



UNIVERSITY OF CAPE TOWN

**Prevalence and Determinants of Unplanned Pregnancy in
HIV-infected and Uninfected Pregnant Women Seeking Antenatal
Care in Cape Town, South Africa**

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Dedication

To Prof. J.F Iyun

Acknowledgements

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Abstract

Background: Prevention of unplanned pregnancy is a crucial aspect of preventing mother-to-child HIV transmission (PMTCT). However, we have little understanding of how HIV status and antiretroviral therapy (ART) may influence pregnancy planning. There are few data on pregnancy planning in HIV-infected South African women, and no comparative data with HIV-uninfected women.

Methods: We conducted a cross-sectional study of 2105 pregnant women (1512 HIV-infected; 593 HIV-uninfected) ages 18-44 making their first antenatal clinic visit at a primary-level health care facility in Gugulethu, Cape Town. All women completed structured questionnaires including the London Measure of Unplanned Pregnancy (LMUP), a 6-item scale that categorizes pregnancies into planned, ambivalent and unplanned. Analyses examined LMUP results across 4 groups of participants: HIV-infected established on ART; known HIV-infected but not currently on ART; newly diagnosed HIV-infected; and HIV-uninfected.

Results: Overall, the mean age was 29 years (SD: 5.63), 43% of women were married or cohabiting and 20% were nulliparous. The LMUP performed well across all groups (Cronbach's $\alpha=0.84$). Levels of unplanned pregnancy were higher in HIV-infected versus HIV-uninfected women (50% vs. 33%, $p<0.001$); and highest in women not on ART. Overall, 69% of women reported contraceptive use in the year before pregnancy; this was strongly associated with unplanned pregnancy ($p<0.001$). Compared to HIV-uninfected women, HIV-infected women had significantly higher odds of unplanned pregnancy, even after adjusting for age, parity and cohabiting status. The odds were greatest among women newly-diagnosed with HIV and previously diagnosed but not on ART (OR: 1.43; 95% CI: 1.05-1.94 and OR: 1.56; 95% CI: 1.13-2.15, respectively). Increased parity and age <24 years were also associated with unplanned pregnancy (OR 1.83; 95% CI: 1.24-2.74 and OR 1.42; 95% CI: 1.25-1.60 respectively).

Conclusions: These data indicate high levels of unplanned pregnancy in a high HIV prevalence setting, highlighting missed opportunities for family planning and counselling services for HIV-positive women. Possible explanations for the high level of unplanned pregnancy observed include contraceptive failure and/or misuse thereof. Therefore, women living with HIV require additional support to avoid unplanned, particularly those who are younger and have one or more children.

Keywords: Pregnancy intentions, Unplanned pregnancy, PMTCT, HIV, Women, South Africa

List of Abbreviations

AIDS	Acquired Immune Deficiency Syndrome
ANC	Antenatal Clinic
ART	Antiretroviral Therapy
CUMC-IRB	Columbia University Medical Center Institutional Review Board
DHS	Demographic and Health Survey
DMPA	Depo-Medroxyprogesterone Acetate
HIV	Human Immunodeficiency Virus
IUD	Intrauterine Device
LMIC	Low and Middle Income Country
LMUP	London Measure of Unplanned Pregnancy
MOU	Midwife Obstetrics Unit
MTCT	Mother to Child Transmission
OCP	Oral Contraceptive Pill
PMTCT	Prevention of Mother to Child Transmission
SADHS	South African Demographic Health Survey
SES	Socio-economic Status
SSA	Sub-Saharan Africa
UCT-HREC	University of Cape Town's Faculty of Health Sciences Human Research Ethics Committee
WHO	World Health Organization
WLH	Women Living with HIV

Table of Contents

Plagiarism Declaration.....	i
Acknowledgements.....	iii
Abstract.....	iv
List of Abbreviations	vi
List of Tables	ix
List of Figures.....	ix
PART A: PROTOCOL	1
1. Background.....	2
2. Objectives	5
3. Hypotheses.....	6
4. Methods	6
4.1 Study design.....	6
4.2 Sample size	7
4.3 Study setting	7
4.4 Eligibility criteria.....	8
4.5 Recruitment.....	8
4.6 Research procedure and data collection methods	9
4.7 Population and Sampling Strategy.....	9
5. Data Safety and Monitoring.....	9
6. Statistical Analysis.....	10
7. Ethical Considerations	11
7.1 Informed consent process	11
7.2 Risks	11
7.3 Benefits.....	11
7.4 Privacy and confidentiality	12
8. Logistics.....	12
References.....	13
PART B: LITERATURE REVIEW	18
1. Introduction and Background	19
2. Objectives of Literature Review	21
3. Literature Search Strategy.....	22
4. Definition of Unplanned Pregnancy	22

5.	Prevalence of Unplanned Pregnancy in South Africa.....	23
6.	Measuring Pregnancy Intentions.....	24
7.	Determinants of Unplanned Pregnancy	26
8.	Consequences of Unplanned Pregnancy among HIV Positive Women.....	29
9.	Contraceptive Use and PMTCT	30
10.	Conclusion	32
	References.....	34
	PART C: MANUSCRIPT.....	41
	Abstract.....	43
	Keywords: Pregnancy intentions, Unplanned pregnancy, PMTCT, HIV, Women	44
1.	Introduction.....	45
2.	Methods	47
2.1	Study setting and design	47
2.2	Study population.....	47
2.3	Data collection and analysis.....	48
2.4	Exposure assessment.....	48
2.5	Outcome assessment	49
2.6	Data analysis	49
2.7	Ethical considerations	50
3.	Results.....	50
3.1	Descriptive characteristics	50
3.2	Psychometric properties of the London Measure of Unplanned Pregnancy.....	53
3.3	Unplanned pregnancy	54
3.4	Use of Contraceptives.....	55
3.5	Factors associated with unplanned pregnancy	57
4.	Discussion.....	59
5.	Conclusion and Recommendation	61
	References.....	63
	PART D: APPENDICES	68
1.1	Ethics Approval Letter.....	69
1.2	Ethics approval letter of parent study (MCH-ART study).....	70
1.3	Ethics approval letter of parent study (HU2 study)	71
1.4	Informed consent form (MCH-ART study).....	72
1.5	Informed consent form (HU2 study).....	76

1.6	Baseline demographic questionnaire	80
1.7	Family planning and pregnancy intentions questionnaire.....	87
1.8	The London Measure of Unplanned Pregnancy	89
1.9	Journal submission guidelines: PLOS ONE	90
2.0	Additional results on reliability and validity of the LMUP	91

List of Tables

Table 1:	<i>Demographic characteristics of study participants stratified by HIV status and ART use</i>	<i>52</i>
Table 2:	<i>Reliability of the LMUP in comparison with the single item on pregnancy intentions</i>	<i>53</i>
Table 3:	<i>Demographic characteristics of participants stratified by LMUP pregnancy intentions.....</i>	<i>56</i>
Table 4:	<i>Multivariate logistic regression predicting unplanned pregnancy.....</i>	<i>58</i>
Table 5:	<i>Cronbach's alpha test of reliability of the London Measure of Unplanned Pregnancy</i>	<i>91</i>
Table 6:	<i>Principal component analysis testing the validity of the LMUP</i>	<i>91</i>

List of Figures

Figure 1:	<i>Distribution of pregnancy intentions stratified by HIV status and ART use</i>	<i>54</i>
Figure 2:	<i>Distribution of the LMUP scores among all participants</i>	<i>55</i>

PART A: PROTOCOL

1. Background

An unplanned pregnancy is any pregnancy that is either mistimed or unwanted while a pregnancy that occurs at the desired time or later can be considered planned (1). Globally, out of the 208 million pregnancies that occurred in 2008, 86 million were unplanned and these unplanned pregnancies were mostly due to an unmet need for family planning (2). Although there has been a steady decline worldwide in the rate of unplanned pregnancy, rates are still high in low and middle income countries (LMICs) (2).

Sub-Saharan Africa records the highest incidence of HIV as well as unplanned pregnancies and this region also records the lowest prevalence of contraceptive uptake with an estimated 25% unmet need for family planning among women of reproductive age (3,4). Approximately 20-40% of the total number of pregnancies which occur in sub-Saharan Africa is estimated to be unplanned and 20-35% of women were also estimated to have an unmet need for contraception (2,5).

Since 2003, unplanned pregnancy has been on the increase in South Africa and currently more than 50% of pregnancies which occur are unplanned (6). South Africa also has the highest prevalence of HIV worldwide which makes the occurrence of unplanned pregnancy an extremely critical issue (7). In 2012, 12.2% of the country's population was HIV positive and this was 1.2 million people more than in 2008 (7). Approximately 30% of pregnant women are HIV positive and about 70% of maternal deaths have been attributed to HIV/ AIDS in South Africa (8). Studies conducted in sub-Saharan Africa observed a high rate of unplanned pregnancy among HIV infected women (9–11).

While the concept of pregnancy intention is a complex psychosocial construct to measure, several tools have been developed based on extensive qualitative and psychometric analysis in an attempt to measure pregnancy intentions appropriately (12–14). The need to develop a better understanding of the dynamics of pregnancy intentions is increasingly recognized (15). In LMICs, current measures of the levels of unplanned pregnancy are derived from the Demographic and Health Survey (DHS). The

South African DHS assesses pregnancy intention by asking if the pregnancy for each child born in the preceding five years including the current pregnancy was planned, mistimed or unwanted (16). While questions from the DHS provides useful insights into pregnancy intentions there is a growing awareness of the need to develop a more robust means of measuring this complex construct, particularly one which allows for expression of ambivalence (13,14,17,18). In addition, retrospective assessment of intentions after pregnancy or childbirth has occurred has been criticized because the high probability of pregnancy intentions changing over the course of pregnancy and childbirth (12,18). Prospective measures which assess pregnancy intentions prior to pregnancy, although have been shown to be more valid, rarely follows individual women over time and are not always available particularly in large scale surveys. Therefore retrospective measures remains an important and most widely used approach for measuring population estimates of unplanned pregnancy (18).

The London Measure of Unplanned Pregnancy (LMUP) is an innovative tool for measuring pregnancy intentions of a recent or current pregnancy and it has the potential to be a suitable tool in understanding pregnancy intentions in a variety of settings(13,17,18). The LMUP was developed in the United Kingdom (UK) and was originally designed for self-completion (13,14). It has been formally translated and validated in the United states of America (USA), India and Malawi (19–21). The LMUP comprises of 6 questions which cover contraceptive use, timing, intention, desire for a baby, discussion with partner and preparation. Responses to each of the six questions are scored zero, one or two and scores per item are aggregated such that pregnancy intention is scored on a continuous scale from zero to twelve (13). Each increase in the score represents an increase in pregnancy planning. This tool utilizes a scale which allows for an expression of ambivalence due to the continuous nature of the scale.

In this setting, with high HIV and sexually transmitted infections (STI) prevalence, enabling HIV infected women to avoid unplanned pregnancy is a crucial aspect in preventing mother to child transmission of HIV (PMTCT) and maternal mortality associated with the infection. Unplanned

pregnancies constitute a major public health concern particularly among HIV infected women as it is associated with adverse maternal and child health outcomes which increases the risk of mother to child transmission of HIV infection (MTCT) during the antenatal and postpartum period (22–25).

Prevention of unplanned pregnancies through improving contraceptive availability and uptake among HIV positive women is an effective and cost effective approach towards PMTCT (26). This approach is part of a four-pronged strategy recommended by the World Health Organization (WHO) for prevention of vertical transmission of HIV (27). There is concern about the extent to which this approach is achievable in resource limited settings.

Furthermore, studies conducted in Africa show that very ill women living with HIV (WLH) are seven times more likely to die during childbirth (25). Also, pregnancy which occurs immediately after antiretroviral therapy (ART) initiation, before viral suppression is achieved and when CD4 counts are still low, puts women at a higher risk of death and increases the chance of MTCT (11,28,29). Therefore, proper access to and information on effective contraception is important to aid women, particularly women living with HIV, to avoid unplanned pregnancies (28,30–32). In addition to a higher risk of morbidity and mortality unplanned pregnancies have been associated with other adverse economic, physical and social effects (2,24,31,33,34).

Research suggests that HIV infected women who are uneducated, young, unmarried, have more than two living children and have a low wealth index are more likely to experience an unplanned pregnancy (28,30). Levels of unplanned pregnancy does not necessarily differ by HIV status, however a few studies observed higher rates among HIV-infected women compared to uninfected women (33).

The fertility rate has steadily declined in South Africa from an estimated total fertility rate (TFR) of 2.92 in 2001 to 2.35 in 2011 and approximately 65% of sexually active women of reproductive age in the country utilize a modern contraceptive method (22). Upon initiation of ART, women have been shown to express increased fertility desires and positive pregnancy intentions which leads to

subsequent increase in pregnancy incidence (35,36). In a study conducted by Schwartz et al. in 2012, a high rate of unplanned pregnancy was observed among HIV positive women from four ART clinics in Johannesburg, particularly in the first year after ART initiation (34). This was attributed mainly to the unmet contraceptive needs and inadequate family planning counselling for women during this period (34). Similar findings were also observed from studies in Zimbabwe, Swaziland and Malawi (33,37). There is an increasing recognition of the role of preventing unplanned pregnancies in decreasing MTCT rates. In 2012, the South African National contraception and Fertility Planning Policy and Service Delivery Guidelines redressed the neglected area of preventing unplanned pregnancies among HIV-infected women by integration of HIV testing and counselling as a part of contraceptive counselling (22).

Some studies show that the knowledge of an HIV positive status has minimal influence on pregnancy intentions and individuals who are HIV-infected have similar fertility desires when compared to HIV uninfected individuals (9,11). While another study showed that HIV-infected women were more likely to experience and unplanned pregnancy (33).

There is a need for further research on the impact of HIV status and ART use on pregnancy planning prior to conception. In particular, it would be useful to identify the characteristics of HIV-infected women who have a higher risk of experiencing an unplanned pregnancy. To effectively plan family planning interventions related to HIV care and PMTCT, there is a need for the knowledge of the baseline prevalence of unplanned pregnancy and its associated risk factors among HIV-infected and uninfected women. This study aims to address this gap.

2. Objectives

The aim of this study is to estimate the burden of unplanned pregnancy and identify associated risk factors among HIV-infected and HIV-uninfected women entering antenatal care in Gugulethu, Cape Town. Our objectives were to:

- Describe and compare the prevalence of unplanned pregnancy among known HIV-infected women established on ART, known HIV-infected women who are not on ART, newly diagnosed HIV-infected women not on ART and HIV-uninfected women.
- Identify predictors of unplanned pregnancy across all four groups of women.
- Assess the reliability and validity of the Xhosa-English translation of the London Measure of Unplanned Pregnancy.

3. Hypotheses

- HIV-uninfected women have a higher prevalence of unplanned pregnancy compared to HIV-infected women.
- HIV-infected women who are established on ART have a lower prevalence of unplanned pregnancy compared to known HIV-infected women who are not on ART.
- HIV-infected women who are younger, unmarried/not cohabiting and have low educational status have a higher likelihood of having an unplanned pregnancy.
- Women who are not aware of their HIV status (newly diagnosed) are more likely to have an unplanned pregnancy.

4. Methods

4.1 Study design

The proposed study is a cross-sectional analysis. This study will be utilizing baseline data obtained from HIV-infected and uninfected pregnant women enrolled in two prospective cohort studies conducted at a large primary care facility in Gugulethu, Cape Town: the MCHART study “Strategies to Optimize Antiretroviral Therapy services for Maternal and Child Health” (HIV-infected women) and the HU2 study “Growth, Morbidity and Development of HIV-Unexposed Infants: a Prospective

Cohort Study” (HIV-uninfected women). The MCHART study is a prospective study that consist of three phases, a cross-sectional phase (“Phase 1”), a cohort phase (“Phase 2”) and a randomised control trial phase (“Phase 3”). Meanwhile the HU2 study was conducted as a prospective cohort study with an antenatal and postnatal component. Both studies were approved by the University of Cape Town, Human Research Ethics Committee (HREC).

The main aim of the MCH-ART study was to assess different models of care for delivering treatment services to HIV positive women during the postnatal period while the HU2 study focused on a comparator cohort of unexposed and uninfected infants born to HIV negative women. Enrolment has been completed for both studies, however follow-up is ongoing.

4.2 Sample size

Data from approximately 1550 consenting HIV-infected and 612 HIV-uninfected pregnant women, seeking antenatal care at the Gugulethu Midwife Obstetric Unit (MOU) and consecutively enrolled into both parent studies will be reviewed. This large sample size was estimated for both parent studies in order to ensure precision of estimates and inclusion of heterogeneity within the study population.

