## UNIVERSITY OF CAPE TOWN

# Intimate partner violence among HIV-infected pregnant women initiating antiretroviral therapy in South Africa

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BRNMOL002

Submitted in fulfillment of the requirements for the degree

MASTER OF PUBLIC HEALTH

In the

SCHOOL OF PUBLIC HEALTH AND FAMILY MEDICINE

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March 2015

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# **PREAMBLE**

#### **Declaration**

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Date	21 May 2015

#### **Abstract**

# Intimate partner violence among HIV-infected pregnant women initiating antiretroviral therapy in South Africa

#### Background

Intimate Partner Violence (IPV) is recognized globally as a major public health concern linked to numerous adverse physical, mental, sexual and reproductive health outcomes. IPV is associated with both pregnancy and HIV-infection independently, but there are few data on IPV in populations of HIV-infected pregnant women. We examined the prevalence and predicators of IPV among pregnant women initiating lifelong antiretroviral therapy (ART) in a large primary care clinic in Cape Town, South Africa.

#### Methods

Consecutive pregnant women seeking antenatal care in Gugulethu, Cape Town were recruited into the MCH-ART study examining service models for postpartum ART care. IPV, depression, alcohol and drug use, and emotional distress were assessed using the 13-item WHO Violence Against Women questionnaire, the Edinburgh Postnatal Depression Scale (EPDS), alcohol and drug use disorders identification test (AUDIT/DUDIT) and the Kessler-10 (K-10) scale, respectively. Questionnaires were administered privately by trained interviewers. Women identified with specific IPV or mental health concerns were referred to appropriate services. Logistic regression was used to examine factors independently associated with experiences of IPV after adjusting for age and socioeconomic status.

#### Results

From April 2013-May 2014, 623 women were enrolled (median age, 28 years):97% reported being in a relationship, 38% were married and/or cohabiting and 70% reported not having discussed or agreed on pregnancy intentions prior to conception. Overall, 21%(n=132) reported experiencing ≥1 act of IPV in the past 12 months, including emotional violence(15%), physical violence(15%) and sexual violence(2%). Of those reporting any IPV, 48% reported experiencing multiple types. Emotional and physical violence were most prevalent among women 18-24 years old, while sexual violence was most commonly reported among women 25-29 years old. Women who reported not discussing or disagreeing on pregnancy intentions with their partners prior to conception were significantly more likely to experience violence(p=0.030), and women who experienced IPV reported higher levels of substance abuse, depression and emotional distress(p<0.001 for all associations).

#### Discussion

These data demonstrate high levels of IPV in this population. While the potential impact of HIV-infection, pregnancy and pregnancy intention on the risk of IPV and related factors require further research, IPV-related screening and support services should be considered as part of the package of care for ART in pregnancy.

## Acknowledgements

Thank you to my supervisor Professor Landon Myer for proposing this project, investing countless hours mentoring me through the analysis and writing process, reading a never-ending series of rough drafts, and remaining unwaveringly confident in me along the way.

To my co-supervisor, Dr. Anik Gevers thank you for being an invaluable resource and continuous source of support and positivity this past year. This project would not have been possible with you both.

Thank you also to Tamsin Phillips for all of your help, and the entire MCH-ART study staff. Without your hard work and dedication this project would not exist.

Finally, infinite thanks to Nontokozo Langwenya for your friendship, support, perseverance and hard work these past months.

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#### List of Abbreviations

IPV Intimate Partner Violence GBV Gender-Based Violence

HIV/AIDS Human Immunodeficiency Virus/Acquired Immunodeficiency Syndrome

ART Antiretroviral Therapy

MCH-ART Maternal and Child Health Antiretroviral Treatment PMTCT Prevention of Mother-to-Child Transmission (of HIV)

MTCT Mother-to-Child Transmission (of HIV)

CD4 Cluster of Differentiation 4

AZT Azidothymidine

WHO World Health Organization
NGO Non-Governmental Organization
LMIC Low- and Middle-Income Countries

SADHS South African Demographic and Health Survey PGWC Provincial Government of the Western Cape

SOP Standard Operating Procedure CHC Community Health Centre MOU Maternal and Obstetrics Unit

NHLS National Health Laboratory Services

SES Socioeconomic Status

AUDIT Alcohol Use Disorders Identification Test
DUDIT Drug Use Disorders Identification Test
K-10 Kessler-10 Scale of Emotional Distress
EPDS Edinburgh Postnatal Depression Scale

FAS Fetal Alcohol Syndrome

OR Odds Ratio

# Part I RESEARCH PROTOCOL

### I. Background

Intimate partner violence (IPV) is generally accepted as a major public health concern, with serious effects on victims' physical, mental, sexual and reproductive health. Rates of IPV are found to be higher in low- and middle-income countries (LMICs), and the regional prevalence of IPV in Africa is among the highest globally. Research has shown high levels of IPV among South African populations. This study will be conducted among a vulnerable population of pregnant HIV-infected women accessing health services in Gugulethu, Cape Town. We aim to determine the prevalence of IPV (overall, physical, emotional and sexual violence), identify risk factors associated with women's experiences of IPV and explore potential screening methods to identify women experiencing IPV. A secondary data analysis will be conducted using data from a Maternal and Child Health Antiretroviral Treatment (MCH-ART) study, which is currently underway and aims to evaluate the efficacy of a maternal health-focused antiretroviral treatment care package, with the ultimate goal of preventing mother-to-child transmission (PMTCT) of HIV.

IPV has been shown to increase one's risk of HIV infection, and the 2009-2011 UNAIDS Outcome
Framework identified ending violence against women and girls as a priority in fighting the global
HIV/AIDS epidemic. In South Africa, there is evidence to support IPV as a driver of the HIV epidemic.
While the effects of pregnancy on the risk of IPV are unclear, research suggests that in LMIC settings
pregnancy increases women's risk of experiencing IPV. Besides an increased risk of HIV infection, a
number of negative health outcomes for women experiencing IPV have been established, including
depression, emotional distress, alcohol and drug use, preterm labor, delivering low birth weight babies,
miscarriage and femicide (death).

IPV is a potentially important factor in understanding the HIV epidemic in South Africa and in delivering women the most effective care. Pregnant HIV-positive women experiencing IPV are an extremely

vulnerable group and antiretroviral treatment programs are a potentially important point of access for IPV screening and prevention practices. The prevalence and effects of IPV among pregnant women and among HIV-infected women have been looked at separately, but no known research exists in pregnant and HIV- infected populations in South Africa. This study aims to address that gap in knowledge.

# II. Key issues in IPV as a public health concern

Gender Based Violence (GBV) and more specifically IPV is now recognized as a major public health concern worldwide [1–4]. The World Health Organization (WHO) estimates that 30% of ever-partnered women globally have experienced physical and/or sexual IPV [3], and findings from a multi-country study in sites across the world found that between 15% (Japan) and 71% (Ethiopia province) of women reported experiencing physical and/or sexual IPV in their lifetime[5].

By region, the prevalence of IPV in Africa is among the highest, estimated at 36.6% [3]. Asystematic review of 13 studies of IPV in Africa found prevalence estimates to range from 2-57%, with a meta-analysis prevalence of 15% [6]. A South African population based survey conducted in 1998 found 13% of women reported lifetime experiences of physical IPV, and 6% reported violence in the past year [7].

