Most of them were Christians, had no salaried employment, were in a consensual relationship, and had less than 11 years of education (74%). The majority (64%) of the participants were Bagisu, and most of them had had at least one previous pregnancy. Their male partners had a median age of 30 years (range 18-72 years) and about half of them had completed secondary education.

Overall results
Almost all the new ANC attendees (98.5%, 382/388) had a positive attitude towards routine HIV testing in the clinic. They reported that it helped them to know their HIV status and that this in turn enabled them to plan for their future and that of their babies. They also reported that mothers found to be HIV positive would be able to easily access antiretroviral therapy to reduce

the risk of transmitting HIV to their babies. However, mothers with negative HIV test results would protect themselves from getting infected with HIV.

Participants' opinions and experiences of routine HIV counselling and testing

The majority of the study participants reported that their first visits to the antenatal clinic for the current pregnancy had been good and that they were handled well by the clinic staff (Table 2). Most of the women rated highly the health education talk and the pre-test and post-test HIV counselling they had received at the clinic. The predictors of positive attitude to pre-test counselling for HIV included: residing in an urban area (OR: 3.0, CI: 1.4-6.6); being least poor (OR: 1.9, CI: 1.0-3.7); having three or more pregnancies (OR: 3.0, CI: 1.4-6.8); and being 15 to 24 years of age (OR: 2.5, CI: 1.1-5.4) (Table 3).

Out of 388 new antenatal attendees, 386 (99.5%) tested for HIV and 382 (98.5%) received same-day HIV test results (Table 1). In addition, 54% (211/388) of the women had sought their partners' permission to test for HIV in the antenatal clinic and almost all of them (209/211, 99%) got this permission. The predictors for male partner permission for the HIV test were: being married or cohabiting (OR: 5.6, CI: 2.4-13.3); and having completed secondary school education or more (OR: 3.0, CI: 1.5-5.9) (Table 4). Nearly all the study participants rated

Table 2 Participants' opinions and experiences about routine HIV testing among 388 new antenatal attendees, Mbale, Uganda

Participant's rating of	Responses	
	Very good/good n (%)	Fair/bad/very bad n (%)
the visit to antenatal clinic	308 (79.4)	80 (20.6)
the handling by clinic staff	344 (88.7)	44 (11.3)
the total waiting time in clinic	286 (73.7)[a]	102 (26.3)[b]
the clinic facilities	322 (83.0)	66 (17.0)
the health education talk	350 (90.2)	38 (9.8)
the pre-test HIV counselling	335 (86.3)	53 (13.7)
the post-test HIV counselling	369 (95.1)	19 (4.9)
the routine HIV testing[c]	382 (98.5)	6 (1.5)

[a] Not long waiting time.
[b] Too long waiting time.
[c] Participants were asked, "Nowadays in this clinic, all mothers are tested for HIV unless they say no. What do you think about this system?" Responses included "very bad", "bad", "fair", "good" and "very good". The responses, "good" and "very good", were taken as positive attitudes towards routine HIV testing.

highly the routine HIV testing services offered as part of standard antenatal care (Table 2).

Participants' knowledge about PMTCT and infant feeding options

More than 60% of the participants knew that HIV could be passed from an infected mother to her child during pregnancy; however, about 85% of the respondents knew that mother to child transmission could occur during labour and about 89% knew it could occur through breastfeeding (Table 5). However, only 38% (147/388) of women knew the correct number of children who were likely to be infected with HIV through breastfeeding out of 10 HIV-infected women. The majority of the new antenatal attendees (89%, 347/388) knew that a pregnant woman could do something to reduce the risk of mother to child transmission of HIV during pregnancy, and 86% (335/388) of mothers knew that an HIV-infected mother could take some measures to reduce the risk of infecting her child through breastfeeding.

Out of 388 participants, 323 (83%) knew that taking antiretroviral drugs if HIV infected reduced the risk of vertical transmission of HIV during pregnancy. However, few mothers (46%, 177/388) knew that having protected sex with their partners (condom use) reduced the risk of mother to child transmission of HIV during pregnancy (Table 5). Many of the participants (63%, 244/388) knew that in order to reduce risk of vertical transmission of HIV during the breastfeeding period, an HIV-infected mother could use the infant feeding option of exclusive breastfeeding for six months. Similarly, more than 60% of respondents knew that by avoiding breastfeeding and using either infant formula or diluted cow's milk instead, an HIV-infected mother would prevent transmission of HIV to her baby through breastfeeding (Table 5).

The predictors of having knowledge of exclusive breastfeeding as one of the measures for prevention of mother to child transmission of HIV were: having completed secondary school (OR: 2.5, CI: 1.3-4.9): belonging to a non-Bagisu ethnic group (OR: 1.7, CI: 1.0-2.7); and having three or more pregnancies (OR: 2.5, CI: 1.4-4.5) (Table 1). However, only 24% (94/388) reported that they would opt for exclusive breastfeeding for six months as an infant feeding option if they were HIV infected. Instead, 60% (233/388) of the participants said they would hypothetically choose the option of using diluted cow's milk and no breast milk (Table 5).

Study participants' suggestions for service improvement in the antenatal clinic

Although many (79%, 308/388) of the antenatal attendees rated their first visits to the antenatal clinic highly

Table 3 Predictors of positive attitude to pre-test HIV counselling among 388 new antenatal attendees, Mbale, Uganda

Participants' characteristics	Number n (%)	Pre-test HIV counselling positive attitude	
		Unadjusted OR (95% CI)	Adjusted OR (95% CI)
Age groups (years)			
25 or more	168 (43.3)	1.0	1.0
15-24	220 (56.7)	1.2 (0.7-2.1)	**2.5 (1.1-5.4)**[‡]
Place of residence			
Rural	252 (64.9)	1.0	1.0
Urban	136 (35.1)	3.0 (1.4-6.3)	**3.0 (1.4-6.6)**[*]
Education level			
No or incomplete primary	134 (34.5)	1.0	1.0
Completed primary	152(39.2)	0.9 (0.5-1.9)	0.7 (0.4-1.5)
Completed secondary or more	102 (26.3)	1.8 (0.8-4.2)	1.3 (0.5-3.5)
Ethnic group			
Non-Bagisu	141 (36.3)	1.0 (0.6-1.9)	
Bagisu	247 (63.7)	1.0	
Socio-economic status			
Poorest (quintiles: 4th-5th)	159 (41.0)	1.0	1.0
Least poor (quintiles: 1st-3rd)	229 (59.0)	2.3 (1.3-4.1)	**1.9 (1.0-3.7)**[‡]
Occupation			
Salaried	51 (13.1)	1.0	1.0
Not getting a salary	337 (86.9)	2.8 (0.8-9.3)	1.8 (0.5-7.0)
Number of pregnancies			
1-2	201 (51.8)	1.0	1.0
3 or more	187 (48.2)	1.5 (0.8-2.3)	**3.0 (1.4-6.8)**[*]

I. P-value: ‡ = p < 0.05, * = p < 0.01.

II. Marital status and religion were not significantly associated with positive attitude to pre- and post-test HIV counselling.

III. The goodness-of-fit test (Omnibus Tests of Model Coefficients) of the final model for pre-test counselling positive attitude was significant [Chi-square statistic (χ^2) = 17.219, degrees of freedom (df) = 7, p = 0.016] and the Hosmer and Lemeshow goodness-of-fit test was not significant [χ^2 = 9.620, df = 8, p = 0.293] as indicators of model appropriateness.

(good or very good), some of them made some suggestions for service improvement at the clinic (Additional file 1).

Discussion

Overall, our study revealed that most of the study participants had a positive attitude towards routine antenatal HIV counselling and testing (RCT). This finding is similar to that reported in a study in Botswana [28], where 81% of participants reported that they were either extremely or very much in favour of routine testing. The high level of positive attitudes to RCT in our study could be attributed to several factors. It is possible that the pregnant women were less fearful of accepting HIV testing because this approach was offered as part of the "standard of care" given to all women in the antenatal clinic. However, a study done in six health facilities (five health centres and one hospital) in Dodoma, Tanzania, showed that about a quarter of the women were not satisfied with the counselling they received about prevention of mother to child transmission of HIV (24.8%),

privacy (24%) or the waiting time spent in the clinic as they accessed the PMTCT services (28%) [29].

The majority of the new antenatal attendees rated pre-test and post-test HIV counselling highly, tested for HIV and received same-day results. Similar findings were documented in a study in urban Zimbabwe, where 100% and 99.8% of the women received pre-test and post-test HIV counselling, respectively, and 99.9% accepted routine HIV testing [12]. Similar findings were reported from studies in rural areas of Zimbabwe [30,31] and Lilongwe, Malawi [32]. The availability of rapid HIV testing in the clinic and the giving of same-day HIV test results may have contributed to the high participation in the HIV testing. However, in our study, four pregnant women tested for HIV but reported that they did not receive the test results. It is possible that they actually received their results but reported to the contrary, thinking that they were being asked to reveal their HIV sero-status. Use of rapid HIV screening tests in the antenatal clinic ensures same-day results for all mothers who accept HIV testing.

Table 4 Predictors of male partner permission to test for HIV and positive attitude to HIV testing among 388 new antenatal attendees, Mbale, Uganda

Participants' characteristics	Number n (%)	Male partner permission to test for HIV		Positive attitude to HIV-testing[†]	
		Unadj.OR (95% CI)	Adj.OR (95% CI)	Unadj.OR (95% CI)	Adj.OR (95% CI)
Age groups (years)					
15-24	220 (56.7)	1.0	1.0	2.7 (0.5-14.7)	2.5 (0.3-22.3)
25 or more	168 (43.3)	1.2 (0.8-1.8)	1.0 (0.7-1.6)	1.0	1.0
Education level					
No or incomplete primary	134 (34.5)	1.0	1.0		
Completed primary	152 (39.2)	1.2 (0.8-1.9)	1.2 (0.7-2.0)		
Completed secondary or more	102 (26.3)	2.7 (1.5-4.7)	**3.0 (1.5-5.9)**[*]		
Socio-economic status					
Poorest (quintiles: 4th-5th)	159 (41.0)	1.0	1.0	1.0	1.0
Least poor (quintiles: 1st-3rd)	229 (59.0)	1.5 (1.0-2.2)	1.2 (0.7-1.9)	2.9 (0.5-16.2)	1.9 (0.3-12.6)
Ethnic group					
Bagisu	247 (63.7)	1.0	1.0	1.0	1.0
Non-Bagisu	141 (36.3)	1.6 (1.0-2.4)	1.6 (1.0-2.5)	2.9 (0.3-25.0)	2.6 (0.3-23.9)
Marital status					
Single/divorced/separated	35 (9.0)	1.0	1.0	1.0	1.0
Married/cohabiting	353 (91.0)	4.6 (2.0-10.5)	**5.6 (2.4-13.3)**[‡]	2.0 (0.3-18.0)	5.4 (0.4-73.1)
Religion					
Christian	234 (60.3)	1.0	1.0	1.0	1.0
Moslem	154 (39.7)	1.3 (0.9-2.0)	1.4 (0.9-2.2)	1.3 (0.2-7.3)	1.2 (0.2-7.0)
Occupation					
Not getting a salary	337 (86.9)	1.0	1.0		
Salaried	51 (13.1)	1.9 (1.0-3.6)	1.1 (0.5-2.3)		
Education level					
No or incomplete primary	134 (34.5)			1.0	1.0
Completed primary or more	254 (65.5)			3.9 (0.7-21.4)	2.9 (0.4-19.7)

I. Unadj. OR: Unadjusted Odds Ratio, Adj. OR: Adjusted Odds Ratio, CI: Confidence Interval.

II. *P*-value: *p < 0.01, ‡p < 0.00. *P*-value < 0.05 was statistically significant.

III. †Pregnant women who had a positive attitude to routine antenatal HIV testing were 98.5%. Hence there were too few cases in some cells giving rise to the wide confidence intervals of the odds ratios and inability to calculate the odds ratio for occupation.

IV. The goodness-of-fit test (Omnibus Tests of Model Coefficients) of the final model for male partner permission to test for HIV was significant [Chi-square statistic (χ^2) = 41.434, degrees of freedom (df) = 8, p = 0.000] and the Hosmer and Lemeshow goodness-of-fit test was not significant [χ^2 = 5.563, df = 8, p = 0.696] as indicators of model appropriateness.

V. The goodness-of-fit test (Omnibus Tests of Model Coefficients) of the final model for HIV testing was significant [χ^2 = 11.025, df = 8, p = 0.000] and the Hosmer and Lemeshow goodness-of-fit test was not significant [χ^2 = 5.637, df = 8, p = 0.688] as indicators of model appropriateness.

The study also found that the new antenatal attendees aged 15 to 24 years were more likely to have positive attitudes to pre-test HIV counselling. In a study done in Zambia, it was noted that readiness to test for HIV was higher among the young than among older people [33]. The positive attitude to pre-test HIV counselling among pregnant women who were either residing in urban areas or were least poor could be explained by the fact they have more access to information about HIV counselling through the print and electronic media. Therefore, they are more likely to be aware of the benefits of HIV counselling and testing.

Our finding that women who had three or more pregnancies had positive attitudes towards pre-test counselling could be explained by their previous interactions with the healthcare system, which exposed them to

information on HIV testing and associated benefits. The educated women were more likely to seek permission from their male partners to test for HIV than the less educated. This is probably due to the fact that the educated women are more likely to discuss issues concerning their sexuality and health with their spouses. Those who were either married or cohabiting were almost six times more likely to ask for permission from the partners. This could be linked to the desire to obtain support from their partners, including money for transport to such health facilities. Our earlier study in the same setting revealed that the majority of the men (97%) provided financial support to their wives to access antenatal care [34].

Our study also showed that many of the antenatal attendees had correct knowledge about mother to child

Table 5 Participants' knowledge about mother-to-child transmission of HIV and infant feeding options (N = 388), Mbale, Uganda

Questions to participants	Correct answer	Correct responses n (%)
(1) Is it possible that when the mother or the father is HIV positive and their newborn child can be HIV negative?	Yes	296 (76.3)
(2) When can HIV be passed from a mother to her child?		
- during pregnancy	Yes	239 (61.6)
- during labour	Yes	328 (84.5)
- through breastfeeding	Yes	344 (88.7)
- other[a]	Yes	129 (33.2)
(3) If there are 10 HIV infected pregnant women, how many do you think would have babies born with HIV virus?(between 0-10)	1-4	226 (58.2)
(4) How many babies could get HIV infected through breastfeeding out of 10 HIV infected mothers? ....(between 0-10)	1-3	147 (37.9)
(5) What can a mother do to reduce the risk of transmission of HIV to her child during pregnancy?		
- taking antiretroviral drugs	Yes	323 (83.2)
- having protected sex with her partner (condom use)	Yes	177 (45.6)
- other ways[b]	Yes	83 (21.4)
(6)Can an HIV infected mother do anything to reduce the risk of transmission of HIV to her child during breastfeeding period?	Yes	335 (86.3)
(7) What can an HIV positive mother do to reduce the risk of getting her baby infected with HIV during the breastfeeding period?		
- exclusively breastfeed for 6 months	Yes	244 (62.9)
- not breastfeeding, give infant formula	Yes	240 (61.9)
- not breastfeeding, give diluted cow's milk	Yes	268 (69.1)
- good breast care (no sore or cracked nipples)	Yes	139 (35.8)
- other ways[c]	Yes	76 (19.6)
(8) If you were HIV positive, which infant feeding option would be feasible to you? (Give only one answer)		
(a) - infant formula, no breast milk		45 (11.6)
(b) - cow's milk, no breast milk		233 (60.1)
(c) - breast milk only for 6 months		94 (24.2)
(d) - other[d]		13 (3.4)

- [a]sharing sharp instruments like needles and injection needles with the baby.
- [b]abstaining from sexual intercourse, being faithful to your partner.
- [c]using drugs to prevent HIV through breast milk.
- [d]breastfeeding for 3 months, then giving either cow's milk or porridge (from soya/millet flour)

transmission (MTCT) of HIV and how to prevent it. Women who had completed secondary school education were more likely to have correct knowledge of exclusive breastfeeding as a preventive measure for vertical transmission of HIV. A similar finding was reported by the Botswana study [28]. Our study has revealed that pregnant women who had completed secondary education were approximately three times more likely to have good knowledge about exclusive breastfeeding. The educated have better access to health information. An earlier study done in the same region highlighted the positive influence of higher education on infant feeding practices [35].