4.3 Study setting

Both studies took place at the MOU of the Community Health Centre (CHC) in Gugulethu, a limited resource setting in Cape Town with a population of predominantly black Africans. This district records a high prevalence of HIV, with an estimated 30% of women presenting for antenatal care at this facility being HIV positive (8). HIV treatment services have been delivered in this setting since 2003 and PMTCT services have been offered at Gugulethu MOU since 2001. In line with the South African PMTCT guidelines, all pregnant HIV positive women are eligible to initiate ART irrespective of CD4 count. As a result there is a high uptake of ART in this setting.

4.4 Eligibility criteria

The inclusion and exclusion criteria for the cross-sectional phase of the MCH-ART study are as follows:

Inclusion criteria

- Confirmed HIV positive diagnosis using two finger-prick rapid tests or documentation of HIV status for women reporting HIV diagnosis
- Above 18 years of age
- Has not initiated antiretroviral therapy during the current pregnancy
- Ability to provide informed consent

Exclusion criteria

- Not currently pregnant
- Any condition that might affect the ability to consent or participate in the study
- Relocating out of Cape Town in the next 2 years

Similar inclusion and exclusion criteria applied to the HU2 study with the exception that women had to be confirmed HIV negative to be eligible for the HU2 study.

4.5 Recruitment

Potential participants were identified at the MOU, Gugulethu Community Health Centre, Cape Town. Pregnant women attending their first antenatal visit were approached by the MOU staff and briefed about the ongoing study. Interested persons were screened using inclusion and exclusion criteria for the studies as listed above and potential participants were introduced to the study staff at the clinic. An informed consent form was administered by trained study interviewers in the local language to women who were eligible to participate in the study. Recruitment was conducted between March 2013-June 2014 and Nov 2014-August 2015 for the MCH-ART and HU2 study respectively.

4.6 Research procedure and data collection methods

All consenting women were recruited into both studies (MCH-ART and HU2) at their first antenatal visit. A standardized interviewer-administered questionnaire delivered in the local language was used to collect information including demographics, medical history, HIV testing status, socioeconomic status, family planning, pregnancy intentions HIV disclosure status and previous antiretroviral exposure (Appendices 1.6 and 1.8). The London Measure of Unplanned Pregnancy a standardized 6-item tool was utilized to obtain information on pregnancy intentions (see Appendix 1.7). All tools were translated into the local language (Xhosa) by trained field workers who were native Xhosa speakers. The translations were reviewed and approved versions were back translated to English by an English speaker who spoke Xhosa as a second language. This study measurement visit had an approximate duration of 40 minutes.

4.7 Population and Sampling Strategy

Data from all HIV-infected and uninfected women enrolled in the cross-sectional phase of MCHART study (n=1550) and antenatal phase of the HU2 study (n=600) will be included in the study. However participants who do not have a complete response for the London Measure of Unplanned Pregnancy case report form will be excluded from the analysis.

5. Data Safety and Monitoring

Data capturing and management took place at the study site located in Gugulethu based on the MCH-ART and HU2 study protocol. Information was collected on structured paper questionnaires which was then captured by trained data capturers into a custom designed Microsoft Access Database that is password protected and maintained in a firewall protected UCT server. The database was developed and maintained by a data manager who managed data quality control activities. Quality control was done through data inspection to identify out of range values, missing observations and logic violations.

Data quality verification was in the form of robust database structure and platform, in addition to data checks to real time database query generation.

All study records and data to be used for this analysis will contain anonymous participant identification numbers that uniquely identified participants. Databases and datasets will be password protected and no names or identifying information will be used.

6. Statistical Analysis

Data will be exported to STATA Version 12.0 (Stata Corporation, College Station, Texas) for cleaning, management and analysis.

Baseline characteristics of the study population will be summarized using medians and inter-quartile ranges for continuous variables and proportions and frequencies for categorical variables. Bivariate analysis using contingency tables will be conducted to describe and compare the study population

The primary outcome of interest for this analysis is unplanned pregnancy. Levels of unplanned pregnancy will be calculated using a standardized tool; the London Measure of Unplanned Pregnancy (LMUP). This is a 6-item tool that includes questions on contraception, timing and partner involvement. Scores of 0-2 will be assigned to each response scores based on the recommended method (38) and an aggregate score from 0-12 in order of increasing level of intention will be calculated for each participant. These scores will be used to describe the proportion of unplanned pregnancies in the study population. Based on these scores, pregnancy intentions will be grouped into the following categories; unplanned (0-3), ambivalent (4-9) and planned (10-12). However for the purpose of the logistic regression models these scores will be dichotomized into unplanned (0-9) and planned (10-12). An additional analysis of interest will be carried out to compare the levels of unplanned pregnancy across four categories of participants: known HIV positive women established on ART, known HIV positive women not on ART, newly diagnosed HIV positive women not on ART and HIV negative women.

Univariate logistic regression models will be fitted to determine the unadjusted odds ratios with 95% confidence intervals for predictors of unplanned pregnancy. Variables considered to be correlated to the time of pregnancy will be included in the modelling. Variable with $P < 0.20$ in the univariate analyses will be considered as candidates for the multivariable logistic regression model. A multivariable logistic regression model will be fitted to predict unplanned pregnancy in the study population. Test for co variability will be conducted for the final model. A $P = 0.05$ significance level will be set.

A Cronbach's α test will be conducted to examine the internal consistency of the Xhosa translation of the LMUP using a cut-off point of 0.7 as the limit for acceptable reliability. Also, principal component analysis test will be carried out to assess the validity to the Xhosa-LMUP. The scale will be considered valid if all items loaded onto one component with an Eigen value larger than one.

7. Ethical Considerations

7.1 Informed consent process

Although this study will not be dealing directly with participants, the parent studies obtained informed consent before enrolment by the use of an Informed consent form delivered in participants' home language (isiXhosa). Participation was entirely voluntary and women could exit the study at any time.

7.2 Risks

This study is a secondary analysis of existing datasets which protects the identity of participants by the use of participant identifying numbers, as such poses no potential risks to the study participants.

7.3 Benefits

Findings from this study have the potential to inform and improve an efficient HIV treatment cascade that effectively integrates reproductive and HIV services for women living with HIV. This may well lead to a decrease in the rates of MTCT and horizontal transmission of HIV, in addition to preventing

other adverse physiological, economic and psychological effects associated with unplanned pregnancies among all women.

7.4 Privacy and confidentiality

All data to be analyzed and case report forms contain only participant identification numbers which are securely kept and password-protected where necessary hence there is assurance that the participants' privacy will be maintained.

8. Logistics

This is a secondary analysis of existing data from MCH-ART and HU2 studies which have received approval from CUMC-IRB and UCT-HREC. The student will conduct an analysis on the existing data as a result no further cost or payment will be required during the course of this analysis.

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PART B: LITERATURE REVIEW

1. Introduction and Background

In South Africa an estimated 6.4 million people were living with HIV in 2012 (1). The consistently high incidence and prevalence among women constitutes a major public health concern (2). Women have a 3-4 times greater risk of acquiring HIV infection than men (1). The national HIV prevalence is estimated at 30% among pregnant women booking for antenatal care and 18.2% in the general population in the Western Cape province (3). Although the rate of mother-to-child transmission of HIV (MTCT) has recently declined, this mode of transmission still accounts for 90% of new paediatric HIV infections in sub-Saharan Africa (4).

Mother to child transmission occurs during pregnancy, delivery and through breastfeeding (5). The risk of MTCT of HIV in South Africa remains high and having an unplanned pregnancy is known to increase this risk (4). As part of a global effort towards HIV prevention through the elimination of MTCT, the World Health Organization (WHO) has recommended a comprehensive four-pronged strategy for effective prevention of mother-to-child transmission of HIV (PMTCT). Amongst these strategies include prevention of unplanned pregnancy among HIV-infected women (6).

An unplanned pregnancy is any pregnancy that is either mistimed or unwanted at the time of conception (7). These pregnancies could result in births, induced abortions and miscarriages. They are also associated with adverse maternal and child health outcomes particularly in low and middle income countries (LMIC) (8).

A study suggested that pregnancies which are unwanted are associated with poor birth outcomes including premature rupture of membranes and preterm delivery (8). This same study found that women who had ambivalent pregnancy intentions were more likely to deliver a low birth weight baby (8). Women with unplanned pregnancies are more likely to present late for antenatal care and to use tobacco and alcohol during pregnancy compared to women whose pregnancies were planned (9). This has implications for PMTCT taking into account that a fairly high proportion of women only find out

their HIV positive status at first antenatal booking which could result in a delay in starting antiretroviral therapy (ART) and possible poor adherence (10).

Existing evidence suggests that younger age, higher parity, low socioeconomic status, the use of antiretroviral therapy (ART) and low level of education is associated with a high risk of unplanned pregnancies (11–14). While another study has shown that women in a marital or cohabiting relationship have lower risks of an unplanned pregnancy (15).

In sub-Saharan Africa, 14 million unplanned pregnancies were estimated to occur annually (16). A high discontinuation rate, inconsistent use and incorrect use of short term hormonal contraceptives are known contributors to the burden of unplanned pregnancy (16). Improving access to and the accurate use of modern contraceptive methods has been shown to be a useful and cost effective approach to reduce unplanned pregnancies, and hence MTCT (17). Although contraceptive uptake in South Africa is particularly high (65%) relative to other sub-Saharan countries however, levels of unplanned pregnancy remain undesirable (18). Findings from a study conducted in South Africa among non-pregnant HIV-infected women on ART revealed that 65% experienced an unplanned pregnancy.

The high proportion of unplanned pregnancy among HIV-infected women has been linked to an increase in fertility desire particularly after ART initiation. Younger age, knowledge of PMTCT and ART use has been associated with pregnancy desire. However, it is unclear how the use of ART may modify pregnancy intentions. A meta-analysis carried out in 2013 found that a significant proportion of HIV-infected individuals desire to have more children in the future and this increased fertility desire was not associated with ART use (19). Swartz et al. found that the cumulative incidence of pregnancy was not different between recent ART initiators compared to ART experienced women (14). Meanwhile, other studies have linked this desire to a feeling of increased wellbeing and improved health from being on ART (20,21). The effect of societal and cultural norms and partner influence has

also been highlighted as a key explanation for the high fertility intentions observed among HIV-infected individuals (20).

Furthermore, In 2007 Myer et al. found that majority of HIV-infected men and women on ART in the study population reported a desire to have children in the future (15). In addition, fertility intentions may increase after ART initiation. It has been suggested that HIV-infected individuals do not differ from uninfected individuals in the likelihood of having future pregnancies (20). Initiating antiretroviral therapy (ART) is associated with increased pregnancy rates and a high proportion of these pregnancies have been shown to be unplanned (14,21). Research further suggests that women who are unaware of their HIV status before conception are more likely to experience an unplanned pregnancy (10).

There is inconsistent evidence to show that HIV-infected women experience higher levels of unplanned pregnancies compared to HIV-uninfected women (10,22,23). In this era of extensive ART availability in South Africa, and evidence of high level of unplanned pregnancy among women on ART, very little is known about how ART use influences pregnancy intentions. The complexity of pregnancy intentions and lack of consistent evidence, leave room to explore the different factors that influence unplanned pregnancy in all women, particularly those living with HIV.

2. Objectives of Literature Review

The aim of this literature review was to examine the prevalence of unplanned pregnancy worldwide and in South Africa with a focus on HIV-infected women. This review also aims to identify current issues related to pregnancy intentions, with special attention to studies that speak to the influence of ART use and the knowledge of HIV status on pregnancy planning. It will serve to highlight the determinants of unplanned pregnancy and reliability of current measures of pregnancy intentions. This is to better inform the primary purpose of this dissertation: To describe the prevalence and determinants of unplanned pregnancy in HIV-infected and uninfected pregnant women seeking antenatal care in Cape Town, South Africa.

3. Literature Search Strategy

A literature search was conducted through Google Scholar and Pubmed for peer-reviewed articles, systematic reviews, government policy handbooks and national guidelines published up until January 2016. Search terms used in combination and alone were “unplanned pregnancy”, “unintended pregnancy”, “pregnancy intentions,” “fertility intentions,” “HIV positive women”, “women”, “contraceptives” “South Africa”, “Africa”, “prevention of mother-to child transmission” and “PMTCT”. Studies conducted in South Africa as well as international studies were included. Relevant literature from reference lists of articles examined was also incorporated.

4. Definition of Unplanned Pregnancy

Santelli et al. describes an unplanned pregnancy as any pregnancy that occurs when a woman did not intend to become pregnant. A woman could either have been using a contraceptive method or not when this pregnancy occurred (7). The South African Department of Health defines an unplanned pregnancy as a pregnancy that was not desired at the time it occurred. A pregnancy that happens later than desired or not desired at all is termed a mistimed and unwanted pregnancy respectively (18).

Another terminology commonly used to refer to an unplanned pregnancy in the literature is unintended pregnancy. An unintended is described as a pregnancy that is mistimed or unwanted (7). However, these concepts are not normally applied exclusively in practice. Also, distinctions between these terminologies are not always clearly accounted for in the majority of measures used (24). Questions from most measures of pregnancy intentions do not incorporate the word “unintended” and the degree of mistiming is not adequately reported (7). For the purpose of this literature review, unplanned pregnancy will be used interchangeably with pregnancies listed as unintended, mistimed and unwanted in the literature.

5. Prevalence of Unplanned Pregnancy in South Africa

Globally, 40% of all pregnancies were unplanned in 2012 (25). It is important to note that even though the rates of unplanned pregnancy has declined in Africa from 92 to 80 per 1000 women in 2012, Africa still maintains the highest regional rate (25,26). Southern Africa records an unacceptably high unplanned pregnancy proportion of 55% (25).

In South Africa, 47% of all pregnancies that occurred between 1998 and 2003 were unplanned (18). However, the prevalence has more recently been shown to be as high as 61% (27). Similarly high levels of unplanned pregnancy were highlighted in findings from international studies conducted in Canada, India and the United States of America (28–30).

Unplanned pregnancy among HIV-infected women in South Africa

Evidence from several studies within sub-Saharan Africa reveal that a significant portion of pregnancies among HIV-infected women are unplanned and these pregnancies account for over half of pregnancies that occur in this population (14,23,26,31,32).

Research investigating unplanned pregnancy among HIV-infected women in South Africa appears limited. In a cross sectional survey of HIV-infected women on ART in Cape Town, 62% of participants reported that their most recent pregnancy was unplanned (14).

It has been suggested that HIV infected women have higher rates of unplanned pregnancies compared to HIV uninfected women (33). However, evidence on this remains largely inconsistent. A study found that more than half of all women reported their most recent pregnancy as unplanned and this did not differ by HIV status (22). Supporting this, a study examining associations between pregnancy intentions and HIV status among Nigerian and Zambian women in 2014, found that HIV-infected and uninfected women did not differ in their odds of having an unplanned pregnancy (26). In contrast, McCoy et al. in 2014 found that HIV-infected women reported a higher frequency of unplanned pregnancy relative to HIV-uninfected women.

6. Measuring Pregnancy Intentions

Pregnancy intention is a nuanced psychosocial construct and is usually an emotional event in a woman's reproductive life. Most conventional measures of unintended pregnancy are designed to reveal a woman's intention prior to conception (34). Though the interest in pregnancy intentions can be traced back to the initial population surveys of fertility in 1941, systematic questions which measure this concept were only recently developed (7,35). Questions about pregnancy intentions that differentiated between mistimed and unwanted pregnancy were first developed for the National Survey of Family and Growth (NSFG) in the United States of America (USA) and this was piloted in 1973. They comprised of a series of questions which operationalise unintended pregnancy as the sum of unwanted and mistimed pregnancies. On the other hand pregnancy intention has also been measured by a single question as utilized by the Centre for infectious disease control (CDC) Pregnancy Risk Monitoring Assessment System (PRAMS). The question asked by PRAMS mainly refers to the woman's emotional state of mind when she became aware of her pregnancy with particular focus on timing and desire (7).

The Demographic and Health Survey (DHS) which is conducted largely in developing countries including South Africa, also asks a single question; "Did you want to become pregnant then, later, or did you want no (more) children at all?". Most epidemiological studies and surveys assessing unplanned pregnancy in South Africa are derived from questions in the DHS. The DHS pregnancy intention question categorizes intentions as either intended (wanted a child at the time of conception) or unintended (wanted a child later or did not want a child at all) depending on a woman's desire at the time she realized she had conceived (14,22). However, over the past two decades there has been increasing critique of the concept of pregnancy intention and its measurements (24,36). This includes a growing recognition of the limitation of these DHS-style questions and the need to develop more complex method for measuring unintended pregnancy (37).

One of the major issues identified in the measurement of unplanned pregnancy across different studies and surveys is that most of them measure pregnancy intentions retrospectively using a cross-sectional or survey designed approach (18,22,26). Reporting intentions after delivery has been shown to be more likely positive due to the presence of a baby (38). Women may report changing intentions from unplanned to planned after a birth has occurred (38). Another limitation of existing measures is the heterogeneity within the category of unintended pregnancy. The distinctions between an unwanted pregnancy and a mistimed one are not often clearly made (39). Furthermore, an assumption that not intending to fall pregnant is associated with a change in behaviour such as use of contraceptives is another limitation of most measures in use (37).