IPV is associated with a number of adverse physical, mental, sexual and reproductive healthoutcomes, including: bruises; welts; fractures; head, back and neck injuries; chronic health problems; stress-induced physiological issues; post-traumatic stress disorder; depression; emotional distress; drug and alcohol abuse; unsafe sexual behaviors; increased risk of HIV infection; unintended pregnancies; and adverse pregnancy events such as preterm labor, delivering low birth weight babies and miscarriage [1–5, 8]. In 2009, the rate of women killed by intimate partners in South Africa was 5.6/100,000, more than double that of the United States[9].

IPV is considered a critical influencing agent of the HIV epidemic in sub-Saharan Africa [10, 11]. Higher rates of IPV are seen among HIV-infected populations, and the WHO estimates that women who are HIV-positive have 1.52 greater odds of experiencing IPV compared to women who are not HIV-positive [1, 3]. Researchers have argued that this is likely a result of gender inequalities and relationship inequities that decrease a woman's power and decision-making ability in a relationship, and increase risk-taking behaviors [1–3, 10–13].

Existing data on the effects of pregnancy on the risk of IPV are not conclusive, however there is evidence to suggest that in a LMIC setting such as South Africa, the risk of experiencing IPV increases during pregnancy [8]. A recent study found that among a population of women attending a public clinic in Durban, South Africa, 21% reported experiencing IPV in their recent pregnancy, and 25% reported some form of IPV in the first four months postpartum [14]. In another study, 30% of women attending an antenatal clinic in Soweto, South Africa reported experiencing physical or sexual IPV in the past 12 months [15].

The MCH-ART study aims to evaluate two models of antiretroviral therapy (ART) delivery; the standard practice of care currently offered in South Africa, and a maternal health-centered method of ART delivery during prenatal and postpartum periods. The goal is to maximize ART retention and adherence by optimizing treatment for pregnant women and new mothers. Research has shown that HIV-infected women are faced with a unique set of challenges surrounding ART adherence in pregnancy and during the postpartum period in particular[16]. Optimizing ART treatment to maximize retention and adherence will have positive health outcomes for HIV-infected women and their exposed infants[17]. Women's experiences of IPV play a potentially crucial role in achieving this goal. Research has linked IPV in HIV-infected populations to a decrease in ART adherence [18]. Similarly, emotional distress, a common comorbidity seen among women experiencing IPV [19], has been found to make women receiving HIV treatment less adherent [20].

## III. Study objectives

The role of IPV in this population represents a potential barrier to optimizing ART treatment [18]. Further research is needed to evaluate the burden of IPV in this population, understand the factors associated with IPV and evaluate the potential benefits of including screening, support and prevention strategies in the package of care for ART in pregnancy. In order to address these gaps in knowledge, this study aims to fulfill a number of objectives:

*Primary objective:* Determine the prevalence of IPV (overall, physical, emotional and sexual) in the past 12 months among pregnant HIV-infected women in Gugulethu, Cape Town.

#### Secondary objectives:

- 1) Identify risk factors associated with women's experience of violence in the past 12 months.
- 2) Examine the relationship between participants' time of first HIV-positive diagnosis and their risk of experiencing IPV in the past 12 months.
- 3) Examine the relationship between participants' pregnancy intentions prior to conception and their risk of experiencing IPV in the past 12 months.

# IV. Methodology

#### Research setting

Research will be conducted at the Gugulethu Community Health Centre (CHC) in Cape Town.

Researchers have been involved with treatment and service delivery at the facility since 2003 and have previously had success carrying out research in conjunction with the provincial government. HIV prevalence in 2011 was 31% and 24% among women attending the Gugulethu antenatal clinic and those

in the surrounding district, respectively. The Gugulethu Maternal and Obstetrics Unit (MOU) is responsible for providing primary antenatal care services. In 2010, an estimated 4,900 women sought antenatal care at the MOU where PMTCT services have been offered since 2001.

Study design

The MCH-ART study, a multi-phase study design, will provide the data for this study.

*Phase 1* is a cross-sectional evaluation of consecutive HIV-infected pregnant women presenting for care at the MOU (their first antenatal visit).

*Phase 2* is an observational cohort study of women from Phase 1 who were eligible for lifelong antiretroviral treatment initiation, according to local guidelines at the time, upon presenting for antenatal care at the MOU. This phase will follow women from their second antenatal visit through their first postpartum visit (within one week of delivery).

Analysis for this study will be conducted as an observational cross-sectional study, with data collected during participants' first visit of Phase 2, i.e. their second antenatal visit. Some demographic data collected only during Phase 1, (e.g. age, socioeconomic and marital status) will also be used in analysis.

Characteristics of the study population

Phase 1 participants will be consenting pregnant HIV-infected women presenting for antenatal care at the Gugulethu MOU. Phase 2 participants will be those phase 1 participants who are eligible for ART initiation (based on the current local guidelines) at their first antenatal visit.

Inclusion criteria

Phase 1:

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- 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
- Able to provide informed consent for research

Phase 2: Phase 1 participants who are ART-eligible

- Consented and participated in Phase 1
- 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)
- Women who were previously receiving lifelong ART must have not used ART for at least six months.
- Able to provide informed consent for research (Appendix P1)

#### Exclusion criteria

Individuals meeting any of the following criteria will be excluded:

- Not currently pregnant
- Intention to relocate out of Cape Town permanently during the study period (Phase 2 only)
- 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
  - Denial of HIV status

#### Recruitment and enrolment

All women presenting at the MOU for their first antenatal visit during this pregnancy with documented HIV infection will be told about the study by MOU staff. If a potential participant shows interest in enrolling MOU staff will either (a) introduce her to a study staff member based at the MOU or (b) ask the potential participant if a member of the study staff can approach her directly. Study staff will provide potential participants with basic information regarding the study. If women express interest in enrolling in the study, study staff will administer a screening process to ensure potential participants meet the inclusion/exclusion criteria previously outlined. Those women determined to be eligible will complete an informed consent form, which includes consent to have medical data abstracted from their patient records and to be approached at a later date regarding future research.

At the second antenatal visit, Phase 1 participants determined to be ART-eligible and fulfill the inclusion requirements outlined above will be approached by study staff to participate in Phase 2. If a participant agrees she will complete a second written informed consent form (Appendix P1) and be enrolled in Phase 2. Women who participate in Phase 1 but are ineligible or refuse to participate in further phases will have information abstracted from their routine clinical records. This is outlined in the Informed Consent form provided to participants enrolling in both Phases 1 and 2.

Throughout the study, trained staff members will ensure that participants are aware that they are free to refuse and/or withdraw from the study at any point. Additionally, all participants will be informed that all study procedures are completely separate from standard antenatal and postnatal care offered at the facility, and that their decision to refuse and/or withdraw from the study will in no way prevent them from accessing any health care services offered at the MOU or other public sector health centers.

#### Research procedures and data collection methods

Study procedures will include data collected from routine antenatal PMTCT and ART services offered at the Gugulethu MOU as a part of the local standard of care (presented below as 'antenatal services at the Gugulethu MOU'), as well as additional study-specific data collected during the study measurement visits also outlined below.

