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Family planning behaviours among South African HIV-infected and HIV-uninfected women during the postpartum period

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Declaration

I, *Jenna Oosthuizen*, hereby declare that the work on which this dissertation/thesis is based is my original work (except where acknowledgements 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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Thesis Abstract

There has been growing research on the impact of HIV on family planning and fertility behaviours with studies showing conflicting results. However, these relationships have been understudied in sub-Saharan Africa, especially during the postpartum period. Based on the differences reported in different studies as well as the lack of studies performed in South Africa during the postpartum period, further research is required to investigate differences in fertility desire and use and need for family planning among and between HIV-infected and HIV-uninfected women. The aim of this study was to compare family planning use, fertility desires and unmet family planning need at 12 months postpartum in a population of HIV-infected and HIV-uninfected women from Gugulethu, Cape Town.

The thesis components include a study protocol, a literature review investigating previous work on family planning uptake, fertility desire and unmet family planning need in sub-Saharan Africa, and an analysis of secondary data from three contributing studies performed in Gugulethu, Cape Town of HIV-infected and HIV-uninfected women who participated at 12 months postpartum. Logistic regression was used to model associations between HIV status and family planning use, fertility desires and unmet family planning need.

Of the 854 women included in this analysis, 497 (58.0%) were HIV-infected and 357 (42.0%) were HIV-uninfected. Family planning prevalence was 62.3%, injectable contraceptives were the most common FP methods used among participants (>90.0%) and 37.2% of participants had an unmet family planning need. Only 8 participants (0.9%) had an immediate fertility desire (wanted to have a child within the next 12

months) and 20.9% wanted to have a child sometime in the future.

Family planning use and unmet family planning need did not differ by HIV status however, fertility desires significantly differed by HIV status. In multivariable analysis, HIV status was not associated with family planning use or unmet family planning need. HIV status was significantly associated with future fertility desire. HIV-infected women were significantly less likely to have a future fertility desire than HIV-uninfected women (OR=0.3, 95% CI=0.2 to 0.4, $p<0.001$). Age, parity, intended pregnancy and discussed family planning/ pregnancy with partner were also significantly associated with future fertility desire.

HIV status appears to be associated with fertility desires in this population. No significant association was found between family planning use and unmet family planning need in this population by HIV status. Family planning services need to be strengthened for all women in this population and access to a larger variety of family planning methods is needed.

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List of abbreviations

ART: antiretroviral therapy

CHC: community health centre

FP: family planning

HIV: human immunodeficiency virus

HU2: HIV-unexposed, uninfected study

IQR: interquartile range

IUD: intrauterine device

LMICs: low-and middle-income countries

MCH-ART: Maternal and Child Health-Antiretroviral Therapy study

MOU: midwife obstetric unit

MTCT: mother-to-child transmission

PACER: Post-partum Adherence Clubs to Enhance Retention study

PMTCT: prevention of mother to child transmission

SD: standard deviation

SES: socioeconomic status

SSA: sub-Saharan Africa

WHO: World Health Organization

PART A: PROTOCOL

Background

South Africa contains the largest number of people living with human immunodeficiency virus (HIV) globally at approximately 7.1 million in 2015, with a large percentage of these individuals being women of childbearing age (1). In 2013, approximately 30% of all pregnant women who attended public sector health care facilities in South Africa were HIV-infected (2). In sub-Saharan Africa (SSA), women, children and infants account for more than 60% of new HIV infections (3). Countries with high rates of HIV, usually also have low rates of family planning (FP) use and high rates of unmet FP need and unintended pregnancy (4).

FP is a cost-effective strategy for the prevention of mother to child transmission (PMTCT) of HIV and for avoiding unintended pregnancies (3,5). Preventing subsequent unintended pregnancies in HIV-infected women during the postpartum period is especially critical in reducing maternal mortality related to HIV infection as these women have a higher risk of death during pregnancy or childbirth than HIV-uninfected women (6–8). In low-resource settings such as SSA, women have limited access to and a large unmet need for FP services in the postpartum period (8). Women are especially vulnerable to unintended pregnancies in this period when their menstrual cycle returns as a result of stopping or decreasing breastfeeding (9,10). In order to increase FP uptake, women require access to a variety of contraceptive methods in order to choose the optimum method that aligns with their pregnancy intentions (11). This is even more important for newly diagnosed HIV-infected women who may alter their pregnancy intentions as a result of their HIV status (12).

There is conflicting evidence on whether HIV status has an effect on women's fertility desires and FP practices. A study by Agadjanian et al. found that women in Mozambique with confirmed or suspected HIV infection had an increased likelihood of contraceptive use (13). In KwaZulu-Natal, South Africa HIV-infected women were found to be more likely to use condoms than HIV-uninfected women in the first year postpartum (14). However, a study by Ngugi et al. found that the odds of FP use did not differ amongst HIV-infected and HIV-uninfected Kenyan women (15). Another study in the Eastern Cape of South Africa found no differences in contraceptive use between HIV-infected and HIV-uninfected women in the postpartum period (16).

Most studies that have investigated fertility desires by HIV status have found that HIV-infected women are less likely to have a fertility desire than HIV-uninfected women. A study by Kimani et al. concluded that HIV-infected Kenyan women were 2.5 times more likely to report not wanting to have any more children compared to HIV-uninfected women (17). A cohort study by Peltzer et al. in the Eastern Cape of South Africa found that HIV-infected women were significantly less likely to want more children compared to HIV-uninfected women (16). Of the few studies that have investigated the association between HIV status and unmet FP need, mixed associations have been found (18–21). Based on these observed differences found in different populations, there is a need to understand the association between HIV status and FP use, fertility desires and unmet FP need the postpartum period in a cohort of women from Gugulethu, Cape Town.

Aims and objectives

Aim:

Compare a) FP use, b) fertility desires and c) unmet FP need at 12 months postpartum in a population of HIV-infected and HIV-uninfected women from Gugulethu, Cape Town.

Objectives:

- Describe a) FP use, b) fertility desires and c) unmet FP needs in HIV-infected and HIV-uninfected women
- Measure association between HIV status and a) FP use, b) fertility desires and c) unmet FP need
- Investigate other factors associated with a) FP use, b) fertility desires and c) unmet FP need

Study design

Secondary data analysis will be performed using data from three studies: the Maternal and Child Health-Antiretroviral Therapy study (MCH-ART), Post-partum Adherence Clubs to Enhance Retention study (PACER) and HIV-unexposed, uninfected study (HU2). The MCH-ART study (HREC 451/2012) is a 3-phase study completed at the Gugulethu Community Health Centre in Cape Town. HIV-infected pregnant women attending their first antenatal clinic visit were informed about the study and if interested in participating were recruited and followed until 12 months postpartum. Phase 1 was a cross-sectional evaluation of the health status of HIV-infected pregnant women seeking antenatal care and the services they receive at the Gugulethu Midwife Obstetric Unit

(MOU). Phase 2 of the study consisted of a cohort of women eligible for antiretroviral therapy (ART) initiation. The women were followed from their second antenatal clinic visit until their first postpartum clinic visit. The purpose of this was to describe ART initiation and antenatal follow-up and measure and describe changes in women's clinical and/or psychosocial characteristics between the antenatal and postnatal periods. This was to determine how these characteristics are related to maternal HIV viral suppression and maternal retention in ART services at 12 months postpartum. Phase 3 was a randomized trial consisting of women from phase 2 who breastfed their infants. The women were randomized to receive one of two approaches of HIV care and treatment services (local standard of care vs. MCH-ART intervention) during the postpartum period. The local standard of care consisted of referral of women and their infants from the MCH clinic to general adult ART services at 4-8 weeks postpartum. Women randomized to the MCH-ART intervention continued to attend the MCH clinic throughout the period of breastfeeding where they received HIV-specific services and routine infant care (22). These women were followed up until 18 months postpartum in order to determine the impact of these two different HIV care strategies on maternal HIV viral suppression and maternal retention in ART services.

The PACER study (HREC 775/2014) is a cohort study following HIV-infected women immediately after giving birth to 12 months postpartum in order to assess the acceptability and cost-effectiveness of adherence clubs in managing women on ART in the postpartum period. Women who initiated ART during pregnancy were recruited at their first routine postnatal clinic visit. This study also serves as a comparison to the two types of care services in the MCH-ART study.

The HU2 study (HREC 567/2014) is a cohort study of HIV-uninfected women and their infants. Women were recruited at their first antenatal clinic visit at the Gugulethu MOU and followed up to 12 months postpartum. The main purpose of this study is to provide a comparison group for the MCH-ART study by recruiting an otherwise similar cohort of HIV-uninfected mothers and infants from the same community. The same procedures and measurement tools as for the MCH-ART study were used in order to obtain comparable measures of the same infant health outcomes in the absence of maternal HIV infection.

Using data from these three studies, we will compare FP use, fertility desires and unmet FP need between HIV-infected and HIV-uninfected women at 12 months postpartum. Furthermore, we will investigate what other factors are associated with FP use, fertility desire and unmet FP need at 12 months postpartum.

Study population

The MCH-ART study consists of phase 1, phase 2 and phase 3 participants. Phase 1 participants are HIV-infected pregnant women seeking antenatal care at the Gugulethu MOU that had not initiated ART. Phase 2 participants are a subset of phase 1 participants who were eligible for initiation of ART. Phase 3 participants are a subset of phase 2 participants who breastfed their infants and initiated ART during the antenatal period.

Participants in the PACER study were HIV-infected women receiving postnatal care at the Gugulethu MOU. Additionally, participants were women who were breastfeeding within one month postpartum, initiated ART during the antenatal period, were virally supressed, were clinically stable and were residents of the catchment area.

Participants in the HU2 study were HIV-uninfected women seeking antenatal care at the Gugulethu MOU that were followed until 12 months postpartum. Women who were 18 years or older, had a confirmed pregnancy and a negative HIV test result during their pregnancy were included in the antenatal phase. Women were included in the postnatal phase if they had been enrolled in the antenatal phase, had at least one antenatal study visit, had a negative HIV test during or after their third trimester and were currently breastfeeding.

Inclusion and exclusion criteria

Inclusion and exclusion criteria for MCH-ART, PACER and HU2 taken verbatim from study protocols (22, 23).

MCH-ART

<u>Inclusion criteria:</u>

- Age 18 years or older
- Documented HIV-infection according to two finger-prick rapid tests using different test types (per routine protocol in this setting) or documentation of HIV status for those women self-reporting HIV diagnosis.