In addition, research has revealed a high level of ambivalence as regards pregnancy intentions among women which cannot be fully captured using questions derived from the DHS. This ambivalence has been attributed to the complex nature of a woman's pregnancy intentions (38). More recently, an improved measure of pregnancy intentions, the London Measure of Unplanned Pregnancy was developed to better capture the nuanced picture of pregnancy intentions (37).

The London Measure of Unplanned Pregnancy

The London Measure of Unplanned Pregnancy (LMUP) is a more recent psychometric tool developed in 2004 by means of a series of qualitative research investigating women's feelings around pregnancy intentions (37). The LMUP is a 6-item tool that has been used in several studies to measure pregnancy intentions (40–42). A main distinguishing feature of this tool is that it accounts for ambivalence and measures pregnancy intentions by use of a continuous scale rather than defined categories. The LMUP was developed in English, however it has been adapted for use by a study conducted in Malawi after being translated into the local language (43). This is the only study that has tested the reliability of the LMUP in Africa. Other studies validation of the LMUP conducted outside Africa also showed that the LMUP was an improvement over existing measures and that it accurately measured pregnancy intentions (40,41). However, one study found that removing the first item on contraceptive use slightly

improved the performance of the tool (43). The LMUP therefore represents an improvement over other measures of pregnancy intention.

7. Determinants of Unplanned Pregnancy

A number of socio-demographic factors come into play with regards to unplanned pregnancy among HIV-infected and uninfected women. This literature review focuses on factors highlighted in our hypothesis including factors such as age, parity, contraceptive use, HIV status and ART use. This section will examine what recent literature has shown about these predictors.

Age

Research shows that age has been consistently shown to be a significant determinant of unplanned pregnancy. Unplanned pregnancies can occur among women of different ages but it has been somewhat linked with extremes of reproductive age. Younger women aged 15-19 years have been shown to be at greatest risk of having an unplanned pregnancy (12,13). This has been linked to a lack of empowerment for young women to negotiate contraceptive use with male partners and an increased level of sexual activities and risky sexual behaviour in this group (44). In addition, strong fertility desires have been reported in the younger age group (<30 years) among HIV-infected women (19).

Younger women having highest rates of unplanned pregnancy has huge implications for HIV prevention efforts since this indicates that these groups of women, who have the highest HIV prevalence rate in South Africa, engage in unprotected sex. Repeated unplanned pregnancy is common among adolescents and this has been associated with inconsistent contraceptive use (45). A study looking at risk factors for unplanned pregnancy among women in Zambia and Nigeria revealed that older women have a significantly reduced risk of an unplanned pregnancy (26). In contrast Loufty et al. found no association between age and experiencing an unplanned pregnancy (28).

Parity

Unplanned pregnancy has been shown to be common among women who are nulliparous and those with high parity (28,46). Research has revealed that HIV-infected women with two or more living children are more likely to have an unplanned pregnancy (29,47). In a similar vein Mantell et al. found that having greater numbers of biological children was associated with lower odds of intending pregnancy (48). It could therefore be inferred that future pregnancies occurring among women with two or more living children will be more likely be unplanned than first or second pregnancies.

Socioeconomic status

Socioeconomic status has been shown to be an important risk factor for unplanned pregnancy. In particular, lower socioeconomic status may increase the risk of unplanned pregnancy (10). This has also been linked to having fewer years of education.

Education is also an important factor highlighted in studies assessing pregnancy intentions. There is mixed evidence on the influence of educational level on the risk of an unplanned pregnancy. Research shows that individuals with more years of education have lower odds of intending pregnancy (48). Women with more years of education are less likely to want to fall pregnant intentionally (48). In contrast, a study analysing data from Kenya and Swaziland found that having a tertiary education was associated with having a lower likelihood of an unwanted or mistimed pregnancy (23).

Contraceptive use

Inconsistent use of contraceptives has been associated with an increased risk of experiencing an unplanned pregnancy (16). Among HIV infected women using contraceptives, method failure has been reported as an important factor related to unplanned pregnancies (49). This failure could be as a result of poor adherence and improper use of contraceptive method (16).

Partner involvement

Reports from epidemiological studies in sub-Saharan Africa have consistently shown that women who are unmarried or not cohabiting with their partners have a greater likelihood of experiencing an unplanned pregnancy (12). A study conducted in Canada found that among HIV positive women, never been married was significantly associated with unplanned pregnancy (28). Among HIV-infected women in particular, those who disclosed their status to their partners and discussed contraceptives were significantly more likely to have a planned pregnancy (47). Intimate partner contribution to reproductive decision making has positive effects on pregnancy intentions (48). Evidence further suggests that pregnancies which occurred within marital unions were less likely to be unplanned compared to those that occurred outside marital union (45). Women who had not disclosed their HIV status or discuss reproductive intentions with their partners were shown to be less likely to use any modern family planning methods increasing their risk of experiencing an unplanned pregnancy (50). Akelo et al. recommends integration of couple services into HIV care services considering that partner or spousal support may be a key determinant of contraceptive use (31).

HIV status and ART use

Currently, there remains limited data on the influence of serostatus on pregnancy intentions and available evidence is inconsistent. In a study conducted in Zimbabwe, women who were aware of their HIV status prior to the survey were more likely to report an unintended pregnancy (33). While Mayondi et al. found that women who were newly diagnosed were more likely to experience an unplanned pregnancy (10). Although research has shown that HIV-infected women have high rates of unplanned pregnancy, some studies suggest that the frequency does not differ from rates of unplanned pregnancy observed among HIV-uninfected women. Bankole et al. found that HIV-infected compared to uninfected women had similar odds of having an unplanned pregnancy (26). Similar findings were observed in several studies conducted in sub-Saharan Africa (10,22,23). In contrast, a study showed

that unplanned pregnancy was significantly higher in HIV-infected women than HIV-uninfected women (33).

In a Canadian study investigating unintended pregnancy in HIV-infected women of reproductive age, Loufty et al. found that there was a high rate of unplanned pregnancy among a cohort of HI- infected women, with 56% of women reporting their most recent pregnancy was unplanned (28). However, another study found that women living with HIV were more likely to report their pregnancy as unplanned compared to HIV-uninfected women (33).

With the rapid scale-up of PMTCT programmes and adoption of Option B+ guidelines, increasing number of women are being initiated onto lifelong ART. There is limited evidence on the association between ART use and pregnancy intentions. Nevertheless, some studies show that initiation of ART is strongly associated with high rates of unplanned pregnancy (14,21). In addition, research conducted in Rwanda and South Africa showed that HIV-infected women, particularly those recently initiating ART compared to ART experienced women, had higher rates of unplanned pregnancy (14,32). Conversely, in a study conducted in South Africa by Schwartz et al. in 2012, unplanned pregnancy was as high as 62% among women on ART with no difference between women who were ART experienced and those who had recently initiated ART (14).

As noted by studies conducted in South Africa, the availability of ART and knowledge of PMTCT has also positively affected childbearing desires (20,21). A 2010 study of HIV-infected women on ART in Cape Town, found that a significant proportion of women had positive fertility intentions and this was significantly associated with duration on ART (21).

8. Consequences of Unplanned Pregnancy among HIV Positive Women

An unplanned pregnancy could lead to a range of adverse maternal and child outcomes among both HIV-infected and uninfected women alike. Evidence is mixed regarding the association between

pregnancy intentions and poor birth outcomes. However, some studies highlighted an association between unwanted pregnancy and preterm delivery, low birth weight and early rupture of membranes (8,51). Meanwhile, a Kenyan study found that unplanned pregnancy was not significantly associated with adverse birth outcomes (45). On the other hand, research has shown that unplanned pregnancy predisposes women other adverse psychosocial outcomes such as pre and postpartum depression, physical abuse and risky prenatal behaviours such as late pregnancy detection and subsequent late antenatal booking (45,51). These risky prenatal behaviours may predispose HIV-infected women to late ART initiation during pregnancy thereby increasing the risk of MTCT. Women with unintended pregnancies are less likely to seek antenatal care (8). This is particularly crucial to PMTCT as women who present late may not receive proper support and information regarding safety measures during pregnancy.

Furthermore, unplanned pregnancy imposes significant financial and social burden on the society, reducing quality of life and workforce effectiveness (52). Lowering the levels of unplanned pregnancy is demonstrated to improve socio-economic growth and development of a society (52). Preventing unplanned pregnancies among HIV-infected women has been shown to be the most cost effective method of preventing mother to child HIV transmission (53).

9. Contraceptive Use and PMTCT

In 2008, a study conducted by Reynolds et al. revealed that compared to other PMTCT strategies, contraceptive approach prevents 28.6% more infants from perinatal transmission of HIV (17). Studies have shown a high unmet need for contraceptives in sub-Saharan Africa (53). Research reveals that short acting contraceptive methods such as condoms, oral contraceptive pills (OCPs), and depo-medroxyprogesterone acetate (DMPA) injectables are utilized in sub-Saharan Africa. Uptake of longer acting methods such as the intrauterine device (IUD) and sterilization is generally low in this region (16).

The DHS revealed that 65% of women in South Africa use at least one modern form of contraception (18). A high contraceptive uptake of 89% was observed among HIV-infected with similar high proportions observed in uninfected women in Cape Town (22). Among HIV-infected women in South Africa, the most commonly used form of contraceptive is the 3-monthly injectable hormonal contraceptive. Use of male condoms and oral contraceptive pills is also prevalent (44).

There are a host of socio-demographic factors that influence contraceptive use among women in South Africa. Some of these include socioeconomic status, partner and family expectations, education levels, place of residence (urban or rural), knowledge of contraceptive methods, access and access to contraceptive services (44).

In South Africa, Schwartz et al. found that the unmet need for contraceptives among HIV-infected women was 50% higher among those who recently initiated ART compared to those on ART for more than one year. Short acting hormonal contraceptive use was prevalent and this was attributed to recommendations by health workers and convenience (14).

Awareness of a HIV positive status has been associated with a higher uptake of contraceptives (54). In 2015, a survey conducted in Malawi among women aged 15-49, shows that women who were aware of their HIV status were more likely to use family planning options (54). Supporting this, a Ugandan cross-sectional study among HIV-infected women showed that 68% of women reported using a modern contraceptive method (50). A similar finding was also observed Kenyan survey of women aged 15-49 (49).

The importance of the role that family planning plays in prevention of HIV is widely recognized. Over 120,000 unintended births can be prevented annually by use of contraceptives (55). South Africa boasts of a successful PMTCT programme roll-out. However, the main focus of most of these programmes is treatment using ART with minor attention paid to the reproductive healthcare needs of women living with HIV. In 2013, the National Contraception and Fertility Planning and Service

Delivery Guidelines were revised and special attention was paid to improving the integration of family planning and HIV care in line with the global PMTCT target (44). Currently, most HIV-infected women in South Africa have access to free fertility planning services within the public sector; however it is hypothesized that these women are limited to methods available or only those recommended by the health care workers (44).

Despite the well documented knowledge of contraception and high utilization of modern contraceptives methods among HIV-infected women, levels of unplanned pregnancy still remain high. This highlights a major gap in PMTCT through suboptimal delivery of reproductive health care services for HIV-infected women. An apparent lack of engagement of health care workers on issues relating to pregnancy intentions, contraception and general reproductive wellness is highlighted as an important factor (56). These point to a need to improve awareness and training of health workers involved with PMTCT.

10. Conclusion

Literature relating to pregnancy intentions in the context of the HIV epidemic was reviewed. Prevalence of unplanned pregnancy among HIV-infected women is high despite a high contraceptive uptake documented in this group. Women on ART have high future fertility intentions and rates and high levels of unplanned pregnancy.

There is evidence that HIV-infected women may be making more efforts at preventing unplanned pregnancy but appear to be unsuccessful in doing so. There is a high rate of contraceptive failure observed among both HIV-infected and uninfected women which is worrying. Evidence suggests that unplanned pregnancy indirectly increases the risk of MTCT through adverse maternal and child health outcomes among HIV-infected and uninfected women alike. There appears to be a gap between unplanned pregnancy and the use of modern contraceptive. Women who do not want future

pregnancies are not necessarily using contraceptives and those who use contraceptives may be doing so inaccurately. This is also important with regards to prevention of horizontal transmission among discordant couples through the use of condoms.

Several factors that contribute to the risk of experiencing an unplanned pregnancy have been identified but they remain largely inconsistent. There has been one study in South Africa comparing unplanned pregnancy by HIV status and this study found no difference in levels of unplanned pregnancy experienced by HIV-infected and uninfected women. And as identified in other literature, there were limited insights to how ART use or knowledge of HIV status may have modified pregnancy intentions.

In light of the evidence presented, this dissertation addresses the knowledge gap by focusing on pregnancy intentions among HIV-infected and uninfected women in a LMIC with particular examination of the influence of ART use and knowledge of HIV status on pregnancy intentions. This analysis looks at a variety of socio-demographic factors in studies conducted in other populations in order to explore their association with unplanned pregnancy in this population. This study will hopefully inform further research which will aim to explore causal relationships of pregnancy intentions and a range of correlates including ART use, HIV status, adverse birth outcomes and undesirable maternal behaviour. Findings will hopefully serve to inform innovative interventions for meeting the sexual and reproductive health needs of HIV-infected women in particular.

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PART C: MANUSCRIPT

PREVALENCE AND DETERMINANTS OF UNPLANNED PREGNANCY IN HIV-INFECTED AND UNINFECTED PREGNANT WOMEN SEEKING ANTENATAL CARE IN CAPE TOWN, SOUTH AFRICA

Short title: Pregnancy intentions of HIV-infected and uninfected women in South Africa

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Abstract

Background: Prevention of unplanned pregnancy is a crucial aspect of preventing mother-to-child HIV transmission (PMTCT). However, we have little understanding of how HIV status and antiretroviral therapy (ART) may influence pregnancy planning. There are few data on pregnancy planning in HIV-infected South African women, and no comparative data with HIV-uninfected women.

Methods: We conducted a cross-sectional study of 2105 pregnant women (1512 HIV-infected; 593 HIV-uninfected) ages 18-44 making their first antenatal clinic visit at a primary-level health care facility in Gugulethu, Cape Town. All women completed structured questionnaires including the London Measure of Unplanned Pregnancy (LMUP), a 6-item scale that categorizes pregnancies into planned, ambivalent and unplanned. Analyses examined LMUP scores across 4 groups of participants: HIV-infected established on ART; known HIV-infected but not currently on ART; newly diagnosed HIV-infected; and HIV-uninfected.

Results: Overall, the mean age was 29 years (SD: 5.63), 43% of women were married or cohabiting and 20% were nulliparous. The LMUP performed well across all groups (Cronbach's $\alpha=0.84$). Levels of unplanned pregnancy were higher in HIV-infected versus HIV-uninfected women (50% vs. 33%, $p<0.001$); and highest in women not on ART. Overall, 69% of women reported contraceptive use in the year before pregnancy; this was strongly associated with unplanned pregnancy ($p<0.001$). Compared to HIV-uninfected women, HIV-infected women had significantly higher odds of unplanned pregnancy, even after adjusting for age, parity and cohabiting status. The odds were greatest among women newly-diagnosed with HIV and previously diagnosed but not on ART (OR: 1.43; 95% CI: 1.05-1.94 and OR: 1.56; 95% CI: 1.13-2.15, respectively). Increased parity and age <24 years were also associated with unplanned pregnancy (OR 1.83; 95% CI: 1.24-2.74 and OR 1.42; 95% CI: 1.25-1.60 respectively).

Conclusions: These data indicate high levels of unplanned pregnancy in a high HIV prevalence setting, highlighting missed opportunities for family planning and counselling services for HIV-positive women. Possible explanations for the high level of unplanned pregnancy observed include contraceptive failure and/or misuse thereof. Therefore, women living with HIV require additional support to avoid unplanned pregnancy, particularly those who are younger and have one or more children.

Keywords: Pregnancy intentions, Unplanned pregnancy, PMTCT, HIV, Women

1. Introduction

South Africa has the highest number of HIV-infected individuals living with HIV worldwide and women are disproportionately affected (1). Women have a far higher prevalence of compared to men (14.4% compared to 9.9%) and this prevalence goes up to 18.8% among females aged 15-49 (1). Almost 30% of women seeking antenatal care in South Africa are HIV-infected (2). In the Western Cape province, infant HIV exposure was 22% in 2012 (3).

With the roll out of Option B+ guidelines within PMTCT services, significant advancements have been made in the prevention of vertical transmission of HIV in South Africa (3). However, mother-to-child transmission of HIV (MTCT) remains a major driving force of the HIV epidemic in South Africa. MTCT can occur during pregnancy, delivery and through breastfeeding (4).