Antenatal services at the Gugulethu MOU (local standard of care services)

- Routine blood testing (including ABO blood group, syphilis screening and haemoglobin) sent to the
   National Health Laboratory Services (NHLS) laboratory
- Medical and obstetric history and examination performed by a nurse-midwife
- Rapid HIV testing, with pre/post-testing counseling
  - Women who are HIV-infected receive counseling, undergo venesection for serum creatinine and CD4 enumeration, and then women not already taking ART are started on a triple-drug antiretroviral regimen immediately, per local PMTCT guidelines.
  - O Breastfeeding counseling begins at the first antenatal care visit, with all women encouraged to exclusively breastfeed for 6 months. Follow-up counseling is provided throughout the antenatal period.
  - Pregnant women receiving ART at the MOU return 1-2 monthly for follow-up visits and medication refills until delivery. Women already receiving ART elsewhere, continue their care at their current ART clinic.

Study measurement visits

Phase 1: After recruitment and informed consent are completed at the first antenatal care visit, women will complete a brief (approximately 20 minutes) study measurement visit in which (a) a standardized questionnaire will be used to collect additional information and (b) 5mL of venous blood for batched viral

load testing will be collected. Questionnaires administered in this study measurement visit will collect information regarding:

 Demographic characteristics, socioeconomic status, medical history, family planning, HIV testing history and disclosure status, and previous antiretroviral exposure.

Phase 2: At the end of their second antenatal visit, participants who are ART-eligible according to current local guidelines and deemed to meet eligibility requirements will be invited to participate in Phase 2.

Women who agree and complete the Informed Consent #2 form (Appendix P1) will undergo three study measurement visits. For the purposes of this analysis, only data from the first of these three visits (study visit 2) will be considered. This study measurement visit will last approximately 30-45 minutes.

Participants will be administered a series of questionnaires and 5mL of venous blood will be collected for storage and batched viral load testing. Questionnaires administered in this study measurement visit will collect information regarding:

 Demographics and medical history, IPV, mental health, substance use, pregnancy history and intentions, social support, HIV status disclosure, and ART use and beliefs.

#### Referrals

If during any study visit a participant is found to have an unmet health need (medical, obstetric, reproductive, mental or otherwise) trained staff will urgently refer them to the appropriate health care services, either within the CHC or elsewhere, as necessary. Particularly:

 Any participant reporting any form of gender-based violence or intimate partner violence will be immediately referred to the local NGO providing support services (MOSAIC) and the South African Police Services (per the Domestic Violence Act, No. 116 of 1998). Adequate focus will be given to this issue in future follow-up. Any participant found to be non-adherent to ART throughout the course of the study will be referred
to the appropriate ART service, be it general adult or MCH-focused, through the Gugulethu MOU
and receive extensive counseling on ART-adherence along with referrals to relevant services.

#### Laboratory measures

Laboratory specimens taken within the scope of this research project will amount to approximately 5 mL maternal venous blood per study measurement visit, for a maximum total of approximately 10 mL per participant. Each specimen will be collected in SST tubes and transported to the National Health Laboratory Services (NHLS) laboratory for storage. Maternal specimens will be used for HIV viral load testing (Abbott Molecular RealTime HIV-1 assay (Abbott Molecular, Illinois, USA)), done in batch testing. The remaining plasma will be divided into 3-4 aliquots of ±80μL each and stored for future research in Sarstedt screw cap tubes at -80°C. All specimen extraction, handling, processing and storing will adhere to standard protocols.

#### Data abstraction

In addition to the measures described above, data abstraction from medical charts and files will be used to collect important data on participants' antenatal and obstetric care and ART initiation and follow-up.

These procedures will be outlined in the informed consent documents described below.

Authorization for data abstraction will be obtained by (a) the participant (via informed consent), (b) the research oversight body of the Provincial Government of the Western Cape (PGWC), (c) the participating IRB/REC, and (d) the facility managers of each participating health facility. None of the data abstracted from medical files will be used in this analysis.

#### Staff training

Before the beginning of the study, any staff member to have participant contact will undergo a multi-day training program specific to the MCH-ART study. Training will cover study purpose and objectives, study design and methodology, conduct of study assessments, tracking of participants, data collection, participant enrolment procedures, staff responsibility, ethical guidelines for research including human participation, issues of confidentiality, participants' rights and informed consent procedures.

Study staff training will be hands-on and include an introduction to the forms and data collection procedures and techniques to be used throughout the study. Mock interviews will be used to allow staff to practice delivering information to participants and role-play as both staff members and as participants. Training will also prepare staff to handle crisis situations, including reports of IPV which may be disclosed during participant interviews. Procedures to handle such situations and make appropriate referrals will be established at the study site and outlined in study standard operating procedures (SOPs). Additional training days will be scheduled for all staff members throughout the course of the study to maintain the highest level of staff efficacy possible.

#### Data safety and monitoring

Data will be managed at the MOU using standard operating procedures that have been established and successful in multiple previous studies. Any data collected on paper will be entered into a Microsoft Access database which has been specially designed and will be maintained in a UCT server, protected by a firewall and backed-up nightly. The database, which a senior data manager will design and maintain, will be password protected per standard password safety procedures. The data manager will also create the data dictionary, handle queries, and ensure quality control whilst supervising the data enterer. Data quality control will be achieved through a robust database design and set-up, "front-end" data checks and

real-time queries. All data queries will be logged; references to source forms and separate program files will be used for data edits. All participant records will use anonymous participant identification numbers and no names or identifiers will be recorded. Any data disseminated to personal computers for the purposes of analysis will not contain participant names or identifiers, and will be password protected.

#### Data analysis

All data analysis will be done in Stata 12 (Stata Corporation, College Station, Texas). All analyses will be conducted under the supervision of Professor Landon Myer, MCH-ART Principal Investigator, with the additional advisement of the study statistician as needed.

The analysis population will include all Phase 1 participants found to be ART-eligible who presented and consented to Phase 2 participation. To fulfill our primary objective, the prevalence of overall, physical, emotional and sexual IPV will be calculated.

To address secondary objectives number 1, descriptive statistics will be used on all demographic, relationship and behavioral characteristics of interest. Ranksum tests, 2-sample t-tests,  $\chi^2$  and Fisher's exact tests will be used to determine if these characteristics are statistically significantly different among women who reported IPV in the past 12 months compared to those who did not. Logistic regression will be used to evaluate factors associated with experiences of IPV, adjusted for age and socioeconomic status. Models including relationship characteristics will be built separately from those including behavioral characteristics in order to avoid confounding and inducing associations through back-door variable relationships. In order to address secondary objective numbers 2 and 3, logistic regression models stratified by (a) time of first HIV-positive diagnosis and (b) pregnancy intention prior to conception will be run.

Statistical significance for all analyses will be evaluated using 95% Confidence Intervals and an  $\langle$ -level of 0.05.

#### **Budget**

This study will not require any further budget allotment. All costs associated with data collection, maintenance, management, etc. will be covered by the MCH-ART budget.

#### IV. Ethical considerations

The MCH-ART study was granted ethics approval from both the University of Cape Town Faculty of Health Services Research Ethics Committee (UCT-HREC) and the Columbia University Medical Center Institutional Review Board (CUMC-IRB). No additional data will be collected from participants for the purposes of this secondary analysis. However, as with any research involving human subjects, certain risks are present, and outlined below.