Our study also revealed that women who had three or more pregnancies were three times more likely to have good knowledge about exclusive breastfeeding. This

could be explained by their previous interaction with the healthcare system, which exposed them to information on exclusive breastfeeding and its associated benefits Many of study participants (63%) reported that exclusive breastfeeding (EBF) for six months reduced the risk of MTCT. However, few (24%) of them thought it a feasible infant feeding option if they were HIV positive; instead, many (60%) reported that they would use cow's milk.

At the time the study was conducted, modified cow's milk was one of the replacement feeding options for infants of HIV-infected mothers, according to the national policy guidelines[18], if affordable, feasible, acceptable, sustainable and safe (AFASS). However, according to the most recent WHO recommendations [36], home-modified animal milk is not recommended as a replacement food for infants in the first six months of life. In a region where breastfeeding is almost universal [37], counselling about EBF in the antenatal clinic should be intensified as studies in sub-Saharan Africa have revealed that EBF reduces postnatal HIV transmission [38-40]. Knowledge is an important determinant for behavioural change. Hence, good quality HIV counselling is important for the success of PMTCT efforts.

The study also identified some challenges to the implementation of antenatal routine HIV testing. Although the majority of the women were satisfied with the services in the antenatal clinic, some gaps were identified. These included the following: inadequate supply of drugs and equipment; shortage of midwives and/or counsellors and low male involvement in routine antenatal HIV testing services. Some women felt that individual counselling was inadequate while others felt they were pressured to test for HIV. Similar challenges have been reported from other studies in east Africa [29,41,42].

The factors hindering male involvement in the PMTCT programme have been reported in a previous study in this region [34]. As shown in this study, about 54% of the women sought permission from their spouses to have an HIV test. However, some studies have documented that some women refuse to test for HIV because of the need to seek their partners' assent [43,44]. There is need for more male involvement in antenatal HIV counselling and testing as this has been shown to increase the use of PMTCT interventions in resource-limited settings [45-47].

In a recent study in Uganda by Wabwire-Mangen and his colleagues, many (43%) of the new HIV infections in adults (15-49 years) occurred among people in discordant monogamous relationships [4]. Hence, there is a need for increased couple counselling and testing in the PMTCT programme, as recommended in the Uganda national policy on HIV counselling and testing [23]. This would most likely facilitate couples' ability to follow through on intentions and decisions made

during the HIV counselling and testing sessions [48]. One way of promoting men's participation in antenatal HIV counselling and testing could be by health staff sending written notes inviting them to come to the clinic, as suggested by participants. This suggestion had been alluded to in a previous study in this study population [34].

Our study had some potential limitations. Being a cross-sectional survey, causality cannot be inferred from our findings. Although the study participants were from both rural and urban areas, they may not be representative of the whole population of Uganda. Therefore, country-wide generalization of our study findings is not implicit and it is not possible to generalize our findings to other sub-Saharan Africa countries. Since we enrolled the antenatal attendees consecutively, our study may have suffered from selection bias, thus affecting the internal validity of the study. In addition, participants' self-reports could have introduced misclassification and bias. We attempted to reduce social desirability bias by presenting study aims to the respondents in general terms. In our study, we deliberately did not ask the women about their HIV status in order to assure confidentiality and also maximize validity.

Conclusions

Our study findings have demonstrated that antenatal routine HIV counselling and testing seems to be largely acceptable to the pregnant women in eastern Uganda and has enabled most of them to know their HIV status as part of the PMTCT package of services. To ensure good quality service in the antenatal clinic, there is a need for adequate supplies of drugs, sundries, HIV test kits and equipment, and enough numbers of health workers equipped with good counselling skills. More concerted efforts by programme managers are needed to scale up this service to antenatal clinics in lower level health units in order to maximize its potential benefits for the population. Finally, further work through research and innovative interventions is needed in order to improve male partner involvement in HIV testing in antenatal clinics.

Additional material

Additional file 1: Study participants' suggestions about service improvement in antenatal clinic in Mbale Regional Referral Hospital, Uganda.

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Authors' contributions
RB participated in the conception, design and implementation of the study, statistical analysis, interpretation and drafting of the manuscript. JKT participated in the design, and implementation of the study, interpretation and drafting of the manuscript. GN participated in the design of the study, interpretation and drafting of the manuscript. CASK participated in interpretation and the drafting on the manuscript. TT participated in the conception and design of the study, interpretation and drafting the manuscript. All authors read and approved the final manuscript.

Competing interests
The authors declare that they have no competing interests.

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III

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RESEARCH   **Open Access**

Determinants of male involvement in the prevention of mother-to-child transmission of HIV programme in Eastern Uganda: a cross-sectional survey

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Abstract

Background: Mother-to-child transmission of HIV (MTCT) accounts for over 95% of all paediatric HIV infections worldwide. Several studies have shown that male participation in the antenatal care of their spouses together with couple counselling and testing for HIV, increases use of the interventions for HIV prevention. The prevention programme of MTCT (PMTCT) was launched in Uganda in 2000 and Mbale in 2002. Less than 10% of the pregnant women accepted antenatal HIV testing at Mbale Regional Referral Hospital in 2003; couple counselling and testing for HIV was low. Therefore, we conducted the study to determine the level of male involvement and identify its determinants in the PMTCT programme.

Methods: A cross-sectional survey of 388 men aged 18 years or more, whose spouses were attending antenatal care at Mbale Regional Referral Hospital, was conducted in Mbale district, Eastern Uganda. A male involvement index was constructed based on 6 questions. The survey was complemented by eight focus group discussions and five in-depth interviews.

Results: The respondents had a median age of 32 years (inter-quartile range, IQR: 28-37). The majority (74%) had a low male involvement index and only 5% of men accompanied their spouses to the antenatal clinic. Men who had attained secondary education were more likely to have a high male involvement index (OR: 1.9, 95% CI: 1.1-3.3) than those who had primary or no formal education. The respondents, whose occupation was driver (OR: 0.3, 95% CI: 0.1-0.7) or those who had fear of disclosure of their HIV sero-status results to their spouses (OR: 0.4, 95% CI: 0.2-0.8), were less likely to have a high male involvement index. Barriers to male involvement in the PMTCT programme were related to both the poor health system, to socio-economic factors and to cultural beliefs.

Conclusions: Structural and cultural barriers to men's involvement in the PMTCT programme in Mbale district were complex and interrelated. Community sensitization of men about the benefits of antenatal care and PMTCT and improving client-friendliness in the clinics needs to be prioritised in order to improve low male participation and mitigate the effect of socio-economic and cultural factors.

Background

It is estimated that about 25 million HIV-infected people are living sub-Saharan Africa. About 2 million of them are children below the age of 15 years and account for about 90% of all the HIV-infected children worldwide. Over 1700 children become infected with HIV worldwide each day. Over 95% of them get it through mother-to-child transmission (MTCT) [1,2]. In high-income countries, MTCT of HIV has been virtually eliminated through effective voluntary counselling and testing (VCT) for HIV or routine testing of HIV, the use of anti-retroviral therapy and the use of safe, affordable and accessible breast-milk substitutes. Since the year 2000, prevention of mother-to-child transmission of HIV (PMTCT) programmes have been initiated in many

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resource-poor countries as an integrated service in the antenatal care. Nevirapine has been the most commonly used antiretroviral drug in many of the programmes because it is cheap and easy to administer [3,4]. Studies have shown that the utilisation of PMTCT services by the pregnant women is influenced both by factors related to the health system such as accessibility of VCT services, and by individual factors such as fear of disclosure of HIV results, lack of male partner support, fear of domestic violence, abandonment and stigmatization [5-11].

The Uganda National PMTCT programme started as a pilot intervention in the year 2000 and by the end of 2003 it had expanded to cover 38 sites in 56 districts. It was launched in Mbale Regional Referral Hospital in May 2002. In the year 2003, less than 10% of the pregnant women accepted antenatal testing and couple VCT was low [12,13]. Participation of men in the antenatal care of their spouses and couple VCT increase the utilisation of interventions to prevent HIV-1 transmission [14,15]. From July to August 2004, we conducted this study to determine the level of participation of male partners in the PMTCT programme and to identify factors that determine male participation in this programme.

Methods

Mbale district is situated at the foothills of Mt Elgon in the eastern region of Uganda. It is divided into three counties (rural) and one municipality (urban); namely Bubulo, Bungohko and Manjiya counties and Mbale municipality. In 2003, the district had a population of over 720,000, of which about 90% were rural and the average household-size was 7 people. About 80% of the residents depend on agriculture (subsistence farming) [16]. Its population is predominantly *Bagisu* and the main language is *Lumasaba/Lugishu.* The HIV prevalence rate in 2002 at the Mbale antenatal sentinel site was 5.9% [17].

The study was carried out in Mbale municipality and the surrounding Bungokho County. These were purposively selected to provide a rural and an urban population. The study consisted of two parts. The quantitative part was a cross-sectional survey of men aged 18 years or more, whose spouses were attending antenatal care at Mbale Regional Referral Hospital and resided in the study area. The qualitative part consisted of 8 focus group discussions and 5 in-depth interviews. We calculated the sample size based on the estimation of the proportion of male involvement (defined as men attending antenatal care with their spouses) in the population of 10%, an absolute precision of 3% and a 5% level of significance. We increased the sample size by 10% to cater for anticipated non-response. Hence the total sample size was estimated to be 422 men.

The participants were recruited into the study through their wives. In July and August 2004, all mothers who

were coming for their second antenatal visit at Mbale Regional Referral hospital, and resided in the study area, were informed about the study by the midwives. They were requested to provide information concerning their partners' place of work and residential addresses. Subsequently, the men were traced and 388 of them accepted to participate in the study and they were interviewed (participation rate of 92%). The non-response rate was 8% (6 declined, 28 absent). A pre-tested, structured, interviewer-administered questionnaire used to collect the quantitative data consisted of three parts: (1) socio-demographic characteristics (age, marital status, religion, level of education, occupation, place of residence, ownership of a radio, land and livestock, and type of housing), (2) general perceptions and experiences about the PMTCT programme, and (3) perceptions and experiences about antenatal and postnatal care.

The quantitative data was collected by 10 research assistants, entered using EPIDATA http://www.epi-data.dk and exported to SPSS version 13 for analysis. Incomplete data of one respondent was not included in the analysis (Figure 1: study profile). The data was summarised and the odds ratios (OR) estimated; and their corresponding 95% confidence intervals (95%CI) were computed. The level of male involvement in PMTCT was determined using an *ad hoc male involvement index.* This index was constructed using six variables with equal weight in the score:

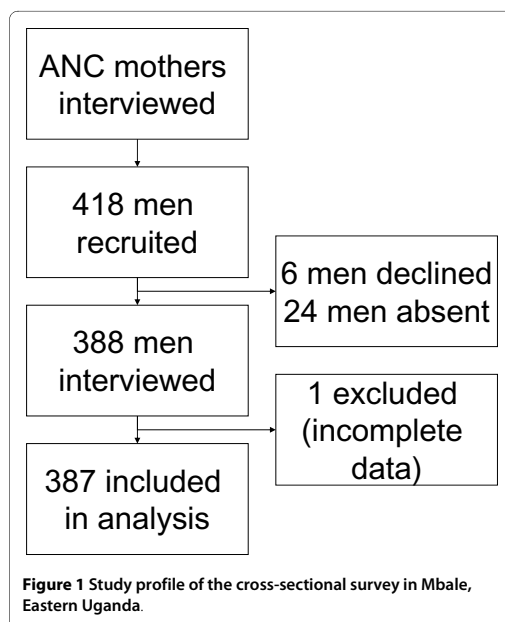1. The man attends antenatal care with his partner

Figure 1 Study profile of the cross-sectional survey in Mbale, Eastern Uganda.

2. The man knows the partner's antenatal appointment

3. The man discusses antenatal interventions with his partner

4. The man supports his partner's antenatal visits financially

5. The man has taken time to find out what goes on in the antenatal clinic

6. The man has sought permission to use a condom during the current pregnancy

The involvement score for each respondent could range from 0 = no involvement to 6 = involved in all 6 activities. A total score of 4-6 was considered as a 'high' male involvement score and 0-3 as 'low' relative to this particular population.

Bivariate analysis was performed between high male involvement index as the dependent variable and each independent variable. Since the number of variables was small, they were all entered into the binary logistic regression model at a go. Interaction and confounding between the ages of respondents, their place of residence and the significant variables (after bivariate analysis) were checked for.

We also conducted 8 focus group discussions (FGDs) and 5 in-depth interviews. The purpose of the FGDs was to explore and obtain information about the factors hindering male involvement in PMTCT and its influence on the utilisation of the PMTCT programme.

The participants in the FGDs were not selected from male partners of women attending antenatal clinics. Instead participants included men purposively selected from the Aids Information Centre (AIC), the Aids Support Organization (TASO) and the four administrative divisions in Bunghoko county and Mbale municipality.

In each division, two FGDs were held, one for young men aged 18-35 and another for men 36 years and above. The participants were divided into two age groups because we assumed that the young participants would not feel free to discuss or express issues regarding sexuality amidst older participants. The contact person in each of the four administrative divisions assisted in recruiting the participants. Each FGD consisted of 6 to 12 participants. Overall, 76 men participated in the 8 focus group discussions. The FGDs were moderated by an experienced social scientist using a topic guide. Another research assistant (a note taker) recorded the discussions by hand and by tape recorder. Each discussion was conducted in a comfortable place away from distraction with participants seated in a circle. The data was transcribed and summarized into themes.

The topics covered in the focus group discussion included HIV in general - terminology, frequency, causes, prevention, and treatment; HIV in children - terminology, occurrence, causes, prevention, treatment; voluntary counselling and Testing for HIV; stigma and discrimination in HIV; cultural issues; social networks and support for mothers; the health care system; suggestions as to how to involve men in the PMTCT programme.

In addition to the FGDs, in-depth interviews of health care providers were conducted bringing up the following issues about PMTCT: views about voluntary counselling and testing for HIV for pregnant mothers (VCT); testing using the opt-in or opt-out approach; how to increase acceptance of VCT by men; the role of men in promoting VCT in pregnancy, and the acceptability and feasibility of couple VCT. The key informants were also asked about factors influencing male participation in antenatal and PMTCT services in the hospital. Finally, they made suggestions as to how to get male partners more involved in both antenatal care and PMTCT programme.

The health care providers who were interviewed included 3 men and 2 women, namely the Nursing Officer in charge of ANC/PMTCT; the Medical Superintendent of Mbale Hospital; the Reproductive Health Coordinator (Eastern region); the managers of AIC and TASO, Mbale branches respectively. The focus group discussions and the in-depth interviews were conducted mainly in English. However four FGDs were conducted in the local language (Lugishu/Lumasaba). The sessions lasted one to two hours. The data was transcribed, coded using the OpenCode program, version 2.1: June, 2001 and examined for the main themes.

Research and ethical clearances were obtained from Makerere University Faculty of Medicine Research and Ethics Committee, the Uganda National Council of Science and Technology and Mbale District Local Government. Informed consent was obtained from all participants in the study.

Results
Socio-demographic characteristics
Of the 387 respondents included in the analysis, 199 (51%) were in the 25-34 age group. The median age was 32 years with inter-quartile range (IQR) of 28-37 years.

Thirty-five percent of the participants were urban, while the rest were rural. The literacy rate was 80% in the urban population and 74% among the rural participants, table 1.

The median period of the completed years of schooling by the respondents was 7 years (range: 0-18 years). Fifty percent of the respondents were Muslims. The respondents in the urban areas were more educated compared to those in the rural areas; 8 years compared to 7 years (p-value < 0.001: Mann-Whitney U test). There were more participants whose occupation was farmer in the rural areas than in urban areas, 21% versus 5% (Odds Ratio [OR] = 5.1; 95% Confidence Interval [CI]: 2.3 - 11.5). For

Table 1: Socio-demographic characteristics of the 387 respondents who participated in the survey in Mbale, Uganda.

Variable	Respondents N (%)
Age (years)	
19-24	49 (13)
25-34	199 (51)
35-44	113 (29)
45 or more	26 (07)
Place of residence	
Rural	250 (65)
Urban	137 (35)
Highest level of education	
No formal education	25 (07)
Primary	206 (53)
Secondary	127 (33)
Tertiary	29 (07)
Religion	
Catholic	69 (18)
Protestant	110 (28)
Muslim	193 (50)
Other	5 (04)
Marital status	
Unmarried (single)	11 (03)
Married	376 (97)
Occupation	
Builder	26 (07)
Casual labourer	26 (07)
Driver	47 (12)
Farmer	61 (16)
Mechanic	32 (08)
Professional	31 (08)
Trader	143 (37)
Other	21 (05)

the men who participated in the FGDs, their median age was 34 years with an inter-quartile range of 24-44 years.