Globally, increased efforts to further reduce mother-to-child transmission are ongoing and research has highlighted the significance of unplanned pregnancy among HIV-infected women on the risk of MTCT. In addition, reduction of unplanned pregnancies among women living with HIV is one of the four-pronged strategies recommended by the WHO towards eliminating mother-to-child transmission of HIV infection (5).

The timing and intention of a pregnancy are important indirect risk factors for transmission of HIV from mother to child (6,7). Unplanned pregnancies strongly predict maternal behaviour during pregnancy and in the postpartum period (7–9). Women with unplanned pregnancy may be less likely to initiate antenatal care during the first trimester, breastfeed for more than 8 weeks or adhere to the recommended preparations and medication during pregnancy (7–10). Increased risk of an unplanned pregnancy has been associated with younger age and increased number of biological children (11–14).

Unplanned pregnancies frequently arise from non-use or misuse of contraceptives and contraceptive failure. Prevention of unplanned pregnancy among HIV-infected women through the use of contraceptives is known to be a highly effective and cost effective approach to PMTCT and may be

more cost effective than ART use among HIV-infected women. Compared to other countries in sub-Saharan Africa (SSA), South Africa records a particularly high contraceptive uptake of 65% among women of reproductive age (15).

Results of a meta-analysis conducted in 2013 revealed that a considerable number of HIV-infected individuals have desire for fertility and this was not associated with ART use. However, some studies found that women who initiated ART were more likely to experience an unplanned pregnancy(14,16,17). Thus integrating HIV care and reproductive healthcare is important to help inform reproductive decision making in this group (18).

In spite of the importance of planning pregnancies among HIV-infected women, many remain unplanned. Unplanned pregnancy accounts for 55-65% of pregnancies which occur among HIV-infected women globally (17,19,20). South Africa has the second highest proportion of unplanned pregnancy in Southern Africa, with rates as high as 61% (21). In Rwanda, two thirds of HIV positive women who were aware of their HIV status and on antiretroviral therapy (ART) had an unplanned pregnancy (14). Women who were not aware of their HIV status prior to conception are also more likely to have an unplanned pregnancy (22).

Evidence relating to the association between HIV status, ART use and unplanned pregnancy appears inconsistent. McCoy et al. found that HIV-infected women had higher levels of unplanned pregnancies compared to uninfected women (23). While a few other studies found no association between unplanned pregnancy and HIV status (13,22,24). Keeping the focus on PMTCT through prevention of unplanned pregnancy among HIV positive women is an important component in fighting the HIV epidemic (25).

This study, using a large sample and a HIV-uninfected comparator group, examined the prevalence and determinants of unplanned pregnancy among HIV-infected women. In particular, we aimed to assess the influence of HIV status and ART use on pregnancy intentions. Specifically, the objectives

were to (a): determine proportions of unplanned pregnancy across the following four categories of women: known HIV-infected but not on ART, known HIV-infected established on ART, newly diagnosed HIV-infected and HIV-uninfected; (b): explore the demographic and socio-economic determinants of unplanned pregnancy among all women; and (c) assess the reliability and validity of the Xhosa translation of the London Measure of Unplanned Pregnancy as a tool for assessing pregnancy intentions in a resource-limited setting.

2. Methods

2.1 Study setting and design

This cross-sectional analysis utilized baseline data obtained from two large prospective studies: the “MCHART study”: Strategies to optimize antiretroviral therapy services for maternal and child health (HIV infected women) and the “HU2 study”: Growth, morbidity and development of HIV unexposed infants: a Prospective Cohort Study (HIV-uninfected women). Participants were recruited into both studies from the Midwife and Obstetrics unit (MOU) in Gugulethu, Cape Town in South Africa. Enrollment was conducted between March 2013-June 2014 and Nov 2014-August 2015 for the MCHART and HU2 study respectively.

This district records a high prevalence of HIV; approximately 33% of women attending the antenatal unit of the clinic are HIV positive. HIV treatment services have been delivered in this setting since 2003 and PMTCT services offered at Gugulethu MOU since 2001.

2.2 Study population

HIV-infected and uninfected pregnant women aged >18years booking for their first antenatal clinic (ANC) visit were consecutively enrolled into the MCHART and HU2 studies respectively. Trained study staff identified and approached women presenting for their first antenatal visit in this facility for possible participation in the study. Eligible participants were enrolled on same day as first booking for antenatal care at the Gugulethu MOU.

2.3 Data collection and analysis

All women completed a structured interviewer-administered questionnaire. The interviews were conducted in the local language (isiXhosa) and information was captured into a custom designed Microsoft Access database. Information collected included basic socio-demographic characteristics, medical history, pregnancy intentions, family planning history. Same data collection tools were utilized by both the MCH-ART and HU2 studies (See Appendix 1.6 - 1.8).

Pregnancy intentions were assessed using a validated 6-item questionnaire, the London Measure of Unplanned pregnancy (LMUP). This tool enabled women to report the circumstances of their most recent pregnancy and categorized intentions into unplanned, ambivalent and planned. The LMUP was originally developed in English as a self-administered tool. However, it was adapted to suit the context by translating it into the local language (isiXhosa) and administering it as an interviewer-based tool. The Xhosa translated tool was then back-translated into English by a native Xhosa speaker who spoke English fluently. This process was carried out for all data collection tools.

2.4 Exposure assessment

Participants were categorized into four main exposure groups; known HIV-infected and established on ART, known HIV-infected but not on ART, newly diagnosed HIV-infected women and HIV-uninfected women. Women were asked the question “Did you test HIV positive in this pregnancy?”(Yes or no). Participants who answered ‘yes’ were further asked if they were currently on ART. Based on this women who had tested HIV positive prior to their current pregnancy and reported already being on ART were defined as ‘known HIV-infected on ART’ while women who were diagnosed of HIV prior to their current pregnancy but were not yet on ART on the day of booking were categorized as ‘known HIV-infected not on ART’ and women who reported testing HIV positive ‘in this pregnancy’ (only on the day of antenatal booking) were defined as ‘newly diagnosed’.

2.5 Outcome assessment

The primary outcome was unplanned pregnancy as obtained from the LMUP scores. Each item in the tool was scored 0, 1 or 2 and women's scores were summed for all 6 items. The scale of the LMUP ranges from 0-12 and each point increase represents an increase in pregnancy intention. The total LMUP scores were categorized into three broad preliminary categories of pregnancy intentions; unplanned (0-3), ambivalent (4-9) and planned (10-12). For analytic purposes, the outcome variable was dichotomized into unplanned or planned pregnancy. This was obtained by combining the scores for unplanned and ambivalent (0-9) as unplanned and categorising scores from 10-12 as a planned pregnancy.

2.6 Data analysis

Statistical analyses were performed using STATA software, version 12.0 (Stata Corporation, College Station, Texas, USA). Basic descriptive analyses were performed, including a comparison of baseline characteristics stratified by HIV serostatus and ART exposure. A categorical variable was created for socio economic status (SES) using the variables; employment status level of education, housing type and number of amenities in the household. The SES variable was then categorized into quartiles. Pearson's chi-squared test and Fisher's exact test were used to examine overall bivariate associations between the outcome and predictor variables. Bivariate analysis comparing the Xhosa LMUP with a single item three level response question (was this current pregnancy intended? Yes, No, Unsure) was conducted. We examined levels of unplanned pregnancy using the standardized scoring system of the LMUP (26).

Univariate and multivariable logistic regression modeling was performed to assess predictors of the outcome variable. Models were fitted using an iterative variable selection approach and the likelihood ratio test was analysed for the significance of the coefficients. In the univariate logistic regression analyses, all potential predictors with a p-value <0.2 were considered for inclusion in the multivariate

model. The level of significance was set at $p=0.05$ for the multivariate model. Age and SES of the participants were considered as *a priori* confounders and were adjusted in the multivariate model. Cronbach's α statistic was computed to assess the reliability of the Xhosa-translated LMUP in this population. A cut-off of 0.7 is widely recognized as the cut-off point for acceptable reliability and internal consistency. In addition, the Chi-squared test was used to evaluate the reliability of the Xhosa-translated LMUP by describing proportions of pregnancy intentions and comparing the categories to responses from a single item question on pregnancy intentions; "Was this pregnancy intended? Yes /no/ unsure". Principal component analysis was used to evaluate the internal structure and variability explained by each component of the LMUP.

2.7 Ethical considerations

Ethics approval for both the MCHART and HU2 studies was obtained from the Human Research Ethics Committee (UCT HREC) at the University of Cape Town (UCT HREC number 451/2012 and 567/2014 respectively). All women provided written informed consent prior to study participation and participant confidentiality was maintained at all times.

This study is a secondary analysis of existing data and as such poses no potential risks to the study participants. There are no direct benefits of this study to participants however, results obtained from this study will contribute to closing the gaps in the PMTCT treatment cascade through increasing focus on integration of reproductive health and HIV services for women living with HIV (WLH).

3. Results

3.1 Descriptive characteristics

As shown in Table 1, the median age of the participants was 28 (IQR 24-33) years, 29% completed high school, 61% were unemployed and 42% were married or lived with their current partner. The median parity was 1, 20% were nulliparous and 69% reported contraceptive use in the year before

pregnancy. SES varied slightly by HIV status with 29% of HIV-infected women in the lowest SES bracket compared to 15% of HIV-uninfected women.

Among the HI- infected women at enrolment, 37% had known HIV status and were established on ART, 29% of women had known HIV status but were not on ART while 34% were newly diagnosed with HIV. Compared to HIV-uninfected women, all HIV-infected women were slightly older, less educated, more likely to live in informal housing and less likely to be employed. HIV- uninfected women and newly diagnosed HIV-infected women were younger and slightly more educated than women who had a known HIV status prior to booking regardless of ART use.

Table 1: Demographic characteristics of study participants stratified by HIV status and ART use

Baseline Characteristics	All Women	Known HIV+ On ART	Known HIV+ Not On ART	Newly Diagnosed	HIV- Negative	p-value*
	n (%) or median(IQR)	n (%) or median(IQR)	n (%) or median(IQR)	n (%) or median(IQR)	n (%) or median(IQR)	
	2105	556	444	512	593	
Age	28 (24-33)	31 (28-34)	29 (26-32)	26 (22-30)	27 (23-32)	
Age Category						
18-24	532 (25)	51 (9)	77 (17)	187 (37)	217 (37)	<0.001
25-34	1235 (59)	368 (66)	307 (69)	276 (54)	284 (48)	
35-44	338 (16)	137 (25)	60 (14)	49 (9)	92 (15)	
Gravidity	2 (2-3)	3 (2-3)	3 (2-3)	2 (1-3)	2 (1-3)	
Parity	1 (1-2)	2 (1-2)	2 (1-2)	1 (0-2)	1 (0-2)	<0.001
Completed High School						
Yes	601 (29)	109 (20)	103 (23)	359 (70)	236 (40)	<0.001
No	1504 (71)	447 (80)	341 (77)	153 (30)	357 (60)	
Level of Education						
Primary	73 (3)	24 (4)	18 (4)	15 (3)	16 (3)	<0.001
Secondary	1973 (94)	520 (94)	417 (94)	480 (94)	556 (94)	
Tertiary	59 (3)	12 (2)	9 (2)	17 (3)	21 (3)	
Employment Status	2103					
Employed	833 (39)	210 (38)	144 (32)	200 (39)	275 (46)	<0.001
Unemployed	1281 (61)	346 (62)	300 (68)	312 (61)	316 (54)	
Housing						
Informal	1100 (52)	318 (57)	236 (53)	270 (53)	276 (47)	0.005
Formal	1002 (48)	238 (43)	208 (47)	242 (47)	314 (53)	
Socioeconomic Status (SES)	2099	556	444	512	587	<0.001
Low	524 (25)	166 (30)	132 (30)	139 (27)	87 (15)	
Low-Moderate	469 (22)	134 (24)	103 (23)	108 (21)	124 (21)	
Moderate-High	565 (27)	164 (30)	116 (26)	127 (25)	158 (27)	
High	541 (26)	92 (16)	93 (21)	138 (27)	218 (37)	
Married/Cohabiting	2058	549	433	494	582	
Yes	882 (43)	258 (47)	200 (47)	180 (36)	244 (42)	<0.001
No	1176 (57)	291 (53)	233 (54)	314 (64)	338 (58)	
Disclosed HIV Status To Current Partner	1476					
Yes	816 (55)	462 (84)	289 (67)	65 (13)	NA	<0.001
No	660 (45)	87 (16)	144 (33)	429 (87)	NA	
Intention Status Of Current Pregnancy	2104	556	444	512	592	
Unintended	1347 (64)	310 (56)	291 (66)	343 (67)	403 (68)	<0.001
Intended	752 (36)	244 (44)	152 (34)	167 (33)	189 (32)	
Unsure	5 (0)	2 (0)	1 (0)	2 (0)	0 (0)	
Used Contraceptives In Past 12 Months	2105	556	444	512	593	
Yes	1459 (69)	414 (74)	287 (65)	320 (63)	438 (74)	<0.001
No	646 (31)	142 (26)	157 (35)	192 (37)	155 (26)	
Contraceptive Method Used In Past 12 Months						
None	646 (31)	142 (26)	157 (36)	192 (38)	155 (26)	<0.001
Oral Contraceptives	57 (3)	5 (1)	8 (2)	12 (3)	32 (5)	
Injectables	752 (36)	152 (27)	139 (31)	155 (30)	306 (52)	
IUD	8 (0)	0	2	2 (0)	4 (1)	
Sterilization	1 (0)	0	0	0	1 (0)	
Condoms	641 (30)	257 (46)	138 (31)	151 (29)	95 (16)	
Discussed Family Planning With Partner In Past 12months	1971	512	402	466	591	
Yes	964 (49)	275 (54)	198 (49)	235 (50)	256 (44)	0.006
No	1007 (51)	237 (46)	204 (51)	231 (50)	335 (56)	

HIV+, HIV-infected; HIV-, HIV-uninfected; ART, Antiretroviral therapy; IQR, inter-quartile range

*Chi-squared and Fisher's exact tests were used to assess bivariate associations

3.2 Psychometric properties of the London Measure of Unplanned Pregnancy

Results from bivariate analysis comparing the Xhosa LMUP with a single item three level response question showed that almost all women (99%) whose pregnancy was categorized as unplanned by the LMUP also reported their pregnancy as not intended. Among those who reported that their current pregnancy was planned in response to the single question, 91% of women were correctly categorized as having a planned pregnancy by the LMUP. This suggests a high level of reliability of the LMUP in this setting (Table 2).

Table 2: *Reliability of the LMUP in comparison with the single item on pregnancy intentions*

Pregnancy Intention (Single Item)	LMUP pregnancy intention categories			
	Total (n=2105)	Unplanned (n=959)	Ambivalent n=607	Planned n=539
No	1347 (64)	950 (99)	346 (57)	51 (9)
Yes	752 (36)	8 (1)	256 (42)	488 (91)
Unsure	5 (0)	0 (0)	5 (1)	0 (0)

The LMUP performed well overall with Cronbach's $\alpha=0.84$ (See Table 5 in the Appendix). There was no variation in the Cronbach's alpha coefficients across HIV status (HIV-infected = 0.85 and HIV-uninfected = 0.80). Item-rest correlations were above or around 0.7 for all items.

The principal component analysis showed that five items of the LMUP clearly measured one construct as they loaded onto one component with an Eigen value of 3.6 (See Table 6 in the Appendix).

3.3 Unplanned pregnancy

Nearly half of all pregnancies in this population were unplanned (LMUP score: 0-3). The median LMUP score among the entire study population was 4 (1QR 3-10) (See Figure 2). Newly diagnosed HIV-infected women and women previously diagnosed but not established on ART had a similar low score of 3 indicating that their current pregnancy was highly likely to have been unplanned. Approximately 29% of women had ambivalent pregnancy intentions (LMUP score: 4-9) and 25% had a planned pregnancy (LMUP score: 10-12). Compared to the HIV positive women, fewer HIV negative women experienced an unplanned pregnancy (33% vs. 50%, $p < 0.001$). Across the four groups of women, the highest level of unplanned pregnancy was observed in women with a known HIV status but not on ART while HIV uninfected women were the least likely group to have an unplanned pregnancy (Figure 1).