#### Description of risks and benefits

Possible risks to participants:

The potential risks to participants involved in this study include:

- The post-traumatic stress associated with reporting and recalling a history of IPV. As previously
  mentioned, interviewers and study staff will be trained in dealing with the disclosure of such
  traumatic events, and will be ready and able to make referrals to appropriate services as necessary.
- Similarly, other questionnaires regarding mental health, substance use, HIV status disclosure and
  treatment adherence may hold risk of increasing participants' emotional distress. As above, study
  staff will be trained in how to deal with these disclosures, and refer participants to the relevant
  services as needed.

- The potential complications associated with drawing blood and the collection of biological samples.
- The potential loss of confidentiality resulting from study procedures, for example during data collection. As outlined below, an array of measures will be taken to prevent this from occurring.

None of the above risks are specific to the study, and each of them may be encountered similarly during standard practice of care. All potential risks to participants will be clearly outlined in the informed consent forms given to participants, as will the study measures taken to prevent them.

#### Possible benefits to participants:

The main benefit of study participation is optimized ART treatment and care during pregnancy. By making ART treatment as effective as possible, the risk of mother-to-child HIV transmission (MTCT), which is particularly high among ART-eligible women, will decrease. Optimizing maternal care in this manner will have positive effects on the health of both mothers and babies, regardless of their HIV status. Additionally, for women experiencing IPV, psychosocial issues or harmful behavioral patterns, study participation will provide referrals for health and/or support services they may have been otherwise unaware of or unable to access. Therefore any risks associated with participation in this study are substantially less than the possible benefits.

#### Possible benefits to the community:

Learning more about the prevalence and predictors of IPV in this community will allow us to better understand the complexities of the HIV epidemic in South Africa, and thus more deeply understand the needs of women presenting for care. By identifying the optimal method for administering ART, HIV-infected women in this community and across South Africa will benefit from more efficacious care. The involvement of policy makers and other stakeholders involved in HIV care and maternal and child health will also aid in strengthening health services for HIV-infected pregnant women, thus increasing the indirect benefits of this research.

#### **Informed consent process**

Informed consent will be obtained before enrollment to any study phase by trained interviewers in participants' home language (isiXhosa), using a standardized script. This script will clearly outline the purpose of the study all study procedures and the risks and benefits that participants in the study may encounter. At the time of obtaining informed consent, and throughout the study, interviewers and study staff will stress to participants that participation is voluntary and they are free to decline and/or withdraw from the study at any point without fear of losing access to standard care offered at public sector health centers or experiencing diminished quality of care. Each phase of the study requires its own informed consent, with specific regards to the nature of that phase.

#### Informed consent #1:

This will be given to all participants in Phase 1. The consent form will be completed by HIV-infected pregnant women presenting to the Gugulethu MOU for their first antenatal visit and determined to meet the eligibility requirements. This consent form provides information regarding study purpose and the following procedures: (a) completion of a demographic and behavioral questionnaire (b) obtaining a blood sample (c) permission to review medical charts and abstract information and (d) permission to contact the participant at a later date regarding future research.

#### *Informed consent #2:*

This consent form will be used for all Phase 1 participants who are deemed eligible for Phase 2 (i.e. ART-eligible and satisfy inclusion/exclusion criteria outlined above). This consent form introduces the purpose of the remaining two phases of this study (the observational cohort and randomized trial phases) as well as the specific procedures to be initiated in the remaining phases. A full version of this document can be found in Appendix P1.

#### Privacy and confidentiality

A number of provisions will be made to ensure confidentiality is maintained, including:

- All study staff will be trained specifically in confidentiality and subjects of patient protection
- Per standard practice, all patient files and study-related documents will be kept in a locked cabinet at the study office either in Gugulethu or at UCT
- Anonymous and random patient identification numbers will be used on all study materials. Names
  will only be recorded on informed consent documents, location tracing materials and a study
  identification key. All of these materials will remain locked in separate locations from the
  aforementioned study materials, accessible only by the project coordinator and local PI
- All electronic data will be stored in password-protected and encrypted files. Data storage at UCT will
  be restricted to a firewall-protected SQL server

Efforts will be made to ensure confidentiality at all times, however should staff discover that a participant poses a possible threat to themselves or others, including but not limited to issues of child abuse or neglect, measures to notify the appropriate authorities will be taken. Participants will be made aware of this exception in all informed consent documents presented to them.

#### Reimbursement for participation

Participants will be compensated for their time in the form of R20 in cash to cover transportation costs to attend their next scheduled study visit, R80 in grocery vouchers and up to R50 in refreshments, as well as a small gift at their first and last post-partum visits.

# V. Dissemination strategy

Upon completion of analysis and reporting, student researcher will discuss publication options with both supervisors. The goal will be to publish findings in a peer-reviewed journal in order to add to the limited body of existing research focusing on IPV among pregnant and HIV-positive women in LMIC settings. Publication and presentation of the results of this study will be discussed and agreed upon by all involved parties. These decisions, along with those regarding the nature of the data to be presented, will be made independently of the funding agency.

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# Part II LITERATURE REVIEW

## I. Objectives

This literature review aims to:

- Describe the epidemiology of IPV globally, regionally and locally, and among pregnant women and HIV-infected women individually
- Contextualize the theoretical basis for the proposed analysis
- Review existing literature on the effects of IPV on ART adherence
- Identify any gaps in knowledge that the proposed analysis will address

# II. Methodological approach to literature review

An initial search of PubMed and Google Scholar was conducted to find relevant literature. Search terms used were "Intimate Partner Violence AND HIV AND pregnancy", "Intimate Partner Violence AND Africa", "Intimate Partner Violence AND HIV", "Intimate Partner Violence AND HIV AND Africa", "Intimate Partner Violence AND HIV AND South Africa", "Intimate Partner Violence AND pregnancy", "Intimate Partner Violence AND pregnancy AND Africa", "Intimate Partner Violence AND pregnancy AND South Africa", "Intimate Partner Violence AND pregnancy AND South Africa", "Intimate Partner Violence AND pregnancy", "Intimate Partner Violence AND ART", "Intimate Partner Violence AND ART AND adherence", "Intimate Partner Violence AND alcohol AND South Africa", "Intimate Partner Violence AND drugs AND South Africa", "Intimate Partner Violence AND South Africa", "Intimate Partner Violence AND drugs AND South Africa", "Intimate Partner Violence AND depression AND South Africa", and "Intimate Partner Violence AND emotional distress AND South Africa". Reference lists of resources produced in initial searches were used to identify further relevant literature.

# III. Background

#### What is Intimate Partner Violence (IPV)?

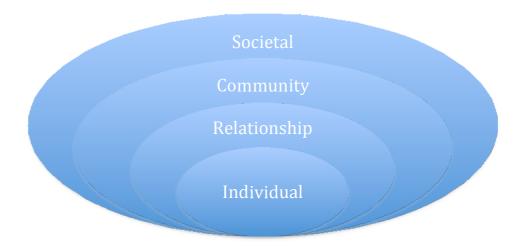
Intimate Partner Violence (IPV) is defined as any "behavior within an intimate relationship (current or former spouses or partners) that causes physical, sexual and psychological harm, including acts of physical aggression, sexual coercion, psychological harm, and controlling behaviors." [1]

The World Health Organization estimates that between 15% and 71% of women around the world experience at least one act of physical and/or sexual intimate partner violence at some point in their lives [1–4]. IPV has been identified as a major global public health concern, with serious consequences for victims' physical, mental, sexual and reproductive health [5].

