UNIVERSITY OF CAPE TOWN
IYUNIVESITHI YASEKAPA • UNIVERSITEIT VAN KAAPSTAD

POSTPARTUM CONTRACEPTIVE USE IN HIV-POSITIVE WOMEN WHO STARTED ANTIRETROVIRAL THERAPY IN PREGNANCY IN CAPE TOWN

REGINALD T. SHUUYA

STUDENT NUMBER: SHYREG001

Dissertation submitted in partial fulfilment of the requirements for the degree of

Master of Public Health

(Epidemiology and Biostatistics)

Supervisor: Dr. Jasantha Odayar

July 2023

PREAMBLE

Declaration

I, Reginald Tuleni Shuuya (SHYREG001), hereby declare that the work on which this dissertation/thesis is based is my original work (except where acknowledgement indicate otherwise) and that neither the whole work nor any part of it has been, is being, or is to be submitted for another degree in this or any other university.

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Acknowledgements

First and foremost, I would like to express my sincere gratitude to Almighty God for strength, protection, guidance, and blessings during the course of the study. Most importantly, I would like to thank my supervisor Dr. Jasantha Odayar, for it would have been impossible for me to complete this study without her outstanding and significant support and advice. Moreover, I would like to thank to thank all my lecturers and classmates for their academic contribution towards the success of this project. I would also like to thank my mother Anna Ndamonako Shipale for her endless support (financial, spiritual, and emotional) throughout the course of my study. Furthermore, I thank Ms. Lahja Hipondoka for her continuous support. Lastly, I would like to thank my friends and family for their valuable contribution towards my studies and for always believing in me.

Abstract

Objective: This study described factors associated with at least one episode of unmet need for contraception up to 24 months postpartum in women who began ART during pregnancy in Gugulethu, Cape Town.

Methods: This was a retrospective review of data from a broader trial of antiretroviral drug delivery to women living with HIV during the postpartum period. Between 11 January 2016 and 10 November 2017, a total of 409 women living with HIV who had been on ART for at least three months, were at least 18 years old and within 28 days of delivery participated in the study. Interviews were conducted to get information on family planning use and pregnancy intentions. The proportion of women who do not want to get pregnant in the next 12 months and are not using contraception was used to calculate the unmet demand for contraception. The factors associated with unmet need for contraception up to 24 months postpartum in women who began ART during pregnancy were investigated using binary logistic regression. The outcome of interest is the episode of unmet need for contraception.

Results: Contraceptive use was high at each visit with the uptake of 97.80% at the first visit (enrolment). The overall prevalence of unmet family planning need was 19.60%. Women who are not married in this study were (OR=2.09, 95% CI: 1.26-3.47) more likely to have an unmet need for family planning and women who had been pregnant twice or more were (OR=2.24, 95% CI: 1.66-3.03) more likely to have an unmet need for family planning compared to the once who had been pregnant once.

Conclusion: Contraceptive use among these women was high. The findings highlight that unmet need remains a source of concern in unmarried women and those who have been pregnant more than once. The findings can help drive national public health strategies to meet unmet contraceptive needs in women living with HIV through improving family planning

initiatives and more effectively integrating family planning services into HIV treatment facilities.

List of abbreviations

AC-Adherence Club

ANC- Antenatal care

ART- Antiretroviral therapy

HIV- Human Immunodeficiency Virus

MOU- Midwife obstetric unit

PACART- postpartum adherence clubs for antiretroviral therapy trial

PMTCT- Prevention of mother-to-child-transmission

STIs-Sexually Transmitted Infections

SA-South Africa

SSA-Sub-Saharan Africa

SPSS- Statistical Package for Social Science

UCT- University of Cape Town

UCT-HREC- University of Cape Town Human Research Ethics Committee

Viral Load-VL

WHO- World Health Organization

Organization of the dissertation

The dissertation is organized into three sections (A, B, and C).

Part A is the research protocol, which outlines the background literature, study rationale, methods, statistical analysis strategy, ethical considerations, and references.

Part B is the journal manuscript formatted in accordance with the submission standards. This section describes the study's background, methodologies, study results, discussion of the findings, and conclusion based on the findings.

Part C is the appendices portion, which comprises ethical approval documentation, supplemental tables, and questionnaires used. The Vancouver referencing style was applied throughout the dissertation.

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PART A: RESEARCH PROTOCOL

Protocol Synopsis

The population living with Human Immunodeficiency Virus (HIV) must use contraception in order to meet their reproductive health demands [1,3]. At the end of 2019, there were 36.6 million persons living with HIV worldwide [1, 7], with around 9.7 million receiving antiretroviral medication (ART) [3]. Unmet family planning needs among women living with HIV continue to be a major concern [4]. According to a survey from the UN, more than 10% of HIV-positive women desire to delay or avoid getting pregnant but are not using any family planning methods [4, 27]. However, a high proportion of unintended pregnancies among HIV-positive women is linked to a higher risk of an unfavorable pregnancy outcome [7]. Women living with HIV tend to have more unfavorable pregnancy outcomes than women without HIV, on average [7, 33]. Despite this, there is little background about contraceptive use and unmet need in women who began ART in pregnancy, furthermore, there is an insufficient data in studies that assessed the factors associated with an unmet need for family planning in South Africa.

The objective of the proposed study is to determine the factors associated with at least one episode of unmet contraceptive demand in women who started ART during pregnancy up to 24 months postpartum. Additionally, it will establish the percentage of women who still need contraception.

The proposed study will be a secondary analysis of data obtained from a broader investigation on delivery of antiretroviral therapy to women living with HIV during postpartum period at the Gugulethu Midwife Obstetric Unit, “postpartum adherence clubs for antiretroviral therapy trial” (PACART), which got ethical permission from the local government, the facility management, and the Human Research Ethics Committee (HREC) of the Faculty of Health Sciences at the University of Cape Town (REF 194/2015). The study will make use of information that was previously gathered as part of PACART, such as demographic and

medical history learned through interviews, details on medical care gleaned from clinical records, and laboratory results gained from the PACART database.

The criteria for enrollment include females living with HIV who are less than 28 days postpartum and at least 18 years old. PACART enrolled women in the research based on community-based Adherence Club (AC) entry criteria, which included no comorbidities requiring frequent clinical follow-up and a suppressed Viral load (VL) throughout the past three months (VL 400 copies/ml) [5]. In April 2016, the eligibility criteria were broadened to include postpartum women who were up to 70 days old. Exclusion criteria included women who had the intention of relocating outside Cape Town or lost their foetus or infant. Women enrolled in the parent study were included in this analysis if they are HIV positive postpartum and started ART.

In the main study, potentially eligible women attending the Gugulethu MOU ART clinic or postnatal clinic visit were screened and if eligible and interested in the study were (mother-infant pair) referred for informed consent process to the study counsellor. Women were enrolled if informed consent was provided, underwent an enrolment interview, questionnaires were administered, blood samples were taken (VL) and they were randomized to either the general adult ART clinic management strategy or the adherence club strategy.

Participation in this study carries a significant risk of loss of confidentiality. The study will be conducted in accordance with the HREC guidelines, and no personal identifiers will be included in the extracted dataset. Only the researcher and supervisor will have access to the dataset. The data will be stored in a computer protected password and will be destroyed (5 years) after publication of the findings according to the University of Cape Town Research Ethics guidelines.

Women did not directly profit from the PACART, and they will not benefit directly from taking part in this particular analysis. The results may help the general public recognize the unmet need for contraception among postpartum women living with HIV and improve service management.

The results of this study will advance knowledge of family planning practices and hazards associated with unmet demand for contraception, as well as HIV-positive women's use of contraception, particularly during the postpartum period. It will also contribute to our understanding of the relationship between HIV, pregnancy, unmet need, and contraceptives.

1. Introduction

1.1 Background

Pregnant women are at high risk for HIV infection, with 30% of those in South Africa (SA) seeking prenatal care testing HIV positive [1]. Globally, 36.6 million persons had HIV as of the end of 2019 [1,7], with around 9.7 million receiving antiretroviral medication (ART) [1, 3]. SA carries the largest burden of HIV infection [2], with estimates that it is home to 17% of the HIV positive population in the world [2], with a prevalence of the adults (15-49) is 17.9% in 2016 [2, 8]. ART became available in SA at public clinics in 2004 and 700 000 adults were receiving ART in 2008 with the antiretroviral coverage at 31% [8]. In South Africa, Antiretroviral therapy (ART) with triple drug is administered to more than 95% of expectant HIV-positive women, lowering the risk of mother-to-child transmission from 8% in 2008 to 1.3% in 2016 [1].

Contraception and family planning are critical for women living with HIV for their own health, minimizing or reducing the likelihood of HIV infection spreading from mother to infants, and, in most circumstances, managing their fertility [9]. Furthermore, contraception can improve mother and infant health by delaying first birth, increasing birth intervals, preventing unexpected pregnancies and unsafe abortions, and also liming the number of children born to a woman [10, 26]. South Africa's (SA) fertility rate is quite low compared to other Sub-Saharan African nations, most women desire, on average, only two children [6]. Evidence revealed that, contraception also lowers the number of HIV-positive newborns [10].

Contraception use is essential in women living with HIV in order to satisfy their demands in terms of reproductive health [13]. Effective contraception can reduce new infections practically to zero [30]. Every year, more than 2 million women living with HIV become pregnant worldwide [11]. Approximately 35%-65% of women living with HIV's pregnancies in Sub-

Saharan Africa are unplanned [1], with South Africa accounting for two-thirds of these unplanned pregnancies [1, 26]. Every year, around 600,000 women living with HIV die as a result of pregnancy problems, the majority of whom live in settings with restricted resources [11, 32]. Maternal mortality could be prevented if HIV-infected women of reproductive age are encouraged to use contraception properly and consistently. Numerous studies in Africa show that many pregnancies are unplanned [1, 10, 21]. According to a South African study, among women with and without HIV, respectively, half and one-third of pregnancies were unwanted [1].

Women living with HIV are more likely to experience poor pregnancy outcomes when they become pregnant unintentionally [15]. This is due to the increased risk of unfavourable pregnancy outcomes among HIV-positive women, including unsafe abortion, the spread of STIs, delayed prenatal care, poor maternal and mental health, a decreased level of mother-child bonding, physical abuse and aggression against women, an increased risk of low birth weight, an increase in morbidity and mortality [15, 26]. Evidence suggested that women living with HIV are more likely than HIV-negative women to have poor pregnancy outcomes [7, 33]. Evidence indicated that Vertical HIV transmission causes more than 90% of paediatric AIDS [20]. However, little is known regarding pregnancy outcomes linked with unwanted pregnancies after mothers learn their HIV seropositive status, as well as usage of family planning among women living with HIV on ART [20].

Concerns about unmet need for family planning are high among HIV-positive women [25]. Over 10% of HIV-positive women desire to put off having children but do not use any methods for contraception [4, 27]. Family planning services are in great need in underdeveloped nations [26], and this may be present among women living with HIV in South Africa [28]. The World Health Organization (WHO) estimates that 222 million women in poor nations still require family planning services [4, 28]. According to several research, women living with HIV had

greater rates of undesired pregnancy and unmet family planning needs than women in the general population [22, 25, 26], but such studies for South Africa specifically are not known. In a South African study, which examined 12-month patterns of unmet need for contraception among 850 HIV-positive women who were not pregnant and receiving ART, over time, it was found that more than a quarter of the women displayed patterns of altering unmet need, and half of the women had a high risk of having their needs unmet [24]. The study did not investigate factors linked with unmet contraceptive need.

Evidence from Kenya that looked at the causes of unwanted pregnancy, poor birth outcomes and post-partum contraception among teenage girls living with HIV found that having multiple unwanted pregnancies among HIV-positive women is partially caused by inconsistent contraceptive use to prevent recurrence, while abortion is somewhat to blame for poor birth outcomes in higher order pregnancies [19]. A similar picture is most likely to be present in women living with HIV in SA. According to research from South Africa, women with HIV have higher rates of unintended births than women without the disease. This calls for more possibilities for better family planning and counselling services for women living with HIV in South Africa [1, 18]. In a similar vein, additional data point to the necessity of enhancing family planning counselling as well as addressing the unmet demand and contraceptive use among women living with HIV [10, 15].

This study discovered that although there is some background information about contraceptive use and unmet demand in women who began ART during pregnancy, there is a lack in research that examined the factors linked to unmet family planning needs in South Africa. Given well documented negative effects of unplanned pregnancies in women living with HIV, there is an urgent need for insights for the causes of unmet contraceptive needs in postpartum HIV-positive women in South Africa, who began taking ART during pregnancy [16]. The goal of this study is to pinpoint the factors that are associated with at least one instance of unmet need

for contraception up to 24 months postpartum in women who began taking ART during pregnancy. This is different from the authors who did a similar study but only followed up for 12 months instead of 24 months [24]. The difference in time would contribute to new understanding about contraceptive use in postpartum women living with HIV, and this study will fill knowledge gaps in South Africa.

1.2 Rationale of the study

Unplanned pregnancies are prevalent among women living with HIV [1]. Unplanned pregnancies among women living with HIV are connected with poor pregnancy outcomes and have unfavourable consequences for both mother and the unborn child [15, 26]. In African countries, women living with HIV are more likely to have poor pregnancy outcomes than women who do not have HIV [7], the factors associated with developing these poor pregnancy outcomes has not been evaluated in women living with HIV in the postpartum period in South Africa [15]. Despite the fact that the unmet demand for family planning is reported to be high in women living with HIV, there is a gap in research that examined the factors linked to an unmet need for family planning in South Africa [26]. By determining the factors associated with at least one episode of unmet need for contraception, we aim to provide data that will guide in predicting who is going to have an unmet need for contraception. It will also help us identify the people who are at high risk and who we must focus on in terms of addressing the unmet family planning need. The study's findings will also shed light on questions that will stimulate additional investigation into the nation's unmet need for contraception.

2. Aims and objectives

2.1 Study aim

The purpose of this study is to examine the usage of contraception among postpartum women who began ART during pregnancy and identify indicators of unmet contraceptive need up to 24 months postpartum.

2.2 Objectives of the study

1. To determine the proportion of women who started ART in pregnancy who use at least one contraceptive method post-delivery and at 3-6 monthly intervals up to 24 months postpartum.
2. To identify the pregnancy intentions in the post-delivery period and at 3-6 monthly intervals up to 24 months postpartum among women who started ART in pregnancy.
3. To determine the proportion with unmet need for contraception (do not intend to have a baby soon but are not on contraception) post-delivery and at 3-6 monthly intervals up to 24 months postpartum.
4. To determine the factors associated with at least one episode of unmet need for contraception up to 24 months postpartum in women who started ART in pregnancy.

3. Methodology

3.1 Introduction

This chapter focuses on the methods used in this study, the population, sample and the methods used for data collection and analysis. To investigate postpartum family planning use among HIV-positive women in Gugulethu, Cape Town, who began antiretroviral medication (ART). The study will use a quantitative approach. This study seeks to examine contraceptive use, determine the proportion with an unmet need for contraception and investigate predictors of having an unmet need for contraception up to 24 months postpartum.

3.2 Research design and Data source

This mini dissertation will use secondary data obtained, with permission, from the Postpartum Adherence Clubs for Antiretroviral Therapy Trial (PACART). The PACART study was a pragmatic randomized control trial comparing two delivery strategies for postpartum HIV-positive women who began ART during pregnancy [5]. As part of routine care, women starting ART in pregnancy in this setting obtain their HIV care from the antenatal clinic and are referred to the routine clinic for ongoing HIV care after delivery. For the parent study, postpartum women were enrolled and randomized to either the routine ART clinic (standard of care) or adherence clubs (AC; intervention group) [5]. Adherence clubs are the local differentiated service delivery model. General adult patients begin treatment at the regular ART clinic as part of standard care, and they may be referred to the AC if they have been on ART for at least six months, have a viral load that has been suppressed (VL 400 copies/ml), and do not have any comorbid conditions that call for ongoing clinical follow-up [5].