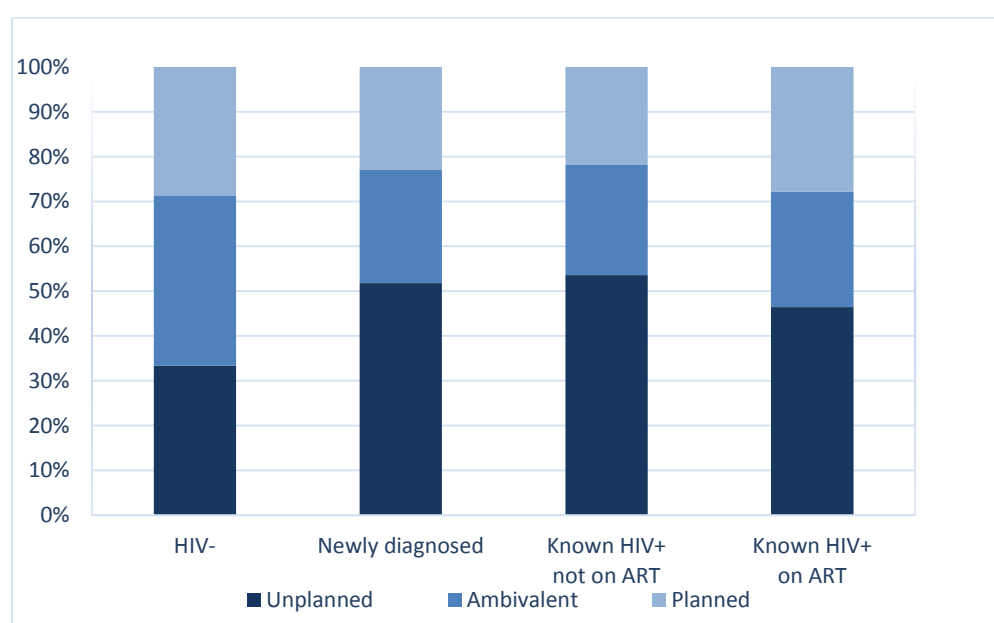


Figure 1: *Distribution of pregnancy intentions stratified by HIV status and ART use*

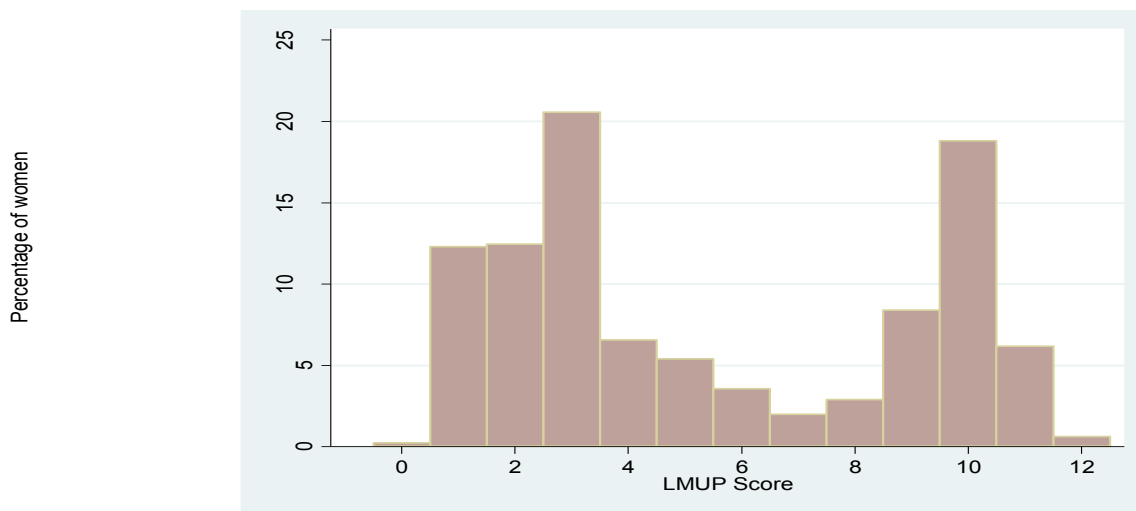


Figure 2: *Distribution of the LMUP scores among all participants*

3.4 Use of Contraceptives

Overall, 69% reported using at least one contraceptive method in the past year. HIV-infected women on ART and HIV uninfected women were more likely to be using a contraceptive method in the year prior to conception compared to those with a known status but not on ART and newly diagnosed women (74% and 74% versus 65% and 63% $p<0.001$). Women on ART were more likely to use condoms compared to those who were not yet on ART (46% vs 31% $p<0.001$). Condom use was particularly high among women previously diagnosed and on ART compared to those previously diagnosed but not on ART, recently diagnosed and HIV negative women (46% versus 31%, 29%, 16% respectively).

In addition, HIV-uninfected women were more likely to use a short term injectable hormonal contraceptive compared to known HIV-infected women on ART, known HIV-infected not on ART and newly diagnosed women (52% versus 27%, 31%, 39% $p<0.001$). Results of the bivariate analysis revealed that among all women with an unplanned pregnancy, 75% reported contraceptive use in the year prior to conception. Among all women with partners, 26% of those with an unplanned pregnancy had discussed family planning with their partner in the past year compared to 78% whose pregnancies were planned (Table 3).

Table 3: Demographic characteristics of participants stratified by LMUP pregnancy intentions

Baseline Characteristics	All Women	Unplanned	Ambivalent	Planned	p-value*
	n (%) or median (IQR)	n (%) or median (IQR)	n (%) or median(IQR)	n (%) or median(IQR)	
	2105	959	607	539	
Age	28 (24-33)	28 (24-32)	28 (25-33)	29 (25-33)	
Age Category					
18-24	532 (25)	274 (29)	150 (25)	108 (20)	
25-34	1235 (59)	548 (57)	356 (59)	331 (61)	0.004
35-44	338 (16)	137 (14)	101 (17)	100 (19)	
Gravidity	2 (2-3)	2 (2-3)	2 (2-3)	2 (2-3)	
Parity	1 (1-2)	1 (1-2)	1 (1-2)	1 (1-2)	
Completed High School					
Yes	601 (29)	236 (25)	205 (34)	160 (30)	<0.001
No	1504 (71)	723 (75)	402 (66)	379 (70)	
Level of Education					
Primary	73 (3)	38 (4)	16 (3)	19 (3)	
Secondary	1973 (94)	889 (93)	574 (94)	510 (95)	0.309
Tertiary	59 (3)	32 (3)	17 (3)	10 (2)	
Employment Status	2103				
Employed	833 (39)	352 (37)	265 (44)	212 (39)	0.022
Unemployed	1281 (61)	607 (63)	341 (56)	326 (61)	
Housing	2102				
Informal	1100 (52)	476 (50)	307 (51)	317 (59)	0.002
Formal	1002 (48)	481 (50)	299 (49)	222 (41)	
Socioeconomic Status	2099				
Low	524 (25)	274 (29)	118 (19)	132 (25)	
Low-Moderate	469 (22)	195 (20)	143 (24)	131 (24)	0.004
Moderate-High	565 (27)	251 (26)	167 (28)	147 (27)	
High	541 (26)	238 (25)	175 (29)	128 (24)	
Married/Cohabiting	2058				
Yes	882 (43)	273 (30)	242 (40)	367 (69)	<0.001
No	1176 (57)	646 (70)	362 (60)	168 (31)	
Disclosed HIV Status To Current Partner (HIV+ Women)	1476				
Yes	816 (55)	367 (50)	214 (56)	235 (64)	<0.001
No	660 (45)	362 (50)	165 (44)	133 (36)	
Intention Of Current Pregnancy	2104				
Unintended	1347 (64)	950 (99)	346 (57)	51 (9)	
Intended	752 (36)	8 (1)	256 (42)	488 (91)	<0.001
Unsure	5 (0)	0 (0)	5 (1)	0 (0)	
Used Contraceptive In Past 12 Months	2105				
Yes	1459 (69)	721 (75)	427 (70)	311 (58)	<0.001
No	646 (31)	238 (25)	180 (30)	228 (42)	
Contraceptive Method Used In Past 12 Months					
None	646 (31)	238 (25)	180 (30)	228 (42)	
Oral Contraceptives	57 (3)	26 (3)	16 (3)	15 (3)	
Injectables	752 (36)	335 (35)	233 (38)	184 (34)	<0.001
IUD	8 (0)	4 (0)	2 (0)	2 (0)	
Sterilization	1 (0)	0 (0)	1 (0)	0 (0)	
Condoms	641 (30)	356 (37)	175 (29)	110 (20)	
Discussed Family Planning With Partner In Past 12months	1971				
Yes	964 (49)	234 (26)	347 (60)	383 (78)	<0.001
No	1007 (51)	671 (74)	229 (40)	107 (22)	

*Chi-squared and Fisher's exact tests were used to assess bivariate associations
IQR, Inter-quartile range

3.5 Factors associated with unplanned pregnancy

After adjusting for age, parity, cohabiting status and socioeconomic status, compared to women with intended pregnancies, women with unplanned pregnancies were more likely to be newly-diagnosed with HIV or previously diagnosed but not on ART (OR: 1.43; 95% CI: 1.05-1.94 and OR: 1.56; 95% CI: 1.13-2.15, respectively). Increased parity and younger age (<24 years) were also associated with unplanned pregnancy (OR 1.42; 95% CI: 1.25-1.60 and OR 1.83; 95% CI: 1.23-2.74 respectively). Use of family planning methods twelve months prior to current pregnancy was also significantly associated with higher odds of having an unplanned pregnancy (OR=1.94; 95% CI: 1.55- 2.43). Whereas, being married/cohabiting (OR=0.19; 95% CI: 0.15-0.24) was associated with lower odds of experiencing an unplanned pregnancy (Table 4).

Table 4: *Multivariate logistic regression predicting unplanned pregnancy*

Characteristics	Univariate			Multivariate		
	OR	95% CI	p-value	AOR	95% CI	p-value
Age Category						
35-44						
25-34	1.15	0.88 - 1.49	0.309	1.29	0.95-1.75	0.099
18-24	1.65	1.20-2.26	0.002	1.84	1.23-2.75	0.003
Parity	1.07	0.98-1.17	0.136	1.42	1.25-1.61	0.000
HIV Status And ART Use						
HIV Negative						
Newly Diagnosed	1.36	1.03-1.78	0.028	1.43	1.06-1.94	0.020
Previously Diagnosed-No ART	1.44	1.08-1.92	0.013	1.57	1.14-2.16	0.006
Previously Diagnosed-On ART	1.04	0.80-1.34	0.766	1.10	0.82-1.48	0.513
Married/Cohabiting						
No						
Yes	0.23	0.19- 0.29	0.000	0.20	0.15-0 .25	0.000
Used Contraceptive In Past 12 Months						
No						
Yes	0.73	0.59-0.91	0.005	1.94	1.55-2.43	0.000
Socioeconomic Status						
Low						
Low-Middle	0.87	0.65-1.15	0.329	1.80	0.58-1.09	0.151
Middle-High	0.96	0.73-1.26	0.755	0.74	0.56-1.01	0.054
High	1.09	0.82-1.44	0.561	0.84	0.61-1.16	0.301
Finished High School						
No						
Yes	0.93	0.75-1.15	0.499	-	-	-
Employed						
No						
Yes	1.00	0.8-1.22	0.994	-	-	-
Housing						
Informal						
Formal	1.42	1.17-1.73	0.000	-	-	-
Gravidity	1.06	0.97-1.16	0.201	-	-	-

OR, Odds ratio; AOR, Adjusted Odds ratio; CI, Confidence interval

4. Discussion

This study is one of the first to examine pregnancy intentions by HIV status and ART exposure in South Africa. Overall, almost half of all pregnancies in this population were unplanned. This high level of unplanned pregnancy is consistent with findings from other studies conducted in South Africa (17,27). Levels of unplanned pregnancy were higher among HIV-infected women compared to HIV-uninfected women. A few studies had similar findings (13,22,27). This problem is not limited to Africa, as related findings were reported among HIV-infected women in Ontario, Canada and the United States (19,20).

Compared to HIV-uninfected women, newly diagnosed women and those with a known HIV status who were on ART, women who had a known status but were not on ART had the highest level of unplanned pregnancy. Newly diagnosed women also had high levels of unplanned pregnancy. Our findings are in contrast to most other studies in the region, which report a high level of unplanned pregnancy among HIV infected women on ART (11,28) but provide additional evidence that women in SSA who were not aware of their HIV status prior to conception (newly diagnosed) were more likely to have an unplanned pregnancy (22).

In addition, our results suggest that being engaged in HIV care may be protective against having an unplanned pregnancy, as demonstrated by lower levels of unplanned pregnancy among ART users. This could potentially be linked to the family planning counselling services received by HIV- infected women engaged in care. With one-third of women newly diagnosed at their first ANC appointment, this suggests missed opportunities for HIV diagnosis before pregnancy, pregnancy planning and contraceptive counselling for HIV-infected women.

This study provides additional evidence that risk factors for unplanned pregnancy include younger age (<24), increasing parity and contraceptive use in year prior to conception as identified in other

studies (14,29–31). Surprisingly, in contrast to several findings, SES and level of education were not associated with unplanned pregnancy in our study (22,32).

Reported use of contraceptives prior to unplanned pregnancy was high overall. Primarily, the use of male condoms and short-acting hormonal contraceptives requiring daily or quarterly adherence was widespread. Type of contraceptive methods used and levels of uptake prior to conception differed significantly by HIV serostatus, in contrast with recent findings from Botswana which reported that the majority of women with an unplanned pregnancy, regardless of HIV serostatus, reported using a contraceptive method prior to pregnancy (22). These data highlight an unmet need for family planning, particularly contraceptive failure or incorrect use which may have contributed to the high levels of unplanned pregnancy particularly among HIV-infected women, similar to findings from recent studies (13). HIV-infected women were more likely to utilize condoms compared to HIV-uninfected women, suggesting that the use of condoms for pregnancy prevention may not be an effective strategy (33).

Previous studies from Southern Africa have shown that there is a poor recommendation of safe and effective long-acting contraceptive methods to HIV infected women by health workers mostly due to limited skills and knowledge of health care workers and poorly integrated reproductive health and HIV services (11,25,33). Women need to be informed of the high failure rate of condom use, oral contraceptive pills and the importance of consistent and correct use of short acting contraceptive methods prevalent in this setting. In a highly prevalent HIV and sexually transmitted infections (STI) area, a dual method approach is recommended involving a combination of a long-acting hormonal contraceptive and condoms (34). Our results highlight the gaps in our understanding of reproductive healthcare for women living with HIV particularly with regards to adequate counselling on contraceptive choice and use.

While this study focused on women, the role of involvement of intimate partner and education in preventing unplanned pregnancy also requires attention. Our results show that women who were married or living with their male partners, those who had family planning discussions with their

partners before conception and HIV infected women who had disclosed their status to their partners were less likely to have an unplanned pregnancy. Similar results from other studies have shown that male partners' attitude towards contraception impacts strongly on contraceptive choice and use among HIV infected and uninfected women in this setting (33).

The LMUP translated into the local language, proved to be a valid and reliable measure of pregnancy intention among women who speak Xhosa and is therefore recommended for use in research in South Africa. This is the first time the LMUP has been validated in a LMIC country in Africa. This finding is similar to that from the only other validation of the LMUP in Africa (35).

This study has some limitations. The cross-sectional nature of this study means that causal associations could not be examined and consequently the significance of some of the predictors identified need to be further explored using longitudinal studies. In addition, this study was specific to a single setting in South Africa and although this study is largely representative of existing sexual and reproductive practices within the country, further research is needed to explore pregnancy intentions in other resource limited settings. Women who may have opted for an abortion without presenting for antenatal care were not included in this study; therefore the prevalence of unplanned pregnancy may have been underestimated. Furthermore, convenience sampling was used and participants were enrolled at the point of presentation in the antenatal clinic meaning that we may have missed women who presented late or not at all for antenatal care. Women who presented for antenatal care may be more likely to have better health seeking behaviours compared to women who did not present or opted for an abortion. This is a possible source of bias to our results.

5. Conclusion and Recommendation

In conclusion, this study presents key differences exist among HIV-infected women and uninfected women regarding pregnancy intentions and family planning practices. It is evident from our findings that HIV-infected women regardless of ART exposure need additional support to avoid unplanned

pregnancy. While additional research is required, women who are younger than 24 years, not on ART and have had more than one child may be particularly vulnerable and there is an urgent need to empower all HIV-infected and uninfected women with the skills to prevent an unplanned pregnancy if they desire to.

Strengthening of the reproductive healthcare services and effective integration of this component with ART services has been shown to be effective and is therefore recommended (36). These data highlight the importance of focused and innovative interventions to improve women's understanding of various options for effective contraception including how to properly use them. With the high percentage of women newly diagnosed at antenatal booking, there is a clear need to close the gap in the PMTCT cascade by improving coverage of HIV diagnosis prior to conception and strengthening family planning counselling for HIV-infected women. Implementation of reproductive healthcare guidelines for HIV-infected women requires regular monitoring and evaluation.