Level of male involvement in PMTCT programme

The level of male involvement in PMTCT was assessed using the variables shown in Table 2. Only 18 (4.7%) of the 387 men had attended ANC with their partners, but most of them (377 [97%] out of 387) provided financial support to their spouses to attend ANC. The majority of respondents (236 [61%] out of 387) had not asked their partners whether they (the men) could use condoms during sexual intercourse with them (the women). Only 99 (26%) of the 387 respondents had a high male involvement index.

Determinants of male involvement in the PMTCT programme and antenatal care

In univariate analysis, the determinants of male involvement in PMTCT programme included: education level, knowing HIV sero-status and having heard about PMTCT.

Men who had had 8 or more years of education were 2 times more likely to get involved in the PMTCT programme than those with less education. Those who knew their HIV sero-status were 4 times more likely to get involved in the PMTCT programme. In addition those who had heard about the PMTCT programme were 2 times more likely to get involved. Those who feared to disclose their HIV status to their spouses were less likely to get involved (Table 3).

On logistic regression, the respondents who had attained secondary education or higher were twice as likely to have a high male involvement index (Table 3). However, those who had fear of disclosure of HIV results to their spouses and men whose occupation was driver were less likely to have a high male involvement index. Age, religion and place of residence of the respondents were not associated with male involvement in PMTCT of HIV (Table 3). Of the 31 professionals, 6 (19.4%) had attended ANC with their wives compared to only 12 (3.4%) of the 356 non-professionals (Table 4). This difference was statistically significant. Men who knew their HIV sero-status or knew their wives' ANC appointments or those willing to go for VCT were more likely to attend ANC with their wives (Table 4).

Barriers to male participation in the PMTCT programme

Factors hindering men's participation in the PMTCT programme that were identified in the focus group discussions were related to the health system, to socio-economic status and to culture.

Health system factors

Several factors related to the health system were identified as barriers to male participation in the ANC. The first major factor consistently identified by all the focus groups was rudeness and rough handling of the pregnant women by the health-workers in the antenatal clinics, as reflected in the following men's responses:

"Medical personnel handling pregnant mothers are very rough especially when it comes to examination of the abdomen", said a respondent from Bongokho sub-county. Another one from the AIC focus group said, *"During check-ups midwives over-press the pregnant mother's abdomen. We are fed up with the female health-workers. These midwives are very rude to the mothers. They are too harsh and abuse the pregnant women".*

Table 2: Level of involvement of the 387 men in ANC activities.

Item (variable)	Respondents' responses N (%)	
	Yes	**No**
Ever attended ANC with partner	18 (05)	369 (95)
Knows partner's ANC appointments	214 (55)	173 (45)
Provides financial support to partner to attend ANC	377 (97)	10 (03)
Discusses with partner information or interventions given in ANC	114 (30)	273 (70)
Asked partner if he could use a condom	151 (39)	236 (61)
Takes time to find out what goes on in ANC	105 (27)	282 (73)

The second factor reported by the respondents was that in some instances the health-workers do not allow them to enter the antenatal clinics with their pregnant women.

A third factor cited as one of the barriers to male participation was the charging of un-official user-fees. Lack of adequate space in the antenatal clinics was cited as a fourth factor. One respondent said: *"The clinics are congested. There is not enough space to accommodate the women and their husbands. Men will not feel comfortable sitting with women who are strangers to them. They will rather wait outside and if the procedures take long they will leave".* The last factor was the geographical distance to the services, one respondent said: *"The antenatal clinics are far from the local people"*

Socio-economic factors

The second area mentioned as an obstacle to male participation was socio-economic. Several of the men reported that due to socio-economic difficulties, they did not have time to attend ANC with their partners as demonstrated by the following quotations: *"I am busy trying to make ends meet. I don't have time to go with her to the antenatal clinic. I don't have enough money for transport for two people"*, said a respondent from a rural village. *"We have to struggle to look for money to provide for our families"*, said a respondent from Bongokho FGD.

Cultural factors

The third hindrance to male participation was cultural beliefs. A negative attitude of some men was common, as demonstrated by the AIC focus group discussion: *"I believe it is not good to follow your wife to the antenatal clinic. Even though she exposed her privacy to you at home but when you reach the antenatal clinic it is different. So it is better she goes alone".* Another one said, *"If I accompanied my wife to hospital every time she goes for her antenatal check up, my friends would think I am a weakling. They would laugh at me".* One of the key informants said: *"Because of cultural beliefs, most men do not like to accompany their wives to the antenatal clinics. Men who accompany their wives to ANC are perceived to be weaklings by their peers".*

Respondents' suggestions for improving male involvement in ANC/PMTCT activities

The suggestions as to how improvements could be made came from mainly health care providers (key informants). However the participants (males) in the FGDs were also emphatic on their recommendations as to how to improve the situation and their suggestions included the following:

1. Sensitize men about ANC and PMTCT, and their benefits
2. Conduct refresher courses for midwives and nurses
3. Men should be invited by staff to attend ANC using the ANC cards of their wives
4. Government should bring services closer to the people
5. Welfare of the staff should be improved
6. More staff be recruited into the health service

Specifically, the respondents suggested that retraining of the health-care providers should include customer-care skills. In addition they suggested provision of better remuneration to the health workers and building more health units by the government closer to the local people where antenatal care could be offered.

Some respondents suggested that midwives should write on the antenatal cards informing the men to come with their wives on subsequent ANC visits. A respondent from the Bungokho focus group said: *"Men should be identified from the communities, trained on PMTCT and then sent back to the communities to inform and mobilize other men. Health workers should use all fora to inform men about PMTCT; the churches and mosques are good entry points".* Another one said:

"Midwives should be given refresher courses because they seem to be losing direction. Nurses and midwives should become friendlier to the mothers in ANC than they are at the moment"

Table 3: Factors influencing men's involvement in the prevention of mother-to-child transmission of HIV programme (N = 387).

Factor (Variable)	Respondents with high involvement index n/N (%)	Unadjusted Odds Ratio (95% CI)	Adjusted Odds Ratio (95% CI)
Age (years)			
19-29	37/146 (25)	1.0	1.0
30+	62/241 (26)	1.0 (0.6-1.6)	1.1 (0.6-1.8)
Education (years)			
0-7	45/231 (20)	1.0	1.0
8+	54/156 (35)	2.2 (1.4-3.5)**	1.9 (1.1-3.3)*
Residence			
Rural	65/250 (26)	1.0	1.0
Urban	34/137 (25)	0.9 (0.6-1.5)	0.8 (0.5-1.5)
Religion			
Muslim	43/193 (22)	1.0	1.0
Christian	56/194 (29)	1.4 (0.9-2.2)	1.1 (0.6-1.9)
Occupation			
Others	82/309 (26)	1.0	1.0
Driver/Bodaboda cyclists	4/47 (08)	0.3 (0.1-0.7)*	0.3 (0.1-0.9)*
Professional	13/31 (42)	2.0 (0.9-4.3)	1.1 (0.5-2.7)
Fears disclosure of HIV results to wife			
No	78/252 (31)	1.0	1.0
Yes	14/100 (14)	0.4 (0.2-0.7)**	0.4 (0.2-0.7)**
Knows his HIV sero-status			
No	78/347 (22)	1.0	1.0
Yes	21/40 (52)	3.8 (2.0-7.4)**	1.9 (0.9-4.4)
Ever heard of PMTCT			
No	51/257 (20)	1.0	1.0
Yes	48/130 (37)	2.4 (1.5-3.8)**	1.6 (0.9-2.7)

I. * is $0.01 \le P \le 0.05$ and ** is $P < 0.01$. **II**. The variables in the final multivariate logistic regression model were: age, education, place of residence, religion and occupation of the respondents; fears disclosure of HIV sero-status results to his wife, knows his sero-status and ever heard of PMTCT. **III**. The sample size was 387 men (analysed for male involvement index). **IV**. OR, odds ratio; CI, confidence interval; PMTCT, prevention of mother-to-child transmission of HIV; HIV, Human immunodeficiency virus.

Discussion

In this study, conducted to establish determinants of male involvement in the PMTCT programme in Eastern Uganda, we found that only 1 in 4 male partners were involved in the PMTCT programme. This level of involvement is low but higher than what is reported from other studies from East Africa [18]. For example one study from Mulago Hospital in Kampala, Uganda, showed that male participation in the PMTCT activities was low (16%) [14,18]. Similarly, a study conducted at a Nairobi antenatal clinic, Kenya revealed that male partner participation in antenatal VCT with their spouses

Table 4: Factors influencing men's participation in antenatal care with their partners in Mbale district, Uganda (N = 387)

Factor (Variable)	Not Attended ANC n = 369	Attended ANC n = 18	Unadjusted OR (95% CI)	Adjusted OR (95% CI)
Age (years)				
19-29	142	4	1.0	
30+	227	14	2.2 (0.7-6.8)	
Residence				
Rural	236	14	1.0	
Urban	133	4	0.5 (0.2-1.6)	
Education (years)				
0-7	222	9	1.0	
8+	147	9	1.5 (0.6-3.9)	
Religion				
Other	188	5	1.0	
Christian	181	13	2.7 (0.9-7.7)	
Occupation				
Other	344	12	1.0	1.0
Professional	25	6	6.9 (2.4-20)**	5.4 (1.7-17)**
Knows his HIV sero-status				
No	335	12	1.0	
Yes	34	6	4.9 (1.7-14)**	
Bothers to know what goes on in ANC				
No	276	6	1.0	1.0
Yes	93	12	5.2 (1.9-14)**	3.1 (1.2-9.2)*
Knows his wife's ANC appointments				
No	172	1	1.0	1.0
Yes	197	17	14.8 (2 - 110)**	8.6 (1.0-72)*
Discussed with wife ANC interventions				
No	267	6	1.0	
Yes	102	12	5.2 (2.0-14)**	
Willing to go for HIV test				
No	122	1	1.0	
Yes	247	17	8.4 (1.1-63)*	
Ever heard of PMTCT				
No	249	8	1.0	
Yes	120	10	2.6 (1.0-6.7)*	
Would go with wife for VCT				
No	205	4 (2)	1.0	1.0
Yes	164	14 (8)	4.4 (1.4-13)	3.6 (1.1-12)

Notes: **I**. * is $0.01 \leq P \leq 0.05$ and ** is $P < 0.01$. **II**. All variables in the above table were entered in the final multivariate logistic regression model. **III**. OR, odds ratio; CI, confidence interval; PMTCT, prevention of mother-to-child transmission of HIV; HIV, Human immunodeficiency virus; ANC, antenatal care.

was low (15%) [14]. The difference between our findings and these other studies could be attributed to the different methods used.

In this study we have found a number of factors associated with male participation in the PMTCT programme. These included heath system, socio-economic and cultural factors. First the structural set up of the ANC clinics is not male user-friendly. Furthermore, our findings from the qualitative data have indicated that the health-providers in the ANC clinics were perceived by the men not to be client-friendly. Similar observations have also been made by others. For example focus group participants in Kenya mentioned rude health care staff as a hindrance to participation in PMTCT services [19].

Other factors hindering male involvement in the PMTCT programme were socio-economic. Although the majority of the men expressed willingness to go for HIV counselling and testing, they said that they either lacked time or money to facilitate their involvement in the ANC/PMTCT activities. Similar constraints have been found in Dodoma, Tanzania [20]. In addition, the level of education and occupation of the respondents influenced male participation in the PMTCT programme. Similar studies in Uganda and elsewhere have found that education level is an important determinant of participation in PMTCT services [21,22].

Increased access to information, knowledge and awareness facilitates good choices. In our study men who had heard about PMTCT programme were 2 times more likely to get involved in PMTCT activities than those who had not. This is consistent with results of a similar study in Mambwe district in Zambia [23].

In addition, another study from Chipata in Zambia revealed that males were not fully participating in PMTCT programmes and reasons given were lack of information and lack of a direct link between PMTCT staff and males [24].

Cultural factors were also found to be hindering male involvement in the PMTCT programme in Mbale. For example antenatal care was perceived a women's affair.

As has been shown in other studies [25], it is conventional in many African cultures for men not to accompany their partners to antenatal and postnatal care consultations as pregnancy and child birth are regarded as a women's affair [26,27].

One of the strengths of this study is that we interviewed men and not their spouses. The information collected in this study is likely to reflect the men's views better than information obtained from women. The other strength is that we used both quantitative and qualitative methods during data collection. The qualitative findings assisted in explaining the findings from the quantitative part of the study.

There are some potential weaknesses, though, in the methodology. First, the recruitment of respondents through their spouses in the ANC in a hospital setting could have introduced selection bias. In this study, the level of non-response was modest (7%), unlikely to have biased our estimates in any major way. Second, it is possible that husbands of the women attending ANC were different from the partners of the women who did not attend ANC. However, since over 90% of women in Uganda attend at least one ANC visit [28], the potential selection bias is limited.

Third, our male involvement index has not been used before and its validity and reliability have not been established in this environment. To our knowledge, there exists no established instrument to assess male involvement. We still believe this index is likely to divide the men in the two groups of high and low involvement relative to this population, but not in absolute terms as even the 'high involvement' group represents a modest involvement in absolute terms.

PMTCT programmes have been started at different times in the different African countries. The programmes with the longest history demonstrate many similarities in their development from start-up to a mature programme. Men's involvement and understanding of any PMTCT programme is likely to develop along with the maturation of the programme. This study was conducted in the early days of the programme and the study results may in part reflect this. In a follow-up study it would be interesting to assess how much has changed since 2003.

Conclusions and recommendations

The level of male involvement in PMTCT programme in Mbale was low in 2003. Several factors appear to contribute including health system factors such as: health workers' behaviour and unfriendly environment and clinics designed for women. Socio-economic factors such as costs of transport, education level, occupation and culture also contribute.

Improvements in the health care system and community sensitization of men about the benefits of antenatal care and the PMTCT programme are essential for mitigating the effect of socio-economic and cultural factors.

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IV

RESEARCH Open Access

Male partner antenatal attendance and HIV testing in eastern Uganda: a randomized facility-based intervention trial

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Abstract

Background: The objective of the study was to evaluate the effect of a written invitation letter to the spouses of new antenatal clinic attendees on attendance by couples and on male partner acceptance of HIV testing at subsequent antenatal clinic visits.

Methods: The trial was conducted with 1060 new attendees from October 2009 to February 2010 in an antenatal clinic at Mbale Regional Referral Hospital, Mbale District, eastern Uganda. The intervention comprised an invitation letter delivered to the spouses of new antenatal attendees, while the control group received an information letter, a leaflet, concerning antenatal care. The primary outcome measure was the proportion of pregnant women who attended antenatal care with their male partners during a follow-up period of four weeks. Eligible pregnant women were randomly assigned to the intervention or non-intervention groups using a randomization sequence, which was computer generated utilizing a random sequence generator (RANDOM ORG) that employed a simple randomization procedure. Respondents, health workers and research assistants were masked to group assignments.

Results: The trial was completed with 530 women enrolled in each group. Participants were analyzed as originally assigned (intention to treat). For the primary outcome, the percentage of trial participants who attended the antenatal clinic with their partners were 16.2% (86/530) and 14.2% (75/530) in the intervention and non-intervention groups, respectively (OR = 1.2; 95% CI: 0.8, 1.6). For the secondary outcome, most of the 161 male partners attended the antenatal clinic; 82 of 86 (95%) in the intervention group and 68 of 75 (91%) in the non-intervention group were tested for HIV (OR = 2.1; 95% CI: 0.6 to 7.5).

Conclusions: The effect of the intervention and the control on couple antenatal attendance was similar. In addition, the trial demonstrated that a simple intervention, such as a letter to the spouse, could increase couple antenatal clinic attendance by 10%. Significantly, the majority of male partners who attended the antenatal clinic accepted HIV testing. Therefore, to further evaluate this simple and cost-effective intervention method, adequately powered studies are required to assess its effectiveness in increasing partner participation in antenatal clinics and the programme for prevention of mother to child transmission of HIV.

Trial Registration: ClinicalTrials.gov Identifier: NCT01144234.

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Background

Approximately 370,000 children were newly infected with HIV during 2009 through mother to child transmission [1]. Sub-Saharan Africa, the region most affected by HIV, accounts for 67% of HIV infections worldwide and 91% of new infections among children [2]. HIV counselling and testing is the access point to HIV prevention, care and treatment programmes. However, access to services for preventing mother to child transmission of HIV in low- and middle-income countries remains limited, with only 26% of pregnant women in such countries receiving HIV tests during 2009 [1].