3.3 Study setting

The original study was carried out at the Gugulethu Midwife Obstetric Unit (MOU) in Cape Town, South Africa, which is part of the Gugulethu Community Health Centre (CHC) and provides HIV care to the general adult community of approximately 350 000 HIV-infected postpartum women predominant low socioeconomic status [5]. The midwife-nurse in the MOU provides prenatal care (ANC), PMTCT prevention services, obstetric services, and postnatal care to around 4000 women each year [5]. This population has a strong uptake of ANC, at more than 95% [5]. In 2013, the prevalence of HIV among expecting mothers attending the Gugulethu CHC was 30% [5].

3.4 Study population

Inclusion criteria included women living with HIV who were 18 years or older and within 28 days postpartum [5]. Additional eligibility criteria were based on community-based Adherence Club (AC) admision criteria, which included a suppressed VL (VL < 400 copies/ml) in the previous three months and the absence of any comorbidities necessitating regular clinical follow up [5]. In April 2016, the eligibility conditions were revised to include women up to 70 days postpartum [5]. Exclusion criteria included women who planned to relocate outside of Cape Town or who had lost a foetus or newborn. Exlusion criteria also included women living with HIV who were not keen to consent to the study.

3.5 Recruitment

In the parent study, potentially eligible women attending the Gugulethu MOU ART clinic or postnatal clinic visit were screened and if eligible and interested in the study were (mother-infant pair) referred for informed consent process to the study counsellor. Women were enrolled if informed consent was provided, underwent an enrolment interview, questionnaires were administered, blood samples were taken (VL) and they were randomized to either the general adult ART clinic management strategy or the adherence club strategy [5].

3.6 Research procedures and data collection methods

This analysis makes use of PACART data for women from the age of 18 years and above, who are expected be in the childbearing ages. There were six visits scheduled at <70 days, three months, six months, twelve months, eighteen months, and twenty-four months postpartum during the parent study. At each visit, questionnaires were used to gather data on the mother and infants, including their demographics, medical histories, and a range of ART adherence indicators (Table 1). Questionnaires were used to assess behaviour and contraception, psychological and emotional state, which may have an impact on adherence, as well as

depression, anxiety, the presence of social support, the patient-provider connection, and stigma associated with HIV [5]. Questionnaires were used for VL assessment, which was done apart from usual clinical monitoring at each study measurement visit. PACART identified eligible women for the study at a clinical visit and interviewed them once they agreed to participate.

Table 1:Baseline Characteristics

Variable	**Variable type**	**Dependent/ Independent**
Age (years)	Numerical-Continuous	independent
Province of origin	Categorical-Nominal	independent
HIV status disclosure	Categorical-binary	independent
Previous ART use	Categorical-binary	independent
HIV status of partner	Categorical-binary	independent
Status of children	Categorical-binary	independent
Number of pregnancies	Numerical-discrete	independent
Family planning use (0: yes, 1:No)	Categorical-binary	independent
Unmet need for contraception (0: yes, 1:No)	Categorical-binary	dependent
Discussed family planning with partner (1:Yes, 0:No)	Categorical-binary	independent
Pregnancy intentions: • I have decided that I do not want to have a child in the future • I may want to have a child in the next 12 months • I may want to have a child sometime in the future but not in the next 12 months • I am unsure about whether or not I want to have a child in the future	Categorical-Nominal	independent
Educational level	Categorical-ordinal	independent
Employment status	Categorical-binary	independent
Housing type	Categorical-binary	independent
Income status	Categorical-ordinal	independent
Marital status	Categorical-binary	independent
parity	Numerical-discrete	independent
NC=Numerical – Continuous, C= Categorical, B= Binary, N=Nominal, O=Ordinal		

3.7 Data analysis

The PACART study coordinator will retrieve data from the PACART database. The Statistical Package for Social Science (SPSS) Version 28 software will be used to analyze the data. The student will keep and analyse the data for this project on a computer at the University of Cape Town (UCT), and this data will not be accessible to anyone else.

The data summary statistics will be discussed whereby normally distributed data will be summarized using means and standard deviations. Non-normally distributed data will be described by the median and interquartile ranges. We shall summarize categorical variables using frequencies and proportions. The interaction between each independent variable (table 1) and each category of dependent variable will be described using cross tabulation.

Objective 1: To determine the proportion of women who started ART in pregnancy who use at least one contraceptive method post-delivery and at 3-6 monthly intervals up to 24 months postpartum. Descriptive statistics will be summarised into frequency tables and proportions. The variable that will be used for this objective "Are you using or are you on any family planning"?

Objective 2: To identify the pregnancy intentions in the post-delivery period and at 3-6 monthly intervals up to 24 months postpartum among women who started ART in pregnancy.

Descriptive statistics summarised into frequency tables and proportions. The variable that will be used for this objective "Which of the following statements best describes your own thinking about having a child in the future"? The pregnancy intention options were:

- I have decided that I do not want to have a child in the future.
- I may want to have a child in the next 12 months.
- I may want to have a child sometime in the future but not in the next 12 months.

- I am unsure about whether or not I want to have a child in the future.

Objective 3: To determine the proportion with unmet need for contraception (do not intend to have a baby in the near future but are not on contraception) post-delivery and at 3-6 monthly intervals up to 24 months postpartum. Participants who are not using contraceptives will be considered for this objective.

Data will be summarised into frequency tables and proportions. The variable that will be used for this objective "Which statement best describes your own thinking about having a child in the future"? The percentage of women who do not want children but are not currently utilizing any form of contraception will be evaluated to determine whether there is an unmet need for contraception. Women who have chosen from objective 2 that they do not want to have a child in the future, as well as those who may wish to have a child in the future but not within the next 12 months, are the ones with unmet need for contraception.

Objective 4: To determine the factors associated with at least one episode of unmet need for contraception up to 24 months postpartum in women who started ART in pregnancy. The outcome of interest is the episode of unmet need for contraception and exposure/ independent variables refer to the baseline demographic variables (table 1).

Logistic regression will be performed to identify the factors linked with at least one episode of unmet contraceptive need. The binary logistics model findings will be expressed as odd ratios to determine the relationship between the dependent variable (unmet need) and the independent variables (Table 1). The statistical significance threshold will be set at 0.05. and all significant conclusions will be concluded at 95% confident interval.

4. Ethical consideration

The Human Research Ethics Committee (HREC) of the Faculty of Health Sciences at the University of Cape Town (REF 194/2015) has already granted PACART ethical permission for the study; approval has also been secured from the local government and the facility manager. Permission for the use of PACART data will be obtained from HREC prior to submission of the request.

4.1 Risks and Benefits

The greatest risk of taking part in this study is losing one's confidentiality. The research will be carried out in conformity with the HREC criteria, and no personal identifiers will be included in the extracted dataset. Only the student and supervisor will have access to the dataset. The information will be stored in a computer protected password, and they will be destroyed (5 years) after publication of the findings according to the University of Cape Town Research Ethics guidelines.

The PACART trial did not directly benefit women, therefore taking part in this study will not result in any benefits. The results can improve service management and raise public awareness of the unmet need for contraception among postpartum women living with HIV.

4.2 Informed consent

The study staff of the parent study obtained informed consent from eligible women who agreed to participate in the PACART. For ease of understanding, the informed consent form was written in the participants' native language (isiXhosa or English). Informed consent was done in a private interview room on one-on-one basis, and they could ask questions. It was explained to clear out the issue of misunderstanding. The forms were submitted to HREC and local government before the start of the study.

A copy of the informed consent document that explained the study's objective was given to the participants, data collection methods, duration of the study, potential risks and benefits of participation, confidentiality, and anonymity of data. Authorization to analyse the databases was incorporated in the informed consent. Data has already been collected as part of PACART through interviews and database review will be used for this study.

4.3 Privacy and confidentiality

Privacy and confidentiality were skills instilled in all personnel during PACART data collection and management process. Informed consent documents which where names of the participants and other identifiers were recorded, were kept in a locked cabinet at the Gugulethu office or at UCT and only the PACART study coordinator/researcher have access to these files.

All recorded data and analysis for this project will be safely saved and analysed on a UCT computer that is password protected and only the researcher has access to. Furthermore, data will be electronically backed up on external hard drives and housed in a lockable cabinet. This information and results will be kept for 5 years.

4.4 Use of Information and publications

Presentation of the results of this analysis will be approved in cooperation with the project coordinator of the parent study.

4.5 Conclusion

This study will use secondary data collected from PACART study to investigate the contraceptive use among HIV positive women who began ART during pregnancy. All research ethical consideration will be considered at all stages of data handling. Descriptive statistics will be carried out to answer all the study objectives. Similarly, a binary logistic regression will be

carried out to investigate the association between unmet need for contraception and the demographic variables.

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PART B: MANUSCRIPT

Postpartum contraceptive use in women living with HIV who started antiretroviral therapy in pregnancy in Cape Town.

*__Reginald Tuleni Shuuya1__

Affiliations: (1) Division of Epidemiology & Biostatistics, University of Cape Town, South Africa

*Corresponding author

Reginald Shuuya, Division of Epidemiology and Biostatistics, School of Public Health and Family Medicine, Faculty of Health Sciences, University of Cape Town, Western Cape, South Africa.

Email: shyreg001@myuct.ac.za

Abstract

Objective: This study's goal was to determine the risk variables for at least one episode of unmet contraceptive need in pregnant women who started ART and followed up 24 months later.

Methods: A secondary analysis using information from a broader investigation of the administration of ART to HIV-positive women during the postpartum period. Between 11 January 2016 and 10 November 2017, ART had been administered to 409 HIV-positive women for at least three months, were at least 18 years old, and had given birth within the previous 28 days were enrolled in the study. Interviews were conducted to get information on family planning use and pregnancy intentions. The unmet need for contraception was determined by looking at the percentage of women who do not want to get pregnant in the future or within the next 12 months but are not currently using any form of contraception. For women who started ART during pregnancy, binary logistic regression was used to identify the variables associated with unmet need for contraception up to 24 months postpartum. The episode of unfulfilled need for contraception is the subject of interest.

Results: This group had a high rate of family planning use, with 97.80% using it at the enrollment visit and 80.80% using it at the 24-month postpartum visit. 19.60% of women had unmet needs for family planning throughout the course of the first 24 months after giving birth. The number of pregnancies and the kind of relationship were both important predictors of unmet family planning demand in this study.

Conclusion: Even though these women often utilized contraceptives, a significant unmet need for contraception still exists. Addressing these women's unmet need for contraception would have a significant positive impact on public health by lowering unwanted births.

Introduction

Pregnant women in South Africa are more likely to contract the Human Immunodeficiency Virus (HIV), with roughly 30% of those who seek prenatal treatment testing HIV positive [1]. At the end of 2019, there were around 9.7 million people receiving antiretroviral medication (ART) [3,41] and about 36.6 million people living with HIV worldwide [3]. Globally, the major contributor of new HIV infections in children are through the vertical transmission of HIV [3,7]. 90% of all new HIV infections in 2019 occurred in Sub-Saharan Africa (SSA), with over 310 000 new infections in children [3,37,41]. New pediatric infections are nevertheless a public health issue, despite efforts to reduce vertical HIV transmission in high-burden environments [1,37].

There were 121 million unwanted pregnancies between 2015 and 2019 in the general population worldwide, and during that time, Sub-Saharan African (SSA) countries had higher rates of unplanned pregnancies than the world as a whole (91 vs. 64 unplanned pregnancies per 1000 women aged 15–49 per year, respectively) [39]. Every year, more than 2 million HIV-positive women get pregnant globally [36], of this more than 300 000 die of pregnancy-related complications annually [39]. According to a Sub-Saharan publication, there is a need to develop ways to encourage use of contraceptives for birth control and prevention of unwanted pregnancy in the postpartum period [1]. In addition, despite the fast development of ART programs in South Africa, the uptake of family planning among pregnant women living with HIV remains inadequate [36] and for these women, unwanted births still pose a serious concern [35]. Unplanned pregnancies put women living with HIV at risk because they increase the likelihood that they will delay the initiation of antenatal care (ANC), delay the diagnosis and treatment of maternal HIV, and expose the unborn child to perinatal HIV transmission [39]. Furthermore, unintended pregnancy increases maternal and child mortality and abortion rates

in HIV-positive women [34]. According to the evidence, family planning services should assist women living with HIV who are at risk of repeated unplanned pregnancies [14].

There are few unplanned pregnancy studies and unmet contraceptive needs in women living with HIV [10]. Unmet need is defined as the percentage of women of reproductive age who are married or in committed relationships, do not use contraception, do not want any more children, or want to delay having the next kid, according to a study done in Africa [15, 38]. The total unmet demand for family planning among women living with HIV in Sub-Saharan Africa was 23.70% in 2020 [41]. Addressing unmet family planning needs is a global goal for reducing maternal mortality [14]. In addition, addressing the unmet family planning needs of HIV-positive women lowers the risks and occurrence of vertical HIV infection [14]. Vertical transmission cannot be avoided until access to family planning is expanded among people living with HIV, thus eliminating unmet contraceptive need among all females has been recognized as an effective strategy to prevent new HIV infections [38].

Unmet need for family planning remains a threat to females living with HIV [28]. Furthermore, unmet need is recognized as the main cause of unplanned pregnancies [29]. The unmet demand for contraception among women living with HIV is largely due to stigma and discrimination, lack of access to family planning services, inaccurate or incomplete information about family planning use, and other factors [29].

This study concludes that there is little background about contraceptive use and unmet need in HIV positive women. Even though different efforts in SA have been made to measure unmet demand for family planning, only the magnitude and not the factors associated with unmet need was reported [1]. More research is required on the factors related to an unmet need for contraception in South African women living with HIV in order to better understand unmet demand and the associated determinants in women living with HIV in high HIV load settings.

A retrospective study on postpartum contraception use in HIV positive women who began ART during pregnancy was carried out in Cape Town to address this issue. In women who started ART during pregnancy, the study sought to identify the variables associated with at least one episode of unmet contraceptive need up to 24 months following birth. Methods

Study setting

For this analysis, a retrospective cohort analysis was done as part of a wider investigation of ART services for HIV-positive women during pregnancy. The Postpartum Adherence Clubs for Antiretroviral Therapy experiment (PACART) tested two methods for providing ART to postpartum HIV-positive mothers who began ART during pregnancy [5]. It was a randomized controlled trial. The parent research was carried out at a public primary care facility and more than 4000 women get prenatal care (ANC), PMTCT services, and postnatal care at the facility each year [5]. In 2013, the prenatal HIV prevalence among women attending the facility was approximately 30% [5].

Study Methods

Women living with HIV who had been on ART for at least three months, were at least 18 years or older, and were less than 28 days postpartum were eligible for enrollment [5]. Furthermore, prospective participants had to have a suppressed viral load (VL 400 copies/ml) in the three months prior and no comorbidities necessitating ongoing clinical monitoring, while women who had lost their fetus or newborn or who planned to leave Cape Town during the study period were not included [5]. When more women than anticipated attended their first postpartum clinic session after 28 days, the eligibility requirements were changed to allow for women up to 70 days postpartum in April 2016 [5].

Routine postnatal and ART services

Women who began ART during pregnancy in this environment received HIV care from the prenatal clinic and were subsequently referred to the routine clinic for continuous HIV care post-delivery as part of standard care. Women receive a standard postnatal clinic visit after delivery. Postpartum mothers who provided consent underwent an enrolment interview and VL testing and were then randomly assigned to either the general adult ART clinic management strategy (control group) or the Adherence club strategy (intervention group) [5]. The local differentiated service delivery model is adherent clubs. General adult patients began treatment at the routine ART clinic and may be referred to the AC if they have been taking ART for a minimum of six months, have a suppressed viral load (VL 400 copies/ml), and do not have any comorbid conditions that necessitate consistent clinical follow up [5].

Recruitment

In the parent study, after receiving a brief explanation of the study and being screened for interest, subsequent potentially eligible women attending a prenatal clinic locally known as a Midwife-Obstetric Unit (MOU) were recruited for the study [5]. The informed consent process was conducted by the study counsellors with those who satisfied the study's eligibility requirements and expressed interest. Women who supplied consent were enrolled, and VL was tested before being randomly assigned to either the conventional adult ART clinic management plan (standard of care) or the Adherence club (AC; intervention group) [5].