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PART D: APPENDICES

1.1 Ethics Approval Letter



UNIVERSITY OF CAPE TOWN
Faculty of Health Sciences
Human Research Ethics Committee



Room 253-46 Old Main Building
Groot Schuur Hospital
Observatory 7925
Telephone (021) 406 6492
Email: sunmyah.ericfdien@uct.ac.za
Website: www.health.uct.ac.za/fhs/research/humanethics/forms

05 August 2016

HREC REF: 457/2016

Prof L Myer

Division of Epidemiology and Biostatistics
School of Public Health & Family Medicine
Falmouth Building-FHS

Dear Prof Myer

PROJECT TITLE: PREVALENCE AND DETERMINANTS OF UNPLANNED PREGNANCY AMONG HIV-INFECTED AND HIV-UNINFECTED WOMEN ATTENDING ANTE-NATAL CARE IN CAPE TOWN, SOUTH AFRICA (Master's-candidate- Dr V Iyun)

Thank you for submitting your study to the Faculty of Health Sciences Human Research Ethics Committee (HREC) for review.

It is a pleasure to inform you that the HREC has **formally approved** the above-mentioned study.

Approval is granted for one year until the 30 August 2017.

Please submit a progress form, using the standardised Annual Report Form if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period.

(Forms can be found on our website: www.health.uct.ac.za/fhs/research/humanethics/forms)

Please quote the HREC REF in all your correspondence.

We acknowledge that the student; V Iyun will also be involved in this study.

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Please note that for all studies approved by the HREC, the principal investigator **must** obtain appropriate institutional approval before the research may occur.

Yours sincerely

Signed by candidate

PROFESSOR M BLOCKMAN
CHAIRPERSON, FHS HUMAN RESEARCH/ETHICS COMMITTEE

Federal Wide Assurance Number: FWA00001637

HREC 457/2016

1.2 Ethics approval letter of parent study (MCH-ART study)

 UNIVERSITY OF CAPE TOWN THE UNIVERSITY OF CAPE TOWN		HUMAN RESEARCH FACULTY OF HEALTH SCIENCES Human Research Ethics Committee 76 OCT 2015 	
FHS016: Annual Progress Report / Renewal		HEALTH SCIENCES FACULTY UNIVERSITY OF CAPE TOWN	
HREC office use only (FWA00001837; IRB0001838)			
This serves as notification of annual approval, including any documentation described below.			
☒ Approved	Annual progress report	Approved until next renewal date	30.10.2016
☐ Not approved	See attached comments		
Signature Chairperson of the HREC	Signed by candidate	Date Signed	7/11/2015
Comments to PI from the HREC			
Principal Investigator to complete the following:			
1. Protocol information			
Date (when submitting this form)	23 SEP 2016		
HREC REF Number	461/2012	Current Ethics Approval was granted until	30 OCT 2014
Protocol title	Strategies to optimise antiretroviral therapy services for maternal & child health: the MCH-ART study		
Protocol number (if applicable)	N/A		
Are there any sub-studies linked to this study?	☒ YES		
If yes, could you please provide the HREC Refs for all sub-studies? <i>Note: A separate FHS016 must be submitted for each sub-study.</i>	HREC REF 194/2013 Estimation of delivery dates using obstetric ultrasound in the MCH-ART study HREC REF 550/2015 Childbearing, family planning and relationships among women living with HIV in Gugulethu, Cape Town		
Principal Investigator	Prof Landon Myer		
Department / Office Internal Mail Address	CIDR, School of Public Health and Family Medicine, Faculty of Health Sciences		
1.1 Does this protocol receive US Federal funding?	☒ Yes	☐ No	
1.2 If this study receives US Federal Funding, does the annual report require full committee approval?	☐ Yes	☒ No	
23 July 2014	Page 1 of 1	FHS016	
(Note: Please complete the Closure form (FHS010) if the study is completed within the approval period)			

1.3 Ethics approval letter of parent study (HU2 study)



UNIVERSITY OF CAPE TOWN
UNIVERSITY OF CAPE TOWN

F

FHS016: Annual Progress Report / Renewal

HREC office use only (FWA00001637; IR000001938)		
This serves as notification of annual approval, including any documentation described below.		
☒ Approved	Annual progress report	Approved until/next renewal date <u>20 Aug. 2016</u>
☐ Not approved	See attached comments	
Signature Chairperson of the HREC	Signed by candidate	Date Signed <u>11/9/2015</u>

Comments to PI from the HREC

Principal Investigator to complete the following:

1. Protocol information

Date (when submitting this form)	30 August 2015		
HREC REF Number	567/2014	Current Ethics Approval was granted until	28 August 2015
Protocol title	Growth morbidity and development of HIV-unexposed infants: a prospective cohort study		
Protocol number (if applicable)	Version 1.1		
Are there any sub-studies linked to this study?	☐ Yes	☒ No	
If yes, could you please provide the HREC Ref's for all sub-studies? Note: A separate FHS016 must be submitted for each sub-study.			
Principal Investigator	Professor Landon Myer		
Department / Office Internal Mail Address	Landon.Myer@uct.ac.za		

1.1 Does this protocol receive US Federal funding?	☐ Yes	☒ No
1.2 If the study receives US Federal Funding, does the annual report require full committee approval?	☐ Yes	☐ No
1.3 Has sponsorship of the study changed? If yes, please attach a revised summary of the budget	☐ Yes	☒ No



23 July 2014

Page 1 of 5

FHS016

(note: Please complete the Closure form (FHS016) if the study is completed within the approval period)

1.4 Informed consent form (MCH-ART study)

Phase 1 Informed Consent Form

TITLE OF RESEARCH: Strategies to optimize antiretroviral therapy services for maternal & child health: the MCH-ART study

WHAT IS THE PURPOSE OF THIS STUDY?

We are from the University of Cape Town and ICAP at Columbia University. You are being asked to take part in a study that is being conducted at the Gugulethu Midwife Obstetric Unit (MOU). The purpose of this study is to understand how to improve health care services for HIV-positive women during their pregnancy and after they deliver the baby.

We know that it is important for their own health as well as the health of their baby, that HIV-positive women receive the HIV care and treatment that they need both during and after delivery. Information learned in this study will help us to improve HIV services for pregnant women.

You are being asked to take part in this study because you are a pregnant woman who is HIV-positive and you are getting your pregnancy care here at the Gugulethu MOU. The purpose of this consent is to give you information to help you decide if you want to take part in this study.

WHAT DO I HAVE TO DO IF I AGREE TO TAKE PART?

If you agree to take part, you will do the following at today's visit:

- Answer questions about your household, medical history, partnership status, HIV testing history and disclosure status, family planning and previous use of HIV drugs
 - If you are currently taking HIV drugs, we will ask you additional questions about HIV and HIV drugs (including side effects and adherence).
- Have 5mLs (1 teaspoon) of blood drawn from your arm)

NOTE: The blood that is drawn today will be stored and used to check your viral load (this is the amount of HIV in your blood) at a later time. Results from these tests will **not** be available to you, the clinic, or the study staff. When the health care providers at the clinic need to check your viral load, they will take a separate blood specimen. When it is stored, your blood and test results will not have your name or any other way of identifying you attached to it.

Review of medical records

As part of this study, we will also be looking at and taking information from your antenatal, obstetric, ART clinic, laboratory and pharmacy records. From these records, we are interested in learning about the pregnancy care you received as well as information about your delivery. We also want to learn about the HIV care and treatment that you received during your pregnancy and after you delivered. Finally, we want to learn about your baby's health status after delivery as well.

All data that we review and abstract is confidential and no participant names are recorded on study documents.

Contact for future study

After the completion of this visit, it is possible that we will contact you again at your next clinic visit or at another time in the future to take part in additional research studies. At that time, you would be asked to review and sign another consent form. You can choose to not take part in any future studies if you are asked. You will be asked to provide contact information so that we may get in touch with you regarding additional research studies. Study staff will talk with you about the best way to contact you.

WHAT ARE THE POTENTIAL RISKS?

If you decide to participate, you may feel uncomfortable about some of the personal questions you are asked about your health or your pregnancy. You may refuse to answer any question that you do not want to answer. There is some risk in sharing personal and medical information. We will be careful to keep all your information as private as possible.

Drawing blood is normally done as part of routine medical care and presents a slight risk of discomfort. Experienced staff will draw blood under sterile conditions in order to protect you against these risks.

WHAT ARE THE POTENTIAL BENEFITS?

There is no direct benefit to you if you take part in this study but if we identify any health care problem during the course of the study, we will make sure you are referred to the appropriate health care services. The information gained in this study may help to improve ART services for HIV-infected pregnant women in Cape Town, the Western Cape Province, and across South Africa.

WHAT ARE THE ALTERNATIVES TO TAKING PART?

The alternative to taking part in this study is to continue with your usual care at the MOU.

WHAT ABOUT CONFIDENTIALITY?

If you agree to take part, all information collected during the study will be kept strictly confidential. Your name will not be written on the study forms and will not be used in connection with any information or lab specimens that are collected as part of the study.

All study materials will be stored in locked filing cabinets. Only study staff and personnel involved in routine audits will have access to these materials. All staff involved in data collection and management will get specific training in confidentiality.

Even with these procedures in place, if the study staff learns that you are a risk to yourself or someone else or of possible child abuse and/or neglect, study staff will tell the proper authorities.

WILL I BE GIVEN ANYTHING FOR TAKING PART?

No, there is no compensation for taking part in the study today.

ARE THERE ANY COSTS?

There is no cost for being in this study.

CAN I LEAVE THE STUDY?

You have the right to decide not to take part in the study, to refuse to answer any questions, or to withdraw from the study at any time without any penalty. It will have no effect on the care that you receive at the Gugulethu MOU or any other health facility.

FUTURE USE OF SPECIMENS:

Phase 1 Informed Consent Form

If you agree, any leftover blood from the sample you have provided for this research project may be used for future HIV related research. It is possible that these stored samples may be tested to see if the HIV in your blood is resistant to any types of HIV medications or to look at other questions related to HIV.

At this time, we cannot provide details of when this testing may be conducted. However, additional testing will not be done using these stored samples without the approval of the appropriate ethics committees involved in this research.

If you agree to let us keep your stored samples for future research, they may be kept in a locked freezer for up to 5 years. If we do use your samples in the future, your name or other identifiers will not be included with this information (as with the rest of the information we collect for this study).

Please initial below to indicate whether or not you give permission for your specimens to be used for future research. You may still remain in the study, no matter which you choose.

_____ (initial) I agree to have my blood stored for future research.

_____ (initial) I agree to have my blood stored for future research related to this study ONLY.

_____ (initial) I do NOT agree to the storage of my blood for future research.

DO YOU HAVE ANY QUESTIONS?

If there is anything that is unclear or if you need further information, please ask us and we will provide it.

Do you have any questions?

FOR ADDITIONAL INFORMATION:

If you have any questions or have any problems while taking part in this research study, you should contact:

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Tel: +1 212 342 0543

Email: ejal@columbia.edu

If you have any questions about your rights as a research participant, you may contact the following member of the ethics committee:

Prof Marc Blockman

Chair, Human Research Ethics Committee

Faculty of Health Sciences, University of Cape

Columbia University Medical Center IRB

Tel: +1 212 305 5883

Phase 1 Informed Consent Form

Town

Tel: 021 406 6338

CONSENT STATEMENT:

I have read this form, or someone has read it to me. I have been offered a copy of this consent form. I was encouraged and given time to ask questions. I agree to be in this study. I know that after choosing to be in this study, I may withdraw at any time. My being in the study is voluntary. I understand that whether or not I participate will not affect my health care services received today, or at any time in the future.

Please indicate your consent with your signature.

Volunteer's name _____

Signature of Volunteer Date

Staff member's name _____

Signature of study staff Date

If the volunteer is unable to read or write the entire counselling process must be observed by an independent witness who can then confirm the procedure once the she has given consent.

Fingerprint of volunteer:

Witness:

I confirm that I am independent of the study and that I witnessed the entire informed consent counselling process in the home language of the volunteer

Witness's name _____

Signature of witness Date

Thank you.

1.5 Informed consent form (HU2 study)

HIV-unexposed infant cohort study: Antenatal Phase Informed Consent Form #A

TITLE OF RESEARCH: Growth, morbidity and development of HIV-unexposed infants: a prospective cohort study

WHAT IS THE PURPOSE OF THIS STUDY?

We are from the University of Cape Town. You are being asked to take part in a study that is being conducted at the Gugulethu Midwife Obstetric Unit (MOU). The purpose of this study is to investigate how babies grow and learn during their early life, and to identify possible ways to help mothers so that their babies can grow and learn at their best. This study will also help us to understand possible reasons for any differences seen between babies whose mothers have HIV infection and babies whose mothers are HIV negative.

We know that the mother's health during pregnancy, after delivery and during breastfeeding can affect how babies grow and learn during the first year of life. You are being asked to take part in this study because you are an HIV-negative pregnant women receiving antenatal care at the Gugulethu MOU. The purpose of this consent form is to give you information to help you decide if you want to take part in this study.

WHAT DO I HAVE TO DO IF I AGREE TO TAKE PART?

If you agree to take part, you will come in for up to 3 visits. These visits will take place today while you are in the clinic, when you are getting close to delivering your baby and within one week of delivering your baby. These study visits are separate from the usual clinic visits that you will have for your pregnancy and infant care. Study visits will be timed so that they take place on the same days that you come in for your usual pregnancy and/or other care. Each visit will take about 30-60 minutes.

At the two visits that are conducted *while you are pregnant*, you will do the following:

- Answer questions about your recent pregnancy- and general health care
 - At different visits, we will ask you additional questions about social support, infant feeding plans, family planning, experiences of partner violence, and mental health (including drug and alcohol use).
- Have an ultrasound ("scan") test to help us to work out how old your unborn baby is, and to evaluate the growth of your baby during pregnancy

One week after delivery:

Within one week after you give birth to your baby, you will come to the clinic for a visit that will include the following:

- Answer questions about your recent pregnancy and delivery
- Answer questions about family planning after delivery, infant feeding practices and infant health and health care.

Review of medical records

As part of this study, we will also be looking at and taking information from your antenatal, obstetric, laboratory and pharmacy records. From these records, we are interested in learning about the pregnancy care you received as well as information about your delivery. We also want to learn about any tests, procedures or treatment that you received after delivery. Finally, we want to learn about your baby's health status after delivery as well.

Page 1 of 4

Version 2.0, 22nd June 2014

HIV-unexposed infant cohort study: Antenatal Phase Informed Consent Form #A

Ultrasound measurements

Fetal ultrasound is commonly used to determine the duration of the pregnancy (how old the unborn baby is), the expected delivery date, to find problems with the development of the baby, and to see if there are any pregnancy complications. When you have an ultrasound, the sonographer (person doing the scan) places a small amount of gel onto the skin of the abdomen (stomach area), and uses a rounded, hand-held device to transmit sound waves into the body through the skin. The sound waves are reflected off the body, and turned into a picture on the monitor. The ultrasound test takes between 10-30 minutes, and is safe for you and your baby.

These ultrasound scans in no way replace the routine antenatal care that you receive at Gugulethu MOU. If your health care providers at the MOU need an ultrasound scan, they will do this during your routine care. However, if during a research scan, we detect any problems or abnormalities, you will be immediately referred to your usual antenatal care providers for further tests and treatment.

Follow-up of missed visits

You will be asked to provide contact information so that we may get in touch with you during the study. Study staff will talk with you about the best way to contact you. In the event that you miss one of the scheduled study visits, a member of the study staff will contact you in order to find another day and time to complete your visit. If you repeatedly miss study visits or the staff is unable to contact you using the information that you provide, it may be necessary to visit you at home in order to reschedule the missed study visit. Your privacy will be respected at all times.

Contact for future study

After the completion of the visit one week after delivery, it is possible that we will contact you again at your next clinic visit or at another time in the future to take part in additional research studies. At that time, you would be asked to review and sign another consent form. You can choose to not take part in any future studies if you are asked. You will be asked to provide contact information so that we may get in touch with you regarding additional research studies. Study staff will talk with you about the best way to contact you.

WHAT ARE THE POTENTIAL RISKS?

You may feel uncomfortable about some of the personal questions you are asked. You may refuse to answer any question that you do not want to answer. There is some risk in sharing personal and medical information. We will be careful to keep all your information as private as possible.

Ultrasound has been widely and safely used for decades. Fetal ultrasound is a painless procedure with no known risks to you or the baby you are carrying.

WHAT ARE THE POTENTIAL BENEFITS?

There is no direct benefit to you if you take part in this study. However, if during a research ultrasound scan, or during other study measurements, any problems or abnormal findings are identified, you will be referred immediately to the public sector antenatal care service for further investigation and treatment.

The information gained in this study may help to improve care and support for pregnant women and their newborn babies in Cape Town, the Western Cape Province, and across South Africa.

WHAT ARE THE ALTERNATIVES TO TAKING PART?

The alternative to taking part in this study is to continue with your usual care at the MOU.

HIV-unexposed infant cohort study: Antenatal Phase Informed Consent Form #A

WHAT ABOUT CONFIDENTIALITY?

If you agree to take part, all information collected during the study will be kept strictly confidential. Your name will not be written on the study forms and will not be used in connection with any information or lab specimens that are collected as part of the study.