Following World Health Organization (WHO) recommendations [3], routine antenatal counselling and testing for HIV has been introduced into prevention of mother to child transmission (PMTCT) of HIV programmes in resource-limited settings; this has increased HIV testing rates among antenatal attendees in several sub-Saharan countries [4-10]. Engaging men as partners is a critical component of the PMTCT programme, but their involvement in antenatal care (ANC) and PMTCT services has remained low [11-15]. However, men exercise a huge influence on their wives regarding sexual and reproductive health issues [16,17]. Male involvement in antenatal HIV counselling and testing increases the use of PMTCT interventions in resource-limited settings [18-21] and is associated with reduced mother to child transmission of HIV-1 and reduced infant mortality [22].

In Uganda, HIV is a major public health problem and there was an estimated adult HIV prevalence rate of 6.7% in 2006 [23], yet only 15% of adults know their HIV status. The PMTCT programme was launched in Uganda in 2001 and is currently integrated into mainstream antenatal care services. However, the proportion of male partners of pregnant women tested in antenatal clinics for HIV is low. Further, the proportion of HIV discordance among couples who test is high, ranging from 35% to 50% [23-26]. One objective of the Uganda's policy change from antenatal voluntary counselling and testing (VCT) to routine antenatal counselling and testing in June 2006 was to increase the proportion of male partners of pregnant women offered HIV counselling and testing services from the PMTCT programme from 3% to 25% by 2010 [27].

A study in Mbale Regional Referral Hospital in Mbale District, eastern Uganda, revealed high antenatal HIV testing rates (more than 90%) among pregnant women [5] as a result of routine antenatal counselling and testing. Nonetheless, antenatal attendance and HIV testing among their male partners remained very low (4.7%) [28] despite the fact that counsellors encouraged the antenatal attendees to invite their male partners for clinic attendance and HIV testing [29]. However, measures to increase male partner participation in PMTCT programmes in Uganda have not been investigated. Therefore, this trial was conducted to evaluate the effect of a written invitation letter delivered to the spouses of women attending their first antenatal visit on couple attendance and partner acceptance of HIV testing at subsequent antenatal clinic appointments within a four-week follow-up period.

Methods

A randomized, parallel group, health facility-based intervention trial was conducted among 1060 new attendees (530 individuals in the intervention group and 530 in the control group) at the antenatal clinic in Mbale Regional Referral Hospital from October 2009 to February 2010. The trial setting has been described elsewhere [29]. Routine HIV counselling and testing were carried out according to the Uganda Ministry of Health guidelines (2006) [27].

A sequential HIV testing algorithm with same-day results, which includes three rapid tests, is carried out using one blood sample: *Determine HIV 1/2 assay (Abbott Laboratories, Abbott Park, IL, USA)* for first screening; *STAT-PAK HIV 1/2 dipstick assay (Chembio Diagnostic Systems Inc.)* as a second test; and *Uni-Gold Recombigen HIV (Trinity Biotech, Wicklow, Ireland)* as a "tie-breaker". An ANC attendee is classified as uninfected if Determine is negative and as HIV infected if the *Determine* and *STAT-PAK* tests are positive. Discordant *Determine* and *STAT-PAK* blood samples are further tested using the *Uni-Gold* test. The HIV test result is reported as positive if the *Uni-Gold* test is positive and as negative if the *STAT-PAK* and *Uni-Gold* tests are negative.

Since 2006, ANC clinic attendees who are HIV-positive undergo CD4 cell counts before being administered appropriate treatments according to the national PMTCT guidelines [27]. The sample size for this trial was calculated using a computer programme, OpenEpi, version 2 (http://www.openepi.com/SampleSize/SSCohort.htm). Based on the assumptions that antenatal couple attendance and HIV testing would increase from 4.5% (without intervention) to 9% (with intervention) with 80% power and 95% confidence intervals, 1060 new antenatal attendees, 530 in each group, were enrolled into the trial. The trial was completed four weeks after enrolment of the last participant.

Eligible trial participants were new attendees, aged 15 years or above, who agreed to attend subsequent antenatal visit(s) within the four-week follow-up period at Mbale Hospital, and were willing to give the invitation and information letters to their male partners.

A male partner was defined in this trial as the male who impregnated the antenatal attendee in the current pregnancy. The exclusion criteria included women who attended with their spouses at the first antenatal visit or did not consent to participate in the trial, or had spouses who were inaccessible.

Women attending without spouses at the first antenatal visit were identified at reception in the antenatal clinic. They were tracked until they had undergone all the standard clinic procedures (namely registration, health education, pre- and post-test counselling for HIV, HIV testing, obstetric examination and treatment). Individuals were approached by research assistants and informed about the trial's objective and the intervention. Those who agreed to participate in the trial by providing written consent were enrolled into the trial using an enrolment form with a randomly generated identification number.

Each woman was provided with a letter addressed to her spouse and given an appointment for a return visit two weeks later. If the participant was not able to attend with her partner on the scheduled visit, she was given another appointment for a return visit two weeks later. Their identification numbers were marked on their antenatal cards to aid follow up at the next clinic visit. The importance of adhering to their ANC visits was uniformly emphasized. Women who did not return to the antenatal clinic for their scheduled visits during the four-week follow-up period were classified as "lost to follow up".

At enrolment into the trial by the research assistants, participants were randomly assigned to two parallel groups, the intervention and non-intervention groups, with an allocation ratio of 1:1. The intervention comprised an invitation letter addressed to the male partner of the woman attending her first ANC visit, requesting him to accompany her on the next ANC visit. The comparative arm (non-intervention group) received a letter containing information concerning services offered in the antenatal clinic at Mbale Regional Referral Hospital.

Detailed in the invitation letter was the following information: the appointment date of the woman's next antenatal visit; that the antenatal and PMTCT services are free (no user charges); that these services are beneficial to the couple and their unborn baby, and that their utilization by men is low; that he was cordially invited to accompany the woman at her next scheduled antenatal visit to discuss important issues concerning her antenatal care; and that the time spent in hospital would be minimal.

The information letter, the leaflet, contained details concerning services provided in the antenatal clinic, and these included checking the woman's blood pressure to detect and manage high blood pressure during pregnancy. It explained that the woman's urine is tested for protein, sugar and infections, that her blood is checked for low haemoglobin levels, and that her abdomen is examined to investigate the wellbeing of the baby. Lastly, the leaflet informed the woman and her partner that PMTCT services in the clinic were free of charge. The letters were of similar length, and content was comparable, with one being an invitation and the other being an information leaflet only. Each letter was duly signed by the principal investigator.

The random allocation list of the identification numbers was randomly generated by an independent statistician from TASO Uganda (The AIDS Support Organisation). A random sequence generator (computer programme) at the RANDOM.ORG website [30], which employed a simple randomization procedure, was utilized. The random numbers were hand-written at the bottom of the back page of the letters for the intervention and non-intervention groups by the principal investigator. Each letter was inserted into an opaque envelope and sealed with adhesive glue to ensure that participants would not open their husbands' letters.

The corresponding randomization number was written on the back of the envelope. No antenatal clinic staff, co-investigators, research assistants or pregnant women knew whether the sealed envelopes contained the intervention or non-intervention letters. The randomization code was kept securely by the principal investigator. Each woman enrolled into the trial by the research assistants was given an identification number (serial number). The appropriate envelope, whose randomization number corresponded to the serial number, was selected and given to the participant to give to her spouse. The randomization code was revealed to the co-investigators during data analysis.

Data were collected by five trained research assistants using a standardized, pre-tested questionnaire, administered to participants in English or Lumasaba (local language) during exit interviews at subsequent clinic visits during the four-week follow-up period. Four weeks after enrolment into the trial, women who had not returned for their subsequent antenatal visits were deemed to have been lost to follow up. The research assistants were knowledgeable in the local language and interview techniques, and had been trained in terms of the trial objectives and methods.

The structured interview covered topics concerning the participant's education, occupation, religion, ethnic group, number of pregnancies, household assets, opinions and experiences relating to routine HIV counselling and HIV testing in the antenatal clinic, and knowledge of mother to child transmission of HIV and infant feeding options for HIV-infected mothers. Furthermore, her partner's age, occupation and

education was discussed. Participants were asked about partner clinic attendance and partner antenatal HIV testing acceptance. Questionnaires were checked for completeness at the end of each day by the principal investigator and clarification sought from research assistants when queries arose. Data were entered using Epi-Data version 3.1 [31] by two data entry clerks and were validated by the principal investigator. The data file was exported to PASW Statistics 18 [32] (formerly SPSS) for analysis.

Ethical clearance to conduct the trial was obtained from the Research and Ethics Committee of the School of Medicine, Makerere University, and from the Uganda National Council of Science and Technology. Permission to conduct the trial in the antenatal clinic was obtained from the Mbale Regional Referral Hospital administration through the local institutional review board. Written informed consent was provided by all trial participants. The trial was registered with the Clinical-Trials.gov registry (Identifier: NCT01144234).

The pre-specified primary outcome measure of the trial was the proportion of pregnant women who attended ANC with their partners at the subsequent antenatal visit. The secondary outcome measure was the proportion of men who accepted routine antenatal HIV testing. All participants were included in the analysis for the primary outcome measure in the groups to which they were originally assigned (intention to treat); analysis for the secondary outcome included only participants who attended their scheduled return clinic visits during the follow-up period (per protocol analysis).

The socio-demographic characteristics of the trial participants in the intervention and non-intervention groups were compared using independent sample *t*-test for continuous variables and the Pearson chi-square test for categorical variables. Correlates of couple ANC attendance (male antenatal clinic attendance) and male partner antenatal HIV-testing in the intervention and non-intervention groups was determined using the Pearson Chi-square test and the independent *t*-test. Multicollinearity among the independent variables and outliers were investigated. Interactions were explored and binary logistic regression was used to test for confounding variables.

All variables that were significant at the level of $p < 0.2$ in binary analysis, and the age of participants, were retained in the multivariate regression model. All p values were two-tailed at a significance level of 5%. As indicators of model appropriateness, the goodness-of-fit test (Omnibus Tests of Model Coefficients) of each the final models for male partner antenatal attendance and for partner antenatal HIV-testing in the trial groups was significant ($p < 0.05$), and the Hosmer and Lemeshow

goodness-of-fit test was not significant (p value > 0.05) (see tables 1 and 2).

Results
Trial population and follow up
A total of 1060 new antenatal attendees were enrolled and randomly assigned to the intervention and non-intervention groups (530 women in each group) (Figure 1). Of these, 290 and 310 pregnant women in the intervention and non-intervention groups, respectively, attended the subsequent two antenatal visits as scheduled; response rates were 55% (290/530) for the intervention group and 58% (310/530) for the non-intervention group. No major differences in the socio-demographic characteristics of the trial participants were recorded between the groups (Table 3).

Analysis by intention to treat demonstrated that the proportions of participants who attended with their partners were 16.2% (86/530) and 14.2% (75/530) in the intervention and non-intervention groups, respectively (Odds Ratio, OR = 1.2; 95% Confidence Interval, CI: 0.8 to 1.6) (see Table 4). There was no difference between the intervention and control groups with respect to the main outcome variable using bivariate analysis [Pearson chi-square value (χ^2) = 0.35, *p*-value = 0.55]. The majority of male partners in the intervention group (95%) and non-intervention group (91%), who attended the antenatal clinic with their spouses, accepted HIV testing. There was no statistically significant difference between the intervention and non-intervention groups with respect to male partner antenatal HIV testing using bivariate analysis (OR = 2.1; 95% CI: 0.6 to 7.5) and multivariate analysis (OR = 1.6; 95% CI: 0.4 to 6.8), table 4. The men in the two groups were similar (*p*-value = 0.39).

The majority of male partners (93%, 150 out of 161) in both trial arms who accepted antenatal HIV counselling and testing were HIV sero-negative. Three men in the intervention group tested positive for HIV (Table 4).

All the female antenatal attendees who participated in the trial accepted antenatal HIV testing. Twenty-five (11 in the intervention group and 14 in the control group) tested positive for HIV (Table 4). Significantly, the male partners of most of these HIV-positive women (84%; 21/25) were not tested for HIV in the antenatal clinic (10 men did not attend the clinic; 11 men attended, but declined to be tested). Of the five couples with known HIV test results, three were discordant: in one couple, the woman was HIV negative and male partner was HIV positive; in two couples, the women were HIV positive and the partners were HIV negative. Two couples were concordant (both partners had HIV-positive test results). Therefore, in this trial, of the 150 couples

Table 1 Correlates of couple antenatal attendance among 600 pregnant women at Mbale Regional Referral Hospital

Study participants' characteristics (Variables)[a]	Male partner antenatal clinic attendance in intervention group (N = 290)[b]				Male partner antenatal clinic attendance in non-intervention group (N = 310)[c]			
	Attended n (%)	Did not attend n (%)	Unadjusted OR[d] (95% CI)	Adjusted OR (95% CI[e])	Attended n (%)	Did not attend n (%)	Unadjusted OR (95% CI)	Adjusted OR (95% CI
Age (years)								
15-24	42 (28)	111 (72)	1	1	40 (24)	130 (77)	1	1
25 or more	44 (32)	93 (68)	1.3 (0.8-2.1)	1.2 (0.7-2.1)	30 (25)	105 (75)	1.1 (0.6-1.8)	1.0 (0.6-1.8)
Education level								
No or incomplete primary	34 (28)	86 (72)	1		28 (24)	88 (76)	1	
Completed primary	52 (31)	118 (69)	1.1 (0.7-1.9)		47 (24)	147 (76)	1.0 (0.6-1.7)	
Occupation								
Not salaried	47 (30)	109 (70)	1		59 (22)	207 (78)	1	1
Salaried	39 (29)	95 (71)	1.0 (0.6-1.6)		16 (36)	28 (64)	2.0 (1.0-4.0)	1.5 (0.7-3.2)
Ethnic group								
Bagisu	55 (30)	128 (70)	1		41 (21)	151 (79)	1	1
Non-Bagisu	31 (29)	76 (71)	0.9 (0.6-1.6)		34 (29)	84 (71)	1.5 (0.9-2.5)	1.6 (0.9-2.9)
Religion								
Muslim	30 (24)	93 (76)	1	1	29 (23)	97 (77)	1	
Christian	56 (34)	111 (67)	1.6 (0.9-2.6)	1.6 (0.9-2.6)	46 (25)	138 (75)	1.1 (0.7-1.9)	
Asked partner permission to test for HIV								
No	27 (22)	95 (78)	1	1	24 (17)	119 (83)	1	1
Yes	59 (35)	109 (65)	1.9 (1.1-3.2)[f]	1.9 (1.1-3.3)[f]	51 (31)	116 (69)	2.2 (1.3-3.8)[g]	1.8 (1.0-3.2)[f]
Partner's age (years)								
19-29	28 (29)	68 (71)	1		27 (26)	76 (74)	1	
30 or more	49 (37)	82 (63)	1.5 (0.8-2.6)		32 (26)	92 (74)	1.0 (0.3-1.8)	
Partner's occupation								
Not salaried	47 (30)	109 (70)	1		34 (20)	134 (80)	1	1
Salaried	39 (29)	95 (71)	1.0 (0.6-1.6)		41 (29)	101 (71)	1.6 (1.0-2.7)	1.4 (0.8-2.5)
Partner's education level								
No or incomplete primary	16 (27)	43 (73)	1		9 (16)	47 (84)	1	1
Completed primary	62 (32)	133 (68)	1.3 (0.7-2.4)		59 (29)	147 (71)	2.1 (1.0-4.5)	1.7 (0.8-3.8)

[a]Other variables not statistically significant in univariate analysis were: Participant's place of residence, marital status and total number of pregnancies. Age as a possible confounder and all variables that were significant at the level of p < 0.2 in univariate analysis were retained in the multivariate regression model. Multicollinearity and interaction among the independent variables, and outliers were checked for.

[b]The goodness-of-fit test (Omnibus tests of Coefficients) of the final logistic regression model in the intervention group was significant [Chi-square statistic (χ^2) = 9.376, degrees of freedom (df) = 3, p = 0.025] and Hosmer and Lemeshow goodness of fit test was not significant [χ^2 = 2.785, df = 6, p = 0.835] as indicators of model appropriateness.

[c]For the non-intervention group, the goodness-of-fit test (Omnibus tests of Coefficients) of the final logistic regression model was significant [χ^2 = 13.018, df = 6, p = 0.043] and Hosmer and Lemeshow goodness of fit test was not significant [χ^2 = 5.617, df = 8, p = 0.690 as indicators of model appropriateness.

[d]OR: odds ratio

[e]CI: confidence interval

[f]Statistically significant: p < 0.05 (two-tailed)

[g]Statistically significant: p < 0.01(two-tailed)

who accepted antenatal HIV testing, 2% (three of 150) were identified as HIV sero-discordant.