Data collection

This analysis used PACART data, a combination of data from both the intervention and control groups. There were six visits scheduled at <70 days, three months, six months, twelve months, eighteen months, and twenty-four months postpartum during the parent study. Every session

involved the use of questionnaires to gather data on mothers, including demographics, medical history, a variety of ART adherence metrics, family planning use, and pregnancy intentions (Table 1). The mothers' behavior, psychological state, and mental health condition were all investigated using questionnaires, which may have an impact on ART adherence [5]. At each study measurement visit, VL was measured in a manner distinct from usual clinical monitoring [5].

Statistical analysis

Summary statistics of the data were described. Means and standard deviations were used to describe data that had a normal distribution. Medians and interquartile ranges were used to depict non-normally distributed data. Frequency and proportions were used to summarize categorical variables.

Objective 1: The proportion of women who started ART in pregnancy who use at least one contraceptive method post-delivery and at 3-6 monthly intervals up to 24 months postpartum was determined. Here, women were asked by trained interviewers whether or not they were using any family planning using at least one contraceptive method post-delivery and at 3-6 monthly intervals up to 24 months postpartum.

Objective 2: The pregnancy intentions in the post-delivery period and at 3-6 monthly intervals up to 24 months postpartum among women who started ART in pregnancy were described. Women were asked by trained interviewers to choose their own thinking about having a child in the future. They had to choose from the 4 pregnancy intention options which were: “I have decided that I do not want to have a child in the future”, “I may want to have a child in the next 12 months”, “I may want to have a child sometime in the future but not in the next 12 months, I am unsure about whether or not I want to have a child in the future” and “other” were they had to specify if they chose other.

Objective 3: The proportion with unmet need for contraception was then determined at post-delivery and at 3-6 monthly intervals up to 24 months postpartum. Here, women who decided that they do not want to have a child in the future and those who may want to have a child sometime in the future but not in the next 12 months and were not on contraception are the ones with unmet need for contraception.

Objective 4: Binary logistic regression was carried out to determine the factors associated with unmet need for contraception up to 24 months postpartum in women who started ART in pregnancy. The outcome of interest is at least one episode of unmet need for contraception and exposure/ independent variables such as age, educational level, home type, relationship type, parity etc. (table 1) as they have been associated with family planning use in other studies. To determine the relationship between the dependent variable (unmet need) and the independent factors, a binary logistics model was described in terms of odd ratios. The threshold for statistical significance was set at 0.05, and all significant results were reached with a 95% confidence interval. The Statistical Package for Social Science (SPSS) version 28 was used to analyze all the data.

Ethical consideration

The Human Research Ethics Committee (HREC) of the Faculty of Health Sciences at the University of Cape Town (REF 194/2015) granted PACART ethical permission for the study; approval was also acquired from the local government and the facility manager. HREC (REF: 160/2022) provided ethical permission for the use of PACART data for this secondary analysis.

Results

Baseline and demographic characteristics of participants

This analysis comprised 409 women who participated in the study between 11 January 2016 and 10 November 2017. The median age (IQR, 26-32) was 29 years (Table 1). The median duration of ART use in pregnancy was 149 days (IQR, 114, 183), median duration of ART use at enrolment was 163 (IQR, 127, 199) and the median duration postpartum at randomisation was 10 days (IQR, 6-20). 96% of the women were born in South Africa. Out of 409 women, 12% previously used ART before index pregnancy. 98.5% of women had at least some secondary education and above, 68% were not studying or working, 53% women were living in informal housing, and 60% were not married. Almost eighty percent (79%) of the women had been pregnant twice or more and 75% had 2 or more than two children.

Table 1: Baseline characteristics of participants

Characteristic, n (%)	**N = 409**
Born in South Africa	
No	18 (4)
Yes	391 (96)
Age: Median age (IQR) years	**29 (26, 32)**
Age categories	
18-24 years	66 (16)
25-28 years	115 (28)
29-34 years	159 (39)
35 and more	69 (17)
Median duration of ART in pregnancy (IQR) days	149 (114,183)
median duration on ART at randomisation	163 (127,199)
median duration postpartum at randomisation	10 (6,20)
Index pregnancy delivered in hospital (vs clinic)	251 (61)
infant tested HIV positive at birth	0
previous ART before index pregnancy	49 (12)
Educational level	
Primary	6 (1.50)
Secondary and above	403 (98.5)
Currently working or studying	
No	278 (68)
Yes	131 (32)
Home type	
Formal Housing	192 (47)
Informal housing	217 (53)
Relationship type	
Married/cohabitating	163 (40)
Not married	246 (60)
How many times have you been pregnant	
Once	86 (21)
Twice or more	323 (79)
Parity	
1 child	103 (25)
2 or more children	306 (75)

IQR: Interquartile range

Family planning use of women at post-delivery and 3-6 months up to 24 months postpartum

Table 2 depicts family planning use of women at post-delivery and at 3-6 monthly intervals up to 24 months postpartum. As shown in table 2, most women 97.80% of 409 at <70 days postpartum has used family planning, remained constant (95.00% of 357) at 3 months visit.

There was a decrease of 14.60% in women who used family planning from 6 months (89.20% of 379) to 12 months (74.60% of 368) postpartum visit. Out of 366 women in total who attended the 18 months postpartum visit 85.20% have used family planning. There was a 10.60% increase in the number of women who used family planning from 12 (74.60 of 368) months to 85.20% of 366 at 18 months postpartum visit. There was a 4.40% decrease in women who used family planning from the 18 months to the 24 months postpartum visit.

Table 2: Family planning use of participants at post-delivery and at 3-6 monthly intervals up to 24 months postpartum.

Visits	Used Family planning	Did not use family planning	Total
<70 days PP (enrolment)	400 (97.80)	9 (2.20)	409 (100.00)
3 months PP (V2)	339 (95.00)	18 (5.00)	357 (100.00)
6 months PP (V3)	338 (89.20)	41 (10.80)	379 (100.00)
12 months PP (V4)	305 (74.60)	63 (25.40)	368 (100.00)
18 months PP (V5)	312 (85.20)	54 (14.80)	366 (100.00)
24 months PP (V6)	294 (80.80)	70(19.20)	364 (100.00)

PP: Postpartum; V: Visit

Pregnancy intentions of participants at post-delivery and at 3-6 monthly intervals up to 24 months postpartum

Table 3 presents the pregnancy intentions of participants at post-delivery and at 3-6 monthly intervals up to 24 months postpartum. As shown in table 3 women who have made the decision that they don't want to have children in the future were 237 (57.90%) of the 409 at the first visit. There has been an increase at each visit in the women who decided that they do not want to have a child in the future whereby more than seventy percent (72.00% of 364) was observed at the last (24 months) visit. Women who may want to have a child in the next 12 months were only 3 (0.70%) of 409 at the first visit (< 70 days PP), the highest (4.90% of 368) increase was

observed at the 12 months visit which later decreased to 2.50% of 364 at the 24 months visit. Women who may want to have a child sometime in the future but not in the next 12 months were 17.60% of 409 which increased to 21.40% of 379 at 6 months visit and later decreased to 16.00% of 364 at 24 months visit. In addition, women who were unsure whether or not they want a child in future have decrease over time (from 23.70 of 409 at the first visit to 7.40% of 364 at 24 months postpartum visit).

Table 3: Pregnancy intentions of women at post-delivery and at 3-6 monthly interval up to 24 months postpartum.

Visits	Decided that I do not want to have a child in the future	May want to have a child in the next 12 months	May want to have a child sometime in the future but not in the next 12 months	Unsure about whether or not I want to have a child in the future	Other	Total
<70 days PP	237 (57.90)	3 (.70)	72 (17.60)	97 (23.70)	-	409 (100)
3 months PP	217 (60.80)	7 (1.70)	72 (20.10)	62 (17.40)	-	357 (100)
6 months PP	237 (62.50)	11 (2.90)	81 (21.40)	50 (13.20)	-	379 (100)
12 months PP	240 (65.20)	18 (4.90)	73 (19.80)	37 (10.10)	-	368 (100)
18 months PP	250 (68.30)	13 (3.60)	58 (15.80)	40 (10.90)	5 (1.40)	366 (100)
24 months PP	262 (72.00)	9 (2.50)	57 (16.00)	27 (7.40)	8 (2.10)	364 (100)

PP: Postpartum

Proportion of unmet need for contraception at post-delivery and at 3-6 monthly intervals up to 24 months postpartum

The proportion of unmet need for contraception was determined at post-delivery and at 3-6 monthly intervals up to 24 months postpartum (Table 4). The unmet need for contraception (women who have decided not to have children in the future and those who might want to have children in the future but not in the next 12 months) was calculated using the percentage of women who do not want to become pregnant but are not currently using any form of

contraception. At the first visit (<70 days postpartum) a total of 5 (1.20%) women had unmet need for contraception. Total unmet need for contraception at the 3 months postpartum was 14 (3.90) and at the 6 months postpartum was 33 (8.70%). A total of 51 (13.90%) women had unmet need for contraception at 12 months postpartum visit and a total of 42 (11.50%) and 53 (14.60%) women had unmet need for contraception at 18- and 24-months postpartum visits respectively. The total unmet need has increased overtime. An increase (18.00%) was observed from 6 to 12 months postpartum and decreased by 9.00% at 18 months postpartum visit.

Table 4: Proportion with unmet need for contraception at post-delivery and at 3-6 monthly intervals up to 24 months postpartum.

Visits	**Family planning use**	**Pregnancy intentions**		**Total unmet need**
		Decided that I do not want to have a child in the future	**May want to have a child sometime in the future but not in the next 12 months**	
< 70 days PP (enrolment)	No	5 (2.10)	0 (0.00)	5/409
3 Months PP	No	8 (3.70)	6 (8.30)	14/357
6 Months PP	No	22 (9.30)	11 (13.60)	33/379
12 Month PP	No	38 (15.80)	13 (17.80)	51/368
18 Months PP	No	32 (12.90)	10 (17.20)	42/366
24 Months PP	No	44 (16.90)	9 (15.80)	53/364

PP: Postpartum

Percentage of women with and without at least one episode of unmet need for contraception over 24 months.

Table 5 presents the percentage of women with and without at least one episode of unmet need for contraception over 24 months. Women not born in SA have 27.80% of at least one episode of unmet need for contraception while women born in SA have a proportion of 32.00% of at least one episode of unmet need for contraception. Women in the age group 29-34 years have the highest proportion (34.60) of at least one episode of unmet need for contraception, while

25-28 have the lowest proportion (14.78) of at least one episode of unmet need for contraception. Concerning educational level, women with primary education have no episode of unmet need for contraception. Women who are not married have a higher proportion (50.41%) of at least one episode of unmet need for contraception compared to those that are married (15.30%) and women who have been pregnant twice or more have 52.00% of at least one episode of unmet need for contraception compared to the ones who have been pregnant only once (46.51%).

Table 5: Demographic variables in women with and without at least one episode of unmet need for contraception up to over 24 month.

Characteristic, n (%)	**Women with at least one episode of unmet need for contraception**	**Women without at least one episode of unmet need for contraception**
Born in South Africa		
No	5 (27.80)	13 (72.20)
Yes	125 (32.00)	266 (68.00)
Age categories		
18-24 years	14 (21.21)	52 (78.79)
25-28 years	17 (14.78)	98 (85.22)
29-34 years	55 (34.60)	104 (65.40)
35 and more	23 (33.30)	46 (66.70)
Educational level		
Primary	0 (0.00)	6 (100.00)
Secondary and above	130 (32.30)	273 (67.70)
Currently working or studying		
No	85 (30.60)	193 (69.40)
Yes	45 (34.40)	86 (65.60)
Home type		
Formal Housing	67 (35.10)	124 (64.90)
Informal housing	63 (28.90)	155 (71.10)
Relationship type		
Married/cohabitating	25 (15.30)	138 (84.70)
Not married	124 (50.41)	122 (49.59)
How many times have you been pregnant		

Once	40 (46.51)	46 (53.49)
Twice or more	168 (52.00)	155 (48.00)
Parity		
1 child	32 (31.10)	71 (68.90)
2 or more children	98 (32.00)	208 (68.00)

Binary logistic regression model for at least one episode of unmet need for family planning up to over 24 months postpartum.

A binary logistic regression model was used to identify the factors associated with at least one episode of unmet contraceptive need over a 24-month period. According to the logistic regression model (table 6), women who were not married were (OR=2.09, 95% CI: 1.26-3.47) more likely to have an unmet need for family planning than women who were married or cohabiting. Furthermore, women who have been pregnant twice or more were (OR=2.24, 95% CI: 1.66-3.03) more likely to have an unmet need for family planning compared to the once who had been pregnant once. All other variables (born in South Africa, age, Median duration on ART at randomisation, previous ART before index pregnancy, educational level, currently working or studying and home type) were not significantly associated with at least one episode of unmet need for contraception over 24 months.

Table 6: Binary logistic regression model for at least one episode of unmet need for family planning up to over 24 months postpartum.

Variable	Unadjusted OR [95% CI]	Adjusted OR [95% CI]	P-value
Born in South Africa			
No	Reference	Reference	-
Yes	1.96 [0.67-5.75]	1.82 [0.50-6.55]	0.362
Age in years			
18-24 years	Reference	Reference	-
25-28 years	0.88 [0.70-1.11]	0.52 [0.19-1.39]	0.193
29-34 years	0.50 [0.38-3.17]	0.55 [0.21-1.42]	0.216
35 and more	1.84 [0.33-10.18]	0.60 [0.20-1.77]	0.355
Median duration on ART at randomisation	0.67 [0.44-1.01]	6.10 [0.68-55.07]	0.107
previous ART before index pregnancy	0.97 [0.53-1.79]	0.54 [0.06-4.93]	0.584
Educational level			
Primary	Reference	Reference	-
Secondary education and above	1.94 [0.34-10.10]	0.50 [0.04-6.03]	0.580
Currently working or studying			
No	Reference	Reference	-
Yes	1.26 [0.81-1.94]	1.90 [0.21-17.15]	0.568
Home type			
Formal Housing	Reference	Reference	-
Informal housing	0.84 [0.56-1.26]	0.76 [0.13-4.59]	0.763
Relationship type			
Married/cohabitating	Reference	Reference	-
Not married	2.07 [1.28-3.59]	2.09 [1.26-3.47]	**0.004**
How many times have you been pregnant			
Once	Reference	Reference	-
Twice or more	2.05 [1.61-3.81]	2.24 [1.66-3.03]	**<0.001**

OR: odds ratio; CI: confidence interval.

Discussion

The unmet need for contraception is a crucial consideration for developing family planning services, particularly for women living with HIV. The purpose of this study was to identify the variables that contribute to unmet need for contraception up to 24 months postpartum in women who began ART in pregnancy. We found that contraceptive use was high among this cohort, although a slight decrease has been observed from the enrolment period (97.80%) to the 24 months postpartum visit (80.80%). Women whose pregnancy intention was to have a child sometime in the future increased over time and women who were unsure if they want a child or not has decreased overtime. Total unmet need for contraception at the < 70 days postpartum (enrolment) was 1.22% and 19.60% at 24-months postpartum visit. There has been an increase in total unmet need overtime. A huge increase (18%) was observed from 6 to 12 months postpartum visit. Furthermore, women who were not married were (OR=2.09, 95% CI: 1.26-3.47) more likely to have an unmet need for family planning compared to the women who were married or cohabitating and women who have been pregnant twice or more were (OR=2.24, 95% CI: 1.66-3.03) more likely to have an unmet need for family planning compared to the once who had been pregnant once.

According to this study, the number of pregnancies you've had is related to your unmet need for contraception. Surprisingly, compared to women who had given birth once, those who had experienced two or more pregnancies were more likely to have an unmet need for contraception. The study's results also showed that although this cohort used contraception often, there was still a pressing need for family planning that was not being satisfied. This might be as a result of inconsistent or non-existent family planning utilization. This is consistent with research on the contraceptive practices of HIV-positive women receiving ART

in South Africa, which found that these women's high contraceptive usage was a result of their sporadic use of family planning [11].