- Confirmed pregnancy according to urine pregnancy test, ultrasound or clinical assessment
- Has not initiated triple-drug antiretroviral therapy or AZT for PMTCT during the current pregnancy prior to study
- Able to provide informed consent for research
- Participated in all 3 phases
- Documented ART eligibility based on current local guidelines
- Started or scheduled to start ART at Gugulethu MOU in the current pregnancy (women started on AZT for PMTCT during the current pregnancy are eligible)
- Initiated ART during the antenatal period
- Breastfeeding within <7 days postpartum (with an allowable window of up to 28 days postpartum)
- Willingness to be randomized and return for postnatal study visits

<u>Exclusion criteria</u>:

- Not currently pregnant (Phases 1 and 2) or loss of pregnancy/neonate (Phase 3) at the time of eligibility determination
- Intention to relocate out of Cape Town permanently during the study period
- Any medical, psychiatric or social condition which in the opinion of the investigators would affect the ability to consent and/or participate in the study (all phases), including:

  -Refusal to take ART/ARVs

  -Denial of HIV status

PACER

Inclusion criteria:

- Age 18 years or older
- Documented HIV-infection according to two finger-prick rapid tests using different test types (per routine protocol in this setting) or documentation of HIV status for those women self-reporting HIV diagnosis.
- Initiated ART during the antenatal period (during most recent pregnancy)
- Within one month postpartum
- Breastfeeding within one month postpartum
- Willingness to return for postnatal study visits
- Able to provide informed consent for research
- Eligible to receive care at local Adherence Club, based on following local eligibility criteria:

  -Virally suppressed (HIV RNA <1000 copies/mL) per most recent viral load test (conducted during pregnancy)

  -Clinically stable (no active co-morbidity including opportunistic infections)

  -Current resident of catchment area appropriate for Adherence Club referral

Exclusion criteria:

- Receipt of any ART services outside the Gugulethu MOU ART service in the postpartum period
- Intention to relocate out of Cape Town permanently during the following one year

- Any medical, psychiatric or social condition which in the opinion of the investigators would affect the ability to consent and/or participate in the study, including:

  -Refusal to take ART/ARVs

  -Denial of HIV status

HU2

Inclusion criteria:

- Confirmed pregnancy according to urine pregnancy test, ultrasound or clinical assessment
- Maternal age of 18 years or older
- Negative HIV test during current pregnancy during or after third trimester of pregnancy
- Able to provide informed consent for research
- Mother had been enrolled and seen for at least one antenatal study visit
- Breastfeeding
- Willingness to return for postnatal study visits

Exclusion criteria:

- Not currently pregnant (antenatal phase) or loss of pregnancy/neonate (postnatal phase) at the time of eligibility determination
- Intention to relocate out of Cape Town permanently during the study period
- Any medical, psychiatric or social condition which in the opinion of the investigators would affect the ability to consent and/or participate in the study

Recruitment and enrolment

No recruitment or enrolment was performed as this study consists of secondary data analysis of participants who were already enrolled in three existing studies.

Analytic considerations

Data sources

Data that has already been collected from the three above-mentioned studies (MCH-ART, PACER and HU2) will be used for this study. MCH-ART and PACER data will be pooled to form the HIV-infected participants and HU2 data will be used for the HIV-uninfected participants. All three studies collected data with ethics approval and the data has been anonymised.

The three outcomes (FP use, fertility desire and unmet FP need) will be measured using data from the family planning and pregnancy intentions questionnaire (Appendix A). The questionnaire consists of 5 questions that relate to FP use, FP method, location receiving FP, discussion of FP/pregnancy with a partner and fertility desires.

Data analysis

Statistical analysis will be performed using Stata version 13. Descriptive analysis will be performed to summarise the data of all three studies with respect to baseline maternal characteristics. Means, medians, interquartile ranges (IQR) and standard deviations (SD) will be used to describe continuous variables where appropriate and frequencies and proportions will be used to describe categorical variables. Logistic regression will be used to investigate associations between HIV status and the three outcomes (FP use, fertility desire and unmet FP need) while adjusting for possible confounders.

Ethical considerations

Risks and benefits

There are no direct risks or direct benefits to individuals as this study consists of secondary data analysis using data that has already been collected. There may be indirect benefits to the field of maternal health as this study could provide a better understanding of the differences in FP and fertility behaviours between HIV-infected and HIV-uninfected women in the postpartum period generally and in this population of women.

Informed consent

All participants in all three studies provided informed consent prior to participation.

Privacy and confidentiality

All participants have been assigned anonymous participant identification numbers and investigators for this study have no access to individual identifying information. All electronic data is password protected and all electronic communication of study data is via password protected encrypted files. All data is stored within a firewall-protected SQL server at the University of Cape Town.

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PART B: LITERATURE REVIEW

Objectives of the literature review

The objectives of this literature review are to summarise the literature investigating the association between HIV status and family planning use, unmet family planning need and fertility desire, throughout pregnancy and the postpartum period.

Search strategy

Pubmed and Google Scholar were used for the initial search of literature. Search terms used included “HIV and family planning”, “HIV and contraception”, “HIV and unmet family planning need”, “HIV and fertility desire”, “family planning and antiretroviral therapy” and “family planning and HIV viral load”. Additional relevant literature was found amongst the references of the literature found from these searches.

Background

Pregnancy and fertility rates remain high in sub-Saharan Africa (SSA) which also remains disproportionately affected by the human immunodeficiency virus (HIV) epidemic (1,2). In 2016 there were an estimated 36.7 million people living with HIV globally (3). South Africa has the largest number of people living with HIV at approximately 7.1 million and the largest number of people on treatment at 3.4 million in 2016 (3). In SSA, women accounted for 56% of new HIV infections among adults, with the majority of these being women of childbearing age (3–5). In 2013, approximately

30% of all pregnant women who attended public sector health care facilities in South Africa were HIV-infected (6). The high HIV prevalence among pregnant women and in SSA more broadly highlights the need for interventions and focused attention on this key population.

Routine antiretroviral therapy (ART) has significantly improved the quality of life of individuals infected with HIV. Increased access to ART, especially in low-and middle-income settings, has led to improved pregnancy outcomes and decreased risk of mother-to-child transmission (MTCT) among HIV-infected women (7,8). MTCT occurs when HIV infection is transmitted from an HIV-infected mother to her child during pregnancy, labour, delivery or breastfeeding (9).

The prevention of mother-to-child transmission (PMTCT) has been an extremely successful intervention in reducing perinatally infected children and has had a dramatic improvement on maternal and child health (9). Among the 21 countries with the highest rates of HIV-infected pregnant women, new infections among children decreased by 48% between 2009 and 2014 through PMTCT programmes (10). South Africa has made the most progress by reducing new infections among children by 76% (10). The global PMTCT strategy as outlined by the World Health Organization (WHO) consists of four components which aim to 1) prevent HIV infection among women of childbearing age, 2) prevent unintended pregnancies among HIV-infected women, 3) prevent mother to child transmission and 4) ensure adequate care for HIV-infected mothers and their children (9). While great progress has been made in PMTCT, less progress has been made in preventing unintended pregnancies among HIV-infected women (11,12).

Family planning (FP) use by HIV-infected women has been recognized as a cost-effective strategy for PMTCT and for avoiding unintended pregnancies (12–16). However, HIV-infection may still alter the fertility intentions of women compared to those that are not infected with HIV. In SSA, the fertility desires and FP practices of HIV-infected women have been understudied, particularly in the postpartum period, when women are vulnerable to unintended pregnancies as fertility returns unpredictably and have described an unmet need for FP (17,18).

Fertility desire and HIV status

Primary HIV infection in most countries of SSA is highest amongst young women of reproductive age who have not started childbearing and may be more likely to desire a family in the future (7). The decision whether or not to have children is often multifaceted. HIV-infected women have to take into account additional considerations when deciding whether or not to have children, including the possibility of MTCT and adverse health outcomes associated with pregnancy and childbirth related to HIV infection (19,20). Despite PMTCT programmes significantly reducing new infections among children, the MTCT transmission rate was still 14% among the 21 countries with the highest rates of HIV-infected pregnant women in 2014 (10). In 2016, there were still 160000 new HIV infections among children globally, majority of these occurring in SSA (21). Given the role that MTCT still plays in contributing to the epidemic in SSA, the influence of HIV status on fertility intentions is particularly important (22). It is of interest whether HIV status will remain an important factor in predicting fertility desires of HIV-infected women as access to ART increases, providing the possibility for HIV-infected women to have HIV-uninfected children (23).

The relationship between HIV status and fertility desires is a complex one. Prior work has resulted in mixed conclusions with positive, negative or no association between HIV status and fertility intentions being reported. Many studies have concluded that HIV infection reduces the desire to have more children. A study by Kimani et al. examined the fertility desires of a large cohort (N=1959) of Kenyan women who were recruited from 12 public health facilities located in rural and peri-urban settings across five counties in Kenya (1). In this population, HIV-infected women were 2.5 times more likely to report not wanting to have any more children compared to HIV-uninfected women. Additional factors impacting fertility desires were age, socioeconomic status (SES) and education level.

A nationally representative survey of 3583 Kenyan women found that HIV-infected women had significantly lower odds of wanting more children compared to HIV-uninfected women (24). Other factors significantly associated with fertility desire included being of younger age (15-39 years old), having less than two children and not using modern contraceptives.

O'shea et al. assessed whether HIV status was associated with fertility desire among postpartum Malawian women (23). The study was of cross-sectional design and surveyed 634 women who were recruited from the postpartum unit of a government hospital. The study found that HIV-infected women were over 50% more likely to not want any more children compared to HIV-uninfected women.

A cross-sectional study in Rwanda recruited postpartum women from public sector health facilities providing antenatal care and PMTCT services across urban and rural settings and found that HIV-infected women were significantly less likely to report that they wanted more children compared to HIV-uninfected women (25). Additionally, women who were not married or in a union and women with more than four children were less likely to report a desire for more children.

A cohort study by Peltzer et al. recruited pregnant women from a resource poor setting in the Eastern Cape of South Africa at their first antenatal visit and followed 758 women into the postpartum period. The study found that HIV-infected women were significantly less likely to want more children compared to HIV-uninfected women (26). Even so, 39% of HIV-infected women still had a desire to have another child. Among HIV-uninfected women, disclosure to the partner, having fewer children and younger maternal age were associated with fertility desire. Among HIV-infected women, PMTCT knowledge and younger maternal age were associated with fertility desire.