All study materials will be stored in locked filing cabinets. Only study staff and personnel involved in routine audits will have access to these materials. All staff involved in data collection and management will get specific training in confidentiality.

Even with these procedures in place, if the study staff learns that you are a risk to yourself or someone else or of possible child abuse and/or neglect, study staff will tell the proper authorities.

WILL I BE GIVEN ANYTHING FOR TAKING PART?

At the end of each visit, you will be given R20 in cash to cover the transport cost to your next scheduled study visit, and an R80 grocery voucher. After the ultrasound measurements, you will be given a small black and white print of the picture of your unborn baby. You will also receive a small gift for the first visit after birth and refreshments will be available at each visit.

ARE THERE ANY COSTS?

There is no cost for being in this study.

CAN I LEAVE THE STUDY?

You have the right to decide not to take part in the study, to refuse to answer any questions, or to withdraw from the study at any time without any penalty. It will have no effect on the care that you receive at the Gugulethu MOU or any other health facility.

DO YOU HAVE ANY QUESTIONS?

If there is anything that is unclear or if you need further information, please ask us and we will provide it.

Do you have any questions?

FOR ADDITIONAL INFORMATION:

If you have any questions or have any problems while taking part in this research study, you should contact:

Dr Stanzi le Roux
School of Public Health and Family Medicine
Faculty of Health Sciences, University of
Cape Town
Tel: 082 925 8259
Email: stanzi.leroux@gmail.com

If you have any questions about your rights as a research participant, you may contact the following member of the ethics committee:

Prof Marc Blockman
Chair, Human Research Ethics Committee
Faculty of Health Sciences, University of Cape
Town
Tel: 021 406 6338

Page 3 of 4

Version 2.0, 22nd June 2014

HIV-unexposed infant cohort study: Antenatal Phase Informed Consent Form #A

CONSENT STATEMENT:

I have read this form, or someone has read it to me. I have been offered a copy of this consent form. I was encouraged and given time to ask questions. I agree to be in this study. I know that after choosing to be in this study, I may withdraw at any time. My being in the study is voluntary. I understand that whether or not I participate will not affect my health care services received today, or at any time in the future.

Please indicate your consent with your signature.

Volunteer's name _____

Signature of Volunteer Date

Staff member's name _____

Signature of study staff Date

If the volunteer is unable to read or write the entire counselling process must be observed by an independent witness who can then confirm the procedure once the she has given consent.

Fingerprint of volunteer:

Witness:

I confirm that I am independent of the study and that I witnessed the entire informed consent counselling process in the home language of the volunteer

Name: _____

Signature: _____

Date: _____

Thank you.

Page 4 of 4

Version 2.0, 22nd June 2014

1.6 Baseline demographic questionnaire

MCH-ART: Demographics & Medical History, Phase 1
Xhosa-English of Version 3.0, 15 October 2013

PID: 1 - _____ - ____

Visit Date: ____/____/____	
1.	Mingaphi iminyaka yakho <i>What is your age?</i>
2.	Uloluphi uhlanga <i>What population group do you belong to?</i>
3.	Uthetha oluphi ulwimi ekhayai? <i>What language do you speak at home?</i>
4.	Lelephi elona banga liphezulu oliphumeleleyo? <i>What is the highest level of schooling/education that you have completed?</i>
5.	Ngoku uyasebenza okanye uyafunda <i>Are you currently working and/or studying?</i>
6.	Ukuba nguEwe, yeyephi kwezi zilandelayo echaza, bhetele ukuba wenza ntoni? <i>If yes, which of one the following best describes what you do?</i> Khetha ibenye /Choose one only
7.	Ngowuphi owona mthombo wemali kwikhaya lakho? <i>What is the MAJOR source of income for your household?</i> Khetha ibenye /Choose one only

8.	Uhlala kwikhaya elinjani? <i>What kind of home do you live in?</i>	Ityotyombe/ uhlaliso olungahlelwanga = 1 <i>Shack/Informal dwelling</i> Indlu yesitena = 2 <i>Formal house</i> Ifleti/ indlu kamasipala = 3 <i>Flat/council home</i> Enye = 4, chaza: _____ <i>Other, specify</i>												
9.	Ingaba indlu yakho inazo ezi zinto zilandelayo: <i>Does your house have the following: Read and answer for all</i>	<table border="1"> <tr> <td>a. Indlu yangasese <i>A toilet inside</i></td> <td>Hayi/No = 0 Ewe/Yes = 1</td> </tr> <tr> <td>b. Amanzi abalekayo empompo <i>Running water inside</i></td> <td>Hayi/No = 0 Ewe/Yes = 1</td> </tr> <tr> <td>c. Umbane <i>Electricity inside</i></td> <td>Hayi/No = 0 Ewe/Yes = 1</td> </tr> <tr> <td>d. Isikhenkcisi <i>A refrigerator</i></td> <td>Hayi/No = 0 Ewe/Yes = 1</td> </tr> <tr> <td>e. Umnxeba <i>A telephone</i></td> <td>Hayi/No = 0 Ewe/Yes = 1</td> </tr> <tr> <td>f. Umabona kude <i>A television</i></td> <td>Hayi/No = 0 Ewe/Yes = 1</td> </tr> </table>	a. Indlu yangasese <i>A toilet inside</i>	Hayi/No = 0 Ewe/Yes = 1	b. Amanzi abalekayo empompo <i>Running water inside</i>	Hayi/No = 0 Ewe/Yes = 1	c. Umbane <i>Electricity inside</i>	Hayi/No = 0 Ewe/Yes = 1	d. Isikhenkcisi <i>A refrigerator</i>	Hayi/No = 0 Ewe/Yes = 1	e. Umnxeba <i>A telephone</i>	Hayi/No = 0 Ewe/Yes = 1	f. Umabona kude <i>A television</i>	Hayi/No = 0 Ewe/Yes = 1
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e. Umnxeba <i>A telephone</i>	Hayi/No = 0 Ewe/Yes = 1													
f. Umabona kude <i>A television</i>	Hayi/No = 0 Ewe/Yes = 1													
10.	Bangaphi abantu abahlala kule ndlu bedibene nawe(abadala, abancinci)? <i>Including yourself, how many people (adults and children) live in your house?</i>	Inani labantu: _____ # of people:												
11.	Bangaphi abadala (iminyaka-16 nangaphezulu) bedibene nawe abahlala kule ndlu? <i>How many adults (aged 16 or older), including you, live in your house?</i>	Inani labadala: _____ # of adults												
12.	Bangaphi abantwana (iminyaka -15 nanganenani) abahlala nawe? <i>How many children (aged 15 and under) live in your house?</i>	Inani labantwana: _____ # of children												
13.	Ukhulelwe kangaphi (kudibene nesi isisu)? <i>How many times have you been pregnant (including current pregnancy)?</i>	Inani lokukhulelwa: _____ # of pregnancies:												
14.	Ingaba ubuzama ukuba nosana ngelishesha ufumanisa ukuba ukhulelwe (Kwesi isisu)? <i>Were you trying to have a baby when you found out you were pregnant (in this pregnancy)?</i>	Hayi/No = 0 Ewe/Yes = 1 Andazi/I don't know = 9												
15.	Bangaphi abantwana obazeleyo? <i>How many children have you given birth to?</i>	Inani labantwana: _____ # of children Ukuba = 0, Gqithela ku Q20 If 0, SKIP to Q20												
16.	Bangaphi kwaba bantwana abaphilayo? <i>How many of these children are living?</i>	Inani labantwana: _____ # of children												
17.	Bangaphi kwaba bantwana abahlala nawe ngoku? <i>How many of these children currently live with you?</i>	Inani labantwana: _____ # of children												
18.	Bangaphi kwaba bantwana ekufumaniseke bakho ukuba baphila nentsholongwane? <i>How many of your children have tested HIV-positive?</i>	Inani labantwana abaphila nentsholongwane: _____ # of HIV-positive children												
19.	Bangaphi kwaba bantwana baphila nentsholongwane abasaphilayo? <i>How many of these children who have tested HIV-positive are currently living?</i>	Inani labantwana abaphila nentsholongwane abaphilayo ngoku: _____ # of HIV-positive children currently alive												

20.	Uya thandana ngoku? <i>Are you currently in a relationship?</i>	Hayi/No = 0 → Gqithela ku Q25 <i>SKIP to Q25</i> Ewe/Yes = 1
21.	Ungaluchaza njani uthando lwakho? <i>How would you describe your current relationship?</i>	Utshatile = 1 <i>Married</i> Anditshatanga, ndiya hlalisana = 2 <i>Not married, living together</i> Nditshatile, asihlali kunye = 3 <i>Married, not living together</i> Anditshatanga, asihlali kunye = 4 <i>Not married, not living together</i> Enye = 5, cacisa: _____ <i>Other, specify</i>
22.	Lileshe ellingakanani unobudlelwana nalomntu? <i>How long have you been in a relationship with this person?</i>	Ixesha Inyanga Months _____ Duration In: Iminyaka Years _____
23.	Ingaba eli qabane lakho ngutata womnye wabantwana bakho(kunye nalo umkhulelweyo)? <i>Is your current partner the parent of any of your children? (Including current pregnancy)</i>	Hayi/No = 0 Ewe/Yes = 1
24.	Ulichazele na iqabane lakho ngesimo sakho sentsholongwane? <i>Have you disclosed your HIV status to your current partner?</i>	Hayi/No = 0 Ewe/Yes = 1
25.	Ubukhe wabelana ngesondo nabanye abantu ingenguye lomntu uthandana naye? <i>In the last 12 months have you had any sexual relationships/sexual partners? (If in a relationship then other than this partner)</i>	Hayi/No = 0 → Gqithela ku Q28 <i>→ SKIP to Q 28</i> Ewe/Yes = 1
26.	Bunjani ubudlelwanebakho namanye amaqabane ngaphandle kweqabane lakho langoku ukuba akhona? <i>What is the nature of your relationship(s)? (other than current partner if applicable)</i> Rhangqa konke okungqamene nawe. <i>Mark all that apply.</i>	a. Umlingane/nditshatile <i>Spouse/ married</i> b. Iqabane lam <i>Boyfriend</i> c. Iqabane lethutyana <i>Casual Partner/One Night Stands</i> d. Omnye, cacisa: _____ <i>Other, specify</i>
27.	Ubaxelele aba bantu wabelana nabo ngesondo ukuba uphila nentsholongwane? <i>Have you disclosed your HIV status to any of these other sexual partners?</i>	Hayi/No = 0 Ewe/Yes = 1
28.	Ubuqala ukufumanisa ukuba unentsholongwane kagawulayo kolumitho okanye phambi kokuba ukhulelwe? <i>Did you first test HIV positive in this pregnancy or before this pregnancy?</i>	Koku ukukhulelwa = 1 → Gqithela ku Q32 <i>In his pregnancy SKIP to Q32</i> Phambi koku ukukhulelwa = 2 <i>Before this pregnancy</i>
29.	Kwakunini ukuqala kwakho ukufumanisa ukuba unentsholongwane kagawulayo? <i>When did you 1st test HIV-positive?</i>	Umhla: _____ Inyanga: _____ Unyaka: _____ Day Month Year
30.	Kwakutheni ukuze oluhlolo lwenziwe? <i>Why was this test conducted?</i>	Ndivavanywe ngelishesha ndikhulelweyo = 1 <i>Tested during pregnancy</i> VCT/Ndandifuna ukuvavanywe = 2 <i>VCT/Wanted to be tested</i> Ndafunyaniswa ndinesifo sephepha (TB) = 3 <i>Diagnosed with TB</i> Ndangeniswa esibhedlele = 4 <i>Admitted to the hospital</i> Enye = 5, cacisa: _____ <i>Other, specify</i>

31.	Ingaba wawukhulelwe ukuqala kwakho ukufumane ukuba unentsholongwane kagawulayo? <i>Were you pregnant when you first tested HIV-positive?</i>	Hayi/No = 0 Ewe/Yes = 1
32.	Wakhe wanazo iziphumo ezingena chaphaza kuvavanyo lwentsholongwane kagawulayo? <i>Have you ever tested negative on an HIV test?</i>	Hayi/No = 0 → Gqithela ku Q36 SKIP to Q36 Ewe/Yes = 1
33.	Ugqibele nini ukuba neziphumo ezingenachaphaza zovavanyo lwentsholongwane kagawulayo? <i>When did you last test HIV-negative?</i>	Umhla: ____ Inyanga: ____ Unyaka: ____ Day Month Year
34.	Kwakutheni ukuze uvavanywe ngelo xesha? What was the reason for you doing the HIV test? <i>Why did you test at that time?</i>	Ndivavanywe ngelishesha ndikhulelweyo = 1 <i>Tested during pregnancy</i> VCT/Ndandifuna ukuvavanywe = 2 <i>VCT/Wanted to be tested</i> Ndafunyaniswa ndinesifo sephepha (TB) = 3 <i>Diagnosed with TB</i> Ndangeniswa esibhedlele = 4 <i>Admitted to the hospital</i> Enye = 5, cacisa: ____ <i>Other, specify</i>
35.	Wawukhulelwe ngeloxesha uvavanyelwa intsholongwane? <i>Were you pregnant at the time of that test?</i>	Hayi/No = 0 Ewe/Yes = 1
36.	Wakhe waxelela nabanina ukuba unentsholongwane kagawulayo? <i>Have you told anyone that you are HIV-positive?</i>	Hayi/No = 0 → Gqithela ku Q39 SKIP to Q39 Ewe/Yes = 1
37.	Ngawaphi amlungu osapho lwakho owaxeleleyo ngesimo sakho sentsholongwane? <i>Which of your family members have you told about your HIV status?</i> Nceda phendula lombuzo ngelungu ngalinye losapho oludweliswe ngezantsi. <i>Please answer this question for each of the family members listed below.</i> Wamxelele u _____ ukuba unentsholongwane kagawulayo? <i>Have you told your _____ that you are HIV positive?</i>	
a.	Umyeni/nkabane <i>Husband/partner/boyfriend</i>	Hayi/No = 0 Ewe/Yes = 1 N/A = 9
b.	Umama <i>Mother</i>	Hayi/No = 0 Ewe/Yes = 1 N/A = 9
c.	Utata <i>Father</i>	Hayi/No = 0 Ewe/Yes = 1 N/A = 9
d.	Udade <i>Sister</i>	Hayi/No = 0 Ewe/Yes = 1 N/A = 9
e.	Umtakwenu <i>Brother</i>	Hayi/No = 0 Ewe/Yes = 1 N/A = 9
f.	Intombi <i>Daughter</i>	Hayi/No = 0 Ewe/Yes = 1 N/A = 9
g.	Unyana <i>Son</i>	Hayi/No = 0 Ewe/Yes = 1 N/A = 9
h.	Umalume <i>Uncle</i>	Hayi/No = 0 Ewe/Yes = 1 N/A = 9
i.	U-anti <i>Aunt</i>	Hayi/No = 0 Ewe/Yes = 1 N/A = 9

j.	Umza wesikhomo <i>Male cousin</i>	Hayi/No = 0 Ewe/Yes = 1 N/A = 9
k.	Umza wesikhomokazi <i>Female cousin</i>	Hayi/No = 0 Ewe/Yes = 1 N/A = 9
l.	Enye indoda yalapha <i>Other male family member</i>	Hayi/No = 0 Ewe/Yes = 1 N/A = 9
m.	Esinye isikhomokazi <i>Other female family member</i>	Hayi/No = 0 Ewe/Yes = 1 N/A = 9
38.	Ngaphandle kwabantu bakowenu aba badweliswe ngentla, ngubani omnye umntu owamxelelyo ukuba uphila nentsholongwane? (funda uphendule yonke imibuzo) <i>Aside from family members listed above, who else have you told about your HIV status? (read and answer for all)</i>	
a.	Amanesi/ogqira <i>Health professionals</i>	Hayi/No = 0 Ewe/Yes = 1 N/A = 9
b.	Iqumru lenxaso labantu abaphila nentsholongwane <i>Support group</i>	Hayi/No = 0 Ewe/Yes = 1 N/A = 9
c.	Umntu owabelana naye ngesondo ongahlali naye <i>A sexual partner who does not live with you</i>	Hayi/No = 0 Ewe/Yes = 1 N/A = 9
d.	Isihlobo <i>Friends</i>	Hayi/No = 0 Ewe/Yes = 1 N/A = 9
e.	Inkokheli ngokwa kwamoya <i>Spiritual leader</i>	Hayi/No = 0 Ewe/Yes = 1 N/A = 9
f.	Umntu okuqashileyo/wayekuqashile <i>Current or former employer</i>	Hayi/No = 0 Ewe/Yes = 1 N/A = 9
g.	Ukuchaza esidlangalaleni <i>Public disclosure/ community</i>	Hayi/No = 0 Ewe/Yes = 1 N/A = 9
h.	Abanye, chaza: _____ <i>Other, specify</i>	Hayi/No = 0 Ewe/Yes = 1 N/A = 9
39.	Wakhe wakhulelwa phambi koku ukukhulelwa? <i>Have you ever been pregnant before this pregnancy?</i>	Hayi/No = 0 → Gqithela ku Q45 SKIP to Q45 Ewe/Yes = 1
40.	Ngokuya ubukhulelwe ngaphambi koku ukukhulelwa wawuke wanikwa amayeza okhusela usana lungosuleleki yintsholongwane (ezeku khusela umntwana hayi amachiza okutho malalisa intsholongwane wobomi bonke) <i>When you were pregnant before this pregnancy have you ever been given medication at the clinic to keep your baby from getting HIV infected? (prophylaxis NOT lifelong ART)</i>	Hayi/No = 0 → Gqithela ku Q45 SKIP to Q45 Ewe/Yes = 1
41.	Ukuba nguEwe, zingaphi izisu ufumane la machiza ngesizathu? <i>If yes, during how many pregnancies have you received medication for this purpose?</i>	Inani lezisu: _____ # of pregnancies