This study demonstrated that women living with HIV had lower levels of unmet need for family planning than other studies among HIV-positive women conducted in Zimbabwe in 2018 [38] and Uganda in 2019 [35], which revealed 37% and 39% of unmet need, respectively. This may be a result of increased contraceptive use, health services, access to ART and family planning, and trained health professionals in South Africa who are providing appropriate health education [4, 5]. Discussions regarding family planning are included in regular clinical follow-ups for women living with HIV who get ART through the health care facility [5]. Furthermore, Despite the fact that contraception is freely available at many public health sector sites in South Africa, women living with HIV are more likely to benefit from long-term, integrated interaction with non-government health care facilities than from the occasional contact with government clinics that women who are not receiving HIV treatment and care are more likely to have [4]. Additionally, it is possible that women with HIV who choose to receive treatment and care will feel more empowered than those who do not, which could result in greater rates of contraception use [8].

This study's higher percentage of contraceptive use among women is similar to data reported in Sub-Saharan Africa, which showed 81% [10]. Our findings are consistent with prior study in the country, where women living with HIV use contraception at a high rate (78%) [8].

Women who are not married in this study were (OR=2.09, 95% CI: 1.26-3.47) more likely to have an unmet need for family planning compared to the ones who were married/cohabitating. These results were in line with research from Botswana and Zimbabwe, where unmet need was twice as likely to occur in unmarried women [26, 34]. These findings could be ascribed to the fact that they are the ones who are not utilizing family planning, or to the fact that health care providers are not emphasizing the benefits of using family planning [10, 31]. These findings

were congruent with those of an Ethiopian study, which found that the probabilities of unmet need were twice as high among unmarried women as among married women [26]. This result may be explained by the widely held belief that because they are not in a legal partnership, unmarried women and their partners are more susceptible to becoming pregnant [26]. Women with unmet needs' most frequent cited reasons for non-use were mostly related to the notion that their lack of marriage and occasional sexual engagement made them less likely to become pregnant [10].

Unmet family planning needs are regarded as the main contributor to unwanted pregnancies, and they continue to pose a risk to women living with HIV [29]. Addressing unmet family planning needs is a global goal for reducing maternal mortality [14]. In addition, reducing the need for family planning among HIV-positive women reduces the likelihood of vertical HIV transmission and its prevalence [15,28]. Vertical transmission cannot be prevented until women living with HIV have more access to family planning, hence minimizing unmet demand among all females has been highlighted as an effective method of preventing new HIV infections [38].

Despite the fact that the majority of respondents said that they have used family planning in this cohort, there is still a considerable unmet need for family planning. Continuous education on the consistent use of family planning is highly advised for women living with HIV particularly those who are not married. Right information on family planning uptake is encouraged through awareness to reduce unmet need for contraception in SA. Furthermore, policymakers should take steps to meet unmet family planning needs by enhancing family planning programs and increase the integration of family planning services into HIV care delivery settings.

Strength and limitations

Although, this is a secondary study it had 6 visits over 24 months postpartum which allowed the participants to be followed for a longer time frame. The study's focus on women living with HIV, who are critical in preventing vertical transmission of HIV, adds to its strength. However, because this study was only carried out in one location in South Africa, more research in other locations is needed to determine how generalizable the research findings are to different health systems. The study excluded pregnant women living with HIV who were migrating outside of Cape Town or who had lost a foetus or infant during the period of the study [5].

Conclusion

In conclusion, although these women utilized contraceptives extensively, there is still concern over the unmet need for family planning. As a result, all ART clinics should provide information about consistent contraceptive use. While more research is needed to analyze the elements that contribute to unmet need for contraception in different locations, the current study's findings can help guide national public health interventions to address the unmet contraceptive requirements of HIV-positive women by enhancing family planning initiatives and better integrating family planning services into environments that provide HIV care. The findings of this study will help women living with HIV make informed decisions regarding contraceptive use, particularly in the post-delivery period, and will contribute to a better understanding of family planning options and the risks associated with unmet contraceptive demand. This research will also help us understand the relationship between HIV, pregnancy, unmet need, and contraception. These findings emphasize the significance of additional study to discover new determinants of unmet demand in women living with HIV.

Acknowledgements

I would like to acknowledge my supervisor, Dr Jasantha Odayar, for her significant assistance, counsel, and guidance throughout this mini dissertation. I would like to thank my mother, Anna Ndamonako Shipale, for her financial assistance during the process. Thank you for this once-in-a-lifetime opportunity.

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PART C: APPENDICES

Appendix 1: University of Cape Town Human Ethics Committee Ethics approval

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

Room 45 E-53-E-Floor- Old Main Building
Groote Schuur Hospital
Observatory 7925
Telephone (021) 406 6492
Email: hrec-submissions@uct.ac.za
Website: www.health.uct.ac.za/fhs/research/humanethics/forms

16 March 2022

HREC REF: 160/2022

Dr J Odayar
School of Public Health & Family Medicine
Falmouth Building- FHS
Email: Jesantha.odayar@uct.ac.za
Student: Shyreg001@myuct.ac.za

Dear Dr Odayar

PROJECT TITLE: POSTPARTUM CONTRACEPTIVE USE IN HIV-POSITIVE WOMEN WHO STARTED ANTIRETROVIRAL THERAPY IN PREGNANCY IN CAPE TOWN- (MASTERS CANDIDATE- REGINALD SHUUYA)

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.

This approval is subject to strict adherence to the HREC recommendations regarding research involving human participants during COVID -19, our letter dated 02 February 2022 provides guidance found on our website:
http://www.health.uct.ac.za/fhs/research/humanethics/forms

Approval is granted for one year until the 30 March 2023.

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)

The HREC acknowledge that the student: - Reginald Shuuya will also be involved in this study.

Please quote the HREC REF 160/2022 in all your correspondence.

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, where necessary, before the research may occur.

Yours sincerely

PROFESSOR H BLOCKMAN
CHAIRPERSON, FACULTY OF HEALTH SCIENCES HUMAN RESEARCH ETHICS COMMITTEE
Federal Wide Assurance Number: FWA00001637. Institutional Review Board (IRB) number: IRB00001938 NHREC-registration number: REC-210208-007
This serves to confirm that the University of Cape Town Human Research Ethics Committee complies to the Ethics Standards for Clinical Research with a new drug in patients, based on the Medical Research Council (MRC-SA), Food and Drug Administration (FDA-USA), International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use: Good Clinical Practice (ICH GCP), South African Good Clinical Practice Guidelines (DoH 2020), based on the Association of the British Pharmaceutical Industry Guidelines (ABPI), and Declaration of Helsinki (2013) guidelines. The Human Research Ethics Committee granting this approval is in compliance with the ICH Harmonised Tripartite Guidelines E6: Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) and FDA Code Federal Regulation Part 50, 56 and 312.

Appendix 2: University of Cape Town Human Ethics Committee Ethics Renewal

UNIVERSITY OF CAPE TOWN

FACULTY OF HEALTH SCIENCES
Human Research Ethics Committee

FHS016: Annual Progress Report / Renewal

HREC office use only (FWA00001637; IRB00001938) This serves as notification of annual approval, including any documentation described below.			
☐ Approved	Annual progress report	Approved until/next renewal date	31/03/2024
☐ Not approved	See attached comments		
Signature Chairperson of the HREC/ Designee		Date Signed	17/4/2023

Note: Please email this form and supporting documents (if applicable) in a combined pdf-file to hrec-enquiries@uct.ac.za.
Please clarify your plan for research-related activities during COVID-19 lockdown.
Please use the latest form found on our website:
http://www.health.uct.ac.za/fhs/research/humanethics/forms

Comments to PI from the HREC

Principal Investigator to complete the following:

1. Protocol information

Date (when submitting this form)	04 April 2023		
HREC REF Number	160/2022	Current Ethics Approval was granted until	31.03.2023
Protocol title	POSTPARTUM CONTRACEPTIVE USE IN HIV-POSITIVE WOMEN WHO STARTED ANTIRETROVIRAL THERAPY IN PREGNANCY IN CAPE TOWN		
Protocol number (if applicable)			
Are there any sub-studies linked to this study?	☐ Yes	✓ No	
If yes, could you please provide the HREC Reference number for all sub-studies? **Note:** A separate FHS016 must be submitted for each sub-study.			
Principal Investigator	Dr Jasantha Odayar		

(Note: Please complete the Closure form (FHS010) if the study is completed within the approval period)

HUMAN RESEARCH ETHICS COMMITTEE
17 APR 2023
HEALTH SCIENCES FACULTY
UNIVERSITY OF CAPE TOWN

Department / Office Internal Mail Address	School of Public Health and Family Medicine

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? **Note:** Any annual approvals for **Full Committee** review MUST be submitted on the monthly HREC submission dates. (Please send electronic copy for full committee review to hrec-submission@uct.ac.za)	☐ Yes	✓ No

If yes in 1.2 please complete section 1.3 below for invoicing purposes

1.3 Ethics Renewal Fee

Please **(tick ✓)**appropriate box for billing purposes:

Submission Type	***Description***	***New fee (Vat Incl.)***	***tick ✓***
Research funded solely from UCT departmental/ divisional/group budget	Annual evaluation of research progress report for re-certification	**R0,00**	☐
Non-sponsored student research for degree purposes at UCT/Other Universities & Colleges	Annual evaluation of research progress report for re-certification	**R0,00**	✓
Annual re-certification / Progress report (FHS016 Form)	Clinical Trial & International Grant Funded Research - Annual evaluation of research progress report for re-certification for Full Committee Approval	**R7000,00**	☐
Annual re-certification / Progress report (FHS016 Form)	Clinical Trial & International Grant Funded Research - Annual evaluation of research progress report for re-certification for Expedited review	**R3 710.00**	☐
Annual re-certification / Progress report (FHS016 Form)	National grant funded research - Annual evaluation of research progress report for re-certification for Full Committee Approval	**R6000.00**	☐
Annual re-certification / Progress report (FHS016 Form)	National Grant funded research for Annual evaluation of research progress report for re-certification for Expedited review	**R1 500,00**	☐

NB: Protocols funded by UCT (e.g. departmental funding / student research) and by certain grant funding organizations (e.g. MRC, NRF, CANSA,) are exempt from these charges.

Please provide details for Invoicing, either complete section 1 or 2 :

1. Invoice billing – Directly to Sponsor

Sponsor's name	
Billing Address of Sponsor:	
Vat Number:	

(Note: Please complete the Closure form (FHS010) if the study is completed within the approval period)

Contact person	
Telephone number	
Email Address	
2. **Internal Journal Billing:**	
Fund Number:	
Cost Centre Number:	
Account Holder Name:	
Division of Account Holder:	

2. List of documentation for approval

3. Protocol status (tick ✓)

☐	Open Enrolment
☐	Closed to enrolment (tick ✓)
☐	Research-related activities are ongoing
☐	Research-related activities are complete, long-term follow-up only
✓	Research-related activities are complete, data analysis only
☐	Main study is complete but sub-study research-related activities are ongoing
☐	Study is closed → Please submit a Study Closure Form (FHS010)

4. Enrolment

Number of participants enrolled to date	N/A
Number of participants enrolled, since last HREC Progress report (continuing review)	N/A
Additional number of participants still required	N/A

5. Refusals

Total number of refusals (participants invited to join the study, but refused to take part)	N/A

(Note: Please complete the Closure form (FHS010) if the study is completed within the approval period)

6. Cumulative summary of participants

Total number of participants who provided consent	**N/A**
Number of participants determined to be ineligible (i.e. after screening)	N/A
Number of participants currently active on the study	N/A
Number of participants completed study (without events leading to withdrawal)	N/A
Number of participants withdrawn at participants' request (i.e. changed their mind)	N/A
Number of participants withdrawn by PI due to toxicity or adverse events	N/A
Number of participants withdrawn by PI for other reasons (e.g. pregnancy, poor compliance)	N/A
Number of participants lost to follow-up. Please comment below on reasons for loss of follow-up.	N/A
N/A	
Number of participants no longer taking part for reasons not listed above. Please provide reasons below:	
N/A	

7. Progress of study

Please provide a brief summary of the research to date including the overall progress and the progress since the last annual report as well as any relevant comments/issues you would like to report to the HREC:
This is a secondary data analysis. Data analysis is almost complete.

8. Protocol violations and exceptions (tick ✓ all that apply)

✓	No prior violations or exceptions have occurred since the original approval
☐	Prior violations or exceptions have been reported since the last review and have already been acknowledged or approved
☐	Unreported minor violations that have occurred since the last review, as well as significant deviations not yet reported, are attached for review

9. Amendments (tick ✓ all that apply)

✓	No Prior amendments have been made since the original approval
☐	Prior amendments have been reported since the last review and have already been approved

(Note: Please complete the Closure form (FHS010) if the study is completed within the approval period)

☐	New protocol changes/ amendments are requested as part of this continuing review (See note below)

Note: If new protocol changes are being requested in this review, please complete an amendment form (FHS006).
Specific changes in the amended protocol and consent/assent forms must be **bolded**, *italicised* or tracked and all changes must include a rationale.

10. Adverse events

10.1 Please provide below or attach a narrative summary of serious adverse events and/ or unanticipated problems since the last progress report. Please indicate changes made to the protocol and informed consent document(s) as a result (if not already reported to the HREC). Please comment on whether causality to any study procedure or intervention could be established.
No adverse events since last protocol. There is no patient contact, this is a secondary data analysis only.

10.2 Have participants received appropriate treatment/ follow-up/ referral when indicated (e.g. in the case of abnormal or incidental clinical findings, distress or anxiety)?		
☐ Yes	☐ No	✓ Not applicable
If yes, please describe:		
N/A. There is no patient contact.		

11. Summary of Monitoring and Audit Activities (tick ✓)

11.1 Was this study monitored or audited by an external agency (e.g. SAHPRA, FDA)?		
☐ Yes	☐ No	✓ Not applicable

11.2 Did a Data and Safety Monitoring Board publish a report?		
☐ Yes	☐ No	✓ Not applicable

11.3 If yes, please identify the agency and attach a summary of the findings.					
Agency Name	N/A	Report attached	☐ Yes	☐ No	☐ Not applicable
		DSMB report attached	☐ Yes	☐ No	☐ Not applicable

11.4 Has there been any agency, institutional or other inquiry into non-compliance in this study, or any finding of non-compliance concerning a member of the research team?	
☐ Yes	✓ No
If yes, please explain:	

(Note: Please complete the Closure form (FHS010) if the study is completed within the approval period)

12. Level of risk (tick ✓)

12.1 In light of your experience of this research, please indicate whether the level of risk to participants has:	
☐	Increased
☐	Decreased
☐	Shown no change
If there has been a change, please explain:	
No change.	

12.2 Please provide a narrative summary of recent relevant literature that may have a bearing on the level of risk.
None

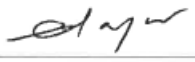
13. Insurance

Please confirm that valid no fault insurance is still in place? **(tick ✓)**			
☐ Yes		✓ No	
If yes, please complete the following:			
Insurer's name:			
Policy no.		*Coverage Period:	
For UCT sponsored studies please liaise the Insurance office via fhs.sponsorship@uct.ac.za regarding the required documentation and information required obtain a renewed UCT No-fault Insurance Certificate.			

14. Statement of conflict of interest

Has there been any change in the conflict of interest status of this protocol since the original approval? (tick ✓)	
☐ Yes	✓No
If yes, please explain and if necessary, attach a revised conflict of interest statement (Section #7 in the New Protocol Application Form FHS013):	
N/A	

15. Signature

My signature certifies that the above is complete and correct.			
Signature of PI		Date	14.04.2023

(Note: Please complete the Closure form (FHS010) if the study is completed within the approval period)

Appendix 3: University of Cape Town Human Ethics Committee Ethics approval (PACART)

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

Room E52-24 Old Main Building
Groote Schuur Hospital
Observatory 7925
Telephone [021] 406 6338 • **Facsimile** [021] 406 6411
Email: shuretta.thomas@uct.ac.za
Website: www.health.uct.ac.za/fhs/research/humanethics/forms

17 April 2015

HREC REF: 194/2015

Prof L Myer
Epidemiology & Biostatistics
Public Health & Family Medicine
Falmouth Building

Dear Prof Myer

PROJECT TITLE: POSTPARTUM ADHERENCE CLUBS FOR ANTIRETROVIRAL THERAPY (PACART)

Thank you for submitting your study to the Faculty of Health Sciences Human Research Ethics Committee 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 30th April 2016.

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.