Despite many studies finding a significant association between HIV-infection and reduced fertility desire, a few studies have found no association between HIV status and fertility desire. Based on the 2003 Kenya Demographic and Health Survey data, a study by Magadi & Agwanda found no significant association between a women's HIV status and their fertility desires (27).

Personal, partnership and social factors can influence fertility desires and in turn the FP practices of HIV-infected women. Cooper et al. interviewed 40 HIV-infected women recruited from public sector health centres situated in Cape Town, South Africa, that provided HIV care and ART services to urban and peri-urban communities (28). The study found that some HIV-infected women did not desire to have children in fear that they would infect their partner in the process of trying to conceive or their child. Strong community disapproval of HIV-infected women reproducing was also a deterrent of pregnancy. On the other hand, many HIV-infected women continued to desire to have more children despite the potential risk of HIV transmission. Among the HIV-infected women who wanted to have children, factors that influenced fertility desire included the wish to experience pregnancy and biological parenthood, children giving them hope and a reason to live and social and cultural expectations for a women to have children.

From the literature it can be seen that different associations between HIV status and fertility desire have been observed in different studies. Even though many studies have shown an overall negative association between HIV infection and fertility desire, many HIV-infected women in SSA continue to desire more children (8,28,29). This could be due to the fact that in many parts of SSA having children has a strong tradition and is seen as a necessary part of adult life (1,19,22). Other factors found to be associated with fertility desire included age, wealth, education, number of children and marital status.

Family planning

FP is defined as the method by which women control the number of children they have and the spacing between their births. There are different FP methods available, with the prevalence and acceptability of certain methods varying from country to country (30). FP methods include male and female condoms, hormonal patches, oral contraceptives, injectable contraceptives, intrauterine devices (IUDs), male and female sterilisation, implants and emergency contraception, with varying degrees of reliability (30).

Among women of reproductive age living in developing regions, modern contraception is estimated to prevent approximately 307 million unintended pregnancies annually (31). Although the percentage of women using contraception increased from 55% to 64% between 1990 and 2015 globally, the global unmet need for FP was estimated to be at least 12% in 2015 (32). It was estimated that in 2015, only 33% of married or in-union women in Africa between the age of 15 and 49 years old used a FP method (30).

In low-resource settings such as most of SSA, majority of women have limited access to and a large unmet need for FP services in the postpartum period (17). The WHO defines postpartum FP as “the prevention of unintended pregnancy and closely spaced pregnancies through the first 12 months following childbirth”(33). Postpartum FP is recommended by the WHO as a key component of healthcare as it has the ability to meet women’s FP needs and in turn save the lives of millions of women and their children in low-and middle-income countries (LMICS) (33). Women are especially vulnerable to unintended pregnancies in the postpartum period as a result of stopping or decreasing breastfeeding as the return to fertility is often unpredictable (18,34) and women frequently become sexually active prior to initiating FP in the postpartum period (35). Strategies that have been suggested for reaching women during the postpartum period in order to reduce unmet FP need include FP antenatal counselling, male partner involvement, integrating FP services with postnatal services, community-based care and promoting long-acting reversible contraceptives such as IUDs (36).

Possible reasons why women do not use FP, even if they have an unmet need, include thinking that they have a low risk of pregnancy (24,37,38), lacking knowledge and/or access to FP and related services (38–40), fear of side effects (24,38,40,41), partner disapproval (37,39) and beliefs against FP use (24,38). Additionally, HIV-infected women may face additional barriers to FP use, including stigmatisation and concerns about interactions with ART (39,42). Understanding the factors contributing to unmet need in HIV-infected women is important so that they can be incorporated into intervention strategies (38).

Family planning and HIV status

Due to the major increases in access to lifelong ART, HIV is now regarded as a chronic but manageable disease (7,43). As a result, many HIV-infected women are leading healthy lives, which includes sexual activity and FP use (1,43). Increased access to ART may also change reproductive decisions and behaviours of HIV-infected women, as ART often leads to improved outcomes of pregnancies including the low risk of MTCT (7,8). Like all women, HIV-infected women have the right to make decisions about their reproductive lives including if, or when, they get pregnant (1). Unintended pregnancies in HIV-infected women may contribute to MTCT (1). Preventing unintended pregnancies using FP, depending on method, may be helpful in reducing horizontal HIV transmission (12–16).

Preventing unintended pregnancies also has other benefits with regards to health, social and economic outcomes (12). Health benefits include reducing maternal and child mortality and morbidity and unsafe abortions (12). Preventing unintended pregnancies also allows young women to remain in school and obtain an education, with lack of education being a risk factor for HIV among young women (12). When comparing different strategies for preventing HIV-positive births in SSA, it has been suggested that FP could avert 29% more HIV-positive births than ART for PMTCT for the same amount of expenditure (13).

Countries in SSA burdened with the highest rates of HIV also have low rates of FP uptake as well as high rates of unmet FP need and unintended pregnancy (44). In LMICS, the number of new HIV infections among children annually is approximately 240 000 (16). Most perinatal infections are a result of MTCT during pregnancy, delivery or breastfeeding (16). Preventing subsequent unintended pregnancies in HIV-infected women during the postpartum period is especially critical in reducing maternal mortality related to HIV infection. There is evidence that HIV-infected women have a higher risk of death during pregnancy or childbirth compared to HIV-uninfected women (17,20,45). HIV-infected women who want to prevent or space their pregnancies after delivery should be aware of, and have access to, effective FP methods (23). In order to increase FP uptake, women require access to a variety of contraceptive methods in order to choose the optimum method that aligns with their pregnancy intentions, especially newly diagnosed HIV-infected women who may alter their pregnancy intentions as a result of their HIV status (22,46,47).

There has been a growing body of research on the impact of HIV on FP and fertility behaviours, including how HIV status and perceived HIV risk affects fertility desires (1,22). Understanding how HIV-infected women consider the implications of their HIV status and how this affects their fertility intentions and reproductive behaviour is vital for informing policy and to design effective reproductive health programs for HIV-infected women, which may need to differ from available non-specific programmes (1,22).

There is conflicting evidence on whether HIV status has an effect on women's FP practices. Agadjanian et al. examined factors affecting FP behaviours of a large rural cohort of women (N=1554) in southern Mozambique through household-based survey data (48). Women with a confirmed or suspected HIV infection had an increased odds of contraceptive use compared to HIV-uninfected women. Education and household wealth were also found to be positively associated with contraceptive use.

A study by Habte & Namasasu investigated FP use among HIV-infected Malawian women using data from the Malawi Demographic and Health Survey of 2010. The study consisted of 489 HIV-infected women from rural and urban settings across Malawi. The study found that knowledge of HIV infection was a significant predictor of current FP use (16). Other factors that were associated with FP use were education and number of children. Elul et al. found that HIV-infected women were more likely to use modern FP compared to HIV-uninfected women (25). Additionally, women who were married/in-union were significantly more likely to report using FP.

Similar findings have been reported by studies done in South Africa. A cross-sectional study by Kaida et al. consisting of 563 women from Soweto, an urban township, found that 86% of HIV-infected ART users reported using FP, whereas only 69% of HIV-uninfected women reported FP use (49). Factors also associated with FP use included number of children, not wanting any more children and age. A cohort study in KwaZulu-Natal, South Africa enrolled 1137 HIV-infected and 1220 HIV-uninfected pregnant women at rural and urban government clinics and followed the women for up to 24 months postpartum (50). The study found that HIV-infected women were significantly more likely to use condoms in the first two years postpartum compared to HIV-uninfected women. Marlow et al. conducted a study in Durban, South Africa using data from a randomized control trial which assessed an integrated model of support for women after their HIV test (51). The study consisted of 821 women who were recruited during pregnancy at a government clinic in an urban township. The study found that HIV-infected women were more likely to use condoms and dual protection at 14 weeks postpartum compared to HIV-uninfected women.

However, some studies have found that HIV status was not associated with FP use. Ngugi et al. assessed FP use among 3583 Kenyan women by HIV status and found that the odds of FP use did not differ amongst HIV-infected and HIV-uninfected women (24).

Factors that were positively associated with FP use included being married or cohabiting, being religious, younger age (20-39 years old), higher wealth, higher education level and having at least one child. Peltzer et al. found no differences in contraceptive use between HIV-infected and HIV-uninfected women from the Eastern Cape in South Africa during the postpartum period (26).

Studies across SSA have found that education, wealth, number of children, marital status and age are associated with FP use. Evidence from studies investigating the relationship between HIV status and uptake of FP is mixed although most studies have found an association between HIV infection and increased FP use. These conflicting results reflect differences among different populations of women.

Unmet family planning need

It is estimated that of the 1.6 billion women of reproductive age living in developing regions, approximately half of them want to avoid pregnancy (31). Of the women who want to avoid pregnancy, 214 million (24%) are not using modern contraceptive methods and therefore are considered to have an unmet need for FP. Unmet need for FP is defined by the WHO as the percentage of women "who are fecund and sexually active but are not using any method of contraception, and report not wanting any more children or wanting to delay the next child"(52).

There are different definitions of unmet FP need used across studies. Most studies use definitions that include women that do not want to have any more children or want to delay the birth of their next child but are not using a FP method (8,16,53–55). Some of these studies specify that the definition includes women who do not want to have another child within the next two years (16,53–55). Some studies are also stricter in their definitions and only include women who are sexually active (8,39,53), fecund (8,54) and married/in-union (30,54). Definitions that do not account for sexual activity and fecundity could overestimate the level of unmet FP need. Women who are not sexually active or fecund are not at risk of unwanted pregnancy and therefore do not have an unmet FP need. Definitions that only include married/in-union women may not produce estimates of unmet FP need that are generalizable to all women as FP behaviours may differ by marital status. Differences in definitions can make it difficult to make comparisons across different studies.

Unmet FP need measures the gap between women's fertility desires and their FP access or behaviour (52). Although the global percentage (2015) for unmet FP need among married or in union women of reproductive age was estimated to be 12%, it is much higher in developing countries at an estimated 22% (30). In SSA, the unmet need for FP was the highest in the world and double the global average at 24% in 2015 (30).

In developing regions, women with an unmet need for modern contraceptive methods are estimated to account for 84% of all unintended pregnancies (31). If the unmet FP needs of all women in developing regions were met, unintended and terminated pregnancies would both decrease by approximately 75% (31). Consequences associated with an unmet need for FP and unwanted pregnancies include death, disability and financial burden. Ensuring that FP services are easily accessible to all women enabling new users to be included in FP programs is the first step in eliminating unintended pregnancies (44). Unmet need for FP among HIV-infected women continues to prevent the elimination of new HIV infections among children (4).