#### The etiology of IPV: An ecological model within the context of Public Health

Intimate partner violence is a complex phenomenon that can be difficult to explain and even more so to understand. In their 2010 report, the World Health Organization outlined a number of perspectives through which IPV can be viewed and understood [1]. One such theoretical foundation of understanding, the ecological model, categorizes factors associated with IPV into four levels [1], as illustrated in Figure 1.

Figure LR1: The ecological model



This paper uses the ecological model to understand the etiology of IPV by understanding associated factors within the context of four categories:

- The individual level includes biological factors, personal history, and any other characteristics that may increase a person's probability of falling victim to IPV.
- Relationship level factors occur between intimate partners and include things such as duration of relationship, marital status, and partner cohabitation.
- The community level is the context within which social relationships thrive: school, work, religious institutions, etc.
- The societal level includes macro-level factors that influence IPV, such as legislation protecting victims and/or prosecuting perpetrators of IPV, cultural belief systems, societal norms, and economic, social or political policies which create or sustain gaps or inequalities that may affect one's risk of IPV.

The ecological models presents a comprehensive approach to understanding IPV, capable of accounting for factors from different levels, spaces and times, and considering how they affect a person's risk of experiencing IPV is various ways [1].

The *Public Health Perspective* is a "science-driven, population-based, interdisciplinary, intersectoral approach based on the ecological model which emphasizes primary prevention." This approach offers the maximum benefit for the greatest amount of people, and has the ability to understand IPV in a complex manner, fitting of the complexities inherent in the phenomenon itself. This approach also allows one to think about ways to improve care and ensure the safety of entire populations.

# IV. Epidemiology of IPV

#### IPV global burden of disease

It is estimated that 30% of ever-partnered women globally have experienced physical and/or sexual violence at the hands of an intimate partner [3]. In 2006, the WHO published findings from the Multi-Country Study on Women's Health and Domestic Violence, which interviewed over 24,000 women, aged 15-49 in 15 sites across 10 countries [4]. The standardized household survey methods found that among ever-partnered women between 15% (Japan) and 71% (Ethiopia Province) reported a lifetime history of sexual or physical violence, or both- with most prevalence estimates falling between 29% and 62%.

Between 4% and 54% reported physical or sexual IPV or both in the past 12 months, with most estimates falling between 15% and 35%.

The majority of women who reported violence in the past year experienced multiple acts of violence in that time. Violence often coexisted, and in most sites, between 30% and 56% of women who reported any violence had experienced both physical and sexual violence. Between 21% and 90% of ever-partnered women experienced at least one act of controlling behavior by their partners, and women who reported physical and/or sexual violence were more likely to have these controlling constraints placed upon them at the hands of their partners, across all sites [4].

Findings suggested that IPV begins early in life, is often part of an ongoing pattern of violence and severe [4]. Consequences of IPV can be extreme, with an estimated 38% of all murders of women occurring globally being perpetrated by intimate partners [3].

#### **IPV** in Africa

Overall, rates of IPV are found to be higher in LMIC settings [6]. According to the WHO, the African region has one of the highest IPV prevalence estimates in the world, at 36.6%[3]. Results from amulticountry study consistently showed some of the highest estimates of IPV coming from African nations [4], suggesting that IPV is a major issue throughout the region. In a survey conducted across eight countries in southern Africa, 18% of women reported experiencing IPV in the past year [7], and a study of women in steady relationships in Rwanda reported a 21% prevalence of past physical violence [8].

#### **IPV** in South Africa

Research has suggested that IPV may be more pervasive in settings with high rates of violence and gender power inequity [4], and in societies in which the status of women is in a state of transition [1]. This backdrop supporting pervasive patterns of violence may be very relevant to a number of South African settings, where levels of violence particularly against women are high and power inequities are well documented [9].

A nationally representative survey conducted in South Africa reported 13% of women had experienced lifetime physical IPV. Violence in the past year was reported by 6% of participants, 43% of whom reported needing medical attention as a result of those experiences of violence [10]. These figures are lower than most other estimates of IPV in South Africa. It is worth noting that under-reporting is common

in this field, and another study in one South African province estimated a 27% prevalence of physical IPV among ever-partnered women in a sub-set of an SADHS enumeration area which was estimated to have a 9% prevalence of physical IPV in this survey study [10].

A study sampling from antenatal clinics outside of Cape Town used a 4-point frequency scale to estimate a lifetime prevalence of 41%, 37% and 12% for emotional, physical and sexual IPV respectively [6]. In a cross-sectional study conducted among rural women, 54% reported some form of lifetime IPV (physical, sexual or emotional) [11]. An analysis of interviews conducted with women in an antenatal clinic in Soweto produced similar findings, with 56% of participants reporting a lifetime history of physical or sexual IPV [12, 13]. Of these women, 43% reported more than one incident of violence in their lifetime, and only 22% of the total sample reported experiencing no IPV in their lifetime [13].

According to a WHO report, 42% of 13-23 year-old females in South Africa reported a history of physical dating violence [2], further supporting the notion that violence often begins young and remainspervasive throughout women's lifetimes. High reported prevalence estimates of IPV by women are further supported by studies among men, in which many admit to IPV perpetration. In a study of men in Cape Town, 42% admitted to perpetrating physical violence against a partner in the past 10 years. Sexual violence in the past 10 years was reported by 15% and emotional abuse reported by 42% [14, 15]. Most extremely, the 2009 rate of intimate partner femicide in South Africa was 5.6/100,000, more than double that of the United States [16].

#### Risk factors associated with IPV

The WHO has identified a number of risk factors for experiencing intimate partner violence [1, 3]. These are presented in Table 1, adapted from a 2010 WHO report [1]. It should be noted that there remains

contestation regarding the truth of an association between IPV and a number of demographic and social factors [17].

Table LR1: Risk Factors for Experiencing IPV

INDIVIDUAL LEVEL		
Demographics	<ul><li>Young age</li><li>Low SES</li><li>Low education</li><li>Pregnant</li></ul>	
Exposure to Child Maltreatment	<ul><li>Intra-parental violence</li><li>Sexual abuse</li></ul>	
Mental Disorder	Depression	
Substance Use	<ul><li>Harmful use of alcohol</li><li>Illicit drug use</li></ul>	
Attitudes and Experiences of violence	<ul><li>Acceptance of violence</li><li>Exposure to prior violence/victimization</li></ul>	
RELATIONSHIP LEVEL		
Relationship Factors	<ul><li>Marital status</li><li>Educational disparity</li><li>Number of children</li></ul>	
Relationship Quality	Marital dissatisfaction/discord	
COMMUNITY LEVEL		
Gender Beliefs	Acceptance of traditional gender roles	
Neighborhood Characteristics	<ul> <li>High rates of poverty</li> <li>High rates of unemployment</li> <li>High rates of female illiteracy</li> <li>Acceptance of violence</li> <li>Low proportion of women with high levels of autonomy</li> <li>Low proportion of women with higher education</li> </ul>	
SOCIETAL LEVEL		
Legislation	<ul> <li>Governmental divorce regulations</li> <li>Lack of legislation on IPV</li> <li>Protective marriage laws</li> </ul>	
Gender Norms	Traditional gender and social norms that support violence	

#### IPV and health outcomes

Battered women experience more negative physical, mental, sexual and reproductive health outcomes than non-battered women [5]. In general, these outcomes can manifest themselves in two ways: direct outcomes (injury, disability, death, etc.) and indirect outcomes (stress-induced physiological changes, chronic health problems, etc.) [1–3]. Table 2 presents a number of direct and indirect health outcomes that have been found to be associated with experiences of IPV.