Correlates of couple antenatal attendance and male partner antenatal HIV testing

Using multivariate logistic regression analysis, participants having asked for their partner's permission to test for HIV was the only variable significantly associated with couple antenatal attendance in the intervention group [adjusted OR (AOR) = 1.9; 95% CI: 1.1 to 3.3] and the comparative group (AOR = 1.8; 95% CI: 1.0 to 3.2) (see Table 1). The likelihood of partner antenatal attendance increased if the partner had completed primary school education (AOR = 1.7; 95% CI: 0.8 to 3.8), but this association was not statistically significant.

The trial demonstrated that the likelihood of male partner HIV testing increased if the participant had asked their partner for permission to test for HIV, and

Table 2 Correlates of male partner HIV testing in the antenatal clinic at Mbale Regional Referral Hospital, eastern Uganda

Study participants' characteristics (variables)[a]	Male HIV testing in antenatal clinic in intervention group (N = 290)[b]				Male HIV testing in antenatal clinic in non-intervention group (N = 310)[c]			
	Tested for HIV n (%)	Not tested for HIV n (%)	Unadjusted OR[d] (95% CI)	Adjusted OR (95% CI[e])	Tested for HIV n (%)	Not tested for HIV n (%)	Unadjusted OR (95% CI)	Adjusted OR (95% CI)
Age (Years)								
5-24	40 (26)	113 (74)	1	1	33 (19)	137 (81)	1	1
25 or more	42 (31)	95 (69)	1.2 (0.7-2.1)	1.2 (0.7-2.1)	35 (25)	105 (75)	1.4 (0.8-2.4)	1.3 (0.7-2.3)
Education level								
No or Incomplete primary	33 (28)	87 (72)	1		23 (20)	93 (80)	1	
Completed Primary	49 (29)	121 (71)	1.0 (0.9-1.2)		45 (23)	149 (77)	1.2 (0.7-2.1)	
Occupation								
Not salaried	72 (28)	188 (72)	1		53 (20)	213 (80)	1	1
Salaried	10 (33)	20 (67)	1.3 (0.6-2.9)		15 (34)	29 (66)	2.1 (1.0-4.2)	1.4 (0.6-3.1)
Ethnic group								
Bagisu	52 (28)	131 (72)	1		37 (19)	155 (81)	1	1
Non-Bagisu	30 (28)	77 (72)	1.0 (0.6-1.7)		31 (26)	87 (74)	1.5 (0.9-2.6)	1.6 (0.9-2.9)
Religion								
Muslim	27 (22)	96 (78)	1	1	25 (20)	101 (80)	1	
Christian	55 (33)	112 (67)	1.7 (1.0-3.0)[f]	1.7 (1.0-3.0)[f]	43 (23)	141 (77)	1.2 (0.7-2.1)	
Asked partner permission to test for HIV								
No	25 (21)	97 (79)	1	1	21 (15)	122 (85)	1	1
Yes	57 (34)	111 (66)	2.0 (1.2-3.4)[g]	2.0 (1.2-3.5)[f]	47 (28)	120 (72)	2.3 (1.3-4.0)[g]	1.9 (1.0-3.6)[f]
Partner's age (years)								
19-29	26 (27)	70 (73)	1		22 (21)	81 (79)	1	
30 or more	47 (36)	84 (64)	1.5 (0.8-2.7)		31 (25)	93 (75)	1.2 (0.7-2.3)	
Partner's occupation								
Not salaried	45 (29)	111 (71)	1		28 (17)	140 (83)	1	1
Salaried	37 (28)	97 (72)	0.9 (0.6-1.6)		40 (28)	102 (72)	2.0 (1.1-3.4)[f]	1.8 (1.0-3.3)[f]
Partner's education level								
No or incomplete primary	16 (27)	43 (73)	1		9 (16)	47 (84)	1	1
Completed primary	58 (30)	137 (70)	1.1 (0.6-2.2)		53 (26)	153 (74)	1.8 (0.8-3.9)	1.5 (0.7-3.4)

[a]Other variables not significant in univariate analysis were: participant's place of residence, marital status, and total number of pregnancies. Age as a possible confounder and all variables that were significant at the level of p < 0.2 in univariate analysis were retained in the multivariate regression model. Multicollinearity and interaction among the independent variables, and outliers were checked for.

[b]The goodness-of-fit test (Omnibus tests of Coefficients) of the final logistic regression model in the intervention group was significant [chi-square statistic (χ^2) = 11.362, degrees of freedom (df) = 3, p = 0.010] and Hosmer and Lemeshow goodness-of-fit test was not significant [χ^2 = 3.585, df = 6, p = 0.733] as indicators of model appropriateness.

[c]For the non-intervention group, the goodness-of-fit test (Omnibus tests of Coefficients) of the final logistic regression model was significant [χ^2 = 15.412, df = 6, p = 0.017] and Hosmer and Lemeshow goodness-of-fit test was not significant [χ^2 = 8.774, df = 8, p = 0.362 as indicators of model appropriateness.

[d]OR: odds ratio

[e]CI: confidence interval

[f]Statistically significant: p < 0.05 (two-tailed)

[g]Statistically significant: p < 0.01 (two-tailed)

this was the case for the intervention (AOR = 2.0; 95% CI: 1.2 to 3.5) and non-intervention groups (AOR = 1.9; 95% CI: 1.0 to 3.6). In addition, the participant being a Christian (AOR = 1.7; 95% CI: 1.0 to 3.0) and their partner being salaried (AOR = 1.8; 95% CI: 1.0 to 3.3) were significantly associated with male partner acceptance of antenatal HIV testing (Table 2).

Discussion

As far as we are aware, this is the second randomized clinical trial to evaluate the effects of a written invitation letter to spouses of antenatal attendees on partner antenatal clinic attendance in sub-Saharan Africa. The effect of the intervention (invitation letter) and the control (information leaflet) on couple antenatal attendance

Figure 1 Trial profile.
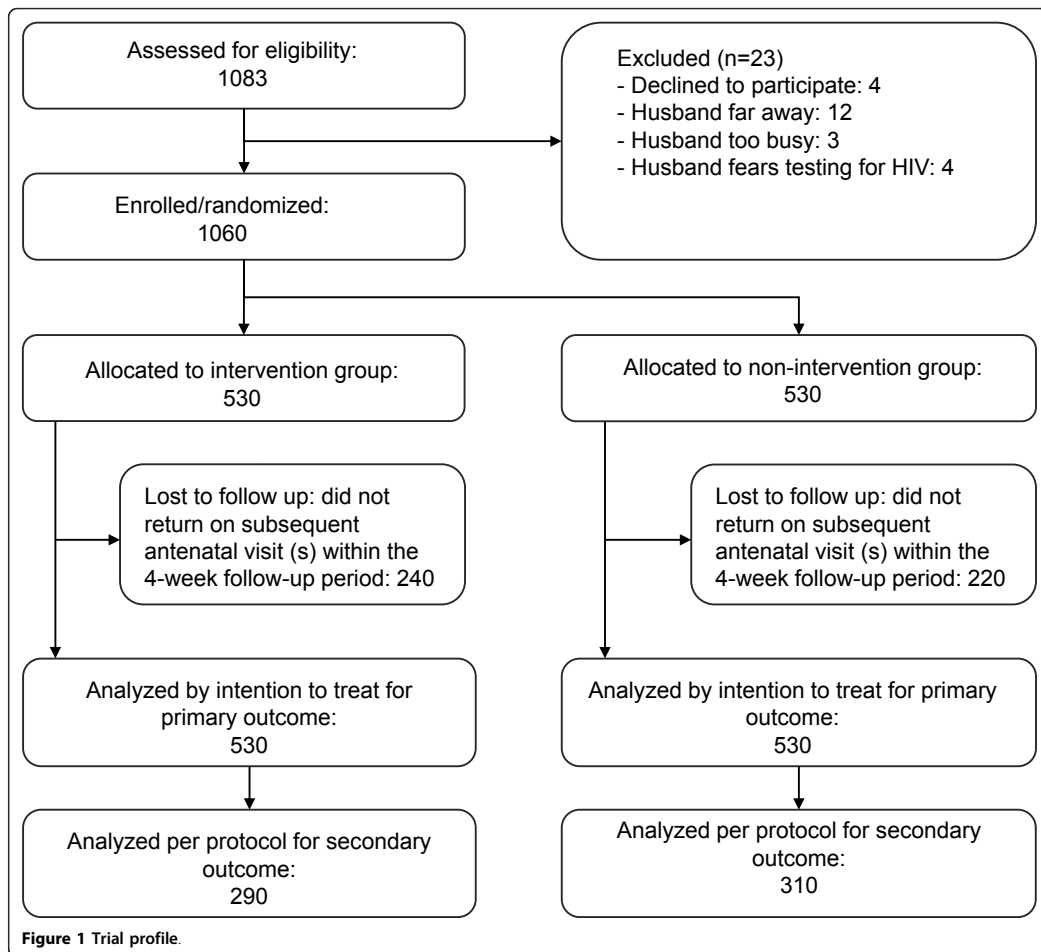
in the trial was similar. The invitation letter and the information leaflet increased couple attendance at the antenatal clinic from approximately 5% [28] to 16% and 14%, respectively. A simple intervention letter to the spouse could increase couple attendance by 10%. This cost-effective intervention could be implemented in almost all African ANC clinics with PMTCT.

The surprisingly equal effect in both arms of the trial could be because the invitation letter (intervention) and the information letter (control) had an official connotation and were perceived by the male partners to be credible as they originated from hospital. Therefore, these letters influenced male antenatal attendance decisions in similar ways, irrespective of the detailed content.

A recent study, carried out in northern Uganda, has documented that the likelihood of male partner antenatal attendance was increased if men were knowledgeable about antenatal care services and if they obtained health information from health workers [33]. The lack of any significant difference between the intervention and the control letter on couple antenatal attendance could be explained by the low power of the trial as a result of the high loss to follow up of trial participants.

The level of male antenatal attendance in this trial is higher than one carried out in northern Tanzania [11], but lower than those documented in studies from northern Uganda [33], central Kenya [22] and Khayelitsha, South Africa [34]. The age groups of the men in these studies were comparable with those of the male partners

Table 3 Demographic characteristics of study participants compared between intervention (N = 290) and non-intervention groups (N = 310)

Characteristics	Study groups		P value
	Intervention n (%)	Non-intervention n (%)	
Age in years[a]			
15-24	153 (52.8)	170 (54.8)	0.64
25 or more	137 (47.2)	140 (45.2)	
Place of residence			
Rural	197 (67.9)	207 (66.8)	0.83
Urban	93 (32.1)	103 (33.2)	
Number of pregnancies			
One	64 (22.1)	72 (23.2)	0.48
Two or more	226 (77.9)	238 (76.8)	
Education level			
No education/incomplete primary	120 (41.4)	116 (37.4)	0.43
Completed primary or more	170 (58.6)	194 (62.6)	
Marital status			
Single/divorced/widowed	4 (1.4)	6 (1.9)	0.75
Married/cohabiting	286 (98.6)	304 (98.1)	
Occupation			
Salaried	30 (10.3)	44 (14.2)	0.19
Not salaried	260 (89.7)	266 (85.8)	
Ethnic group			
Bagisu	183 (63.1)	192 (61.9)	0.83
Non-Bagisu	107 (36.9)	118 (38.1)	
Religion			
Muslim	123 (42.4)	126 (40.6)	0.72
Christian	167 (57.6)	184 (59.4)	
Partner's age in years[b]			
19-29	96 (42.3)	103 (45.4)	0.51
30 or more	131 (57.7)	124 (54.6)	
Partner's education level			
No education/incomplete primary	59 (23.2)	56 (21.4)	0.45
Completed primary or more	195 (76.8)	206 (78.6)	
Partner's occupation			
Not salaried	156 (53.8)	168 (54.2)	0.99
Salaried	134 (46.2)	142 (45.8)	

[a]The median age of the pregnant women was 24 years in both the intervention [interquartile range (IQR): 20-28 years] and non-intervention (IQR: 21-29 years) groups.
[b]The male partners' median age was 30 years in the intervention group (IQR: 26-38 years) and non-intervention group (IQR: 26-35 years), respectively.

in the current trial. It was also reported in the northern Uganda study that the likelihood of male antenatal attendance was higher if men had attained secondary or higher level education [33], but partner education level was not significantly associated with male antenatal attendance in the current trial. The level of partner attendance in this trial was similar to that reported in a study in Nairobi, Kenya [35].

Significantly, the current trial demonstrated that the majority (more than 90%) of male partners who attended the antenatal clinic accepted HIV counselling and testing for HIV. A similar finding has been reported in other studies in the region [22,35]. The implication of this finding is that increasing male antenatal clinic attendance is vital for involving spouses of antenatal attendees in the PMTCT programme. A woman having sought a partner's permission for HIV testing was significantly associated with partner antenatal attendance and HIV testing, as demonstrated using multivariate analysis. A similar finding was reported in the Nairobi antenatal clinic study [35]. This suggests that improved communication between couples regarding HIV is an important factor in increasing the number of men accompanying their spouses to antenatal clinics and accessing HIV counselling and testing services.

However, there was a differential effect because the HIV sero-status of approximately 80% of the HIV-positive women's partners remained unknown, which constitutes a missed opportunity to investigate couple HIV sero-discordance and a failure of the intervention to reach the intended recipients.

The trial demonstrated that at least 2% of the couples were HIV sero-discordant. However, because of the low numbers of male partners tested, this figure is likely to be higher. Other studies in Uganda have reported rates of couples' HIV sero-discordance at 30% to 50% [23-26]. HIV sero-discordance is a key factor that influences rates of new infections among couples [36], thus increasing the risk of mother to child transmission of HIV during pregnancy, delivery and lactation.

The strength of this trial was the surprisingly comparable effect of a letter - a simple, cheap intervention that was easy to administer - in both arms. It could be argued that the main limitation of this trial was the high loss to follow up rate of approximately 40%, reducing the precision (internal validity) and the power of the trial to detect differences between the effect of the invitation letter and the information letter.

There are several possible reasons for the high rate of loss to follow up. Some pregnant women may have continued receiving antenatal care at lower level health units (health centres) nearest to their place of residence on learning from the midwives on their first antenatal clinic visit that they had low risk pregnancies. Others may not have attended follow-up ANC visits owing to transportation problems as the trial site was a referral hospital. Others could have attended clinics for HIV counselling and testing services and decided to continue with ANC elsewhere.

Table 4 Primary and secondary outcomes of the facility based-intervention study at Mbale Regional Referral Hospital, eastern Uganda

	Intervention group: n/N (%)	Non-intervention group: n/N (%)	Unadjusted OR[a] (95% CI[b])	Adjusted OR (95% CI)
Primary outcome				
Couple antenatal attendance				
Intention to treat analysis	86/530 (16.2)	75/530 (14.2)	1.2 (0.8-1.6)	
Per protocol analysis	86/290 (29.7)	75/310 (24.2)	1.3 (0.9-1.9)	1.5 (1.0-2.3)[c]
Secondary outcome(s)				
Partner accepted HIV test[d]	82/86 (95.3)	68/75 (90.7)	2.1 (0.6-7.5)	1.6 (0.4-6.8)[e]
Partner's HIV test results[f]				
HIV positive	3/82 (3.7)	0 (0)		
HIV negative	79/82 (96.3)	68/68 (100)		
Loss to follow up	240/530 (45.3)	220/530 (41.5)	1.2 (0.9-1.5)	
Participant's HIV test results				
HIV positive	11/290 (3.8)	14/310 (4.5)	0.8 (0.4-1.7)	
HIV negative	279/290 (96.2)	296/310 (95.5)	1	

[a]Odds ratio
[b]Confidence interval
[c]Adjusted for the participant's and male partner's age, occupation and education level, the couple antenatal attendance odds ratio
[d]Partner acceptance of antenatal HIV testing analyzed per protocol
[e]Adjusted for male partner's age, occupation and education level
[f]Fisher Exact test two-sided p value was 0.32

It is possible that community sensitization activities to encourage men to participate in ANC activities, as carried out in the Khayelitsha trial in South Africa [34], could have helped reduce the loss to follow up in our trial. Being a randomized, health facility-based trial, it is assumed that random allocation of the trial participants to the comparison groups, and masking of research assistants, health staff in the antenatal clinic and the participants, dealt with known and unknown confounders. As one of the health providers in the hospital, the principal investigator (RB) did not directly participate in administering intervention to the trial participants in order to avoid the Hawthorne effect on the internal validity of the trial. The findings of this trial could be generalized country-wide to populations that are similar to the one in the trial area.