Studies have shown conflicting results with regards to whether HIV status affects unmet FP needs. A study by Wekesa and Coast performed in Nairobi, Kenya found that 33.6% of HIV-infected women had an unmet FP need (53). This level of unmet need was higher than the general population. Unmet need for FP was highest among younger (18-29 years old) and older (≥40 years old) individuals highlighting an unmet need for pregnancy spacing among young women and for pregnancy limiting among older women.

Among HIV-infected women on ART in Ethiopia, 25% reported having an unmet need for FP, which was similar to the general population (54). A study of 3 758 women of reproductive age in Lesotho using Demographic and Health Survey data found that unmet need was lower among HIV-infected women compared to HIV-uninfected women (55).

From the few studies that have investigated unmet FP need by HIV status, conflicting results have been observed. Studies have found higher and lower levels of unmet FP need in HIV-infected women compared to HIV-uninfected women and similar levels of unmet FP need to that of the general population.

Family planning and HIV clinical outcomes

Due to the WHO releasing new guidelines recommending lifelong ART for all HIV-infected individuals, individuals living with HIV that are receiving treatment are healthier and many are sexually active and therefore at risk of becoming pregnant (56). Although scale up and provision is improving across SSA, many HIV-infected pregnant women still do not receive effective PMTCT regimens (57).

In order to increase coverage of PMTCT interventions, integrating FP and HIV services has been shown in one study to be feasible and have positive effects on behavioural and health outcomes (57). It has also been recognized as a crucial strategy to decrease maternal and child mortality and control the HIV/AIDS epidemic (57). Integrating FP and HIV services have shown to increase FP uptake, ART initiation during pregnancy and HIV testing (57,58).

Despite studies investigating the effect of integrating HIV and FP services as well as many studies investigating FP use amongst HIV-infected individuals, no studies have looked at the effect of FP use on HIV clinical outcomes such as ART adherence or viral load control/viral suppression.

Conclusion

From the literature it is clear that studies in Africa have shown conflicting results with regards to the relationships between HIV status and FP use, fertility desires and unmet

FP need. Although, most studies performed in SSA concluded that HIV infection was associated with increased FP use and reduced fertility desire. There is a lack of studies in SSA investigating the relationship between HIV status and unmet FP need.

Of the literature summarised, only a few of these studies were performed in South Africa with even fewer investigating these associations during the postpartum period. The FP and fertility behaviours of postpartum women may differ to that of the general population of HIV-infected and HIV-uninfected women. Based on the observed differences found in different populations as well as the lack of studies performed on postpartum women in South Africa, there is a dearth of evidence to demonstrate differences in uptake and need for FP among and between women with and without HIV. Further research is required to investigate the effect of HIV status on FP and fertility behaviours, especially among postpartum South Africa women.

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PART C: MANUSCRIPT

Family planning behaviours among South African

HIV-infected and HIV-uninfected women during the postpartum period

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Abstract

Introduction: Studies in sub-Saharan Africa have shown conflicting evidence as to how HIV status might affect family planning and fertility behaviours. The aim of this study was to compare family planning use, fertility desire and unmet family planning need at 12 months postpartum in HIV-infected and HIV-uninfected women from Gugulethu, Cape Town.

Methods: Participants were HIV-infected and HIV-uninfected women from three contributing cohorts from Gugulethu, Cape Town who participated at 12 months postpartum. Associations between HIV status and family planning use, future fertility desire and unmet family planning need were modelled using logistic regression.

Results: The analysis included 854 women of which 497 (58.0%) were HIV-infected and 357 (42.0%) were HIV-uninfected. Participants were between the ages of 18 and 46 years old. Overall, 62.3% of women were using family planning and 37.2% of participants had an unmet family planning need. The 3-month and 2-month injectable contraceptives were the most common family planning methods used among participants (>90%). Less than 1.0% of women desired to have a child within the next 12 months and 20.9% wanted to have a child sometime in the future.

Fertility desire significantly differed by HIV status ($p<0.001$) but family planning use and unmet family planning need did not. In multivariable analysis, HIV status was not associated with family planning use or unmet family planning need but was significantly associated with future fertility desire. HIV-infected women were significantly less likely to have a future fertility desire than HIV-uninfected women (OR=0.3, 95% CI=0.2 to 0.4, p<0.001). Age, parity, intended pregnancy and discussed family planning/pregnancy with partner were also significantly associated with future fertility desire.

Conclusion: HIV status is associated with future fertility desire in line with other research. There was no observed association between HIV status and family planning use or unmet family planning need in this population. The high level of unmet family planning need suggests that family planning services need to be strengthened for all women in this population and access to a larger variety of family planning methods is needed.

Introduction

Countries in sub-Saharan Africa (SSA) that have the highest rates of human immunodeficiency virus (HIV), also typically have low rates of family planning (FP) use and high rates of unmet FP need and unintended pregnancy [1]. South Africa has the largest number of people living with HIV at approximately 7.1 million in 2016, with women of childbearing age making up a large proportion of these individuals [2]. The unmet need for FP in South Africa among married or in-union women of reproductive age was estimated at 12.2% in 2015 [3]. High levels of unmet FP need can lead to high levels of unintended pregnancies, which are a known risk factor for mother-to-child transmission (MTCT) of HIV [4,5].

In low-resource settings, many women have an unmet need for FP in the postpartum period when they are especially vulnerable to unintended pregnancies as return to fertility can be unpredictable [6–8]. During this period, HIV-infected women face the possibility of unintended pregnancies which may contribute to MTCT [9]. FP use by HIV-infected women has been recognized as a cost-effective strategy for the prevention of mother-to-child transmission (PMTCT) of HIV as well as for avoiding unintended pregnancies [10–14]. In South Africa, the prevalence of FP use among married or in-union women of reproductive age in 2015 was estimated at 64.8% [3].

There has been growing research on the impact of HIV on FP and fertility behaviours [9,15] however, these relationships have been understudied in SSA. Some research has shown that HIV-infected women are more likely to use FP than HIV-uninfected women [14,16–20], while other studies have shown no association between HIV status and FP use [21,22]. Most studies have shown that HIV-infected women are less likely to have a fertility desire compared to HIV-uninfected women [9,17,21–23]. Among the few studies investigating unmet FP need by HIV status, some studies have found that HIV-infected women have higher levels of unmet FP need than HIV-uninfected women [24,25], while other studies have found lower levels of unmet FP need in HIV-infected women compared to HIV-uninfected women [26]. Other studies have observed similar levels of unmet FP need among HIV-infected women to that of the general population [27].

Understanding how a HIV positive diagnosis affects a woman's FP and fertility behaviours is necessary for designing effective reproductive health programs for HIV-infected women [9,15]. Studies in Africa have shown conflicting results with regards to the relationships between HIV status and FP use, fertility desire and unmet FP need. Only a few studies have been performed in South Africa that investigated these associations in postpartum women. Based on the observed differences found in different populations as well as the dearth of studies with postpartum women in South Africa, there is a need to investigate differences in fertility desire and use and need for FP among and between women with and without HIV. The primary aim of this study was to compare FP use, fertility desire and unmet FP need at 12 months postpartum in a population of HIV-infected and HIV-uninfected women from Gugulethu, Cape Town.

Methods

Data sources

Secondary data analysis was performed using data from the Maternal and Child Health-Antiretroviral Therapy study (MCH-ART), and two associated studies, the Post-partum Adherence Clubs to Enhance Retention study (PACER) and the HIV-unexposed, uninfected study (HU2). MCH-ART was a 3-phase study that recruited HIV-infected women in the antenatal period and followed them until 12 months postpartum [28]. The study aimed to evaluate two different strategies for providing HIV services to HIV-infected women and their HIV-exposed infants during the postpartum period. Participants were women that initiated ART during pregnancy. PACER was a cohort study assessing the acceptability and cost-effectiveness of adherence clubs in managing women on ART in the postpartum period. HIV-infected women seeking postnatal care were recruited and followed from delivery to 12 months postpartum [28]. HU2 was a cohort study that aimed to serve as a comparison group for MCH-ART. HIV-uninfected women were recruited and followed-up from the first antenatal visit until 12 months postpartum [28].

Participants for all three studies were recruited at the Gugulethu midwife obstetric unit (MOU) during routine antenatal (MCH-ART and HU2) or postnatal (PACER) clinic visits. Gugulethu is an urban township situated in Cape Town, South Africa made up of approximately 300 000 people with high levels of poverty and HIV infection [34]. The Gugulethu MOU is a large, primary care facility offering antenatal, obstetric and postpartum services and sees approximately 4000 women annually [28].

Data from the HU2 study was used for HIV-uninfected participants in this study. Data from PACER and MCH-ART studies were pooled to form the HIV-infected participants for this study, as the studies were both conducted in Gugulethu and consisted of similar populations of women. Data was only used for participants who had a 12 month postpartum visit. All participants in all three studies provided informed consent prior to participation (Appendix B). The study was approved by the University of Cape Town's Faculty of Health Sciences Human Research Ethics Committee (HREC 745/2017) (Appendix C).

Measures

The three outcomes that were modelled were FP use, future fertility desire and unmet FP need. All data relating to FP characteristics was obtained from the family planning and pregnancy intentions questionnaire performed at 12 months postpartum (Appendix A).

Participants were classified as using a FP method if they reported that they were using any of the following methods: Oral contraceptive pill, 2-month injectable, 3-month injectable, intrauterine device (IUD), female sterilization, male sterilization, male condom, female condom or implant.

A binary variable was created for future fertility desire. Women were defined as having a future fertility desire if they stated with regards to their fertility desires that they wanted to have a child within the next 12 months or sometime in the future and no future fertility desire if they stated that they did not want another child.

Unmet FP need is related to the fertility desires variable. Women were defined as having an unmet FP need if they reported that they did not want another child, they wanted a child sometime in the future or they were unsure but were not using a FP method. Women who were using a FP method, regardless of their fertility desires and women that reported that they wanted to have a child within the next 12 months and were not using a FP method were not classified as having an unmet FP need.

Statistical methods

Descriptive summaries were calculated to describe the demographic and family planning characteristics of all enrolled women by HIV status and the demographic and clinical characteristics of all HIV-infected women by family planning status. Categorical variables were described by frequencies and percentages and continuous variables were described by medians and interquartile ranges (IQRs). To compare groups, the Chi-square (χ^2) test was used for categorical variables and the Wilcoxon rank sum test was used to compare medians of continuous variables.