*Table LR2: Health outcomes associated with experiences of IPV* 

	OUTCOMES
Physical health [1–3, 5]	Bruises, welts, lacerations, abrasions, abdominal and thoracic
	injuries, fractures, broken bones/teeth, sight and hearing
	damage, head, back and neck injuries, stress-related conditions
	(Irritable bowel syndrome, gastrointestinal symptoms,
	fibromyalgia, chronic pain syndroms, exacerbation of asthma),
	disability, death
Mental Health [1–3, 5]	Depression, PTSD, anxiety, phobias, emotional distress,
	suicidal thoughts, eating and sleep disorders, physical
	inactivity, poor self-esteem, smoking, self-harm and unsafe
	sexual behaviour, alcohol and drugabuse
Sexual/Reproductive	Higher rates of unintended pregnancy, abortions, unsafe
Health [1–3, 5, 18]	abortions, STIs including HIV, adverse pregnancy events
	(miscarriage, pre-term births, stillbirths), pregnancy
	complications, pelvic inflammatory disease, UTIs and sexual
	dysfunction, less likely to report using contraception

#### IPV and causal pathways

Causal pathways between IPV and health outcomes can often be complex and difficult to make sense of, specifically indirect pathways [3]. The figure below, adapted from a 2013 WHO report, presents three ways in which adverse health outcomes can result from experiences of IPV [3]. It should be noted that the proposed analysis is not a thorough investigation of all causal pathways.

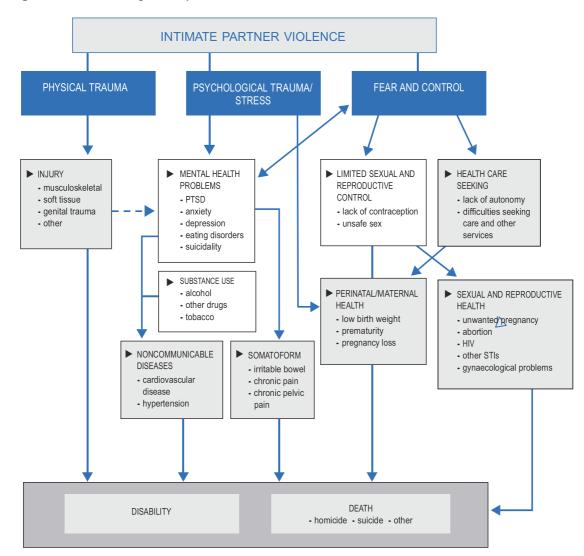


Figure LR2: Causal pathways between IPV and health outcomes

## V. IPV among pregnant women

There remains discord regarding the effects of pregnancy on the risk of IPV. A WHO multi-country study estimated the prevalence of IPV during pregnancy to be between 1% and 28% in sites around the world, with most sites falling between 4% and 12%[4].

Research in Zimbabwe suggests that pregnancy could be protective against IPV due to the value placed on an unborn child's life, or that the risk could fluctuate throughout different stages of pregnancy [19, 20]. However it has generally been found that the risk of experiencing violence increases during pregnancy for women in LMIC settings [6].

#### Health outcomes associated with IPV during pregnancy

Women who experience IPV, especially those in LMICs, also experience a lack of fertility control due to fear and the threat of violence, which can lead to unintended pregnancy [21]. This can have adverse health effects for both the mother experiencing violence and the child being born into an abusive cycle household [21, 22]. Research has shown that women experiencing violence during pregnancy report high levels of anxiety and depression, which can often lead to substance use [21, 22]. Furthermore, IPV in pregnancy has been shown to be associated with unintended pregnancy, induced abortion, late entry to prenatal care, premature labor and delivery, low birth weight or small for gestational age babies, adverse effects on postpartum breastfeeding, fetal injury, miscarriage, stillbirth, fetal death [2, 3, 21, 22]. Children of IPV victims are less likely to be immunized, have higher rates of diarrheal disease and an increased risk of death before the age of 5 [2].

#### IPV among pregnant women in Africa

Research has shown high estimates of IPV prevalence during pregnancy in the region, including 13.5% in Uganda [2]. Demographic and Health survey data from a number of African countries reported a prevalence of physical and/or sexual violence in the past 12 months of 31% in Kenya, 20% in Malawi, 22% in Rwanda, 28% in Zambia and 30% in Zimbabwe [23]. A systematic review of 13 studies of IPV during pregnancy in Africa found prevalence ranges of 2% to 57%, and reported a meta-analysis prevalence of 15.23%[24].

A 2012 qualitative study of IPV during pregnancy in Zimbabwe found that often violence during pregnancy was used as a means of maintaining gender power imbalances and controlling women.

Coercive sexual practices were common, and threats of violence or the use of overt violence was used to control female sexuality. Coupled with cultural norms that undermined women's agency over their own sexuality, and increased financial reliance on men, this constructed a very powerful force of control [20].

A cross-sectional study found all gender inequality factors to be associated with both physical and sexual IPV in Zimbabwe [25]. Both forms of IPV were associated with a younger age at first pregnancy, and independent decision-making regarding pregnancy. Findings showed that pregnancy increased a woman's risk of IPV if she had decided to become pregnant alone, but that it was protective against IPV if the male partner had intended it [25]. Results also suggested that IPV during pregnancy is not an isolated event, but part of a larger pattern of violence. Of women reporting IPV, 10% experienced more than 6 events of violence during pregnancy [25].

#### IPV among pregnant women in South Africa

In a nationally representative survey study, 4% of ever partnered women reported physical violence during pregnancy [10], much lower than estimates gathered from a number of other clinic-based studies. Among pregnant women sampled in a clinic outside of Cape Town 32% and 25% reported emotional and physical IPV respectively in the past 12 months [6]. While 21% of women attending an antenatal clinic in Durban reported IPV in pregnancy [26]. In a similar study from Soweto, 30% of women sampled reported experiences physical or sexual IPV in the past year, and 22% of the overall sample reported experiencing multiple incidents of violence [13].

#### Health outcomes associated with IPV among pregnant women in South Africa

A study conducted outside of Cape Town found that women with a past-year history of physical IPV were significantly more likely to deliver low birth weight babies compared to those who did not report experiences of physical IPV in the preceding 12 months [6], while pregnant women in Durban reporting physical IPV had a 1.48 times great odds of emotional distress for each act of physical violence experienced. The odds of emotional distressed increased by 1.53 and 2.99 for psychological and sexual violence during pregnancy, respectively [26]. Emotional distress has been linked to a number of adverse pregnancy outcomes, including preterm birth and postpartum depression [26].