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

Yours sincerely

pp T Burgess

PROFESSOR M BLOCKMAN
CHAIRPERSON, FHS HUMAN RESEARCH ETHICS COMMITTEE
Federal Wide Assurance Number: FWA00001637.
Institutional Review Board (IRB) number: IRB00001938
This serves to confirm that the University of Cape Town Human Research Ethics Committee complies to the Ethics Standards for Clinical Research with a new drug in patients, based on the Medical Research Council (MRC-SA), Food and Drug Administration (FDA-USA), International Convention on Harmonisation Good Clinical Practice (ICH GCP), South African Good Clinical Practice Guidelines (DoH 2006), based on the Association of the British Pharmaceutical Industry Guidelines (ABPI),and Declaration of Helsinki guidelines.

The Human Research Ethics Committee granting this approval is in compliance with the ICH Harmonised Tripartite Guidelines E6: Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) and FDA Code Federal Regulation Part 50, 56 and 312.

HREC 194/2015

Appendix 4: University of Cape Town Human Ethics Committee Ethics Renewal (PACART)

UNIVERSITY OF CAPE TOWN

FACULTY OF HEALTH SCIENCES
Human Research Ethics Committee

FHS016: Annual Progress Report / Renewal

5 OCT 2016

HEALTH SCIENCES FACULTY
RESEARCH ETHICS COMMITTEE
UNIVERSITY OF CAPE TOWN

HREC office use only (FWA00001637; IRB00001938) This serves as notification of annual approval, including any documentation described below			
☑ Approved	Annual progress report	Approved until/next renewal date	30.10.2017
☐ Not approved	See attached comments		
Signature Chairperson of the HREC		Date Signed	7/10/16

Comments to PI from the HREC

Principal Investigator to complete the following:

1. Protocol information

Date (when submitting this form)	03 Oct 2016		
HREC REF Number	451/2012	Current Ethics Approval was granted until	30 OCT 2016
Protocol title	Strategies to optimize 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 Ref's for all sub-studies? **Note:** A separate FHS016 must be submitted for each sub-study.	**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	CIDER, 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 the study receives US Federal Funding, does the annual report require full committee approval?	☐ Yes	✓ No

(Note: Please complete the Closure form (FHS010) if the study is completed within the approval period)

1.3 Has sponsorship of this study changed? If yes, please attach a revised summary of the budget.	☐ Yes	✓ No

2. List of documentation for approval

1. Protocol version 2.2 08 May 2015

3. Protocol status (tick ✓)

☐	Open to enrolment
✓	Closed to enrolment (tick ✓)
	Research-related activities are ongoing
	Research-related activities are complete, long-term follow-up only
✓	Research-related activities are complete, data analysis only
☐	Main study is complete but sub-study research-related activities are ongoing
☐	Study is closed → Please submit a Study Closure Form (FHS010)

4. Enrolment	
Number of participants enrolled to date	Phase 1: 1554 Phase 2: 628 Phase 3: 472
Number of participants enrolled, since last HREC Progress report (continuing review)	Phase 1: 0 Phase 2: 0 Phase 3: 26
Additional number of participants still required	Phase 1: 0 Phase 2: 0 Phase 3: 0

5. Refusals	
Total number of refusals (participants invited to join the study, but refused to take part)	Phase 1: 0 Phase 2: 2 Phase 3: 8

6. Cumulative summary of participants	
Total number of participants who provided consent	Phase 1: 1554 Phase 2: 628 Phase 3: 472
Number of participants determined to be ineligible (i.e. after screening)	Phase 1: 286 Phase 2: 899 Phase 3: 125
Number of participants currently active on the study	Phase 1: 0 Phase 2: 0 Phase 3: 0
Number of participants completed study (without events leading to withdrawal)	Phase 1: 1527 Phase 2: 597 Phase 3: 463
Number of participants withdrawn at participants' request (i.e. changed their mind)	Phase 1: 0 Phase 2: 3 Phase 3: 5
Number of participants withdrawn by PI due to toxicity or adverse events	N/A
Number of participants withdrawn by PI for other reasons (e.g. pregnancy, poor compliance)	Phase 1: 26 (were never pregnant) 1 (incorrectly enrolled) Phase 2: 0 Phase 3: 1 (incorrectly enrolled)
Number of participants lost to follow-up. Please comment below on reasons for loss of follow-up.	Phase 1: 1 Phase 2: 28 Phase 3: 25

Phase 1: she completed informed consent late on the day of booking and was unable to stay to complete phase 1 CRFs. She was scheduled to return the following day but did not return. No contact details were collected at Phase 1 so unable to recall her.

Phase 2:

12 moved out of Cape Town

5 had a miscarried/stillbirth and did not return for final study visit - we were unable to track them by phone or home visits

11 had no successful contact after repeated telephone calls and home visits. Follow up was discontinued when the mother would have been out of the window for the postpartum phase

Phase 3:

25 women had no successful contact after repeated telephone calls and home visits. Active follow up attempts were discontinued when the mother would have been at least 20 months postpartum

Number of participants no longer taking part for reasons not listed above. Please provide reasons below:	Phase 1: 0 Phase 2: 1 Phase 3: 3

Phase 2: 1 participant died

Phase 3: 1 participant relocated permanently out of South Africa

2 participants died

7. Progress of study

Please provide a brief summary of the research to date including the overall progress and the progress since the last annual report as well as any relevant comments/issues you would like to report to the HREC:

Currently we have completed follow-up for all three phases and we are at data analysis. The primary outcomes have been finalized using dummy allocations and subsequently the random allocations have been unblinded.

Since the last annual renewal work from this study has been presented at international conferences and submitted for publication in peer reviews journals. All study outputs are described in the tables attached. The primary trial outcomes have been submitted for presentation at the 2017 Conference on Retroviruses and Opportunistic Infections (CROI) in Seattle, USA.

Please see attached list of abstracts and posters and submitted as well as manuscripts published in various journals.

8. Protocol violations and exceptions (tick ✓ all that apply)

✓	No prior violations or exceptions have occurred since the original approval

(Note: Please complete the Closure form (FHS010) if the study is completed within the approval period)

☐	Prior violations or exceptions have been reported since the last review and have already been acknowledged or approved
☐	Unreported minor violations that have occurred since the last review, as well as significant deviations not yet reported, are attached for review

9. Amendments (tick ✓ all that apply)

✓	No prior amendments have been made since the original approval
☐	Prior amendments have been reported since the last review and have already been approved
☐	New protocol changes/ amendments are requested as part of this continuing review (See note below)

Note: If new protocol changes are being requested in this review, please complete an amendment form (FHS006).
Specific changes in the amended protocol and consent/assent forms must be **bolded**, *italicised* or tracked and all changes must include a rationale.

(Note: Please complete the Closure form (FHS010) if the study is completed within the approval period)

10. Adverse events

10.1 Please provide below or attach a narrative summary of serious adverse events and/ or unanticipated problems since the last progress report. Please indicate changes made to the protocol and informed consent document(s) as a result (if not already reported to the HREC). Please comment on whether causality to any study procedure or intervention could be established.
No study related adverse events reported.

10.2 Have participants received appropriate treatment/ follow-up/ referral when indicated (e.g. in the case of abnormal or incidental clinical findings, distress or anxiety)?		
Yes	☐ No	✓ Not applicable
If yes, please describe:		
Women were referred to appropriate care services as necessary for counselling and support and/or ART services.		

11. Summary of Monitoring and Audit Activities (tick ✓)

11.1 Was this study monitored or audited by an external agency (e.g. MCC, FDA)?		
☐ Yes	✓ No	☐ Not applicable

11.2 Did a Data and Safety Monitoring Board publish a report?		
☐ Yes	✓ No	☐ Not applicable

11.3 If yes, please identify the agency and attach a summary of the findings.					
Agency Name		Report attached	☐ Yes	☐ No	☐ Not applicable
		DSMB report attached	☐ Yes	☐ No	☐ Not applicable

11.4 Has there been any agency, institutional or other inquiry into non-compliance in this study, or any finding of non-compliance concerning a member of the research team?	
☐ Yes	✓ No
If yes, please explain:	

12. Level of risk (tick ✓)

12.1 In light of your experience of this research, please indicate whether the level of risk to participants has:	
☐	Increased
☐	Decreased
✓	Shown no change
If there has been a change, please explain:	

12.2 Please provide a narrative summary of recent relevant literature that may have a bearing on the level of risk.
N/A

13. Statement of conflict of interest

Has there been any change in the conflict of interest status of this protocol since the original approval? (tick ✓)	
☐ Yes	✓ No
If yes, please explain and if necessary attach a revised conflict of interest statement (Section #7 in the New Protocol Application Form FHS013):	

14. Signature

My signature certifies that the above is complete and correct.			
Signature of PI		Date	4/10/2016

(Note: Please complete the Closure form (FHS010) if the study is completed within the approval period)

Appendix 5: University of Cape Town Human Research Ethics Committee Ethics PACART Closure


UNIVERSITY OF CAPE TOWN
HUMAN RESEARCH ETHICS COMMITTEE
27 JAN 2021
HEALTH SCIENCES FACULTY
FACULTY OF HEALTH SCIENCES
Human Research Ethics Committee

Form FHS010: Study Closure Report

HREC office use only (FWA00001637; IRB00001938)			
Noted and filed. This serves as acknowledgement that this study is closed.			
☑ Approved	Study closure report		
☐ Not Approved	Study closure report		
Chairperson of the HREC signature/Designee		Date	30/1/24

Note: Please note that incomplete submissions will not be reviewed.
Please email this form and supporting documents (if applicable) in a combined pdf-file to hrec-enquiries@uct.ac.za.

Please clarify your plan for research-related activities during COVID-19 lockdown

1. Principal Investigator to complete the following:

Date (when submitting this form)	21 Jan 2020
HREC REF Number	194/2015
Protocol Title	Postpartum Adherence Clubs for Antiretroviral Therapy
Protocol number (if applicable)	Protocol version 5, 01 March 2020
Principal Investigator	Professor Landon Myer
Department / Office Internal Mail Address	5th Floor Falmouth Building, Division of Epidemiology and Biostatistics, School of Public Health & Family Medicine

2. Please confirm (tick ✓)

This study is closed to enrollment	✓ Yes	☐ No
Participants have completed all research-related interventions	✓ Yes	☐ No
Participants have completed all research-related follow-up	✓ Yes	☐ No
Data analysis is complete	✓ Yes	☐ No
Your sponsored protocol is closed	✓ Yes	☐ No

3. What is the reason for closing the study? [tick ✓]

Research completed	✓	No time	
Terminated due to toxicity/sickness event		PI left UCT or affiliated sites	
Slow accrual		Inadequate funding	
Loss of interest		Research never began	
Other: Please specify:			

4. For clinical trials, please describe the arrangements for provision of care after research, including (where applicable) post-trial access to the investigational product.

Not applicable

5. Please explain how the research findings have been disseminated to participants, communities, and/or stakeholders.

Results were presented at the Conference for Retroviruses and Opportunistic Infections 2020. A manuscript of the primary finding has been drafted and is being finalized for submission to a medical journal. Results will be presented at the next Western Cape Provincial Research Day and at the next Guguletu community health centre health promotion event.

6. Please confirm [tick ✓]

Have you submitted a final report to the Provincial Health Research Committee?	☐ Yes	☐ No	✓ N/A
Please note: Researchers must submit final reports to the relevant research co-ordinator/research directorate at: City Health Department, GSH, RXH, TBH, PGWC (for non-tertiary hospitals) within six months of completion of the study and may be required to report the findings of the study to other relevant authorities including the PHRC.			

7. Please indicate how, and for how long, the data will be stored and protected.

Research data will be stored for 5 years post-study closure. Participant files and other study documentation will be archived and stored by Medrite with potential access restricted to the PI.

8. Please list or attach any papers, abstracts, presentations or other outputs generated from this study.

Delayer J, Khabiba TR, Allerton J, Lesesky M, Myer L. Delivery of Antiretroviral Therapy to HIV-Infected Women During the Postpartum Period: The Postpartum Adherence Clube for Adherence Outside Antiretroviral Therapy (PACAART) Trial. Contemporary Clinical Trials Communications Delayer J, Lesesky M, Mabiba TR, Kanyanda S et al. Differentiated Care for Postpartum ART in South African Women Living with HIV: An RCT. In: Conference on Retroviruses and Opportunistic Infections, Boston, USA; 2020.

9. Signatures

Signature of PI	[redacted]	Date	26 January 2021

Appendix 6: Instructions for Authors: Plos One Journal

PLOS ONE Manuscript Guidelines

(copied from the PLOS ONE website in 2015)

1. Format Requirements

PLOS ONE does **not** consider presubmission inquiries. All submissions should be prepared with the following files:

- Cover letter
- Manuscript, including tables and figure legends
- Figures (guidelines for preparing figures can be found at the Figure and Table Guidelines)

Prior to submission, authors who believe their manuscripts would benefit from professional editing are encouraged to use language-editing and copyediting services. Obtaining this service is the responsibility of the author, and should be done before initial submission. These services can be found on the web using search terms like "scientific editing service" or "manuscript editing service." Submissions are **not** copyedited before publication.

In addition to the guidelines below, please refer to our downloadable sample files to make sure that your submission meets our formatting requirements:

- Download sample title, author list, and affiliations page (PDF)
- Download full manuscript sample (PDF)

Submissions that do not meet the *PLOS ONE* Publication Criterion for language standards may be rejected.

Cover Letter

You should supply an approximately one page cover letter that:

- Concisely summarizes why your paper is a valuable addition to the scientific literature

- Briefly relates your study to previously published work
- Specifies the type of article you are submitting (for example, research article, systematic review, meta-analysis, clinical trial)
- Describes any prior interactions with PLOS regarding the submitted manuscript
- Suggests appropriate *PLOS ONE* Academic Editors to handle your manuscript (view a complete listing of our academic editors)
- Lists any opposed reviewers

Your cover letter should **not** include requests to reduce or waive publication fees. Should your manuscript be accepted, you will have the opportunity to include your requests at that time. See *PLOS ONE* Editorial Policy for more information regarding publication fees.

Manuscript Organization

PLOS ONE considers manuscripts of any length. There are no explicit restrictions for the number of words, figures, or the length of the supporting information, although we encourage a concise and accessible writing style. We will **not** consider monographs.

All manuscripts should be double-spaced and include line numbers and page numbers.

Manuscripts should begin with the ordered sections:

- Title
- Authors
- Affiliations
- Abstract
- Introduction

and end with the sections of:

- Acknowledgments
- References
- Supporting Information Captions

Figures should be cited in ascending numeric order upon first appearance. Each figure caption should then be inserted immediately after the first paragraph in which it is cited in the article file.

Figures should not be included in the main manuscript file. Each figure must be prepared and submitted as an individual file. Find more information about preparing figures here.

Tables should be cited in ascending numeric order upon first appearance. Each table should then be inserted immmediately after the first paragraph in which it is cited in the article file.

The title, authors, and affiliations should all be included on a title page as the first page of the manuscript file.

There are no explicit requirements for section organization between these beginning and ending sections. Articles may be organized in different ways and with different section titles,

according to the authors' preference. In most cases, internal sections include:

- Materials and Methods
- Results
- Discussion
- Conclusions (optional)

PLOS ONE has no specific requirements for the order of these sections, and in some cases it may be appropriate to combine sections. Guidelines for individual sections can be found below.

Abbreviations should be kept to a minimum and defined upon first use in the text. Non-standard abbreviations should not be used unless they appear at least three times in the text.

Standardized nomenclature should be used as appropriate, including appropriate usage of species names and SI units.

PLOS articles do not support text footnotes. If your accepted submission contains footnotes, you will be asked to move that material into either the main text or the reference list, depending on the content.

Manuscript File Requirements

Authors may submit their manuscript files in Word (as .doc or .docx), LaTeX (as .pdf), or RTF format. Word files must not be protected.

LaTeX Submissions. If you would like to submit your manuscript using LaTeX, you must author your article using the *PLOS ONE* LaTeX template and BibTeX style sheet. Articles prepared in LaTeX may be submitted in PDF format for use during the review process. After

acceptance, however, .tex files will be required. Please consult our LaTeX guidelines for a list of what will be required.

Microsoft Word Submissions with Equations. If your manuscript is or will be in Microsoft Word and contains equations, you must follow the instructions below to make sure that your equations are editable when the file enters production.