Logistic regression was used to model associations between HIV status and the three outcomes: FP use, future fertility desire and unmet FP need. Variables of interest and demographic variables (age, education, socioeconomic status (SES), marital status, employment status, breastfeeding duration, parity, planned pregnancy and discussion of family planning with partner) were included in the analyses. Statistical analysis was performed using STATA version 13.

Results

A total of 854 women were included in the analysis. Of these women 497 (58.0%) were HIV-infected and 357 (42.0%) were HIV-uninfected (Table 1). Figure 1 summarises the number of HIV-infected and HIV-uninfected participants from the three contributing studies.

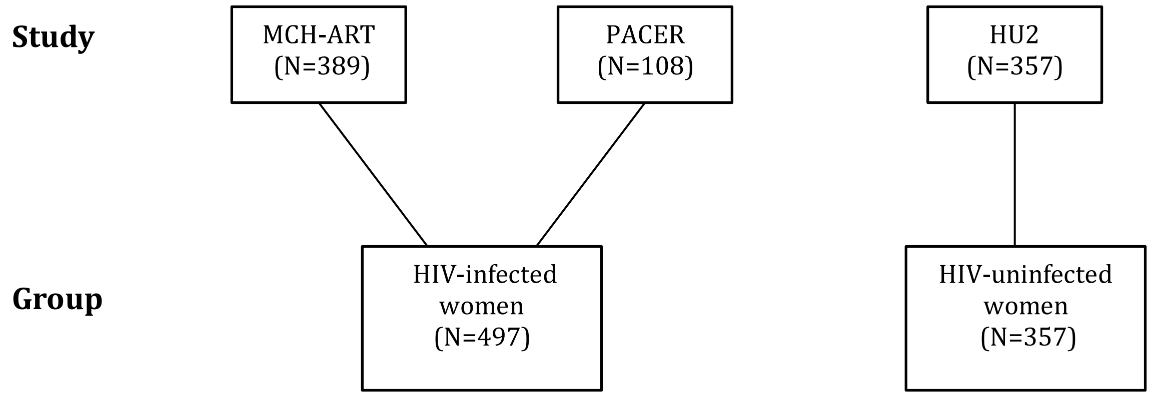

Figure 1. HIV-infected and HIV-uninfected participants obtained from three contributing studies

The median age of participants was 28 years old (range 18-46 years). Approximately two thirds of women (64.5%) had less than secondary education and just over half were single (57.7%). Participants were spread across the three different SES categories although more than half of them were unemployed (58.7%). Over 80% of women had been pregnant prior to this pregnancy and postpartum period. Almost 70% of the current pregnancies were unintended.

Statistically significant differences between HIV-infected and HIV-uninfected participants were identified for education ($p<0.001$), SES ($p=0.028$), parity ($p<0.001$) and employment ($p=0.004$). No differences were found between HIV-infected and HIV-uninfected participants with respect to age, marital status, breastfeeding duration and whether the last pregnancy was planned.

Table 1. Characteristics of all enrolled women with a 12 month postpartum visit by HIV status (N=854)

	All N=854 (100%)	HIV-infected N=497 (58%)	HIV-uninfected N=357 (42%)	P-value
Age (median, IQR)	28 (24, 32)	28 (24,32)	29 (24,33)	0.111
Education				
Less than secondary	551 (64.5%)	351 (70.6%)	200 (56.0%)	
Completed secondary/any tertiary	303 (35.5%)	146 (29.4%)	157 (44.0%)	<0.001
SES				
Lowest SES	229 (26.9%)	124 (25.1%)	105 (29.4%)	
Moderate SES	321 (37.7%)	205 (41.5%)	116 (32.5%)	
Highest SES	301 (35.4%)	165 (33.4%)	136 (38.1%)	0.028
Missing	3	3		
Parity				
Not first pregnancy	702 (82.2%)	435 (87.5%)	267 (74.8%)	
First pregnancy	152 (17.8%)	62 (12.5%)	90 (25.2%)	<0.001
Planned pregnancy				
Unintended	579 (68.0%)	344 (69.6%)	235 (65.8%)	
Intended	272 (32.0%)	150 (30.4%)	122 (34.2%)	0.240
Missing	3	3		
Weeks breastfeeding (median, IQR)	39 (13.1, 52.6)	32.5 (10.4, 56.4)	40.6 (13.3, 52.4)	0.857
Missing	6	4	2	
Marital Status				
Single	492 (57.7%)	299 (60.3%)	193 (54.1%)	
Married/cohabiting	361 (42.3%)	197 (39.7%)	164 (45.9%)	0.070
Missing	1	1		
Employment				
Unemployed	501 (58.7%)	312 (62.9%)	189 (52.9%)	
Employed	352 (41.3%)	184 (37.1%)	168 (47.1%)	0.004
Missing	1			
Timing of HIV diagnosis				
Before this pregnancy		222 (44.8%)	N/A	
During this pregnancy		274 (55.2%)		
Missing		1		
Disclosed HIV status to partner				
No		274 (56.9%)	N/A	
Yes		208 (43.1%)		
Missing		15		
Told anyone about HIV status				
No		207 (41.7%)	N/A	
Yes		289 (58.3%)		
Missing		1		

All categorical variables are displayed as frequency (percentage).
HIV=human immunodeficiency virus; IQR= interquartile range; SES= socioeconomic status

Overall, 532 (62.3%) women were using some method of FP and 321 (37.7%) women were not using FP (Table 2). The FP status of one individual was missing. The 3-month injectable was the most common FP method (78.2%), followed by the 2-month injectable (12.6%). Very few women (0.9%) desired to have a child within the next 12 months and only 20.9% desired to have a child sometime in the future. Almost equal proportions of HIV-infected and HIV-uninfected women were using FP and had an unmet FP need.

When comparing the fertility desires of HIV-infected and HIV-uninfected women, 36.1% of HIV-uninfected women reported that they wanted a child sometime in the future compared to 10.1% of HIV-infected women. A larger proportion of HIV-infected women stated that they did not want another child (63.0%) compared to HIV-uninfected women (52.4%) or stated that they were unsure about their fertility desires (25.3%) compared to HIV-uninfected women (10.7%). In total, 37.2% of participants had an unmet FP need.

Statistically significant differences between HIV-infected and HIV-uninfected groups were found for location receiving FP ($p<0.001$), discussed FP/pregnancy with partner ($p<0.001$) and fertility desires ($p<0.001$). FP use, FP method and unmet FP need did not significantly differ by HIV status.

Table 2. Family planning characteristics of all enrolled women with a 12 month post-partum visit from the family planning and pregnancy intentions questionnaire by HIV status (N=854)

	All N=854 (100%)	HIV-infected N=497 (58%)	HIV-uninfected N=357 (42%)	P-value
Family planning				
No	321 (37.6%)	193 (38.9%)	128 (35.9%)	
Yes	532 (62.4%)	303 (61.1%)	229 (64.1%)	0.363
Missing	1	1		
Family planning method				
Oral contraceptive pill	7 (1.3%)	1 (0.3%)	6 (2.6%)	
2-month injectable	67 (12.6%)	36 (11.9%)	31 (13.6%)	
3-month injectable	415 (78.2%)	240 (79.2%)	175 (76.8%)	
IUD	4 (0.8%)	3 (1.0%)	1 (0.4%)	
Female sterilization	10 (1.9%)	6 (2.0%)	4 (1.8%)	
Male sterilization	1 (0.2%)	1 (0.3%)	0	
Male condom	15 (2.8%)	12 (4.0%)	3 (1.3%)	
Implant	12 (2.3%)	4 (1.3%)	8 (3.5%)	
Missing	1		1	0.074
Location receiving family planning				
Gugulethu MOU	58 (10.9%)	55 (18.2%)	3 (1.3%)	
Gugulethu CHC	30 (5.7%)	12 (4.0%)	18 (7.9%)	
Other	443 (83.4%)	235 (77.8%)	208 (90.8%)	<0.001
Missing	1	1		
Discussed family planning /pregnancy with partner				
No	437 (51.4%)	290 (58.5%)	147 (41.5%)	
Yes	413 (49.6%)	206 (41.5%)	207 (58.5%)	<0.001
Missing	4	1	3	
Fertility desires				
Next 12 months	8 (0.9%)	6 (1.2%)	2 (0.6%)	
Sometime in future	178 (20.9%)	50 (10.1%)	128 (36.1%)	
Don't want another child	498 (58.6%)	312 (63.0%)	186 (52.4%)	
Unsure	163 (19.2%)	125 (25.3%)	38 (10.7%)	
Other	3 (0.4%)	2 (0.4%)	1 (0.3%)	<0.001
Missing	4	2	2	
Unmet family planning need				
No	534 (62.8%)	306 (61.8%)	228 (64.2%)	
Yes	316 (37.2%)	189 (38.2%)	127 (35.8%)	0.474
Missing	4	2	2	

All categorical variables are displayed as frequency (percentage).
HIV=human immunodeficiency virus; IUD= intrauterine device; MOU=midwife obstetric unit; CHC=community health centre.

In the univariable models for FP use, planned pregnancy was the only variable that was significantly associated (Table 3). Women whose last pregnancy was intended were more likely to use FP (OR=1.4, 95% CI=1.0 to 1.9, p=0.030). No variables remained significantly associated with FP use in multivariable analysis.

HIV status, age, education, parity, planned pregnancy, breastfeeding duration and discussed FP/pregnancy with partner were all significant in the univariable models for future fertility desire (Table 3). In multivariable analysis, HIV-infected women were significantly less likely to have a future fertility desire than HIV-uninfected women (OR=0.3, 95% CI=0.2 to 0.4, p<0.001). Women who were younger (OR=0.9, 95% CI=0.8 to 0.9, p<0.001), had only had one pregnancy (OR=2.0, 95% CI=1.2 to 3.5, p=0.012), whose last pregnancy was intended (OR=2.1, 95% CI, 1.4-3.3, p=0.001) and who had discussed family planning/pregnancy with their partner (OR=2.5, 95% CI=1.7 to 3.8, p<0.001) were significantly more likely to have a future fertility desire.

In univariable analysis, planned pregnancy was the only variable that was significantly associated with unmet FP need (Table 3). Women whose last pregnancy was intended were less likely to have an unmet FP need (OR=0.7, 95% CI=0.5 to 0.9, p=0.019). No factors were significantly associated with unmet FP need in multivariable analysis.