In a study conducted in informal drinking establishments outside of Cape Town, 13% of women sampled reported pregnancy, 26% reported IPV, and experiences of IPV were associated with alcohol use among all women in the sample [27]. Alcohol use during pregnancy is associated with a number of negative health outcomes for babies, including Fetal Alcohol Syndrome (FAS), the rates of which in South Africa are the highest globally, particularly in the Western Cape [27].

## VI. IPV among HIV-infected women

Women worldwide remain at an increased risk for both IPV and HIV-infection, both independently and concurrently, and evidence from a number of geographic locations and population groups support the association between experiences of violence and HIV-infection [28]. IPV and gender inequality are increasingly identified as a significant contributor to women's HIV risk [12]. There is a significant overlap between HIV-infected women and battered women [29], and it is estimated that the odds of experiencing IPV among HIV+ women is 1.52 (1.03;2.23) times greater than that of HIV- women[3].

The WHO recognizes gender issues as critically influencing the HIV epidemic both globally and in sub-

Saharan Africa [30]. In southern Africa, it is estimated that 1 in 3 people are involved in the cycle of intersections between GBV and HIV [7]. A study in Rwanda found that reports of IPV were more than double in HIV-infected women compared to those who were not infected (OR=2.38 [1.59;3.57])[31]. And in Zimbabwe, IPV is considered a structural driver of HIV, both of which, authors hypothesize, stem from gender inequalities [19].

#### Gender dynamics and links between IPV and HIV

The association between IPV and HIV is compounded by gender, and the unequal associated power dynamics which exist within such structures [28]. While some of the association between HIV and IPV may a direct outcome, i.e. HIV infection through specific acts of sexual violence, this association can be better understood as an indirect effect of women in controlling and violent relationships [1–3]. Maman et al. describe four mechanisms of vulnerability which increase the risk of HIV acquisition in violent relationships: forced or coerced sex, fear of asking for condom use due to threat of violence, experiences of sexual violence and fear of abuse which contributes to concurrency of women's sexual partners [32].

Qualitative research suggests that notions of masculinity that place value upon controlling women and male strength may translate into sexual risk taking, acts of violence against women and increased risk of HIV acquisition [3]. Women in relationships experiencing IPV often have low levels of power and agency over their own sexual decision-making. For example, a woman in a violent relationship may be unable to negotiate condom use for fear of violence, or struggle to discuss issues surrounding HIV status and protection with her partners [1–3]. There also exists notions of condimization being unnecessary with a woman who is "clean" which increases the likelihood of unprotected sex and hinders a woman's ability to negotiate condom use [30]. Research has shown that men who perpetrate violence are more likely tobe HIV-infected [3], putting disempowered women in violent relationships who are experiencing fear or difficulties negotiating safe sex practices at an even greater risk of HIV-infection.

#### IPV as a driver of HIV in South Africa

The association between IPV and HIV has been shown in a number of South African settings. IPV was significantly associated with HIV seropositivity among women in Soweto (OR=1.48)[12]. Women with violent partners have also been shown to engage in more HIV risk behaviors [30] such as: having multiple partners and non-primary partners, transactional sex and substance abuse [12], not requesting condom use and not reporting condom use in the past six months [29] and having higher numbers of past year partners [33].

In a South African cross-sectional study, women who described their relationship as "not good" were less likely to request condom use [30]. Those who did request condoms were more likely to be educated, have multiple partners, and have a reported history of domestic violence and/or economic abuse. Research has hypothesized that due to the low status of women in many South African communities, a female's social worth is proven by her ability to have and keep a man [30]. There are high stakes and benefits- especially economic stability- that come with being in a relationship [30]. Therefore, fear of abandonment, economic vulnerability and the stigma of being seen as 'less than' if unable to keep a man all contribute to women's position of disempowerment within relationships, and therefore their reluctance to request condom use becomes a major obstacle for women [30].

Conversely women with better relationships were more likely to discuss HIV with their partner, however there was no indication that a history of IPV directly influenced discussions of HIV [30]. A later cohort study of young South African women reported that those with low relationship power equity at baseline and women who reported more than one experience of IPV at baseline were more likely to seroconvert during follow-up [9]. The population attributable fractions of HIV were 13.9% and 11.9% for women with low relationship power equity and women with a history of IPV, respectively [9].

## VII. IPV and ART: implications for adherence and retention

In a study conducted in the United States, IPV was found to have a statistically significant negative effect on ART adherence among HIV-infected women [34]. Treatment adherence is critical for suppressing HIV-infected patients' viral loads, and poor adherence to ART can have a detrimental effect on disease management, causing patients to develop a resistance to medication and eventually result intreatment failure [34]. Furthermore, violent relationships increase women's sexual risk taking behaviors and can impede efforts to negotiate safe sex practices, which are known to increase the risk of HIV exposure and infection [34].

IPV can be a major barrier to ART adherence, and thus must be addressed in HIV treatment and care programs [7]. Antenatal visits can provide a entry point for IPV screening [19]. Efforts to screen women for IPV have been received positively in other settings [35] and should be considered in the context of a maternal-health focused ART treatment program in South Africa.

## VIII. Gaps in research and contribution to the literature

Based on this review, no research exists on the risk of IPV specifically among women who are both pregnant and HIV-positive, however it has been well established that the risk of experiences of violence are pervasive in many subsets of this population, i.e. women in South Africa, pregnant women and HIV-infected women. This research will shed light on the nature of these complex structures and how they coexist. This population represents a vulnerable group accessing health services with a complex and multi-level risk profile, and garnering further knowledge will help inform existing support services,

generate recommendations for expanding and enhancing existing support for IPV survivors, and guide future prevention programs.

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## Part III

# MANUSCRIPT BMC Women's Health

## Title Page

Intimate partner violence among HIV-infected pregnant women initiating antiretroviral therapy in South Africa: a cross-sectional study

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Intimate partner violence among HIV-infected pregnant women initiating antiretroviral therapy in South Africa: a cross-sectional study

#### **Abstract**

#### **Background**

Intimate partner violence (IPV) during pregnancy may be common in many settings where HIV is prevalent but there are few data on IPV in populations of HIV-infected pregnant women. We examined the prevalence and predicators of IPV among pregnant women initiating lifelong antiretroviral therapy (ART) in a primary care clinic in Cape Town, South Africa.

#### Methods

Consecutive pregnant women seeking antenatal care in Gugulethu, Cape Town were recruited into the MCH-ART study examining service models for postpartum ART care. IPV, depression, substance use and emotional distress were assessed using the 13 item WHO Violence Against Women questionnaire, the Edinburgh Postnatal Depression Scale (EPDS), alcohol and drug use disorders identification test (AUDIT/DUDIT) and the Kessler 10 (K-10) scale, respectively. Questionnaires were administered privately by trained interviewers. Women identified with specific IPV or mental health concerns were referred to appropriate services. Logistic regression was used to examine factors independently associated with experiences of IPV after adjusting for age and socioeconomic status.