1. Format display equations only in MathType (http://www.dessci.com/en/products/mathtype/).
2. Inline equations should be completely input via MathType. Do not include an equation that is part text, part MathType.
3. Do not use graphic objects.

If you have already composed your article in Microsoft Word and used its built-in equation editing tool, your equations will become unusable during the typesetting process. To resolve this problem, re-key your equations using MathType.

If you do not follow these instructions, PLOS will not be able to accept your file.

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2. Guidelines for Standard Sections

Title

Manuscripts must be submitted with both a full title and a short title, which will appear at the top of the PDF upon publication if accepted. Only the full title should be included in the manuscript file; the short title will be entered during the online submission process.

The full title must be 250 characters or fewer. It should be specific, descriptive, concise, and comprehensible to readers outside the subject field. Avoid abbreviations if possible. Where appropriate, authors should include the species or model system used (for biological papers) or type of study design (for clinical papers).

Examples:

- Impact of Cigarette Smoke Exposure on Innate Immunity: A *Caenorhabditis elegans* Model
- Solar Drinking Water Disinfection (SODIS) to Reduce Childhood Diarrhoea in Rural Bolivia: A Cluster-Randomized, Controlled Trial

The short title must be 50 characters or fewer and should state the topic of the paper.

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Authors and Affiliations

All author names should be listed in the following order:

- First names (or initials, if used),
- Middle names (or initials, if used), and
- Last names (surname, family name)

Each author should list an associated department, university, or organizational affiliation and its location, including city, state/province (if applicable), and country. If the article has been submitted on behalf of a consortium, all author names and affiliations should be listed at the end of the article.

This information cannot be changed after initial submission, so please ensure that it is correct.

To qualify for authorship, one should contribute to **all** of the following:

1. Conception and design of the work, acquisition of data, or analysis and interpretation of data
2. Drafting the article or revising it critically for important intellectual content
3. Final approval of the version to be published
4. Agreement to be accountable for all aspects of the work

All persons designated as authors should qualify for authorship, and all those who qualify should be listed. Each author must have participated sufficiently in the work to take public responsibility for appropriate portions of the content. Those who contributed to the work but do not qualify for authorship should be listed in the acknowledgments.

When a large group or center has conducted the work, the author list should include the individuals whose contributions meet the criteria defined above, as well as the group name.

All authors must approve the final manuscript before submission. PLOS ONE will contact all authors by email at submission to ensure that they are aware of the submission of the manuscript.

One author should be designated as the corresponding author, and his or her email address or other contact information should be included on the manuscript cover page. This information will be published with the article if accepted.

See the PLOS Editorial and Publishing Policies for more information.

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Abstract

The abstract should:

- Describe the main objective(s) of the study
- Explain how the study was done, including any model organisms used, without methodological detail
- Summarize the most important results and their significance
- Not exceed 300 words

Abstracts should **not** include:

- Citations
- Abbreviations, if possible

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Introduction

The introduction should:

- Provide background that puts the manuscript into context and allows readers outside the field to understand the purpose and significance of the study
- Define the problem addressed and why it is important
- Include a brief review of the key literature
- Note any relevant controversies or disagreements in the field
- Conclude with a brief statement of the overall aim of the work and a comment about whether that aim was achieved

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Materials and Methods

This section should provide enough detail to allow suitably skilled investigators to fully replicate your study. Specific information and/or protocols for new methods should be included in detail. If materials, methods, and protocols are well established, authors may cite articles where those protocols are described in detail, but the submission should include sufficient information to be understood independent of these references.

We encourage authors to submit detailed protocols for newer or less well-established methods as Supporting Information. Further information about formatting Supporting Information files, can be found here.

Methods sections of papers on research using **human or animal subjects and/or tissue or field sampling** must include required ethics statements. See the Reporting Guidelines for human research, clinical trials, animal research, and observational and field studies for more information.

Methods sections of papers with **data that should be deposited in a publicly available database** should specify where the data have been deposited and provide the relevant accession numbers and version numbers, if appropriate. Accession numbers should be

provided in parentheses after the entity on first use. If the accession numbers have not yet been obtained at the time of submission, please state that they will be provided during review. They must be provided prior to publication. A list of recommended repositories for different types of data can be found here.

Methods sections of papers using **cell lines** must state the origin of the cell lines used. See the Reporting Guidelines for cell line research for more information.

Methods sections of papers adding **new taxon names** to the literature must follow the Reporting Guidelines below for a new zoological taxon, botanical taxon, or fungal taxon.

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Results, Discussion, and Conclusions

These sections may all be separate, or may be combined to create a mixed Results/Discussion section (commonly labeled "Results and Discussion") or a mixed Discussion/Conclusions section (commonly labeled "Discussion"). These sections may be further divided into subsections, each with a concise subheading, as appropriate. These sections have no word limit, but the language should be clear and concise.

Together, these sections should describe the results of the experiments, the interpretation of these results, and the conclusions that can be drawn. Authors should explain how the results relate to the hypothesis presented as the basis of the study and provide a succinct explanation of the implications of the findings, particularly in relation to previous related studies and potential future directions for research.

PLOS ONE editorial decisions do not rely on perceived significance or impact, so authors should avoid overstating their conclusions. See the *PLOS ONE* Publication Criteria for more information.

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Acknowledgments

People who contributed to the work but do not fit the *PLOS ONE* authorship criteria should be listed in the acknowledgments, along with their contributions. You must ensure that anyone named in the acknowledgments agrees to being so named.

Funding sources should **not** be included in the acknowledgments, or anywhere in the manuscript file. You will provide this information during the manuscript submission process.

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References

General guidelines

- PLOS uses the reference style as outlined in the ICMJE sample references, also referred to as the "Vancouver" style.
- References must be listed at the end of the manuscript and numbered in the order that they appear in the text.
- In the text, citations should be indicated by the reference number in brackets.
- Authors may cite any and all available works in the reference list.
- Authors may not cite unavailable and unpublished work, including manuscripts that have been submitted but not yet accepted (e.g., "unpublished work," "data not shown").

- If an article is submitted to a journal and also publicly available as a pre-print, the pre-print may be cited.
- If related work has been submitted to PLOS ONE or elsewhere, authors should include a copy with the submitted article as confidential supplementary information, for review purposes only.
- Authors should not state 'unpublished work' or 'data not shown,' but instead include those data as supplementary material or deposit the data in a publicly available database.
- Journal name abbreviations should be those found in the NCBI databases.

Reference formatting

Because all references will be linked electronically as much as possible to the papers they cite, proper formatting of the references is crucial. References should be formatted as follows:

Published papers
1. Hou WR, Hou YL, Wu GF, Song Y, Su XL, Sun, B, et al. cDNA, genomic sequence cloning and overexpression of ribosomal protein gene L9 (rpL9) of the giant panda (*Ailuropoda melanoleuca*). Genet Mol Res. 2011;10: 1576-1588.

Note: Use of a DOI number for the full-text article is acceptable as an alternative to or in addition to traditional volume and page numbers:

Devaraju P, Gulati R, Antony PT, Mithun CB, Negi VS. Susceptibility to SLE in South Indian Tamils may be influenced by genetic selection pressure on TLR2 and TLR9 genes. Mol Immunol. 2014 Nov 22. pii: S0161-5890(14)00313-7. doi: 10.1016/j.molimm.2014.11.005

Accepted, unpublished papers
Same as above, but "In press" appears instead of the page numbers or DOI.

Websites or online articles
1. Huynen MMTE, Martens P, Hilderlink HBM. The health impacts of globalisation: a conceptual framework. Global Health. 2005;1: 14. Available: http://www.globalizationandhealth.com/content/1/1/14.

Books
1. Bates B. Bargaining for life: A social history of tuberculosis. 1st ed. Philadelphia: University of Pennsylvania Press; 1992.

Book chapters
1. Hansen B. New York City epidemics and history for the public. In: Harden VA, Risse GB, editors. AIDS and the historian. Bethesda: National Institutes of Health; 1991. pp. 21-28.

Deposited articles (preprints, e-prints, or arXiv)
1. Krick T, Shub DA, Verstraete N, Ferreiro DU, Alonso LG, Shub M, et al. Amino acid metabolism conflicts with protein diversity; 1991. Preprint. Available: arXiv:1403.3301v1. Accessed 17 March 2014.

Published media (print or online newspapers and magazine articles)
1. Fountain H. For Already Vulnerable Penguins, Study Finds Climate Change Is Another Danger. The New York Times. 29 Jan 2014. Available: http://www.nytimes.com/2014/01/30/science/earth/climate-change-taking-toll-on-penguins-study-finds.html. Accessed 17 March 2014.

New media (blogs, websites, or other written works)
1. Allen L. Announcing PLOS Blogs. 2010 Sep 1 [cited 17 March 2014]. In: PLOS Blogs [Internet]. San Francisco: PLOS 2006 - . [about 2 screens]. Available: http://blogs.plos.org/plos/2010/09/announcing-plos-blogs/.

Masters' theses or doctoral dissertations
1. Wells A. Exploring the development of the independent, electronic, scholarly journal. M.Sc. Thesis, The University of Sheffield. 1999. Available: http://cumincad.scix.net/cgi-bin/works/Show?2e09.

Databases and repositories (Figshare, arXiv)
1. Roberts SB. QPX Genome Browser Feature Tracks; 2013. Database: figshare [Internet]. Accessed: http://figshare.com/articles/QPX_Genome_Browser_Feature_Tracks/701214.

Multimedia (videos, movies, or TV shows)
1. Hitchcock A, producer and director. Rear Window [Film]; 1954. Los Angeles: MGM.

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Figure Legends

Figures should **not** be included in the manuscript file, but figure legends should be. Guidelines for preparing figures can be found here.

Figure legends should describe the key messages of a figure. Legends should have a short title of 15 words or less. The full legend should have a description of the figure and allow readers to understand the figure without referring to the text. The legend itself should be succinct, avoid lengthy descriptions of methods, and define all non-standard symbols and abbreviations.

Figures should be cited in ascending numeric order upon first appearance. Each figure caption should be inserted immediately after the first paragraph in which they are cited in the article file. Further information about figure captions can be found in the Figure Guidelines.

Supporting Information Captions

Because Supporting Information is accessed via a hyperlink attached to its captions, captions must be listed in the article file. Do not submit a separate caption file. It is acceptable to have them in the file itself in addition, but they must be in the article file for access to be possible in the published version.

The file category name and number is required, and a one-line title is highly recommended. A legend can also be included but is not required. Supporting Information captions should be formatted as follows.

S1 Text. Title is strongly recommended. Legend is optional.

Please see our Supporting Information guidelines for more details.

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Data Reporting Guidelines

All data and related metadata underlying the findings reported in a submitted manuscript should be deposited in an appropriate public repository, unless already provided as part of the submitted article. Repositories may be either subject-specific (where these exist) and accept specific types of structured data, or generalist repositories that accept multiple data types. We recommend that authors select repositories appropriate to their field. Repositories may be subject-specific (eg, GenBank for sequences and PDB for structures), general, or institutional, as long as DOIs or accession numbers are provided and the data are at least as open as CCBY. Authors are encouraged to select repositories that meet accepted criteria as trustworthy digital repositories, such as criteria of the Centre for Research Libraries or Data Seal of Approval. Large, international databases are more likely to persist than small, local ones.

To support data sharing and author compliance of the PLOS data policy, we have integrated our submission process with a select set of data repositories. The list is neither representative nor exhaustive of the suitable repositories available to authors. Current repository integration partners include: Dryad and figshare. Please contact data@plos.org to make recommendations for further partnerships.

Instructions for PLOS submissions with data deposited in an integration partner repository:

Deposit data in the integrated repository of choice. Once deposition is final and complete, the repository will provide the author with a dataset DOI (provisional) and private URL for reviewers to gain access to the data. Enter the given data DOI into the full Data Availability Statement, which is requested in the Additional Information section of the PLOS Submission form. Then provide the URL passcode in the Attach Files section. If you have any questions, please contact us at plosone@plos.org

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Accession Numbers

All appropriate datasets, images, and information should be deposited in public resources. Please provide the relevant accession numbers (and version numbers, if appropriate). Accession numbers should be provided in parentheses after the entity on first use. Suggested databases include, but are not limited to:

- ArrayExpress
- BioModels Database

- Database of Interacting Proteins
- DNA Data Bank of Japan [DDBJ]
- DRYAD
- EMBL Nucleotide Sequence Database
- GenBank
- Gene Expression Omnibus [GEO]
- Protein Data Bank
- UniProtKB/Swiss-Prot
- ClinicalTrials.gov

In addition, as much as possible, please provide accession numbers or identifiers for all entities such as genes, proteins, mutants, diseases, etc., for which there is an entry in a public database, for example:

- Ensembl
- Entrez Gene
- FlyBase
- InterPro
- Mouse Genome Database (MGD)
- Online Mendelian Inheritance in Man (OMIM)
- PubChem

Providing accession numbers allows linking to and from established databases and integrates your article with a broader collection of scientific information.

Striking Images

Authors are encouraged to upload a "striking image" that may be used to represent their paper online in places like the journal homepage or in search results. The striking image must be derived from a figure or supporting information file from the paper, ie. a cropped portion of an image or the entire image. Striking images should ideally be high resolution, eye-catching, single panel images, and should ideally avoid containing added details such as text, scale bars, and arrows. If no striking image is uploaded, a figure from the paper will be designated as the striking image.

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Tables

Tables should be cited in ascending numeric order upon first appearance. Each table should be inserted immediately after the first paragraph in which it is cited in the article file. All tables should have a concise title. Footnotes can be used to explain abbreviations. Citations should be indicated using the same style as outlined above. Tables occupying more than one printed page should be avoided, if possible. Larger tables can be published as Supporting Information. Please ensure that table formatting conforms to our Guidelines for table preparation.

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3. Specific Reporting Guidelines

Human Subject Research

Methods sections of papers on research using human subject or samples must include ethics statements that specify:

- The name of the approving institutional review board or equivalent committee(s). If approval was not obtained, the authors must provide a detailed statement explaining why it was not needed
- Whether informed consent was written or oral. If informed consent was oral, it must be stated in the manuscript:
    - Why written consent could not be obtained
    - That the Institutional Review Board (IRB) approved use of oral consent
    - How oral consent was documented

For studies involving humans categorized by race/ethnicity, age, disease/disabilities, religion, sex/gender, sexual orientation, or other socially constructed groupings, authors should:

- Explicitly describe their methods of categorizing human populations
- Define categories in as much detail as the study protocol allows
- Justify their choices of definitions and categories, including for example whether any rules of human categorization were required by their funding agency

- Explain whether (and if so, how) they controlled for confounding variables such as socioeconomic status, nutrition, environmental exposures, or similar factors in their analysis

In addition, outmoded terms and potentially stigmatizing labels should be changed to more current, acceptable terminology. Examples: "Caucasian" should be changed to "white" or "of [Western] European descent" (as appropriate); "cancer victims" should be changed to "patients with cancer."

For papers that include identifying, or potentially identifying, information, authors must download the Consent Form for Publication in a PLOS Journal (PDF), which the individual, parent, or guardian must sign once they have read the paper and been informed about the terms of PLOS open-access license. The signed consent form should not be submitted with the manuscript, but authors should securely file it in the individual's case notes and the methods section of the manuscript should explicitly state that consent authorization for publication is on file, using wording like:

> **The individual in this manuscript has given written informed consent (as outlined in PLOS consent form) to publish these case details.**

For more information about *PLOS ONE* policies regarding human subject research, see the Publication Criteria and Editorial Policies.