Table 3. Factors associated with family planning use, future fertility desire and unmet family planning need in logistic regression

	Family planning use (N=853)			Future fertility desire (N=684)			Unmet family planning need (N=850)		
	Univariable OR (95%CI)	Multivariable OR (95%CI)	P-value	Univariable OR (95%CI)	Multivariable OR (95%CI)	P-value	Univariable OR (95%CI)	Multivariable OR (95%CI)	P-value
HIV status									
HIV-uninfected	ref	ref		ref	ref		ref	ref	
HIV-infected	0.9 (0.7-1.2)	0.9 (0.7-1.2)	0.499	0.3 (0.2-0.4)*	0.3 (0.2-0.4)*	<0.001	1.1 (0.8-1.5)	1.1 (0.8-1.5)	0.612
Age	1.0 (1.0-1.0)	1.0 (1.0-1.0)	0.148	0.9 (0.9-0.9)*	0.9 (0.8-0.9)*	<0.001	1.0 (1.0-1.0)	1.0 (1.0-1.0)	0.233
Education									
Less than secondary	ref	ref		ref	ref		ref	ref	
Completed secondary/any tertiary	0.9 (0.7-1.3)	1.0 (0.7-1.4)	0.923	1.5 (1.1-2.1)*	1.5 (0.9-2.3)	0.119	1.1 (0.8-1.4)	1.0 (0.7-1.4)	0.914
SES									
Lowest SES	ref	ref		ref	ref		ref	ref	
Moderate SES	1.1 (0.8-1.6)	1.1 (0.8-1.6)	0.607	1.1 (0.7-1.7)	1.1 (0.7-1.9)	0.690	1.0 (0.7-1.4)	1.0 (0.7-1.4)	0.846
Highest SES	0.9 (0.6-1.3)	0.9 (0.6-1.4)	0.665	1.1 (0.7-1.6)	0.8 (0.4-1.6)	0.596	1.2 (0.8-1.7)	1.2 (0.7-1.9)	0.475
Parity									
Not first pregnancy	ref	ref		ref	ref		ref	ref	
First pregnancy	1.1 (0.8-1.6)	1.1 (0.7-1.6)	0.809	4.7 (3.1-7.2)*	2.0 (1.2-3.5)*	0.012	0.9 (0.6-1.3)	1.0 (0.6-1.5)	0.850
Planned pregnancy									
Unintended	ref	ref		ref	ref		ref	ref	
Intended	1.4 (1.0-1.9)*	1.3 (0.9-1.8)	0.123	1.8 (1.3-2.6)*	2.1 (1.4-3.3)*	0.001	0.7 (0.5-0.9)*	0.7 (0.5-1.0)	0.074
Weeks breastfeeding	1.0 (1.0-1.0)	1.0 (1.0-1.0)	0.281	1.0 (1.0-1.0)	1.0 (1.0-1.0)	0.873	1.0 (1.0-1.0)	1.0 (1.0-1.0)	0.297
Marital Status									
Single	ref	ref		ref	ref		ref	ref	
Married/cohabiting	1.3 (1.0-1.7)	1.2 (0.9-1.7)	0.180	1.0 (0.7-1.4)	1.1 (0.7-1.7)	0.724	0.8 (0.6-1.1)	0.8 (0.6-1.2)	0.293
Employment									
Unemployed	ref	ref		ref	ref		ref	ref	
Employed	1.0 (0.8-1.3)	1.1 (0.8-1.5)	0.702	1.0 (0.7-1.4)	0.9 (0.6-1.5)	0.807	1.0 (0.8-1.3)	0.9 (0.7-1.3)	0.724
Discussed family planning/ pregnancy with partner									
No	ref	ref		ref	ref		ref	ref	
Yes	1.2 (0.9-1.6)	1.1 (0.8-1.5)	0.426	2.6 (1.8-3.7)*	2.5 (1.7-3.8)*	<0.001	0.8 (0.6-1.1)	0.9 (0.7-1.2)	0.461

*p<0.05

Within HIV-infected women, there were no differences found between those that were using FP (303 (61.0%)) and those that were not (193 (39.0%)) (Table 4). Variables considered were viral suppression, viral load, age, education, SES, parity, planned pregnancy, breastfeeding duration, marital status, employment, timing of HIV diagnosis, disclosure of HIV status to partner or anyone, and discussing family planning/ pregnancy with a partner.

Table 4. Demographic and clinical characteristics of all enrolled HIV-infected women with a 12 month post-partum visit by family planning status (N=497)

	All HIV-infected N=497 (100%)	Using family planning N=303 (61%)	Not using family planning N=193 (39%)	P-value
Viral suppression [a]				
No	105 (22.1%)	58 (19.9%)	47 (25.5%)	
Yes	371 (77.9%)	234 (80.1%)	137 (74.5%)	0.146
Missing	21	11	9	
Log10 viral load (median, IQR)	1.6 (1.6, 2.5)	1.6 (1.6, 2.1)	1.6 (1.6, 3.0)	0.092
Missing	21	11	9	
Age (median, IQR)	28 (24, 32)	28 (24, 32)	28 (24, 32)	0.505
Education				
Less than secondary	351 (70.6%)	211 (69.6%)	139 (72.0%)	
Completed secondary/any tertiary	146 (29.4%)	92 (30.4%)	54 (28.0%)	0.570
SES				
Lowest SES	124 (25.1%)	70 (23.3%)	53 (27.6%)	
Moderate SES	205 (41.5%)	131 (43.5%)	74 (38.5%)	
Highest SES	165 (33.4%)	100 (33.2%)	65 (33.9%)	0.449
Missing	3	2	1	
Parity				
Not first pregnancy	435 (87.5%)	267 (88.1%)	167 (86.5%)	
First pregnancy	62 (12.5%)	36 (11.9%)	26 (13.5%)	0.602
Planned pregnancy				
Unintended	344 (69.6%)	205 (68.3%)	139 (72.0%)	
Intended	150 (30.4%)	95 (31.7%)	54 (28.0%)	0.384
Missing	3	3		
Weeks breastfeeding (median, IQR)	32.5 (10.4, 56.4)	32.7 (12.0, 56.4)	32.1 (9.6, 59.7)	0.840
Missing				
Marital Status				
Single	299 (60.3%)	178 (58.9%)	121 (62.7%)	
Married/cohabiting	197 (39.7%)	124 (41.1%)	72 (37.3%)	0.405
Missing	1	1		
Employment				
Unemployed	312 (62.9%)	188 (62.2%)	123 (63.7%)	
Employed	184 (37.1%)	114 (37.8%)	70 (36.3%)	0.740
Missing	1	1		
Timing of HIV diagnosis				
Before this pregnancy	222 (44.8%)	168 (55.6%)	105 (54.4%)	
During this pregnancy	274 (55.2%)	134 (44.4%)	88 (45.6%)	0.789
Missing	1	1		
Disclosed HIV status to partner				
No	274 (56.9%)	169 (57.7%)	104 (55.3%)	
Yes	208 (43.1%)	124 (42.3%)	84 (44.7%)	0.610
Missing	15	10	5	
Told anyone about HIV status				
No	207 (41.7%)	125 (41.4%)	81 (42.0%)	
Yes	289 (58.3%)	177 (58.6%)	112 (58.0%)	0.899
Missing	1	1		
Discussed family planning/pregnancy with partner				
No	290 (58.5%)	174 (57.4%)	116 (60.1%)	
Yes	206 (41.5%)	129 (42.6%)	77 (39.9%)	0.555
Missing	1			

[a]Viral suppression was defined as an individual having a viral load below 1000 copies/µl.
All categorical variables are displayed as frequency (percentage).
HIV=human immunodeficiency virus; IQR= interquartile range; SES= socioeconomic status

Discussion

This analysis of secondary data from three contributing studies found that a large proportion of women had an unmet FP need and that very few women desired to have a child within the next 12 months. While no associations were found between HIV status and FP use or unmet FP need, there were significant associations between HIV status and future fertility desires.

In this cohort, 62.3% of women were using a FP method. In 2015, contraceptive prevalence among married or in-union women of reproductive age in South Africa was estimated at 64.8% [3]. Other studies in South Africa have also found similar proportions of women using FP [20,22], while some studies have found lower levels [29] and higher levels of FP use [30]. No association was found between HIV status and FP use. This finding is consistent with some studies performed in SSA [21,22], but contradictory to a number of studies that have shown that HIV-infected women are more likely to use FP compared to HIV-uninfected women [14,16–20]. A possible reason could be that women receiving HIV treatment have regular contact with health care professionals where they have the opportunity to discuss and obtain FP [18]. There were signficant differences in sociodemographic characteristics (education, SES and employment) by HIV status. The trend towards the higher level of education, SES and employment in HIV-uninfected women could affect FP use by HIV status however, these variables were adjusted for in multivariable analysis.

Injectable contraceptives were the most common FP methods used in this population of women (>90%). This finding is consistent with other studies in South Africa [19,29–31] and SSA [7,13,14,27] where injectable contraceptives were also the most popular FP method used among women. Given that current data suggests an association between injectable contraceptive use and increased risk of HIV-1 acquisition [32], strengthening access to alternative FP methods may be beneficial. Women who do not want to have any more children should consider long-acting or permanent FP methods such as IUDs, implants and male and female sterilization. Very few women in this population (<6%) used any of these FP methods. The lack of promotion and use of these methods in South Africa has been recognized as an area for improvement in FP services [30,33].

Fewer than 1% of individuals had an immediate fertility desire (wanted to have a child within the next 12 months) and only 20.9% wanted to have a child sometime in the future, reflecting partially the fact that most women in this study already had other children. Comparing fertility desires by HIV status, a higher proportion of HIV-uninfected women reported that they wanted to have a child sometime in the future compared to HIV-infected women with many more HIV-infected women reporting that they did not want another child or were unsure about their fertility desires. These findings are similar to another study in Cape Town, which also found that significantly more HIV-infected postpartum women either did not want another child or were unsure whether they wanted another child compared to HIV-uninfected women [30]. This difference may be attributable to the increased awareness of MTCT. Further research is required to understand the uncertainty with regards to the fertility desires of HIV-infected women and how this translates into FP use. A significant association was found between HIV status and future fertility desire, which remained significant in multivariable models. This result is consistent with many studies in SSA that found that HIV-infected women were less likely to have fertility desire compared to HIV-uninfected women [9,17,21–23]. Age, parity, intended pregnancy and discussed family planning/pregnancy with partner were also significantly associated with future fertility desire. Previous research has also found associations between fertility desire and age [9,21,22] and parity [17,21,22].