Conclusions

The effect of the intervention and the control on couple antenatal attendance was similar in both arms of the trial. In addition, this trial demonstrated that a simple intervention, such as a letter to the spouse, formulated as an invitation or as an information letter, could increase couple attendance by 10%. This intervention could be implemented in almost all African ANC clinics with PMTCT at a modest cost.

The trial also demonstrated that the majority (more than 90%) of the male partners who attended the antenatal clinic accepted HIV counselling and testing for HIV. Therefore, there is a requirement to evaluate this simple, cheap intervention further elsewhere in adequately powered studies to assess its effectiveness in increasing partner participation in antenatal clinics and the prevention of mother to child transmission of HIV. Such studies would better define the trial's implications for the PMTCT programme.

Author details

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Authors' contributions

RB participated in the conception, design and implementation of the trial, statistical analysis, interpretation of data and drafting of the manuscript. ANÅ participated in interpretation of data and the drafting of the manuscript. GN participated in the design of the trial, interpretation of data and drafting of

the manuscript. CASK participated in interpretation of data and the drafting of the manuscript. TT participated in the conception and design of the trial, interpretation of data and drafting the manuscript. JKT participated in the design and implementation of the trial, interpretation of data and drafting of the manuscript. All authors read and approved the final manuscript.

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FACULTY OF MEDICINE
OFFICE OF THE DEAN

8th June, 2009

Dr. Robert Byamugisha
Mbale Regional Referral Hospital

Dear Dr. Byamugisha,

Re: **Approval of Protocol #REC REF 2009- 095**
        "Facility- based intervention to increase male involvement in antenatal care
        and the prevention of mother-to- child transmission of HIV"

Thank you for submitting an application for approval of the above – referenced protocol. The committee reviewed it and granted approval for one year, effective June 8, 2009. Approval will expire on June 7, 2010.

Continuing Review
In order to continue work on this study (including data analysis) beyond the expiration date, the Faculty of Medicine Research and Ethics Committee must reapprove the protocol after conducting a substantive, meaningful, continuing review.
This means that you must submit a continuing report form as a request for continuing review. To best avoid a lapse, you should submit the request six (6) to eight (8) weeks before the lapse date. Please use the forms supplied by our office.

Amendments
During the approval period, if you propose any change to the protocol such as its funding source, recruiting materials, or consent documents, you must seek Faculty of Medicine Research and Ethics Committee approval before implementing it.
Please summarize the proposed change and the rationale for it in a letter to the Faculty of Medicine Research and Ethics Committee. In addition, submit three (3) copies of an updated version of your original protocol application- one showing all proposed changes in bold or 'track changes,' and the other without bold or track changes.

Reporting
Other events which must be reported promptly in writing to the Faculty of Medicine Research and Ethics Committee include:
Suspension or termination of the protocol by you or the grantor

1

Unexpected problems involving risk to participants or others
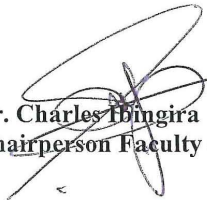
Adverse events, including unanticipated or anticipated but severe physical harm to participants.

Do not hesitate to contact us if you have any questions. Thank you for your cooperation and commitment to the protection of human subjects in research.

Final approval is to be granted by Uganda National Council of Science and Technology.

Yours sincerely

MAKERERE UNIVERSITY
FACULTY OF MEDICINE

★   0 8 JUN 2009   ★

RESEARCH & ETHICS COMMITTEE
P. O. BOX 7072, KAMPALA
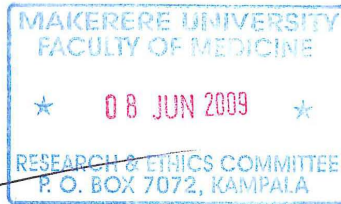
Dr. Charles Ibingira
Chairperson Faculty of Medicine Research and Ethics Committee

Uganda National Council For Science and Technology

(Established by Act of Parliament of the Republic of Uganda)

UNCST

Dr. Robert Byamugisha
C/o Makerere University
College of Health Sciences
P O Box 7072
Kampala

Dear Dr. Byamugisha,

RE: RESEARCH PROJECT, "FACILITY BASED INTERVENTION TO INCREASE MALE INVOLVEMENT IN ANTENATAL CARE AND THE PREVENTION PROGRAMME OF MOTHER TO CHILD PREVENTION OF HIV IN EASTERN UGANDA"

This is to inform you that the Uganda National Council for Science and Technology (UNCST) approved the above research proposal on **July 29, 2009.** The approval will expire on **July 29, 2010.** If it is necessary to continue with the research beyond the expiry date, a request for continuation should be made in writing to the Executive Secretary, UNCST

If it is necessary to continue with the research beyond the expiry date, a request for continuation should be made in writing to the Executive Secretary, UNCST. Any problems of a serious nature related to the execution of your research project should be brought to the attention of the UNCST, and any changes to the research protocol should not be implemented without UNCST's approval except when necessary to eliminate apparent immediate hazards to the research participant(s).

This letter also serves as proof of UNCST approval and as a reminder for you to submit to UNCST timely progress reports and a final report on completion of the research project.

Yours sincerely,

Jane Nabbuto
for: Executive Secretary
UGANDA NATIONAL COUNCIL FOR SCIENCE AND TECHNOLOGY

Consent form for paper II

Title of study: **Facility-based intervention to increase male involvement in antenatal care and the prevention programme of mother-to-child transmission of HIV in Eastern Uganda**

Investigators:
Dr Robert Byamugisha, Mbale Regional Referral Hospital, P O Box 921 Mbale – Uganda.
Tel: +256 772 68 90 28

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Arstadveien 21, N-5009 Bergen – Norway.

Prof. James K Tumwine, Department of Paediatrics and Child Health, Makerere University,
P O Box 7072, Kampala – Uganda

Dr Grace Ndeezi, Department of Paediatrics and Child Health, Makerere University,
P O Box 7072, Kampala – Uganda

Introduction and purpose of the study of the cross-sectional survey

This study is being conducted by doctors from Mbale Regional Hospital, the Department of Paediatrics and Child Health, Makerere University and the Centre for International Health, University of Bergen. The purpose of the cross-sectional study (survey) is to explore the attitudes of women attending antenatal clinic (ANC) at Mbale Regional Referral hospital about the antenatal care and PMTCT services at the hospital. A total of 384 pregnant women attending their first antenatal visit in present pregnancy will be enrolled.

Procedures to be followed
If enrolled in the study, you will be tracked from the reception to the time you exit the clinic. The interview concerning this study will be done at the time of exit. You will be asked questions concerning you, your living conditions and your opinions about issues regarding antenatal care, routine counselling and testing for HIV and prevention of mother to child transmission of HIV services in this hospital.

Risks
There are no anticipated risks arising from this study.

Potential benefits

It is hoped that the results of the study will be used to improve the delivery of antenatal and prevention of mother to child transmission of HIV services, which will be of benefit to you and your unborn child.

Costs or payments

There are no costs or payments to you for participating in this study.

Confidentiality

Your and your spouse's personal information will be strictly kept confidential. We will not give this information to anyone unless we get your permission to do so. You will not be personally identified in any publication or presentation about this study. However, the Makerere University College of Medicine Research and Ethics Committee, and the Uganda National Council for Science and Technology may check your records and the consent form you signed to make sure all rules and guidelines were followed.

Your rights as a research participant/volunteer

Your participation in this study is entirely voluntary. You will be asked to sign the consent form only when you have understood and agreed to participate in the study. You may decide to withdraw from the study at any stage. Such a decision will not affect your medical care or possible participation in future research studies in any way.

Problems or questions

If you have any questions about this study you can ask them now or at anytime during the course of the study. You are free to contact the following persons at any time; Dr. Robert Byamugisha on Telephone 256 772 68 90 28 or Prof James Tumwine on telephone 256 772 494 120 or Dr Grace Ndeezi on telephone 256 772 453191. You are also free to contact the Chairman of the Ethics committee of Makerere College of Medicine on telephone +256 412 530 020.

Respondent's consent

I have understood the information given to me about this study. I understand that my decision to participate in this study is voluntary and my decision not to participate will not alter the care I receive from this hospital. I also understand that my identity will remain anonymous in the use of the information generated from this study. I am aware that I may withdraw from this study any time.

If I have any questions concerning my rights as a research subject, I may contact Makerere University College of Medicine Research and Ethics Committee or the Uganda National Council of Science and Technology (Tel: +256 412 250 499 or +256 412 250 431).

I understand that by signing this consent form, I do not waive my legal rights nor does it relieve investigators of liability but merely indicates that I have been informed about the research study in which I am voluntarily agreeing to participate.

_____   _____   _____
Respondent's Names   Signature/ thumb print   Date

_____   _____   _____
Person administering consent   Signature   Date

_____   _____
Principal Investigator's Signature   Date

Questionnaire for Paper II

Title: Facility-based intervention to increase male involvement in antenatal care and the prevention programme of mother-to-child transmission of HIV in Eastern Uganda

Hello, I come from Makerere University, Uganda and the Centre for International Health, University of Bergen, Norway. The title of study is: Facility-based intervention to increase male involvement in antenatal care and the prevention programme of mother-to-child transmission of HIV in Eastern Uganda

The purpose of the study is to obtain information on women's views on the current service delivery at the antenatal clinic at Mbale Regional Referral Hospital. The results of the study will be used to improve the delivery of health services. The information you give shall be confidential and you will not be personally identified in any publication or presentation about this study.

I. IDENTIFICATION

1. Date of interview   <dd/mm/yyyy> .…/.…/………

2. Name of Interviewer   ………………………………………

3. Participant's ID Number   ……………….

4. Participant's names ……………………………………………………

II. SOCIO-DEMOGRAPHIC CHARACTERISTICS

5. Where do you live?   --------- 1=rural, 2=urban

6   (a) How old were you on your last birthday? --------- (completed years), 99= do not know …….

    (b) When were you born? .... (Year)

7. What is your current marital status?   ………. 1=single, 2=divorced/separated, 3=widower, 4=cohabiting, 5=married

8. Is this your first pregnancy?   1=Yes (skip to 10), 2= No ………

9. If no, how many pregnancies have you had before the current one? ………….

10. What is your religion? ------ 1=Protestant/Lutheran, 2=Catholic, 3=Muslim, 4=other, specify: ---------

11. What is your tribe (ethnic background)? ------ 1=Mugisu, 2=Mugwere, 3=Atesot, 4=Musoga, 5=Muganda, 6=other, specify: ----------

12. Did you attend school? …….. 1=Yes, 2=No (skip to 15)

13. If yes, what level of schooling did you achieve? ....

14 How many completed years of schooling have you had? /do you have? (Exclude repeated years and pre-school) ………

15 What do you do for a living? ---- 1=housewife, 2=farmer, 3=service, 4=business, 5=professional, 6=student, 7=other, specify: ----------

16. How old is your husband/ partner? ----- (completed years), 99=do not know

18. How many completed years of schooling does your husband/partner have? (Exclude repeated years and pre-school)   -------- 99= do not know

19. What does your husband/partner do for a living? ----- 1=farmer, 2=business, 3=skilled worker, 4=unskilled worker, 5=service, 6=official, 7=professional, 8=unemployed, 9=student, 0=other, specify: ----------

20. Do you own the house you live in? ---- 1=Yes,
                              2=No, rent the house,
                              3=No, house of my parents,
                              4=No, house of spouse's parents,
                              5=No, other: --------------

21. What type of house is it? ---- 1=permanent, 2=semi-permanent, 3= other, specify………,.

22. Does your household own any of the following items (functioning)?
    (i) Radio   ----   1=yes, 2=no
    (ii) Bicycle   ----   1=yes, 2=no
    (iii) Sofa   ----   1=yes, 2=no
    (iv) Hurricane lamp   ----   1=yes, 2=no
    (v) Cupboard   -----   1=yes, 2=no
    (vi) TV   ----   1=yes, 2=no
    (vii) Mobile phone   ----   1=yes, 2=no
    (viii) Refrigerator   ----   1=yes, 2=no
    (ix) Car/truck   ----   1=yes, 2=no
    (x) Motorcycle/scooter   ----   1=yes, 2=no

II.   CLINICAL ACTIVITIES
      Now I will ask you some questions about the ANC clinic

23. How was your visit to the antenatal clinic today? ---- 1=very bad, 2=bad, 3=fair,
                                                4=good, 5=very good

24. If a score of 10 is very good and 1 is very bad, please give me your score (out of 10) for how the following worked out for you:
    (i) Handling/treatment by the midwives (staff)   ……
    (ii) Waiting   ……
    (iii) Facilities   ……
    (iv) Health education talk/lection   ……

25.   Have you heard about a programme at the clinic regarding prevention of mother-to-child transmission of HIV? ------- 1=yes, 2=no

26.   Did you get any information about HIV at the antenatal clinic today? ----- 1=yes, 2=no (skip to 28)

27.   If yes, in which form?
       (i) TV   ---- - 1=yes, 2=no
       (ii) General information   ------ 1=yes, 2=no
       (iii) Group counselling   ------ 1=yes, 2=no
       (iv) Individual counselling   ------ 1=yes, 2=no

28.   Were you offered testing for HIV? ---- 1=yes, 2=no (skip to 34)

29.   Did you ask your husband/partner for permission to be tested before testing? ---- 1=yes, 2=no (skip to 33)

30.   Did he agree?   ----- 1=yes, 2=no

31.   Did you test for HIV?   ----- 1=yes, 2=no

32.   Did you receive the results of the test today? ---- 1=yes (skip to 35), 2=no

33.   If no, were you told when to come back for the result? ---- 1=yes, 2=no

34.   If you did not test, have you ever tested for HIV? ---- 1=yes, 2=no

35.   Do you think your husband/partner knows you are being tested for HIV? …… 1=yes, 2=no

36   Did they suggest your husband/ partner to be tested as well? .... 1=yes, 2=no (skip to 39)

37.   How was your pre-test counselling at the antenatal clinic? ----- 1=very bad, 2=bad, 3=fair,   good, 5=very good

38.   How was your post-test counselling at the antenatal clinic? …. 1=very bad, 2=bad, 3=fair,   4=good, 5=very good

39.   Nowadays in this clinic all mothers are supposed to be tested for HIV unless they say no. What do you think about this system? Is it: ----- 1=very bad, 2=bad, 3=fair, 4=good,5=very good

40.   Why do you think it is good or bad?   ---

  VI.   HIV AND INFANTS
        Now I will ask you some questions about HIV and infants

41.   Is it possible that when the mother or the father is HIV positive and their newborn child can be HIV negative?   …… 1=Yes, 2=No

42.   When can HIV be passed from a mother to her child?
       (i) During pregnancy   ----- 1=yes, 2=no
       (ii) Labour   ------ 1=yes, 2=no

(iii) Through breastfeeding   ------ 1=yes, 2=no
(iv) Sexual intercourse   ------ 1=yes, 2=no
(v) Other   ------ 1=yes, 2=no, (specify :----------)

43.   If there are 10 HIV infected pregnant women, how many do you think would have babies born with HIV virus?   ------- (number between 0 and 10)

44.   If the baby gets breast milk from the mother and the mother is HIV positive, can the baby get HIV?   -------- 1=yes, 2=no (skip to 46)

45.   How many babies could get HIV infected through breastfeeding out of 10 HIV infected mothers?   -------- (number between 0 and 10)

46.   Can a mother who HIV positive do anything to reduce the risk of transmission of HIV to her child during pregnancy?   -------- 1=Yes, 2=No, 3=Do not know

47.   If yes, what can a mother do to reduce the risk of transmission of HIV to her child during pregnancy?
(i) Take medicine   -------- 1=yes, 2=no
(ii) Use condoms   --------- 1=yes, 2=no
(iii) Other   --------- 1=yes, 2=no (specify :----------)

48.   Can an HIV infected mother do anything to reduce the risk of transmission of HIV to her child during the breastfeeding period?   -------- 1=Yes, 2=No, 3=Do not know

49.   If yes, what would an HIV positive mother do to reduce the risk of her baby becoming infected with HIV during the breastfeeding period?
(i) Give breast milk only and no other feeds up to 6 months (exclusive breastfeeding)
                                           ------ 1=yes, 2=no
(ii)   Use of condom by partner   ------ 1=yes, 2=no
(iii)   Stop breastfeeding; give infant formula   ------ 1=yes, 2=no
(iv)   Stop breastfeeding; give diluted cow's milk ------ 1=yes, 2=no
(v)   Breast care   ------ 1=yes, 2=no (specify :-------)
(vi)   Other   ------ 1=yes, 2=no (specify :-------)

50.   If you hypothetically were HIV positive, what infant feeding option would be feasible? ----------- 1=Infant feeding formula, 2=Cow milk, 3=Give breast milk only and no other feeds, other (specify) ----------

V.   SERVICE IMPROVEMENT

52.   What would you wish done differently?---

Remind her about her next ANC visit and the importance of adhering to the visits. Complete the interview and thank her cooperation and for participating.