Appendix 7: CRFs

4. MATERNAL DEMOGRAPHICS Visit 1, Version 3

Singathanda ukubuza iimibuzo ngendawo apho usuka khona, inkcukacha ngemfundo yakho, impangelo yakho kwaye nangendlu ohlaya kuyo
We would like to ask some questions about where you are from, your schooling, employment and your household

1. Wawuzalelwe apha eMzantsi Afrika? *Were you born in South Africa?* ☐ Ewe/Yes ☐ Hayi/No

IF YES, PLEASE SKIP TO QUESTION 3

2. Uzalelwe kweliphi ilizwe? *In which country were you born?* _____

SKIP TO QUESTION 4

3. Uzalelwe apha eKapa? *Were you born in Cape Town?* ☐ Ewe/Yes ☐ Hayi/No

IF YES, PLEASE SKIP TO QUESTION 6

4. Uzalelwe kweyiphi na idolophu? *In which town/city were you born?* _____

5. Uzalelwe kweliphi na iphondo? *In which province were you born?*

☐ Western Cape ☐ Eastern Cape ☐ Free State
☐ Gauteng ☐ Kwazulu-Natal ☐ Limpopo
☐ North-West ☐ Northern Cape ☐ Mpumalanga
☐ Omnye, cacisa *Other, specify:*_____ ☐ Don't know

6. Uthetha oluphi ulwimi ekhaya? Khetha ulwimi olunye kuphela. *What language do you speak at home? Choose one.*

☐ isiXhosa *Xhosa* ☐ isiZulu *Zulu* ☐ Isibhulu *(Afrikaans)*
☐ isiNgesi *English* ☐ Omnye, cacisa *Other, specify:*_____

7. Lelephi elona banga liphezulu oliphumeleleyo? *What is the highest level of education that you have **completed**?*

☐ Awufundanga *No schooling*
☐ Isikolo samabanga aphantsi, bhala ibanga ophelele kulo *Primary school, **specify grade*** _____
☐ Isikolo samabanga aphezulu, bhala ibanga ophelele kulo *High school, **specify grade*** _____
☐ Idiploma okanye isatifiketi *Post-secondary diploma or certificate*
☐ Isidanga esiphantsi saseDyunivesithi *Bachelor's degree*
☐ Isidanga esiphezulu saseDyunivesithi *Honour's, master's or doctoral degrees*

8. Uyasebenza ngoku okanye uyafunda? *Are you currently working and /or studying?* ☐ Ewe/Yes ☐ Hayi/No

IF NO, PLEASE SKIP TO QUESTION 10

9. Ukuba nguEwe, yeyephi kwezi zilandelayo echaza, bhetele ukuba wenza ntoni? Khetha ibenye. *Which of one the following best describes what you do? Choose one only.*

☐ Ndiphangela isigxina *Employed full-time* ☐ Ndiphangela ngalomaxesha *Employed part-time*
☐ Ndiphangela izingxungxo/ndingumatheng 'ethengisa *Informal job/hawker* ☐ Ndihamba isikolo/ Ndingumfundi *Attending school/learner*
☐ Uhamba isikolo semfundo enomsila *Attending tertiary education facility* ☐ Omnye, cacisa *Other, specify:*_____

10. Uhlala kwikhaya elinjani? Ketha impendulo enye kuphela. *What kind of home do you live in? Choose one.*

☐ Indlu yesitena *Formal house* ☐ Ehostele *Hostel*
☐ Ityotyombe elisemva kwendlu yomnye umntu *Shack/informal dwelling in backyard* ☐ Ityotyombe /Ematyotyombeni *Shack/informal dwelling in informal settlement*
☐ Eflethini *Flat/apartment* ☐ Omnye, cacisa *Other, specify:*_____

11. Ingaba indlu yakho inazo ezi zinto zilandelayo: Funda kwaye uphendule yonke imibuzo. *Does your house have the following: Read and answer for all.*

a. Indlu yangasese *A toilet inside* ☐ Ewe/Yes ☐ Hayi/No
b. Amanzi abalekayo empompeni *Running water inside* ☐ Ewe/Yes ☐ Hayi/No

c. Umbane *Electricity inside* ☐ Ewe/Yes ☐ Hayi/No

d. Isikhenkcisi *A refrigerator* ☐ Ewe/Yes ☐ Hayi/No

e. Umnxeba *A home telephone* ☐ Ewe/Yes ☐ Hayi/No

f. Umabona kude *A television* ☐ Ewe/Yes ☐ Hayi/No

12. Ngowuphi owona mthombo wemali kwikhaya lakho? Khetha impendulo enye. *What is the MAJOR source of income for your household? Choose one.*

☐ Awukho *None*
☐ Umsebenzi osisigxina *Full-time employment*
☐ Umsebenzi oza ngalomaxesha *Part- time employment*
☐ Umsebenzi wezingxungxo/ Umthengisi *Informal employment*
☐ Umhlala phantsi *Pension*
☐ Imali yesibonelelo kaRhulumente *Social grant*
☐ Imali yesibonelelo sokukhubazeka kaRhulumente *Disability grant*
☐ Enye imali yesibonelelo, chaza *Other grant, specify type:*_____
☐ Omnye, cacisa *Other, specify:*_____
☐ Andazi *Don't know*

13. Ngokulinganisela, uthini umvuzo wendlu yakho ngenyanga? Khetha impendulo enye. *On average, what is your household's monthly income? Choose one.*

☐ ≤ R500
☐ R501 – R1000
☐ R1000 – R5000
☐ R5000 – R10000
☐ R10000 – R15000
☐ R15000 – R25000
☐ ≤ R 25000
☐ Andazi / *Don't know*

14. Bangaphi abantu abahlala kule ndlu bedibene nawe(abadalanabancinci)? *Including yourself, how many people (adults and children) live in your house?* ☐☐

15. Bangaphi abantu abadala (iminyakaeyi-16 nangaphezulu) bedibene nawe abahlala kule ndlu? *How many adults (aged 16 or older), including you, live in your house?* ☐☐

16. Bangaphi abantwana (iminyaka eyi-15 nangaphantsi) abahlala nawe? *How many children (aged 15 and under) live in your house?* ☐☐

Singathanda ngoku ukubuza imibuzo edibene nesimo okuso sothandano
We would now like to ask some questions about your relationships

17. Ukhona umntu othandana naye ngoku? *Are you currently in a relationship?* ☐ Ewe/Yes ☐ Hayi/No

IF NO, PLEASE SKIP TO QUESTION 23

18. Ungaluchaza njani uthando lwakho? *How would you describe your current relationship?*

☐ Nditshatile, sihlala kunye *Married, living together*
☐ Anditshatanga ,ndiyahlalisana *Not married, living together*
☐ Nditshatile, asihlali kunye *Married, not living together*
☐ Anditshatanga, asihlali kunye *Not married, not living together*
☐ Omnye, cacisa *Other, specify:*_____

19. Lixesha elingakanani uthandana naye lomntu? *How long have you been in a relationship with this person?*

☐ Iintsuku *Days, specify number:* _____
☐ Iiveki *Weeks, specify number:* _____
☐ Iinyanga *Months, specify number:* _____
☐ Iminyaka *Years, specify number:* _____

20. Ingaba eli qabane lakho ngutata womnye wabantwana bakho (kunye nalo ukhulelwe nguye)? *Is your current partner the parent of any of your children? (including most recent pregnancy)?* ☐ Ewe/Yes ☐ Hayi/No

21. Kulonyaka udlulileyo, ingaba ukhe wabelena ngesondo nomnye umntu ngaphandle kwakhe lomntu uthandana naye ngoku? *In the last 12 months have you had any sexual relationships/sexual partners other than your current partner?* ☐ Ewe/Yes ☐ Hayi/No

IF NO, PLEASE SKIP TO QUESTION 24

22. Bunjani ubudlelwane bakho namanye amaqabane ngaphandle kweqabane lakho eli uthandana nalo? Rhangqa konke okungqamene nawe. *What is/was the nature of these other relationship(s)?*

a. Umlingane/nditshatile *Spouse/ married* ☐ Ewe/Yes ☐ Hayi/No
b. Iqabane lam *Boyfriend* ☐ Ewe/Yes ☐ Hayi/No
c. Iqabane lethutyana *Casual Partner/One Night Stands* ☐ Ewe/Yes ☐ Hayi/No

d. Omnye *Other:* ☐ Ewe/Yes ☐ Hayi/No

Uti ewe, cacisa *If yes, specify:* _____

SKIP TO QUESTION 24

23. Ingaba luhlobo oluphi lobudlwelwane okanye lothandano okhe wanalo kwezinyanga ziyi-12 zidlulileyo? *What relationship(s) have you had in the past 12 months?*

a. Umlingane/nditshatile *Spouse/ married* ☐ Ewe/Yes ☐ Hayi/No

b. Iqabane lam *Boyfriend* ☐ Ewe/Yes ☐ Hayi/No

c. Iqabane lethutyana *Casual Partner/One Night Stands* ☐ Ewe/Yes ☐ Hayi/No

d. Omnye *Other:* ☐ Ewe/Yes ☐ Hayi/No

Uti ewe, cacisa *If yes, specify:* _____

Singathanda ngoku ukubuza imibuzo edibene nokukhelwa kwakho kwaye nabantwana bakho
We would now like to ask some questions about your pregnancies and children

24. Wakhe wakhulelwa phambi koku ukukhulelwa? *Have you ever been pregnant before this most recent pregnancy?* ☐ Ewe/Yes ☐ Hayi/No

IF NO, PLEASE SKIP TO QUESTION 28

25. Ukhulelwe kangaphi ngaphambili (oku kuquka esi isisu)? *How many times have you been pregnant in total (including most recent pregnancy)?* ☐☐

26. Ngelixesha ubukhulelwe ngaphambili phambi kokuba ukhulelwe ngoku, ingaba ukhe wanikwa amayeza akhusela usana ukuze lungasulelwa yiNtsholongwane kaGawulayo (apha sithetha ngeepilisi ezikhusela umntwana hayi amachiza okuthomalalisa iNtsholongwane kaGawulayo atyiwa ubomi bakho bonke). *When you were pregnant before this last pregnancy have you ever been given medication at the clinic to keep your baby from getting HIV infected? (prophyloxis NOT lifelong ART)* ☐ Ewe/Yes ☐ Hayi/No

IF NO, PLEASE SKIP TO QUESTION 28

27. Ukuba nguEwe, zingaphi izisu ufumane la machiza ngesisizathu? *If yes, during how many pregnancies have you received medication for this purpose?* ☐☐

28. Bangaphi abantwana obazeleyo? *How many children have you given birth to?* ☐☐

CRF COMPLETED BY: ☐☐☐

29. Bangaphi kwaba bantwana abaphilayo? *How many of these children are living?* ☐☐

30. Bangaphi kwaba bantwana abahlala nawe ngoku? *How many of these children currently live with you?* ☐☐

31. Bangaphi kwaba bantwana bakho ekufumaniseke ukuba baphila neNtsholongwane kaGawulayo? *How many of your children have been diagnosed with HIV?* ☐☐

IF NO CHILDREN HAVE TESTED HIV POSITIVE, SKIP TO QUESTION 33

32. Kwaba bantwana baphila Nentsholongwane kaGawulayo bangaphi abasaphilayo? *How many of these children who have tested HIV- positive are currently living?* ☐☐

NGOKU SIFUNA UKUKUBUZA MALUNGA NOHAMBO
WE NOW WANT TO ASK YOU ABOUT TRAVEL

33. Ingaba uneenjongo zokuhamba apha eKapa kwinyanga ezayo? *Are you planning on travelling out of Cape Town in the next month?* ☐ Ewe/Yes ☐ Hayi/No

IF NO, END OF QUESTIONNAIRE

34. Ingaba uzohamba ixesha elingakanani? *Approximately how long will you be away?*

☐ Iintsuku *Days, specify number:* _____ ☐ Iiveki *Weeks, specify number:* _____

☐ Iinyanga *Months, specify number:* _____ ☐ Andazi *Don't know*

☐ Okunye, cacisa *Other, specify*: _____

35. Uneenjongo zokuya kweyiphi idolophu? *To which town/city are you travelling?* _____

36. Uneenjongo zokuya kweliphi iphondo? *To which province are you travelling?*

☐ Western Cape	☐ Eastern Cape	☐ Free State
☐ Gauteng	☐ Kwazulu-Natal	☐ Limpopo
☐ North-West	☐ Northern Cape	☐ Mpumalanga
☐ Omnye, cacisa *Other, specify*: _____		☐ Don't know

5. MATERNAL MEDICAL HISTORY Visit 1, Version 2

Singathanda ukubuza imibuzo edibene nemvelaphi yempilo yakho
We would like to ask some questions about your medical history

1. Ingaba uqale nini ukutya iipilisi zeNtsholongwane kaGawulayo ngelixesha ubukhulelwe ngaphambili?
When did you start taking lifelong ART in your last pregnancy? ☐☐/☐☐☐/☐☐☐☐

NOTE TO INTERVIEWER: Please double-check date treatment started in patient folder/referral letter

2. **NOTE TO INTERVIEWER:** Please document current ART regimen as recorded in file or referral letter :

☐ Tenofivir + Emtricitabine + Efavirenz (Tribuss/Odimune/Atripla)
☐ Other regimen, specify all 3 drugs: _____

3. Phambi kokuba uqale ukutya iipilisi zeNtsholognwane kaGawulayo ngelixesha ubukhulelwe ngaphambili, ingaba wakhe wazitya na iipilisi zeNtsholongwane kaGawulayo? *Prior to starting ART in your last pregnancy, were you ever on lifelong ART before?* ☐ Ewe/Yes ☐ Hayi/No

IF NO, SKIP TO QUESTION 6

4. Mangaphi amatyeli okhe wayeka waphinda waqalisa kwakhona ukutya amachiza akho? *How many times have you stopped and restarted lifelong ART?* ☐☐

MATERNAL PID: ☐☐☐☐☐-☐☐ Date: ☐☐/☐☐☐/☐☐☐☐

5. Sicela usichazele apha ezantsi onke amaxesha apho waqala ukutya iipilisi zeNtsholongwane kaGawulayo waze waziyeka: *For each time that ART was started and stopped, please specify the following:*

	Usuku lokuqala oqale ukutya iipilisi zeNtsholongwane kaGawulayo waze waziyeka *1st time ART was started and stopped*	**Usuku lwesibini apho oqale ukutya iipilisi zeNtsholongwane kaGawulayo waze waziyeka** *2nd time ART was started and stopped*	**Usuku lwesithathu oqale ukutya iipilisi zeNtsholongwane kaGawulayo waze waziyeka** *3rd time ART was started and stopped*
Usutu oqale ngalo ukutya iipilisi zeNtsholongwane kaGawulayo *Date lifelong ART started*	Umhla *Day*: _____ Inyanga *Month*: _____ Unyaka *Year*: _____	Umhla *Day*: _____ Inyanga *Month*: _____ Unyaka *Year*: _____	Umhla *Day*: _____ Inyanga *Month*: _____ Unyaka *Year*: _____
Ingaba olunyango ulufumane kweliphi iziko lezeMpilo? *Where was treatment received?*	Iziko lezeMpilo *Facility*: _____	Iziko lezeMpilo *Facility*: _____	Iziko lezeMpilo *Facility*: _____
Usuku oyeke ngalo ukutya iipilisi zeNtsholongwane kaGawulayo *Date lifelong ART stopped*	Umhla *Day*: _____ Inyanga *Month*: _____ Unyaka *Year*: _____	Umhla *Day*: _____ Inyanga *Month*: _____ Unyaka *Year*: _____	Umhla *Day*: _____ Inyanga *Month*: _____ Unyaka *Year*: _____
Sasiyiyiintoni isizathu sokuba uyeke ukuzitya iipilisi zeNtsholongwane kaGawulayo? *Why was lifelong ART stopped?*			

6.
a. Loluphi usuku owagqibela ngalo ukutya ii-ART? *When was the last day you took ART?* ☐☐/☐☐☐/☐☐☐☐

b. Uwathathe ngabani ixesha amachiza akho okuthomalalisa iNstholongwane kaGawulayo ngale mini? *What time did you take your ART on this day?* ☐☐☐☐ (HH:MM)

7. Ukhe wazitya ii-ART zakho kwezi ntsuku ziyi-7 zidlulileyo? *Have you taken ART at all in the last 7days?* ☐ Ewe/Yes ☐ Hayi/No

IF YES, SKIP TO QUESTION 9

8. Ukuba hayi, kutheni? *If No, why not?*

____

____

9. Ingaba uGqirha okanye uNesi wakho wakuxelela ukuba unayo na i-TB? *Has a doctor or nurse ever told you that you have TB?* .... ☐ Ewe/Yes ☐ Hayi/No

IF NO, SKIP TO QUESTION 11

10. Uqgibele nini ukufumana iziphumo ezichaza ukuba unaso esi sigulo? *When did you receive this diagnosis the last time?* .... ☐☐/☐☐☐/☐☐☐☐