The level of unmet FP need in this study was 37.2%, which is much higher than has previously been estimated for South Africa. Unmet FP need was estimated to be 12.2% among married or in-union women of reproductive age in South Africa in 2015 [3]. Different studies use different definitions of unmet FP need, which could explain the differences in results. The definition of unmet FP need used in this study was consistent with those used in other studies in terms of including women who want to delay the birth of their next child or do not want to have any more children but are not using a FP method. Some studies restrict their definition to women who are sexually active, fecund and married or in a union. Our definition was not limited to women who were married or in a union, did not account for sexual activity or fecundity and included women who reported "unsure" with regards to their fertility desires. Furthermore, many of these estimates are not exclusive to postpartum women, as in our study, during which time many women have described an unmet need for FP [6,8]. These limitations aside, the high rate of unmet FP need is concerning and points to a need for increased or targeted interventions.

No significant association was found between HIV status and unmet FP need in multivariable analysis. Only a few studies have investigated unmet FP need by HIV status with varying results. Studies have found higher levels of unmet FP need in HIV-infected women compared to HIV-uninfected women [24,25], lower levels of unmet FP need in HIV-infected women compared to HIV-uninfected women [26] and similar levels of unmet FP need among HIV-infected women to that of the general population [27]. In the sub analysis of HIV-infected women, no significant demographic or clinical differences were observed between those using and not using FP.

The findings in this analysis are strengthened by the size and direct comparison of HIV-infected and HIV-uninfected postpartum women. This analysis contributes to the growing body of research investigating the effect of HIV status on FP and fertility behaviours, especially among postpartum South African women. As all three studies were performed in Gugulethu, Cape Town at a public sector, primary health care facility, the results are likely generalizable to other urban, public sector settings in South Africa. However, they may not generalize to rural or other African populations with different health care access.

The primary limitations of this analysis are data based on self-report which includes one of the outcome variables, FP use. This could introduce reporting bias. Another limitation was not being able to take sexual activity into account when measuring unmet FP need, which could potentially result in an overestimation of unmet FP need.

Conclusion

FP prevalence in this population of women is similar to previously reported results in South Africa. However, a large proportion of women had an unmet FP need. This analysis found no differences between HIV-infected and HIV-uninfected women in terms of FP use and unmet FP need, but did find that HIV status was associated with fertility desire in line with other research. The high level of unmet FP need suggests that FP services need to be strengthened across both HIV-infected and HIV-uninfected women.

Competing interests

The authors declare that there are no competing interests.

Authors' contributions

JO carried out the analysis and wrote the first draft of the manuscript.

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PART D: APPENDICES

Appendix A:Family planning and pregnancy intentions questionnaire‡

MCH-ART: Family Planning/Pregnancy intentions Phase 3 12mo pp PID:

3 - _ _ _ _ - _ _ Version 2.1, 22 Jan 2013

Visit Date: _ _/_ _ _/_ _ _ _		
We are now going to ask you some questions about your use of family planning methods since we last spoke to you:		
	Are you currently using any family planning method?	No = 0 → SKIP to Q4 Yes = 1
	If yes, what method are you using? *Circle all that apply*	Oral contraceptive pill 2-month injectable ('noristerat NET-en') 3-month injectable ('depo, petogen') Intra-uterine device (IUD) Female sterilization Male sterilization Male condom Female condom Other method, specify:_______________
	Where do you receive your family planning method from?	Gugulethu MOU = 1 Gugulethu CHC = 2 Other = 3
	Since we last saw you have you discussed family planning or pregnancy with your partner?	No = 0 Yes = 1

We are now going to ask about your future pregnancy intentions:		
	Think about how you feel right now. Which of the following statements best describes your own thinking about having a child in the future?	I may want to have a child in the next 12 months. = 1 I may want to have a child sometime in the future but not in the next 12 months. = 2 I have decided that I do not want to have a child in the future.= 3 I am unsure about whether or not I want to have a child in the future.= 4 Other =5, specify: _______________

Date completed: _ _ /_ _ _ / _ _ _ _

Signed counsellor completing CRF: ______________________

Date of QC: _ _ /_ _ _ / _ _ _ _

Signed measurement nurse: ________________

Initials of counsellor: _______

____

‡The same family planning and pregnancy intentions questionnaire was used for MCH-ART, PACER and HU2

Appendix B: Informed consent forms (MCH-ART)§

Phase 1 Informed Consent Form

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

WHAT IS THE PURPOSE OF THIS STUDY?

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

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

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

---

§The same informed consent process was used for MCH-ART, PACER and HU2

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

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

- Answer questions about your household, medical history, partnership status, HIV testing history and disclosure status and previous use of HIV drugs.
- Have 5mLs (1 teaspoon) of blood drawn from your arm so that we can check your viral load (this is the amount of HIV in your blood)

NOTE: Blood drawn today for viral load testing is not part of your routine health care. This blood will be stored and tested at a later time. Results from these tests will not be available to you, the clinic, or the study staff. When the health care providers at the clinic need to check your viral load, they will take a separate blood specimen. When it is stored, your blood and test results will not have your name or any other way of identifying you attached to it.

Review of medical records

As part of this study, we will also be reviewing and abstracting information from your medical records. We are interested in learning about the HIV care and treatment that you receive during your pregnancy and after you delivered. We also want to learn about the pregnancy care you received as well as information about your delivery. All data that we review and abstract is confidential and no participant names are recorded on study documents.

Contact for future study

After the completion of this visit, it is possible that we will contact you again at your next clinic visit to take part in additional study visits like this one. At that time, you would be asked to review and sign another consent form. You can choose to not take part in these additional visits if you are asked.

WHAT ARE THE POTENTIAL RISKS?

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

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

WHAT ARE THE POTENTIAL BENEFITS?

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

WHAT ARE THE ALTERNATIVES TO TAKING PART?

The alternative to taking part in this study is to continue with the standard of care for all HIV-positive pregnant women.

WHAT ABOUT CONFIDENTIALITY?

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

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

WILL I BE GIVEN ANYTHING FOR TAKING PART?

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

ARE THERE ANY COSTS?

There is no cost for being in this study.

CAN I LEAVE THE STUDY?

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

FUTURE USE OF SPECIMENS:

We are specifically looking at your use of antiretroviral therapy during this study, and in particular the amount of HIV in your blood. However, the information and samples being collected from all participants may also help answer other questions about HIV in the future. If there is leftover blood at the end of this study, we may want to use your leftover blood so that other research studies can be done in the future. If you agree to let us keep your leftover samples for future research, they may be kept in a locked freezer for up to 5 years. If we do use your samples in the future, your name or other identifiers will not be included with this information (as with the rest of the information we collect for this study).

Please initial below to indicate whether or not you give permission for your specimens to be used for future research.

_____ (initial) I <u>agree</u> to have my <u>specimens stored for future research</u> by the investigators who are conducting this study.

_____ (initial) I <u>do **NOT** agree</u> to the storage of my blood after the end of this study.

DO YOU HAVE ANY QUESTIONS?

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

Do you have any questions?

FOR ADDITIONAL INFORMATION:

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

Dr Landon Myer

School of Public Health and Family Medicine

Faculty of Health Sciences, University of Cape Town

Tel: 021 406 6661; email: Landon.Myer@uct.ac.za

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

Prof Marc Blockman

Chair, Human Research Ethics Committee

Faculty of Health Sciences, University of Cape Town

Tel: 021 406 6338

CONSENT STATEMENT:

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

Please indicate your consent with your signature, or a tick if you would prefer.

____

Signature of Volunteer [tick optional]   Date

____

Signature of study staff Date

Thank you.

Phase 2 Informed Consent Form

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

WHAT IS THE PURPOSE OF THIS STUDY?

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

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

You are being asked to take part in this study because you are a pregnant woman with known HIV infection who is about to start taking HIV drugs (antiretroviral therapy). The purpose of this consent form is to give you information to help you decide if you want to take part in this study.

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

If you agree to take part, you will come in for up to 3 visits. These visits will take place today while you are in the clinic, during your third trimester and within one week of delivering your baby. Each visit will take about 30-45 minutes.

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

- Answer questions about your recent pregnancy- and HIV-related health care, HIV disclosure, and use of HIV drugs (including side effects and adherence).
    - At different visits, we will ask you additional questions about HIV, stigma, social support, infant feeding practices, family planning, experiences of partner violence, and mental health (including drug and alcohol use).
- Have 5mLs (1 teaspoon) of blood drawn from your arm each time so that we can check your viral load (amount of HIV in your body)

One-week after delivery

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

- Answer questions about your recent pregnancy- and HIV-related health care, HIV disclosure, and use of HIV drugs (including side effects and adherence).
    - At this visit, we will ask you additional questions about family planning after delivery, how you felt about the HIV care that you received, infant feeding practices and infant health care.
- Have 5mLs (1 teaspoon) of blood drawn from your arm so that we can check your viral load (amount of HIV in your body)

NOTE: Blood drawn today for viral load testing is not part of your routine health care. This blood will be stored and tested at a later time. Results from these tests will not be available to you, the clinic, or the study staff. When the health care providers at the clinic need to check your viral load, they will take a separate blood specimen. When it is stored, your blood and test results will not have your name or any other way of identifying you attached to it.

Contact for future study

After the completion of the visit one week after delivery, it is possible that we will ask to see whether you would like to participate in a further research study that aims to understand how best to deliver health care services to HIV-positive mothers and their children. At that time, you will be asked to review and sign another consent form. You can choose to not take part in these additional visits if you are asked.

WHAT ARE THE POTENTIAL RISKS?

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

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

WHAT ARE THE POTENTIAL BENEFITS?

There is no direct benefit to you if you take part in this study. The information gained in this study may help to improve ART services for HIV-infected pregnant women in Cape Town, the Western Cape Province, and across South Africa.

WHAT ARE THE ALTERNATIVES TO TAKING PART?

The alternative to taking part in this study is to continue with the standard of care for all HIV-positive pregnant women.

WHAT ABOUT CONFIDENTIALITY?

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

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

WILL I BE GIVEN ANYTHING FOR TAKING PART?

At the end of each visit, you will be given a R150 grocery voucher.

ARE THERE ANY COSTS?

There is no cost for being in this study.

CAN I LEAVE THE STUDY?