42.	Kwezi zisu siyi _____ ofumene kuzo amachiza, zingaphi izisu otye kuzo iipilisi ngelixesha ubelekayo qha? <i>For the _____ pregnancies that you received medication, For how many pregnancies did you take pills while you were pregnant and for how many pregnancies did you take pills only at delivery?</i>	Ngoku wawubeleka Only at Delivery (Nevirapine) #: _____ Ngelixesha ukhulelwe While you were pregnant (AZT)? #: _____
43.	Bekunini ukugqibela kwakho ukufumana la machiza ngesizathu? <i>When was the last time that you received medication for this purpose?</i>	Umhla: _____ Inyanga: _____ Unyaka: _____ Day Month Year
44.	Uwafumene phi la machiza ukugqibela kwakho? <i>Where did you receive the medication the last time?</i>	Igama leliniki: _____ Name of clinic:
45.	Wawuke wawathatha amachiza okuthomalalisa intsholongwane (awobomi bakho bonke) <i>Have you ever taken triple drug antiretroviral therapy (lifelong ART)?</i>	Hayi/No = 0 → Phela apha/End here Ewe/Yes = 1
46.	Ukuba nguEwe, ingaba wawafumana amachiza okuthomalalisa intsholongwane ukugqibela kakho? <i>If yes, where did you receive ART the last time?</i>	Igama leliniki: _____ Name of clinic:
47.	Uqale nini ukutya la machiza okuthomalalisa intsholongwane kagawulayo? <i>When did you start taking ART?</i>	Umhla: _____ Inyanga: _____ Unyaka: _____ Day Month Year
48.	Usawatya amachiza okuthomalalisa intsholongwane kagawulayo? <i>Are you still on ART?</i>	Hayi/No = 0 Ewe/Yes = 1 → SKIP to Q51
49.	Ukuba nguHayi, uyeke nini ukuwatya amachiza okuthomalalisa intsholongwane kagawulayo? <i>If No, when did you stop taking ART?</i>	Umhla: _____ Inyanga: _____ Unyaka: _____ Day Month Year

50.	Uyekele ntoni ukutya amachiza athomalalisa intsholongwane? <i>Why did you stop taking ART?</i> (rhagqa zonke ezibhekisa kuwe) <i>Circle all that apply</i>	a. Ndaphelelwa ngumchiza andaya ukuyakuwalanda <i>I ran out of medicine and didn't go for refills</i> b. Anencasa embi <i>The medicine tastes bad</i> c. Ndulibala <i>I just forgot</i> d. Bendikhathazwa yimiphumela yawo <i>I was worried about the side effects</i> e. Bendingafuni abanye bandiqaphele ukuba nditya amachiza <i>I did not want others to notice me taking the medicine</i> f. Ndandigula <i>I was ill</i> g. Ndacinga ukuba andisawafuni nganto <i>I didn't think I needed it anymore</i> h. Bendinginga ndingahlala ndiphilile ngaphandle kwawo <i>Can stay healthy without it</i> i. Bendinginga ukuba lamayeza anganobu ngozi kum. <i>I felt the medicine might be harmful to me</i> j. Ndizive ndinoxinizelelo <i>I felt depressed</i> k. Ndandiphilile <i>I was well</i> l. Ebemaninzi la machiza ekufuneka ndiwathathe <i>There was too much medicine to take</i> m. Bendingekho ekhaya <i>I was away from home</i> n. Bendixakekile zezinye izinto <i>I was busy with other things</i> o. Ndiye ndafunda ukuba zikho ezinye iindlela endinganyanga okanye ndiphilise intsholongwane kagawulayo <i>I learned that there are other ways to treat or cure HIV</i> p. Enye, cacisa: _____ <i>Other, Specify</i>
51.	Ubukhe watshaya isigarethi kulenyanga iphelileyo? <i>Did you smoke cigarettes in the last month?</i>	Hayi No = 0 → END Ewe Yes = 1
52.	Utshaya isigarethi ezingaphi ngemini? <i>How many cigarettes do you smoke in a day?</i>	# _____ cigarettes

Date completed: ____/____/____ Signed counsellor completing CRF: _____

Date of QC: ____/____/____ Signed measurement nurse: _____

1.7 Family planning and pregnancy intentions questionnaire

MCH-ART: Family Planning/Pregnancy intentions Phase 2 1st visit
Xhosa-English Version 2.2, 27 Jan 2013

PID: 2 - ____ - ____ - ____

Family Planning and Pregnancy Intentions		Visit Date: ____ / ____ / ____
Siza kubuza imibuzo malunga nendlela zocwangciso ntsapho okhe wasisebenzisa: We are now going to ask you some questions about your use of family planning methods in the past.		
1.	Zeziphi iintlobo zocwangciso ntsapho owakhe wasisebenzisa apha ebomi? What methods of family planning have you used in your life? (Funda urhangqe konke okungqamene nawe) Read and circle all that apply	a. Azikho None b. Ipilisi eziselwayo Oral contraceptive pill c. Isitofu se-2 ('noristerat NET-en') 2-month injectable ('noristerat NET-en') d. Isitofu se-3 ('depo, petogen') 3-month injectable ('depo, petogen') e. Isivalo -mlomo wesibeleko (IUD) Intra-uterine device f. Isivalo nzala sabantu ababhinqileyo Female sterilization g. Isivalo nzala sabantu besikhomo Male sterilization h. Idyasi kamkhwenyana Male condom i. Idyasi kamkhwenyana (yabantu ababhinqileyo) Female condom j. Olunye uhlobo, cacisa _____ Other method, specify
2.	Kwinyanga ezi-12 phambi kolu mitho, ubusebenzisa oluphi uhlobo lokucwangciso ntsapho? In the 12 months before this pregnancy, what methods of family planning did you use? (Rhangqa konke okungqamene nawe) Circle all that apply	a. Ipilisi eziselwayo Oral contraceptive pill b. Isitofu se-2 ('noristerat NET-en') 2-month injectable ('noristerat NET-en') c. Isitofu se-3 ('depo, petogen') 3-month injectable ('depo, petogen') d. Isivalo -mlomo wesibeleko (IUD) Intra-uterine device e. Isivalo nzala sabantu ababhinqileyo Female sterilization f. Isivalo nzala sabantu besikhomo Male sterilization g. Idyasi kamkhwenyana Male condom h. Idyasi kamkhwenyana (yabantu ababhinqileyo) Female condom i. Olunye uhlobo, cacisa _____ Other method, specify
3.	Ingaba uceba ukusebenzisa ucwangciso ntsapho emva kokubeleka? Are you planning to use any form of family planning after delivery?	Hayi No = 0 → Gqithela ku Q5 SKIP to Q5 Ewe Yes = 1

4.	Ukuba ngu-Ewe loluphi uhlobo ocinga ukuba ungalusebenzisa? <i>If yes, what method you think you might use?</i> (Rhagqa konke okungqamene nawe) <i>Circle all that apply</i>	a. Ipilisi eziselwayo <i>Oral contraceptive pill</i> b. Isitofu se-2 ('noristerat NET-en') <i>2-month injectable ('noristerat NET-en')</i> c. Isitofu se-3 ('depo, petogen') <i>3-month injectable ('depo, petogen')</i> d. Isivalo -mlomo wesibeleko (IUD) <i>Intra-uterine device</i> e. Isivalo nzala sabantu ababhinqileyo <i>Female sterilization</i> f. Isivalo nzala sabantu besikhomo <i>Male sterilization</i> g. Idyasi kamkhwenyana <i>Male condom</i> h. Idyasi kamkhwenyana (yabantu ababhinqileyo) <i>Female condom</i> i. Olunye uhlobo, cacisa _____ <i>Other method, specify</i>
5.	Ukuba ngu Hayi, nika izizathu ezingenza ukuba ungalusebenzisa ucwangciso ntsapho? <i>If no, what are the reasons that you might not use a family planning method?</i>	Izizathu: <i>Reason</i>
6.	Kwezi nyanga zi-12 ukhe wabonisana neqabane lakho ngocwangciso ntsapho okanye ukukhulelwa? <i>In the last 12 months, have you discussed family planning or pregnancy with your partner?</i>	Hayi No = 0 Ewe Yes = 1
Siza kubuza ngenjongo zakho zokumitha kwilixa elizayo: <i>We are now going to ask about your future pregnancy intentions:</i>		
7.	Cinga ngendlela oziva ngayo ngoku. Yeyephi kwezintetha zilandelayo echaza bhetele ingcinga zakho ngokuba nomntwana kwixesha elizayo? <i>Think about how you feel right now. Which of the following statements best describes your own thinking about having a child in the future?</i>	Ndingafuna ukuba nomntwana kwithuba lenyanga ezi-12 elizayo = 1 <i>I may want to have a child in the next 12 months.</i> Ndingafuna ukuba nomntwana ngelinye ixesha ingezizo inyanga ezi-12 elizayo = 2 <i>I may want to have a child sometime in the future but not in the next 12 months.</i> Ndingqibe ukuba andifuni ukuba nomntwana kwixesha elizayo = 3 <i>I have decided that I do not want to have a child in the future.</i> Andiqinisekanga ukuba ndiyamfuna okanye andimfuni umntwana kwixesha elizayo = 4 <i>I am unsure about whether or not I want to have a child in the future.</i> Okunye = 5, cacisa: _____ <i>Other = 5, specify</i>

Date completed: _ / _ / _

Signed counsellor completing CRF: _____

Date of QC: _ / _ / _

Signed measurement nurse: _____



1.8 The London Measure of Unplanned Pregnancy

MCH-ART: The London Measure of Unplanned Pregnancy (LMUP)
X-E Version 1.0 17 May 201

PID: 1- _____

Umhla Wotyelelo Visit Date		DD / MMM / YYYY
Ngezantsi kunemibuzo ebuza ngemeko kunye nezimvo zakho ngeli xesha umithe. Noeda cinga ngolu mitho lwangoku xa uphendula lemibuzo ingezantsi. Below are some questions that ask about your circumstances and feelings around the time you became pregnant. Please think of your current pregnancy when answering the questions below.		
1.	Kwinyanga endimthe ngayo.... In the month that I became pregnant..... (Nceda tikisha intetha engqamelene nawe kakhulu): (Please tick the statement which most applies to you):	1. Mna/besingalu sebenzisi ucwangciso. I/we were not using contraception 2. Mna/besilusebenzisa ucwangciso, kodwa hayi lonke ixesha I/we were using contraception, but not on every occasion 3. Mna/besilusebenzisa rhoqo ucwangciso, kodwa sisazi ukuba uhlobo alusebenzi (igqabhukile, ishenxile, iphumile, iphumile ngaphandle, ayisebenzi) kwankanje nje. I/we always used contraception, but knew that the method had failed (i.e. broke, moved, came off, came out, not worked etc) at least once 4. Mna/besilusebenzisa rhoqo ucwangciso. I/we always used contraception
5.	Kwindima yokuba ngumama(okokuqala, okanye ndiphinde) ndiziva ukuba umitho lwenzeke. In terms of becoming a mother (first time or again), I feel that my pregnancy happened at the..... (Nceda tikisha intetha engqamelene nawe kakhulu): (Please tick the statement which most applies to you):	1. Lixesha elilungileyo right time 2. ok, kodwa ayilo xesha elulingileyo ok, but not quite right time 3. lixesha elingalunganga wrong time
4.	Nje phambi kokuba ndimithe.... Just before I became pregnant..... (Nceda tikisha intetha engqamelene nawe kakhulu): (Please tick the statement which most applies to you):	1. Bendizimisela ukumitha I intended to get pregnant 2. Lingcinge zam bezintshentsho my intentions kept changing 3. Bendingazimisele ukumitha I did not intend to get pregnant
4.	Nje phambi kokuba ndimithe.... Just before I became pregnant..... (Nceda tikisha intetha engqamelene nawe kakhulu): (Please tick the statement which most applies to you):	1. Bendifuna ukuba nosana I wanted to have a baby 2. Imizwa yam ibibethabethana ngokuba nosana I had mixed feelings about having a baby 3. Bendingafuni ukuba nomtwana I did not want to have a baby
4.	Phambe kokuba ndimithe.... Before I became pregnant..... (Nceda tikisha intetha engqamelene nawe kakhulu): (Please tick the statement which most applies to you):	1. Iqabane lam, nam sivumelene ukuba ndimithe My partner and I had agreed that we would like me to be pregnant 2. Iqabane lam, nam sixotile ukuba sibababawana sobabini kodwa asavumelana ukuba mna ndimithe My partner and I had discussed having children together, but hadn't agreed for me to get pregnant 3. Asikhangela sixoxe ngokuba nabantwana sobabini We never discussed having children together
4.	Phambi kokuba imithe, ikho into oyenzileyo ukuphucula impilo yakho ulungiselela umitho? Before you became pregnant, did you do anything to improve your health in preparation for pregnancy? (Nceda tikisha zonke engqamelene nawe) (Please tick all that apply)	a. Ndiye iFolic Acid took folic acid b. Ndiyekile okanye ndabuyise unyawo ekutshayeni stopped or cut down smoking c. Ndiyekile okanye ndabuyise unyawo ekuseleni stopped or cut down drinking alcohol d. Ndiye ukutya okusempilweni ate more healthily e. Ndiye ndafuna amacebisa empilo sought medical/health advice f. Ndiye ndathethe amanye amanyathelo nceda chaze: took some other action, please describe: Okanye/or g. Akukho nenye endiyenzileyo kwezi zisentla phambi ndimithe I did not do any of the above before my pregnancy

1.9 Journal submission guidelines: PLOS ONE

Style and Format	
File format	Manuscript files can be in the following formats: DOC, DOCX, RTF, or PDF. Microsoft Word documents should not be locked or protected.
Length	Manuscripts can be any length. There are no restrictions on word count, number of figures, or amount of supporting information. We encourage you to present and discuss your findings concisely.
Font	Use any standard font and a standard font size.
Headings	Limit manuscript sections and sub-sections to 3 heading levels. Make sure heading levels are clearly indicated in the manuscript text.
Layout	Do not format text in multiple columns.
Abbreviations	Define abbreviations upon first appearance in the text. Do not use non-standard abbreviations unless they appear at least three times in the text. Keep abbreviations to a minimum
Reference style	PLOS uses “Vancouver” style, as outlined in the ICMJE sample references.
Manuscript Organization	
Beginning section	The following elements are required, in order: Title page: List title, authors, and affiliations as first page of manuscript Abstract Introduction
Middle section	The following elements can be renamed as needed and presented in any order: Materials and Methods Results Discussion Conclusions (optional)
Ending section	The following elements are required, in order: Acknowledgments References Supporting information captions (if applicable)
Other elements	Figure captions are inserted immediately after the first paragraph in which the figure is cited. Figure files are uploaded separately. Tables are inserted immediately after the first paragraph in which they are cited. Supporting information files are uploaded separately

2.0 Additional results on reliability and validity of the LMUP

Table 5: Cronbach's alpha test of reliability of the London Measure of Unplanned Pregnancy

item	Newly diagnosed	Known HIV+ on ART	Known HIV+ not on ART	HIV negative
Contraception	0.885	0.905	0.905	0.85
Timing	0.781	0.825	0.808	0.744
Intention	0.756	0.802	0.788	0.716
Desire	0.755	0.803	0.79	0.712
Partner	0.769	0.815	0.802	0.727
Preparation	0.867	0.885	0.873	0.858
Test scale	0.836	0.866	0.856	0.806
Overall test scale	0.852			0.806

Table 6: Principal component analysis testing the validity of the LMUP

Items	Component 1 (Eigen value=3.6)	Component 2 (Eigen value=0.9)
Contraception	0.162	0.958
Timing	0.449	0.008
Intention	0.497	-0.144
Desire	0.498	-0.133
Partner	0.475	-0.121
Preparation	-0.22	-0.165