Signature of the interviewer-------------------------   Date-----------

Consent form Paper III

Factors influencing male participation in the Prevention of Mother to Child Transmission of HIV (PMTCT) Programme in Mbale, Uganda

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INFORMED CONSENT
This study is being conducted by doctors from Mbale Regional Hospital, the Department of Paediatrics and Child Health, Makerere University and the Centre for International Health, University of Bergen. Before I can decide whether or not to volunteer for this study, I must understand its purpose, how it may help me and any risks to myself and what is expected of me if I decide to participate in this study. This process is called informed consent.

My rights as a research volunteer:
This consent form gives me information about the study which will also be discussed with me. Once I understand the study and agree to participate, I will be asked to sign this consent form. I understand that my participation in this study is entirely voluntary. I may decide to withdraw from the study at any stage. Such a decision will not affect my medical care or possible participation in future research studies in any way.

Purpose of the study:
The purpose of the study is to obtain information that will be used to understand the factors that influence male participation in the Prevention of Mother to Child Transmission of HIV programme. Interviews will last about one hour while group discussions will last 2 hours. I will only be required to participate in either the interview or the group discussion.

Study procedures:
I understand that if I decide to participate in the study, I will participate in the discussion on questions that will be asked by the moderator. The responses will be recorded, both in writing and by an audio tape recorder. If I decide to participate in the interview, I will be asked some questions.

Risks to me:

I understand that there are no risks to me, except for the temporary anxiety that may arise from the questions to be asked and for the time that I will spend here.

Potential benefits to me:
There are no immediate benefits from this study. However, I understand that the results of the study will be used to improve the delivery of health services, which will be of benefit to my child (ren) and to me.

Costs or payments to me:
There are no costs or payments to me.

Confidentiality:
I understand that the information that I give shall be confidential. I will not be personally identified in any publication or presentation about this study.

Problems or questions:
If I have any questions about this study, I am free to contact the following at any time; Dr. Robert Byamugisha on 077-689028, Dr. Mike. N. Kagawa on 077449613. If I have any questions on my rights as a research volunteer I may also contact Professor E. Katabira on 041-530020.

Respondents consent:
…………………………………………. has described to me what is going to be done, the risks, hazards and benefits involved. I understand that my decision to participate in this study or not to do so will not alter my usual health care. In the use of the information generated from this study such as publications, my identity will remain anonymous. I am aware that I may withdraw from this study any time.
Further information on research subjects' rights is available from the National Council of Science and Technology (Tel: 014- 250499 or 250431).
I understand that by signing this consent form, I do not waive my legal rights nor does it relieve investigators of liability but merely indicates that I have been informed about the research study in which I am voluntarily agreeing to participate.

Respondent's Name:……………….………….Age in completed years……...……..

Volunteer's Signature or Thumbprint:……………………………………………….

Witness' Name…………………………….. Signature:…………………………
Date:……………………………. ID No. [ ][ ][ ]

Questionnaire Paper III

Factors influencing male participation in the Prevention of Mother to Child Transmission of HIV (PMTCT) Programme in Mbale, Uganda.

Interview of Males

I. IDENTIFICATION

1.	ID Number	[ ][ ][ ]
2.	Local Council 1	
3.	Name of respondent	
4.	Status of head of household	[ ] Husband [ ] Mother [ ] Grandmother [ ] Grandfather [ ] Other (specify)
5.	Name of youngest child	
6.	Age of youngest child	**(completed months)**
7.	Name of Interviewers	
8.	Date of interview	

II. SOCIO-DEMOGRAPHIC CHARACTERISTICS

1.	How old are you?	Years_____ (**completed years**) [ ] Do not know
2.	In which year were you born? (*probe if Q1 and Q2 are inconsistent*)	19 ____ [ ] Do not know
3.	Are you married?	[ ] Yes [ ] No
4.	How did you get married?	[ ] Religious [ ] Traditional [ ] Civil [ ] Cohabiting [ ] Other (specify) _____
5.	What is your highest level of education?	Level _____
6.	How many completed years of schooling have you had? (*exclude repeated years and pre-school*)	Years of schooling [ ] [ ]
7.	What is your occupation? (**tick all that apply**)	[ ] Driver [ ] Farmer [ ] Trader (specify)_____ [ ] Shopkeeper [ ] Teacher [ ] Tailor [ ] Health worker [ ] Other (specify) _____
9.	How old is your wife? (if possible check with the wife)	[ ] [ ] (in completed years) [ ] Don't know
10.	In which year was your wife born?	19____ [ ] Don't know
11.	What is the highest level of	_____

	education of your wife?	[ ] Don't know
12.	How many completed years of schooling has your wife had? (probe and exclude repeated years and pre-school)	[ ] [ ] (in completed years) [ ] Don't know
13.	What is your wife's occupation? tick all that apply)	[ ] Farmer [ ] Trader (specify)_____ [ ] Shopkeeper [ ] Teacher [ ] Tailor [ ] Health worker [ ] Other (specify) _____
14.	How many rooms are there in your house?	[ ][ ] rooms
15.	Do you have a working (read the alternative) in your home)?	[ ] Lantern [ ] Radio [ ] Television [ ] Cupboard [ ] Refrigerator [ ] Bicycle [ ] Motorcycle [ ] Car/truck [ ] IGA Machine (specify) _____ [ ] None
16.	What is the main fuel for lighting in your house?	[ ] Wood [ ] Oil lamp (tadooba) [ ] Kerosene lamp [ ] Candle light [ ] Gas light [ ] Electric light [ ] Other (specify) _____
17.	What is the main fuel for cooking in your house?	[ ] Wood [ ] Charcoal [ ] Kerosene [ ] Gas [ ] Electricity [ ] Other (specify) _____
18.	What is your usual source of drinking water?	[ ] Stream/River/Dam [ ] Well [ ] Unprotected spring [ ] Protected spring [ ] Borehole pump [ ] Piped water [ ] Other (specify) _____
19.	What is your religion?	[ ] Protestant [ ] Catholic [ ] SDA [ ] Pentecostal [ ] Muslim

		[ ] Traditional [ ] Other (specify) _____
20.	How many of the following animals/birds do you have in your home?	[ ] Chicken _____ [ ] Turkeys _____ [ ] Goats _____ [ ] Sheep _____ [ ] Pigs _____ [ ] Cattle _____ [ ] Other (specify and No.) _____
21.	Does your family own land?	[ ] Yes [ ] No
22.	What is the floor of the main house made of?	[ ] Mud [ ] Stone [ ] Cement and sand [ ] Wood [ ] Other(specify)_____
23.	What are the walls of your main house made of?	[ ] Mud and poles [ ] Earth bricks [ ] Burnt bricks and cement [ ] Wood [ ] Other (specify)_____
24.	What is the roof of your main house made of?	[ ] Grass/banana fibre [ ] Iron sheets [ ] Tiles [ ] Other (specify)_____
25.	How many people live in your household?	0-5years: No._____ More than 5 years: No.____ Total: No.____

III   GENERAL PERCEPTIONS AND EXPERIENCES

1.	How many times has your wife been pregnant to date?	No._____
2.	Did your wife attend antenatal clinic during her last pregnancy?	[ ] Yes [ ] No *Skip to Q4*
3.	If yes, where did your wife go for antenatal care?	[ ] Mbale Regional Hospital [ ] Other Government health unit [ ] Private health unit [ ] TBA [ ] Other (specify)
4.	Have you heard about the PMTCT programme?	[ ] Yes [ ] No *(skip to 8)*
5.	How did you get information on the PMTCT programme?	[ ] Health care provider [ ] News papers [ ] Radio Programme/ advert [ ]Friend [ ] Wife
6.	What do you know about	

PMTCT?	
7. Would you encourage your wife to participate in PMTCT?	[ ] Yes *(explain)* [ ] No *(explain)*
8. Did you discuss HIV testing during your wife's last pregnancy?	[ ] Yes [ ] No
9. Do you know your HIV status?	[ ] Yes [ ] No
10. Are you willing to go for HIV counselling and testing?	[ ] Yes [ ] No
11. Would you fear taking the test for HIV?	[ ] Yes *(explain)* [ ] No *(explain*
12. Would you fear taking HIV drugs if you were tested HIV positive?	[ ] Yes *(explain)* [ ] No *(explain)*
13. Do you have fears about disclosure of HIV positive status to?	Wife [ ] Yes [ ] No Mother [ ] Yes [ ] No Other relative [ ] Yes [ ] No Friend [ ] Yes [ ] No Neighbour [ ] Yes [ ] No Health worker [ ] Yes [ ] No Other people [ ] Yes [ ] No
14. Would you go for VCT with your wife?	[ ] Yes [ ] No
15. Would you fear giving HIV drugs to your baby if you or your wife were tested HIV positive?	[ ] Yes *(explain)* [ ] No *(explain)*
16. Would you fear not to breastfeed your baby if you or your wife were tested HIV positive?	[ ] Yes *(explain)* [ ] No *(explain)*
17. Who decided/would decide on use of HIV drugs in pregnancy if you or wife were tested HIV positive?	Wife [ ] Yes [ ] No Self [ ] Yes [ ] No Both [ ] Yes [ ]

| | No
Other (specify) |

V   ANTE NATAL CARE AND POST NATAL

1.	Have you ever visited the ante natal clinic with your wife?	[ ] Yes [ ] No (*Skip to Q5*)
2.	If yes, why did you go to ANC?	
3.	Would you encourage other men to go to the ante natal clinic with their wives?	[ ] Yes (explain) [ ] No (Explain)
4.	What are the problems with the current set up of the ANC?	
5.	Do you have to provide your wife with financial support to enable her attend the ANC?	[ ] Yes [ ] No
6.	Would you provide your wife with financial support to attend ANC?	[ ] Yes (explain) [ ] No (explain)
7.	Are you aware of your wife's ANC appointments?	[ ] Yes [ ] No
8.	Would you remind your wife to honour her ANC appointments?	[ ] Yes [ ] No
9.	Have you ever bothered to know your wife's ANC appointments?	[ ] Yes [ ] No
10.	Have you ever taken the time to find out what goes on in the ANC?	[ ] Yes (specify) _____ [ ] No
11.	Do you discuss the interventions and information given in the ANC with your wife?	[ ] Yes (specify)_____ [ ] No
12.	Have you ever withheld financial support for any of the following from your wife?	[ ] Food [ ] Yes [ ] No [ ] Fuel [ ] Yes [ ] No [ ] Clothing [ ] Yes [ ] No [ ] Medical treatment [ ] Yes [ ] No
13.	Do you have children with other women?	[ ] Yes (specify no of wives)_____ [ ] No
14.	If yes, How many children?	[ ] wife 1 _____no of children [ ] wife 2 _____no of children [ ] wife 3 _____no of children
15.	Since you got married, have you ever had sexual intercourse with a woman other than your wife (ves)?	[ ] Yes (*why?*) [ ] No
16.	How do you feel about your	

marriage?	
17. Do you have someone to talk to about your marital relationship?	[ ] Yes [ ] No *Skip to Q19*
18. If yes, who?	
19. Since you got married have you ever used condoms?	[ ] Yes [ ] No *Skip to Q21*
20. If yes, who decided to use the condoms?	[ ] Wife [ ] Self (*why*) [ ] Other (specify) _____
21. Would you use a condom if your wife asked you to use one?	[ ] Yes [ ] No (*why*?)
22. Have you ever asked your partner to use a condom?	[ ] Yes [ ] No (*why*?)
23. If yes, what happened?	

Thank you very much for your cooperation.

Interview guide for Paper III

Factors influencing male participation in the Prevention of Mother to Child Transmission of HIV (PMTCT) Programme in Mbale District, Uganda

In-depth interview of Health Care Providers

I.   IDENTIFICATION AND SOCIO-DEMOGRAPHICS

ID Number   _____
Name   _____
Age   _____
Sex   Male   Female
Position   _____
Interviewer _____
Date of Interview   _____

II   PMTCT

1. How long have you been working in your present post?

2. Do you work with pregnant mothers?

3. What are your views regarding voluntary counselling and testing for HIV of pregnant mothers?

4. Should pregnant mothers be tested using the opt-in or opt-out approach?

5. What can be done to increase acceptance of VCT by males?

6. What is the role of men in promoting VCT in pregnancy?

7. Is couple VCT acceptable and feasible?

8. What can be done in the health care system to encourage males to accept VCT?

9. What factors discourage males from accepting VCT?

10. What can be done in the health care system to encourage males to support their partners during pregnancy (ANC) and child birth?

Topic Guide for Focus Group Discussions

Factors influencing male participation in the Prevention of Mother to Child Transmission of HIV Programme in Mbale District, Uganda

Instructions:

With the help of the local guide, you meet the participants assembled for the group discussion. Find a comfortable place to sit preferably in a circle and away from distraction. The local guide can help to keep away distracters. Greet the participants and thank them for having agreed to come. Introduce yourselves including the participants. Use name tags (tape) for identification of participants and research team. Explain the purpose of the study and the procedures that will be used including use of the tape recorder. Obtain informed consent from each participant. Set the ground rules for the group discussion (respect, input from everyone, honesty, start and end time etc). Emphasize that the discussion will be confidential and participants will remain anonymous. At the end of the session, give participants opportunity to ask questions. Attend to administrative issues (refreshments transport etc). Finally thank the participants and officials and take your leave.

Participants

Number of FGDs:	2 per zone = 8 FGDs
Number of participants:	6 to 12
Type of participants:	Men whose partners have gone through or are attending ANC

Topics

I   HIV in general - terminology, frequency, causes, prevention, treatment

What are the local names used for HIV?
What is their meaning?
Why are the names used to describe HIV?
How common is HIV?
Do participants know persons with HIV?
Do they know persons who may have died of HIV?
What are the causes of HIV?
How can HIV be prevented?
How can HIV be treated?

II   HIV in children – terminology, occurrence, causes, prevention, treatment

What are the local names used for HIV?
What is their meaning?
Why are the names used to describe HIV?
How common is HIV?
Do participants know persons with HIV?
Do they know persons who may have died of HIV?
What are the causes of HIV?
How can HIV be prevented?
How can HIV be treated?

III   Voluntary Counselling and Testing for HIV

Do you know about VCT?
What do you know about VCT?
Do you know people who have had VCT?
What were their feelings after going for VCT?
What do you feel about VCT?

What do you feel about VCT for pregnant women?
What are the problems with VCT?
What are your feelings about couple testing?
Should husbands be counselled and tested for HIV together with their wives?
What are your feelings about disclosure of HIV results?
Should wives who test for HIV disclose their results to their husbands?
Should husbands who test for HIV disclose their results to their wives?

IV   Stigma and discrimination in HIV
What are your feelings about HIV positive people?
Are they responsible for being HIV positive?
Are they immoral?
Should they be sanctioned (penalised)?
Are they contagious and threatening to the community?
Is HIV death undesirable and unclean?
What are your feelings about pregnant mothers who test for HIV?
What are your feelings about HIV positive pregnant mothers?
What are your feelings about pregnant mothers taking HIV drugs?
What are your feelings about giving HIV drugs to newborn babies?
What are your feelings about mothers who do not breastfeed their infants?
What are your feelings about mothers being visited in their homes by health officials e.g. TASO
What are your feelings about having VCT in hospital compared to another place e.g. AIC, JCRC?
What are your feelings about disclosure of HIV positive status to your partner, relatives, friends, and other people?

V   Culture Issues
What is the sexual division of labour?
What is the sexual division of sex?
What is the sexual division of power (making decisions, controlling resources?
What is the sexual division of social status?
What is the perception of masculinity?
What is the perception of femininity?
Can women negotiate for safer sex e.g. use of the condom?
What is the social status of married versus unmarried women?
How does polygamy affect the situation of women?
What does it mean for a woman not to be married?
How do women feel about being abandoned by their husbands?
Do married women have the right to refuse sex from their husbands?
If a man forces his wife to have sex with him, is it acceptable or not?
Do men have the right to have multiple sexual partners?
Do women have the power to reject multiple sexual partners of their husbands?

VI   Social networks and support for mothers (*list and rank*)
If a pregnant mother is asked to test for HIV, can she accept to test without consultation?
If she consults, whom does she consult?
If the pregnant woman is HIV positive, does she tell others?
If yes, whom does she tell?