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

FUTURE USE OF SPECIMENS:

We are specifically looking at your use of antiretroviral therapy during this study, and in particular the amount of HIV in your blood. However, the information and samples being collected from all participants may also help answer other questions about HIV in the future. If there is leftover blood at the end of this study, we may want to use your leftover blood so that other research studies can be done in the future. If you agree to let us keep your leftover samples for future research, they may be kept in a locked freezer for up to 5 years. If we do use your samples in the future, your name or other identifiers will not be included with this information (as with the rest of the information we collect for this study).

Please initial below to indicate whether or not you give permission for your specimens to be used for future research.

______ (initial) I <u>agree</u> to have my <u>specimens stored for future research</u> by the investigators who are conducting this study.

______ (initial) I <u>do **NOT** agree</u> to the storage of my blood after the end of this study.

DO YOU HAVE ANY QUESTIONS?

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

Do you have any questions?

FOR ADDITIONAL INFORMATION:

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

Dr Landon Myer

School of Public Health and Family Medicine

Faculty of Health Sciences, University of Cape Town

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

Prof Marc Blockman

Chair, Human Research Ethics Committee

Faculty of Health Sciences, University of Cape Town

Tel: 021 406 6338

CONSENT STATEMENT:

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

Please indicate your consent with your signature, or a tick if you would prefer.

____

Signature of Volunteer [tick optional]   Date

____

Signature of study staff   Date

Thank you.

Phase 3 Informed Consent Form

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

WHAT IS THE PURPOSE OF THIS STUDY?

We are from the University of Cape Town. You are being asked to take part in a study that is being conducted at the Gugulethu Midwife Obstetric Unit (MOU). The purpose of this study is to compare two different ways of providing HIV treatment to women after they deliver a baby.

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

You are being asked to take part in this study because you are a pregnant woman with known HIV infection who is about to start taking HIV drugs. The purpose of this consent form is to give you information to help you decide if you want to take part in this study.

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

If you agree to take part, you will be randomized (like a flip of a coin) to one of two places to receive your ART, as described below:

1. MCH-focused ART services group: Women assigned to this group will continue to receive HIV care and medicines here, at the MOU, as they did during their pregnancy. When they have stopped breastfeeding, women in this group will be referred to their nearest general ART clinic.

2. General ART services group: Women assigned to this group will be referred to the nearest ART clinic for HIV care and to continue their HIV medicines.

"Randomised" means that you will have a 50% chance of being in the group that will receive on-site care. You will also have a 50% chance of being in the group that receives referred care. Neither the study staff nor you can choose which group you will be assigned to. The decisions are made by a computer and put into an envelope. The staff does not know which group is in each envelope.

This randomization will occur today and you will then come in for up to 4 additional study measurement visits at 6 weeks after delivery and 6, 9, and 12 months after delivery. Each visit will take about 30-60 minutes.

These visits will include the following:

- Answer questions about your recent pregnancy- and HIV-related health care, HIV disclosure, and use of HIV drugs (including side effects and adherence).

    - At selected visits, we will ask you additional questions about HIV, stigma, and mental health (including drug and alcohol use), family planning, infant feeding practices, infant health care and how you feel about the HIV care that you have received.
- Have 5mLs (1 teaspoon) of blood drawn from your arm so that we can check your viral load (amount of HIV in your body)

NOTE: Blood drawn today for viral load testing is not part of your routine health care. This blood will be stored and tested at a later time. Results from these tests will not be available to you, the clinic, or the study staff. When the health care providers at the clinic need to check your viral load, they will take a separate blood specimen. When it is stored, your blood and test results will not have your name or any other way of identifying you attached to it.

At the last visit, we will also draw blood from your baby:

- Baby will undergo a heelstick to collect blood to check your baby's HIV status.
    - We will return the results of this test to you as soon as it is available.

WHAT ARE THE POTENTIAL RISKS?

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

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

WHAT ARE THE POTENTIAL BENEFITS?

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

WHAT ARE THE ALTERNATIVES TO TAKING PART?

The alternative to taking part in this study is to continue with the standard of care for all HIV-positive pregnant women, which means you will be referred from the MOU to your nearest general ART clinic as soon as possible.

WHAT ABOUT CONFIDENTIALITY?

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

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

WILL I BE GIVEN ANYTHING FOR TAKING PART?

At the end of each visit, you will be given a R150 grocery voucher.

ARE THERE ANY COSTS?

There is no cost for being in this study.

CAN I LEAVE THE STUDY?

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

FUTURE USE OF SPECIMENS:

We are specifically looking at your use of antiretroviral therapy during this study, and in particular the amount of HIV in your blood. However, the information and samples being collected from all participants may also help answer other questions about HIV in the future. If there is leftover blood at the end of this study, we may want to use your leftover blood so that other research studies can be done in the future. If you agree to let us keep your leftover samples for future research, they may be kept in a locked freezer for up to 5 years. If we do use your samples in the future, your name or other identifiers will not be included with this information (as with the rest of the information we collect for this study).

Please initial below to indicate whether or not you give permission for your specimens to be used for future research.

______ (initial) I agree to have my specimens stored for future research by the investigators who are conducting this study.

______ (initial) I do **NOT** agree to the storage of my blood after the end of this study.

DO YOU HAVE ANY QUESTIONS?

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

Do you have any questions?

FOR ADDITIONAL INFORMATION:

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

Dr Landon Myer

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Faculty of Health Sciences, University of Cape Town

Tel: 021 406 6661; email: Landon.Myer@uct.ac.za

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

Prof Marc Blockman

Chair, Human Research Ethics Committee

Faculty of Health Sciences, University of Cape Town

Tel: 021 406 6338

CONSENT STATEMENT:

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

Please indicate your consent with your signature, or a tick if you would prefer.

____

Signature of Volunteer [tick optional]   Date

____

Signature of study staff   Date

Thank you.

Appendix C: Human Research Ethics Committee (HREC) approval letter

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

Room E53-46 Old Main Building
Groote Schuur Hospital
Observatory 7925
Telephone [021] 406 6492
Email: sumayah.ariefdien@uct.ac.za
Website: www.health.uct.ac.za/fhs/research/humanethics/forms

09 November 2017

HREC REF:745/2017

Dr M Lesosky
Epidemiology & Biostatistics Division
School of Public Health & Family Medicine
Room 5.39-Falmouth Building

Dear Dr Lesosky

PROJECT TITLE: FAMILY PLANNING BEHAVIOURS AMONG SOUTH AFRICAN HIV-INFECTED AND HIV-NEGATIVE WOMEN DURING THE POST PARTUM PERIOD (MPH- CANDIDATE - MS J OOSTHUIZEN) SUB-STUDY LINKED TO 451/2012

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

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

Approval is granted for one year until the 30 November 2018.

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)

We acknowledge that the student: Ms J Oosthuizen will also be involved in this study.

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.

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 M BLOCKMAN
CHAIRPERSON, FHS HUMAN RESEARCH ETHICS COMMITTEE

Federal Wide Assurance Number: FWA00001637.
Institutional Review Board (IRB) number: IRB00001938

HREC 745/2017

Appendix D: Author Guidelines for Journal of the International AIDS Society (JIAS)

Edited By: Prof. Susan Kippax and Prof. Kenneth H. Mayer

Impact Factor: 6.296

ISI Journal Citation Reports © Ranking: 2016: 6/84 (Infectious Diseases); 24/151 (Immunology)

Online ISSN: 1758-2652

Author Guidelines

Sections

9. Editorial Office Contact Details

1. SUBMISSION

Please carefully read through the Instructions for Authors and prepare your manuscript according to the guidelines, including structuring it manuscript based on the chosen article category. Manuscripts that do not follow the instructions may be returned to the authors for corrections.

Authors should kindly note that submission implies that the content has not been published or submitted for publication elsewhere except as a brief abstract in the proceedings of a scientific meeting or symposium.

Once the submission materials have been prepared in accordance with the Author Guidelines, manuscripts should be submitted online at https://mc.manuscriptcentral.com/jias. The submission system will prompt authors to use an ORCID iD (a unique author identifier) to help distinguish their work from that of other researchers. Click here to find out more.

You will be asked to suggest potential peer reviewers for your manuscript: they should be experts in the field and be able to provide an objective assessment of the manuscript. Any suggested peer reviewers should not have published with any of the authors of the manuscript within the past five years, should not be current collaborators, and should not be members of the same institution. Suggested reviewers will be considered alongside potential reviewers identified by the Editorial team.

Click here for more details on how to use ScholarOne.

2. AIMS AND SCOPE

The *JIAS* welcomes submissions on HIV-related topics from across all scientific disciplines, including but not limited to:

• Basic and biomedical sciences

• Behavioural sciences

• Epidemiology

• Clinical sciences

• Health economics and health policy

• Operations research and implementation sciences

• Social sciences and humanities, including political sciences and media

The *JIAS* prioritizes submissions from operational research and implementation science as publication of such material can provide valuable information on various algorithms for monitoring and providing support for comprehensive, yet affordable and sustainable treatment, prevention and care programmes in different contexts.

Submission of HIV research carried out in low- and middle-income countries is strongly encouraged.

3. MANUSCRIPT CATEGORIES AND REQUIREMENTS

The *JIAS* accepts submissions in the following categories:

• Research

• Short report

• Review

• Debate

• Commentary

• Letter to the Editor

• Viewpoint

Research - full reports of data from original research studies

Headings: Introduction, Methods, Results, Conclusions

Word limit: 350 words

Main text:

Headings: Introduction, Methods, Results, Discussion, Conclusions

Word limit: 3500 words

Numbers of figures and tables: Unlimited

Additional files: Yes

Download the manuscript template

Short report - brief reports of data from original research, such as follow-up or confirmatory studies, case series and negative results

Abstract:

Headings: Introduction, Methods, Results and discussion, Conclusions

Word limit: 350 words

Main text:

Headings: Introduction, Methods, Results and discussion, Conclusions

Word limit: 2500 words

Numbers of figures and tables: 4

Additional files: No

Download the manuscript template

Review - comprehensive, authoritative descriptions and summaries of a specific subject area providing a systematic and substantial overview of the field

Abstract:

Headings: Introduction, Methods (if applicable), Results and discussion (if applicable, otherwise Discussion only), Conclusions

Word limit: 350 words

Main text:

Headings: Introduction, Methods (if applicable), Results and discussion (if applicable, otherwise Discussion only), Conclusions

Word limit: 5000 words

Numbers of figures and tables: Unlimited

Additional files: Yes

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