11. Wakhe walufumana unyango lwe-TB ngaphambili? *Have you ever received treatment for TB?* .... ☐ Ewe/Yes ☐ Hayi/No

IF NO, SKIP TO QUESTION 14

12. Kungamaxesha amangaphi ufumana unyango lwe-TB? *How many times in total have you been treated for TB?* .... ☐☐

13. Kwityeli ngalinye ufumana unyango lwe-TB, sicela usinike iinkcukacha apha ngasezantsi: *For each TB episode, please specify the following:*

	Episode 1	**Episode 2**	**Episode 3**
Uqale nini ukufumana unyanga lwe-TB? ***When was treatment started?***	Umhla *Day:* ________ Inyanga *Month:* ________ Unyaka *Year:* ________	Umhla *Day:* ________ Inyanga *Month:* ________ Unyaka *Year:* ________	Umhla *Day:* ________ Inyanga *Month:* ________ Unyaka *Year:* ________
Unyango lwakho lwe-TB ubulufumene kweliphi iziko lezeMpilo ***Where was treatment received?***	Iziko lezeMpilo *Facility:* ________	Iziko lezeMpilo *Facility:* ________	Iziko lezeMpilo *Facility:* ________
Unyango lwakho lwe-TB ulufumene ixesha elingakanani na? ***Duration of treatment***	☐ Iinyanga ezintandathu *6 months* ☐ Iinyanga ezisibhozo *8 months* ☐ Iinyanga ezilithoba *9 months* ☐ Enye, cacisa *Other,* ***specify*** ________ ☐ Andiyazi *Don't know*	☐ Iinyanga zintandathu *6 months* ☐ Iinyanga ezisibhozo *8 months* ☐ Iinyanga ezilithoba *9 months* ☐ Enye, cacisa *Other,* ***specify*** ________ ☐ Andiyazi *Don't know*	☐ Iinyanga ezintandathu *6 months* ☐ Iinyanga ezisibhozo *8 months* ☐ Iinyanga ezilithoba *9 months* ☐ Enye, cacisa *Other,* ***specify*** ________ ☐ Andiyazi *Don't know*
Intsholongwane ye-TB ibikweyiphi indawo emzimbeni wakho? ***Site of TB***	☐ Imiphunga *Lungs* ☐ Isisu *Abdomen* ☐ Ilungu lozimba eliliwa iiNtsholongwane *Lymph node/ Gland* ☐ Enye, cacisa *Other,* ***specify*** ________ ☐ Andiyazi *Don't know*	☐ Imiphunga *Lungs* ☐ Isisu *Abdomen* ☐ Ilungu lozimba eliliwa iiNtsholongwane *Lymph node/ Gland* ☐ Enye, cacisa *Other,* ***specify*** ________ ☐ Andiyazi *Don't know*	☐ Imiphunga *Lungs* ☐ Isisu *Abdomen* ☐ Ilungu lozimba eliliwa iiNtsholongwane *Lymph node/ Gland* ☐ Enye, cacisa *Other,* ***specify*** ________ ☐ Andiyazi *Don't know*
Ingaba ubukhulelwe ngelixesha ubunesifo sephepha (TB)? ***Were you pregnant at the time that you had TB?***	☐ Ewe/Yes ☐ Hayi/No	☐ Ewe/Yes ☐ Hayi/No	☐ Ewe/Yes ☐ Hayi/No

14. Wakhe wachitha ubusuku esibhedlele? *Have you ever spent the night in hospital?* ... ☐ Ewe/Yes ☐ Hayi/No

IF NO, SKIP TO QUESTION 16

15. Ukuba nguEwe, cacisa ngezantsi ulaliso ngalunye *If yes, list details for each admission below:*

	Isizathu ***Reason for admission***	**Ulaliswe nini?** ***Date of Admission***	**Isibhedlele/kliniki** ***Hospital/ Clinic***	**Wawukhulelwe** ***Were you pregnant at the time of admission?***
1		*Umhla Day:* ________ *Inyanga Month:* ________ *Unyaka Year:* ________		☐ Ewe/Yes ☐ Hayi/No
2		*Day:* ________ *Month:* ________ *Year:* ________		☐ Ewe/Yes ☐ Hayi/No
3		*Day:* ________ *Month:* ________ *Year:* ________		☐ Ewe/Yes ☐ Hayi/No

4		Day:_____ Month:_____ Year:_____		☐ Ewe/Yes ☐ Hayi/No
5		Day:_____ Month:_____ Year:_____		☐ Ewe/Yes ☐ Hayi/No
6		Day:_____ Month:_____ Year:_____		☐ Ewe/Yes ☐ Hayi/No

16. Wakhe walufumana unyango lweepilisi zokuthintela i-TB ngaphambili? *Have you ever taken Isoniazid Preventive therapy (IPT), including currently?* ☐ Ewe/Yes ☐ Hayi/No

IF NO, SKIP TO QUESTION 24

17. Wakhe walufumana izihlandlo ezingaphi unyango lweepilisi zokuthintela-TB? *How many times have you been on IPT?* ☐☐

18. Ingaba uyalufumana na ngoku unyango lweepilisi zokuthintela i-TB? *Are you currently on IPT?* ☐ Ewe/Yes ☐ Hayi/No

IF YES, SKIP TO QUESTION 22

19. Waqala ngoluphi usuku ngelixesha ubufumana ngalo unyango lweepilisi zokuthintela i-TB? *When was IPT started the last time you took it?* ☐☐/☐☐☐/☐☐☐☐

20. Walufumana kweliphi na iziko lezeMpilo unyango lweepilisi zokuthintela i-TB? *Where did you receive IPT the last time you took it?* Name of facility: _____

21. Wazityala ixesha elingakanani iipilisi zokuthintela i-TB? *For how long did you take IPT the last time you were on it?*

☐ Iimini *Days*, **specify number**: _____ ☐ Iiveki *Weeks*, **specify number**: _____
☐ Iinyanga *Months*, **specify number**: _____ ☐ Yiminyaka *Years*, **specify number**: _____

SKIP TO QUESTION 24

22. Waqala ngoluphi na usuku ukufumana olunyango? *When was this course of IPT started?* ☐☐/☐☐☐/☐☐☐☐

23. Walufumana kweliphi na iziko lezeMpilo olunyango lweepilisi zokuthintela i-TB? *Where are you receiving this course of IPT?* _____

24. Ingaba unalo ukhohlokhohlo ngoku? *Are you currently coughing?* ☐ Ewe/Yes ☐ Hayi/No

IF NO, SKIP TO QUESTION 26

25. Lixesha elingakanani na ngoku unalo ukhohlokhohlo? *For how long have you been coughing?*

☐ Ziimini *Days*, **specify number(chaza inani)**: ☐ Iiveki *Weeks*, **specify number**: _____
☐ Iinyanga *Months*, **specify number**: _____ ☐ Yiminyaka *Years*, **specify number**: _____

26. Ingaba unayo ifiva ngoku (ukufudumala komzimba)? *Do you currently have a fever (high temperature, hot to touch)?* ☐ Ewe/Yes ☐ Hayi/No

IF NO, SKIP TO QUESTION 28

27. Lixesha elingakanani na unayo ifiva? *For how long have you had a fever?*

☐ Ziimini *Days*, **specify number**: ☐ Iiveki *Weeks*, **specify number**: _____
☐ Iinyanga *Months*, **specify number**: _____ ☐ Yiminyaka *Years*, **specify number**: _____

28. Ingaba buyehla ubunzima bakho? *Are you currently losing weight?* ☐ Ewe/Yes ☐ Hayi/No

IF NO, SKIP TO QUESTION 31

29. Ingaba lixesha elingakanani na ubunzima bakho busihla? *For how long have you been losing weight?*

☐ Ziimini *Days, specify number:* _____ ☐ Ziiveki *Weeks, specify number:* _____

☐ Ziinyanga *Months, specify number:* _____ ☐ Yiminyaka *Years, specify number:* _____

30. Ingaba ubunzima bakho buhle kangakanani na? *Approximately how much weight have you lost during this period?* ..... Kg ☐☐☐

31. Ingaba uyabila na ebusuku? *Are you currently having night sweats?* ..... ☐ Ewe/Yes ☐ Hayi/No

IF NO, SKIP TO QUESTION 33

32. Ingaba lixesha elingakanani na ubila ebusuku? *For how long have you been having night sweats?*

☐ Ziimini *Days, specify number:* _____ ☐ Ziiveki *Weeks, specify number:* _____

☐ Ziinyanga *Months, specify number:* _____ ☐ Yiminyaka *Years, specify number:* _____

33. Ingaba unazo iintlungu esifubeni sakho? *Are you currently having chest pains?* ..... ☐ Ewe/Yes ☐ Hayi/No

IF NO, END OF QUESTIONNAIRE

34. Ingaba lixesha elingakanani uneentlungu esifubeni sakho? *For how long have you been having chest pains?*

☐ Ziimini *Days, specify number:* _____ ☐ Ziiveki *Weeks, specify number:* _____

☐ Ziinyanga *Months, specify number:* _____ ☐ Yiminyaka *Years, specify number:* _____

8. FAMILY PLANNING & PREGNANCY INTENTIONS Visit 1, Vers 1

Sicela uphendule lemibuzo edibene nezocwangciso kwaye neenjongo onazo zokukhulelwa kwakho kwixesha elizayo

We would like to ask you some questions about family planning and your future pregnancy intentions

1. Kwezi zikhuselo zocwangciso zeziphi owakhe wasisebenzisa ngaphambi kokuba ukhululwe? (Phendula yonke) *Which family planning methods did you ever use prior to your last pregnancy? (Answer all)*

   a. Ipilisi eziselwayo *Oral contraceptive pill* ..... ☐ Ewe/Yes ☐ Hayi/No

   b. Isitofu se-2('noristerat NET-en') *2-month injectable ('noristerat NET-en')* ..... ☐ Ewe/Yes ☐ Hayi/No

   c. Isitofu se-3 ('depo,petogen') *3-month injectable ('depo, petogen')* ..... ☐ Ewe/Yes ☐ Hayi/No

   d. Isivalo –mlomo lwesibeleko (IUD) *Intra-uterine device* ..... ☐ Ewe/Yes ☐ Hayi/No

   e. Isivalo nzala sabantu basetyhini *Female sterilization* ..... ☐ Ewe/Yes ☐ Hayi/No

   f. Isivalo nzala sabantu besikhomo *Male sterilization* ..... ☐ Ewe/Yes ☐ Hayi/No

   g. Idyasi kamkhwenyana *Male condom* ..... ☐ Ewe/Yes ☐ Hayi/No

   h. Idyasi kamkhwenyana (yabantu basetyhini) *Female condom* ..... ☐ Ewe/Yes ☐ Hayi/No

   i. Isivalo nzala esifakwa phakathi kweenyama zakho *Implant* ..... ☐ Ewe/Yes ☐ Hayi/No

   j. Olunye uhlobo *Other method:* ..... ☐ Ewe/Yes ☐ Hayi/No

   Uti ewe, cacisa ***If yes, specify:*** _____

2. Kwezinyanga zilishumi elinesibini phambi kokuba ukhulelwe loluphi uhlobo locwangciso ntsapho ubulisebenzisa? (Phendula yonke imibuzo) *In the 12 months before this last pregnancy, which family planning methods did you use? (Answer all)*

   a. Ipilisi eziselwayo *Oral contraceptive pill* ..... ☐ Ewe/Yes ☐ Hayi/No

   b. Isitofu se-2('noristerat NET-en') *2-month injectable ('noristerat NET-en')* ..... ☐ Ewe/Yes ☐ Hayi/No

   c. Isitofu se-3 ('depo,petogen') *3-month injectable ('depo, petogen')* ..... ☐ Ewe/Yes ☐ Hayi/No

   d. Isivalo –mlomo lwesibeleko (IUD) *Intra-uterine device* ..... ☐ Ewe/Yes ☐ Hayi/No

e. Isivalo nzala sabantu basetyhini *Female sterilization* ☐ Ewe/Yes ☐ Hayi/No

f. Isivalo nzala sabantu besikhomo *Male sterilization* ☐ Ewe/Yes ☐ Hayi/No

g. Idyasi kamkhwenyana *Male condom* ☐ Ewe/Yes ☐ Hayi/No

h. Idyasi kamkhwenyana (yabantu basetyhini) *Female condom* ☐ Ewe/Yes ☐ Hayi/No

i. Isivalo nzala esifakwa phakathi kweenyama zakho *Implant Implant* ☐ Ewe/Yes ☐ Hayi/No

j. Olunye uhlobo *Other method*: ☐ Ewe/Yes ☐ Hayi/No

Uthi ewe, cacisa *If yes, specify*: _____

3. Ingaba ubuzama ukuba nosana ngelixesha ufumanisa ukuba ukhulelwe (Kwesi isisu)? *Were you trying to have a baby when you found out you were pregnant (in this most recent pregnancy)?* ☐ Ewe/Yes ☐ Hayi/No

4. Emva kokuba mntwana wakho ezelwe ukhe wasebenzisa ucwangciso ntsapho? *Since the birth of your baby, have you used any family planning?* ☐ Ewe/Yes ☐ Hayi/No

IF NO, → SKIP TO QUESTION 7

5. Ukube ngoEwe, usebenzisa oluphi uhlobo? *If yes, what method are you using? (Answer all)*

a. Ipilisi eziselwayo *Oral contraceptive pill* ☐ Ewe/Yes ☐ Hayi/No

b. Isitofu se-2('noristerat NET-en') *2-month injectable ('noristerat NET-en')* ☐ Ewe/Yes ☐ Hayi/No

c. Isitofu se-3 ('depo,petogen') *3-month injectable ('depo, petogen')* ☐ Ewe/Yes ☐ Hayi/No

d. Isivalo –mlomo lwesibeleko (IUD) *Intra-uterine device* ☐ Ewe/Yes ☐ Hayi/No

e. Isivalo nzala sabantu basetyhini *Female sterilization* ☐ Ewe/Yes ☐ Hayi/No

f. Isivalo nzala sabantu besikhomo *Male sterilization* ☐ Ewe/Yes ☐ Hayi/No

g. Idyasi kamkhwenyana *Male condom* ☐ Ewe/Yes ☐ Hayi/No

h. Idyasi kamkhwenyana (yabantu basetyhini) *Female condom* ☐ Ewe/Yes ☐ Hayi/No

i. Isivalo nzala esifakwa phakathi kweenyama zakho *Implant* ☐ Ewe/Yes ☐ Hayi/No

j. Olunye uhlobo *Other method*: ☐ Ewe/Yes ☐ Hayi/No

Uti ewe, cacisa *If yes, specify*: _____

6. Ulufumene phi ucwangciso ntsapho emva kokuba umntwana wakho ezelwe? *Where did you get your family planning after the birth of your baby?* _____

SKIP TO QUESTION 8

7. Kutheni ungasebenzisi naluphi na uhlobo locwangciso? *Why are you not using any method of family planning since the birth of your baby?*

_____

_____

8. Kwezinyanga zilishumi elinesibini ukhe wancokola nomlingane wakho ngocwangciso ntsapho? *In the last 12 months, have you discussed family planning or pregnancy with your partner?* ☐ Ewe/Yes ☐ Hayi/No

9. Cinga ngohlobo oziva ngalo ngoku. Khetha ukuba ngowuphi umbono ongqinelana nawo ochaza iinjongo onazo zokuba nomntwana kwilixa elizayo. *Think about how you feel right now. Which of the following statements best describes your own thinking about having a child in the future? Choose one.*

☐ Ndigqibe ukuba andifuni ukuba nomntwana kwixesha elizayo *I have decided that I do not want to have a child in the future*

☐ Ndingafuna ukuba nomntwana kwithuba lenyanga eziyi-12 ezizayo *I may want to have a child in the next 12 months*

☐ Ndingafuna ukuba nomntwana ngelinye ixesha ingezizo inyanga eziyi-12 ezizayo *I may want to have a child sometime in the future but not in the next 12 months*

☐ Andiqinisekanga ukuba ndiyamfuna okanye andimfuni umntwana kwixesha elizayo *I am unsure about whether or not I want to have a child in the future*

☐ Okunye,cacisa *Other, specify*: _____