Whom does she consult when she is choosing the method of feeding her infant soon after delivery?
Who advises her when to introduce other feeds for the child?
Who advises her on her own health?
Who advises her on use of HIV prevention e.g. condoms?
Who advises her on use of HIV drugs?
Who advises her on marital issues?

VII   Health Care System
What do you know about ANC?
What are your feelings about attending ANC with your partner?
What are the problems with the current set up in the ANC?
What could be done to make it more user friendly for the men?

VIII   Suggestions
What can be done to support mothers to test for HIV, use HIV drugs, and use appropriate infant feeding methods to prevent HIV in children?
What should be done to involve the men in the PMTCT programme?

Consent forms for paper IV

Informed consent form for intervention study

Title of study: **Facility-based intervention to increase male involvement in antenatal care and the prevention programme of mother-to-child transmission of HIV in Eastern Uganda**

Investigators:
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Dr Grace Ndeezi, Department of Paediatrics and Child Health, Makerere University, P O Box 7072, Kampala – Uganda

Introduction and purpose of the intervention study

This study is being conducted by doctors from Mbale Regional Hospital, the Department of Paediatrics and Child Health, Makerere University and the Centre for International Health, University of Bergen. The study is a health facility-based intervention to increase male involvement in antenatal care and the prevention programme of mother-to-child transmission of HIV in Eastern Uganda. The study has two components: a cross-sectional survey and clinical trial. The purpose of the intervention study is to obtain information that will be used to understand the impact of a letter to the spouses of pregnant women attending antenatal clinic (ANC) at Mbale Regional Referral hospital on ANC attendance, couple counselling and/or testing for HIV (under the PMTCT programme). A total of 1060 women will be enrolled in the study.

Procedures to be followed
You will be tracked from the reception to the time you exit the clinic. You will be asked questions concerning you and your living conditions. If you are selected for the intervention you will be given a letter to take to your spouse. You will also be requested to attend at least 2 subsequent antenatal visits under the study. An exit interview will be conducted on issues regarding antenatal care, routine counselling and testing for HIV and prevention of mother to child transmission of HIV services.

Risks

There are no anticipated risks arising from this study. However, some questions may address sensitive issues concerning your sexuality such as condom use. This may cause temporary anxiety.

Potential benefits

It is hoped that the results of the study will be used to improve the delivery of antenatal and prevention of mother to child transmission of HIV services, which will be of benefit to you and your unborn child.

Costs or payments

There are no costs or payments to you for participating in this study.

Confidentiality

Your and your spouse's personal information will be strictly kept confidential. We will not give this information to anyone unless we get your permission to do so. You will not be personally identified in any publication or presentation about this study. However, the Makerere University College of Medicine Research and Ethics Committee, and the Uganda National Council for Science and Technology may check your records and the consent form you signed to make sure all rules and guidelines were followed.

Your rights as a research participant/volunteer

Your participation in this study is entirely voluntary. You will be asked to sign the consent form only when you have understood and agreed to participate in the study. You may decide to withdraw from the study at any stage. Such a decision will not affect your medical care or possible participation in future research studies in any way.

Problems or questions

If you have any questions about this study you can ask them now or at anytime during the course of the study. You are free to contact the following persons at any time; Dr. Robert Byamugisha on Telephone 256 772 68 90 28 or Prof James Tumwine on telephone 256 772 494 120 or Dr Grace Ndeezi on telephone 256 772 453191. You are also free to contact the Chairman of the Ethics committee of Makerere University College of Medicine on telephone +256 412 530 020.

Respondent's consent

I have understood the information given to me about this study. I understand that my decision to participate in this study is voluntary and my decision not to participate will not alter the care I receive from this hospital. I also understand that my identity will remain anonymous in the use of the information generated from this study. I am aware that I may withdraw from this study any time.

If I have any questions concerning my rights as a research subject, I may contact Makerere University College of Medicine Research and Ethics Committee or the Uganda National Council of Science and Technology (Tel: +256 412 250 499 or +256 412 250 431).

I understand that by signing this consent form, I do not waive my legal rights nor does it relieve investigators of liability but merely indicates that I have been informed about the research study in which I am voluntarily agreeing to participate.

_____   _____   _____
Respondent's Names   Signature/ thumb print   Date

_____   _____   _____
Person administering consent   Signature   Date

_____   _____
Principal Investigator's Signature   Date

Questionnaire for Paper IV: Initial visit at ANC

Title: Facility-based intervention to increase male involvement in antenatal care and the prevention programme of mother-to-child transmission of HIV in Eastern Uganda

Interview of females

Hello, I come from Makerere University, Uganda and the Centre for International Health, University of Bergen, Norway. The title of study is: Facility-based intervention to increase male involvement in antenatal care and the prevention programme of mother-to-child transmission of HIV in Eastern Uganda

The purpose of the study is to collect information on women's views on the current service delivery at the antenatal clinic at Mbale Regional Referral Hospital and to study how to increase the male partners' involvement in the ANC clinic work. The results of the study will be used to improve the delivery of health services. You will be given a letter to take to your spouse and we are using letters with slightly different content.

The information you give shall be confidential and you will not be personally identified in any publication or presentation about this study.

I.   IDENTIFICATION

1.   Date of interview   <dd/mm/yyyy> .…/.…/………

2.   Name of Interviewer …………………………………………………

3.   Participant's ID Number   ……………….

4.   Participant's names ……………………………………………………

5.   What are your husband's names? ---

6.   Would he be willing to attend ANC with you?   --------- 1=yes, 2=no
        If no, give reasons--

7.   Do you mind taking this written document to him? ------ 1=yes, 2=no
        If no, give reasons--

        If she accepts to take the document, remind her about her next ANC visit and the importance of adhering to the visits. Complete the interview and thank her cooperation and for participating.

        Signature of the interviewer--------------------------   Date--------------

Questionnaire for Paper IV: Return visit at ANC

Title: Facility-based intervention to increase male involvement in antenatal care and the prevention programme of mother-to-child transmission of HIV in Eastern Uganda

Interview of females

Hello, I come from Makerere University, Uganda and the Centre for International Health, University of Bergen, Norway. The title of study is: Facility-based intervention to increase male involvement in antenatal care and the prevention programme of mother-to-child transmission of HIV in Eastern Uganda

The purpose of the study is to obtain information on women's views on the current service delivery at the antenatal clinic at Mbale Regional Referral Hospital. It is also to explore whether a letter of invitation for the male partners will increase couple ANC attendance; and whether the increase in couple ANC attendance will lead to an increase in couple counselling and testing for HIV. The results of the study will be used to improve the delivery of health services. The information you give shall be confidential and you will not be personally identified in any publication or presentation about this study.

I.   IDENTIFICATION

1.   Date of interview   <dd/mm/yyyy> .…/.…/………

2.   Name of Interviewer …………………………………………………

3.   Participant's ID Number   ……………….

4.   Participant's names ……………………………………………………

5.   What are your husband's names? ---

II   SOCIO-DEMOGRAPHIC CHARACTERISTICS

6.   Where do you live?   --------- 1=rural, 2=urban

        (a) How old were you on your last birthday? --------- (completed years), 99= do not know …….

        (b) When were you born? .... (Year)

7.   What is your current marital status?   ………. 1=single, 2=divorced/separated, 3=widower, 4=cohabiting, 5=married

8.   Is this your first pregnancy?   1=Yes, 2= No ………

9.   If no, how many pregnancies have you had before the current one? ………….

10.   What is your religion? ------ 1=Protestant/Lutheran, 2=Catholic, 3=Muslim, 4=other, specify: ---------

11.   What is your tribe (ethnic background)? ------ 1=Mugisu, 2=Mugwere, 3=Atesot, 4=Musoga, 5=Muganda, 6=other, specify: ----------

12.   Did you attend school? …….. 1=Yes, 2=No

13.   If yes, what level of schooling did you achieve? ....

14.   How many completed years of schooling have you had? /do you have? (Exclude repeated years and pre-school) ………

15.   What do you do for a living? ---- 1=housewife, 2=farmer, 3=service, 4=business, 5=professional, 6=student, 7=other, specify: ----------

16.   How old is your husband/ partner? ----- (completed years), 99=do not know

17.   How many completed years of schooling does your husband/partner have? (Exclude repeated years and pre-school)   -------- 99= do not know

18.   What does your husband/partner do for a living? ----- 1=farmer, 2=business, 3=skilled worker, 4=unskilled worker, 5=service, 6=official, 7=professional, 8=unemployed, 9=student, 0=other, specify: ----------

19.   Do you own the house you live in? ---- 1=Yes,
                        2=No, rent the house,
                        3=No, house of my parents,
                        4=No, house of spouse's parents,
                        5=No, other: --------------

20.   What type of house is it? ---- 1=permanent, 2=semi-permanent, 3= other, specify……….,.

21.   Does your household own any of the following items (functioning)?
        Radio   ----   1=yes, 2=no
        Bicycle   ----   1=yes, 2=no
        Sofa   ----   1=yes, 2=no
        Hurricane lamp   ----   1=yes, 2=no
        Cupboard   -----   1=yes, 2=no
        TV   ----   1=yes, 2=no
        Mobile phone   ----   1=yes, 2=no
        Refrigerator   ----   1=yes, 2=no
        Car/truck   ----   1=yes, 2=no
        Motorcycle/scooter   ----   1=yes, 2=no

II.   CLINICAL ACTIVITIES
        Now I will ask you some questions about the ANC clinic

22.   How was your visit to the antenatal clinic today? ---- 1=very bad, 2=bad, 3=fair, 4=good, 5=very good

23.   Did you come to the ANC clinic with your partner (husband)? …… 1=Yes, 2=No

24.   If a score of 10 is very good and 1 is very bad, please give me your score (out of 10) for how the following worked out for you:

Handling/treatment by the midwives (staff) ……
Waiting   ……
Facilities   ……
Health education talk/lection ……

25. Have you heard about a programme at the clinic regarding prevention of mother-to-child transmission of HIV? ------- 1=yes, 2=no

26. Did you get any information about HIV at the antenatal clinic today? ----- 1=yes, 2=no (skip to 28)

27. If yes, in which form?
TV   ---- - 1=yes, 2=no
General information ------ 1=yes, 2=no
Group counselling ------ 1=yes, 2=no
Individual counselling ------ 1=yes, 2=no

28. Were you offered testing for HIV? ---- 1=yes, 2=no (skip to 35)

29. Did you ask your husband/partner for permission to be tested before testing? ---- 1=yes, 2=no

30. Did he agree?   ----- 1=yes, 2=no

31. Did you test for HIV? ----- 1=yes, 2=no (skip to 33)

32. Did you receive the results of the test today? ---- 1=yes (skip to 36), 2=no

33. If no, were you told when to come back for the result? ---- 1=yes, 2=no

34. If you did not test, have you ever tested for HIV? ---- 1=yes, 2=no

35. Do you think your husband/partner knows you are being tested for HIV? …… 1=yes, 2=no

36. Did they suggest your husband/ partner to be tested as well? .... 1=yes, 2=no

37. Was he tested for HIV ? ………….. 1=Yes, 2=No

38. What were his HIV tests? ………….. 1=HIV positive, 2=HIV negative, 3=don't know

39. How was your pre-test counselling at the antenatal clinic? ----- 1=very bad, 2=bad, 3=fair, good, 5=very good

40. How was your post-test counselling at the antenatal clinic? …. 1=very bad, 2=bad, 3=fair, 4=good, 5=very good

41. What were HIV test results? ………… 1=HIV positive, 2=HIV negative

42.   Nowadays in this clinic all mothers are supposed to be tested for HIV unless they say no. What do you think about this system? Is it: ----- 1=very bad, 2=bad, 3=fair, 4=good, 5=very good

43.   Why do you think it is good or bad? ……………………………………………..
        …..……………………………………………………………………………………..

VI.   HIV AND INFANTS
        Now I will ask you some questions about HIV and infants

44.   Is it possible that the mother or the father is HIV positive, and their newborn child is HIV negative?   …… 1=Yes, 2=No

45.   When can HIV be passed from a mother to her child?
        During pregnancy   ----- 1=yes, 2=no
        Labour   ------ 1=yes, 2=no
        Through breastfeeding   ------ 1=yes, 2=no
        Sexual intercourse   ------ 1=yes, 2=no
        Other   ------ 1=yes, 2=no, (specify :----------)

46.   If there are 10 HIV infected pregnant women, how many do you think would have babies born with HIV virus?   ------- (number between 0 and 10)

47.   If the baby gets breast milk from the mother and the mother is HIV positive, can the baby get HIV?   -------- 1=yes, 2=no (skip to 52)

48.   How many babies could get HIV infected through breastfeeding out of 10 HIV infected mothers?   -------- (number between 0 and 10)

49.   Can a mother who HIV positive do anything to reduce the risk of transmission of HIV to her child during pregnancy? -------- 1=Yes, 2=No, 3=Do not know

50.   If yes, what can a mother do to reduce the risk of transmission of HIV to her child during pregnancy?
        Take medicine   -------- 1=yes, 2=no
        Use condoms   --------- 1=yes, 2=no
        Other   --------- 1=yes, 2=no (specify :----------)

51.   Can a HIV infected mother do anything to reduce the risk of transmission of HIV to her child during the breastfeeding period? -------- 1=Yes, 2=No, 3=Do not know

52.   If yes, what would an HIV positive mother do to reduce the risk of her baby becoming infected with HIV during the breastfeeding period?

        Give breast milk only and no other feeds up to 6 months (exclusive breastfeeding) ----- 1=yes, 2=no
        Use condom   ------- 1=yes, 2=no
        Stop breastfeeding; give infant formula   ------ 1=yes, 2=no
        Stop breastfeeding; give diluted cow's milk ------ 1=yes, 2=no
        Breast care   ------- 1=yes, 2=no (specify :----------)

Other   -------- 1=yes, 2=no (specify :----------)

53. If you hypothetically were HIV positive, what infant feeding option would be feasible? ----------- 1=Infant feeding formula, 2=Cow milk, 3=Give breast milk only and no other feeds, other (specify) ----------

V. SERVICE IMPROVEMENT

54. What would you wish done differently?--

Remind her about her next ANC visit and the importance of adhering to the visits. Complete the interview and thank her cooperation and for participating.

Signature of the interviewer--------------------------   Date--------------

Letter to the spouse

Non-intervention letter

Dr. Robert Byamugisha
Department of Obstetrics and Gynaecology
Mbale Regional Referral Hospital
Tel: +256 772 68 90 28

Mbale _____/_____/ 2009

To
Mr _____

RE: INFORMATION ABOUT ANTENATAL CARE OF YOUR SPOUSE

Your spouse has attended her first antenatal visit at Mbale Regional Referral Hospital today. The appointment date for her next antenatal visit has been scheduled. We would like to inform you about the services we provide at our clinic.

At the antenatal clinic, we carry out the following investigations: blood pressure as some women develop high blood pressure during pregnancy; urine test to check for protein and exclude infection; blood test to check if haemoglobin is low (if she has enough blood); blood test to check for syphilis (kabotongo) which can easily be treated. We also check the baby in the womb. In addition to the antenatal services, the hospital offers prevention of mother-to-child transmission of HIV (PMTCT) services free of charge. As a hospital, we have noticed that utilization of these services by the women is high and these services have many benefits to your spouse and the unborn baby.
I hope this brief information can be useful for you and your spouse.

Yours sincerely,

Dr Robert Byamugisha

Intervention letter

Dr. Robert Byamugisha
Department of Obstetrics and Gynaecology
Mbale Regional Referral Hospital
Tel: +256 772 68 90 28

Mbale _____/_____/ 2009

To
Mr _____

RE: INVITATION TO ATTEND ANTENATAL CARE WITH YOUR SPOUSE

Your spouse has attended her first antenatal visit at Mbale Regional Referral Hospital today. The appointment date for her next antenatal visit will be on day………../………/………. at ………….am.

In addition to the antenatal services, the hospital offers prevention of mother-to-child transmission of HIV (PMTCT) services free of charge. As a hospital, we have noticed that utilization of these services by the men is low and yet these services have many benefits to you and your spouse and the unborn baby. Therefore I have the pleasure to invite you to come with your spouse on next antenatal visit as per appointment date. There are important issues we want to discuss with you and your spouse concerning her antenatal care. We shall be happy to answer any questions that you might have concerning her care in this hospital. Your presence is highly appreciated and you will be given first priority to minimize the time spent on the hospital on that day.

I look forward to seeing you on that day.

Yours sincerely,

Dr Robert Byamugisha