#### Results

From April 2013-May 2014, 623 women were enrolled (median age, 28 years):97% were in a relationship, 38% were married and/or cohabiting and 70% reported not discussing or agreeing on pregnancy intentions prior to conception. Overall, 21%(n=132) reported experiencing ≥1 act of IPV in the past 12 months, including emotional(15%), physical(15%) and sexual violence(2%). Of those reporting any IPV, 48% reported experiencing multiple types. Emotional and physical violence were most prevalent among women 18-24 years old, while sexual violence was most commonly reported among women 25-29

years old. Women who reported not discussing or disagreeing on pregnancy intentions with their partners prior to conception were significantly more likely to experience violence(p=0.030), and women who experienced IPV reported higher levels of substance abuse, depression and emotional distress(p<0.001 for all associations).

#### **Discussion**

These data demonstrate high levels of IPV in this population. While the impact of HIV-infection, pregnancy and pregnancy intention on the risk of IPV and related factors require further research, IPV-related screening and support services should be considered as part of the package of care for ART in pregnancy.

## **Keywords**

Intimate Partner Violence (IPV), Pregnancy, HIV, Women's Health, Maternal Health, Antiretroviral Therapy, South Africa.

Intimate partner violence among HIV-infected pregnant women initiating antiretroviral therapy in South Africa: a cross-sectional study

## **Background**

Intimate Partner Violence (IPV) is recognized as a major public health concern globally, associated with negative consequences for victims' physical, mental, sexual and reproductive health[1–3]. Findings from a WHO multi-country study estimate that between 15% and 71% of women globally experience at least one act of physical and/or sexual IPV at some point in their lives[4].

The prevalence of IPV in sub-Saharan Africa is estimated to be over 30%, one of the highest in the world [1]. A systematic review of 13 studies of IPV in Africa found prevalence estimates to range from 2- 57%, with a meta-analysis prevalence of 15%[5]. Population based surveys and local research have shown that South Africa is no exception. The most recent South African population based survey conducted in 1998 found 13% of women reported lifetime experiences of physical IPV, and 6% reported violence in the past year [6].

In many resource limited settings, women who experience IPV may be more likely to be young, of a low socioeconomic status, have limited education, have marital discord, and live in a community with high rates of poverty and low rates of female education[1, 3]. IPV is associated with a number of health sequelae, including: injury, disability, depression, emotional distress, alcohol and drug use, unintended pregnancy and an increased risk of HIV infection [1–4,7].

Research has provided evidence to support an association between IPV and HIV-infection in South Africa. Among women in Soweto, researchers found that seropositivity was significantly associated with experiences of violence (OR=1.48) and those with a history of IPV engaged in more sexual risk taking behaviors [8]. In another study of women attending community health centers, those who reported having violent or controlling partners were less likely to request condom usage and more likely to be HIV positive [9]. Power inequities present in violent relationships, and an inability to negotiate safe sex practices have been cited as contributing factors explaining the association between IPV and HIV-infection [1–3, 10].

The state of pregnancy is another component of the IPV structure, which is specifically and inherently gendered. The prevalence of IPV during pregnancy has been estimated at 1-28% in various sites worldwide [2]. While the effect of pregnancy on the risk of IPV is unclear [11, 12], data suggest that in lower- to middle-income country (LMIC) settings pregnancy most likely increases the risk of IPV [13]. In South Africa, nearly 25% of pregnant women in a study in Durban reported experiencing some type of IPV during pregnancy [14] and among women attending antenatal clinics outside of Cape Town 32%, 28% and 14% reported experiencing emotional, physical and sexual violence in the past 12 months, respectively [13].

IPV has been shown to negatively affect women's adherence to ART [15], as has emotional distress, a common comorbidity of IPV [14, 16]. A meta-analysis of ART adherence during pregnancy revealed that HIV-infected women face a unique set of challenges to ART adherence during pregnancy and post-partum periods, and a pooled analysis revealed that 73.5% of pregnant women had adequate ART adherence [17]. Poor ART adherence can have a number of adverse effects on both mothers and babies, including increased viral load, failure of treatment and MTCT of HIV [18].

IPV is of particular note in the context of HIV and pregnancy. In 2010, over 30% of pregnant women presenting to public health facilities in South Africa were HIV positive [19]. While new policies in South Africa call for widespread use of antiretroviral therapy (ART) in pregnancy, IPV represents a potentially important barrier to ART adherence in this population, and thus efforts to better understand the risks and challenges they face, and the effect upon ART adherence is necessary to optimize ART care and improve maternal and child health outcomes.

Evidence shows that IPV is occurring at high rates among both pregnant [13, 14] and HIV-infected [8–10] populations in South Africa, however no known research on IPV among women who are both pregnant and HIV- infected exists. This study aims to evaluate the prevalence and predictors of IPV, and identify potential screening mechanisms among a sample of pregnant, HIV-infected women initiating ART.

#### **Methods**

#### **MCH-ART Study**

An observational cohort study of 623 pregnant, HIV positive pregnant women was conducted as a part of a larger Maternal and Child Health Antiretroviral Treatment (MCH-ART) study aimed at evaluating the effectiveness of a MCH-focused ART treatment program in Cape Town, South Africa. Phase I of the study was a cross-sectional survey sampling from women arriving at the local clinic for an antenatal visit. Phase II participation was offered to a subset of phase I participants who were found to be ART-eligible according to local guidelines, and due to begin ART during their current pregnancy. Demographic data was collected during a 20-minute long measurement visit on the day of participants' first antenatal clinic visit, while all other data was collected during a 30-45 minute long measurement visit on the same day as participants' second antenatal clinic visit.

All participants signed informed consent forms before participation in both phases of the study. All consent forms and questionnaires were available in English and isiXhosa and were administered in participants' language of choice. Staff underwent multiple training sessions to familiarize them with study protocols and procedures, including issues of confidentiality and referrals for unmet health needs and management of crisis situations.

#### Measures

Intimate Partner Violence was assessed using the WHO Violence Against Women questionnaire developed for the WHO multi-country study [4]. The 13-question measure asked whether participants had experienced specific acts of violence perpetrated by an intimate partner in the past 12 months. A positive response to any of the questions resulted in the participant being included in the total IPV prevalence count, with the specific type specified. There were four questions describing emotional violence, six describing physical violence, and three describing sexual violence. Distinctions between moderate and severe physical violence were based on the likelihood of the act of violence resulting in severe harm or injury to the victim.

Socioeconomic status (SES) global measure was calculated using a number of markers of SES collected during participants' demographic interview, including highest level of education, whether they were currently employed, whether formal employment was their main source of household income, housing type, number of household amenities and number of children living in the home. The scores were then categorized into three levels denoting low, middle and high SES.

*Relationship characteristics* were self-reported by participants during their first antenatal clinic visit and referred to their current partners, if in a relationship. Questions were asked about relationship duration, marital status, partner cohabitation and whether a participant had disclosed her HIV status to her partner.

Participants were also asked about other sexual partners in the past 12 months. Women who reported being in a current relationship for more than a year and reported having had other sexual partners in the past year were confirmed as having engaged in concurrent partnerships in the past year.

Pregnancy intention agreement data was sourced from one question of the London Measure of Unplanned Pregnancy [20] in which participants were asked if they had discussed with their partner and agreed to become pregnant before conception.

Alcohol and drug use data were collected using the Alcohol Use Disorders Identification Test (AUDIT) [21] a 10-item scale, and Drug Use Disorders Identification Test (DUDIT) [22] scales, an 11-item scale, which screened for alcohol and drug use and alcohol- and drug-related problems, respectively. An AUDIT score of 8 or more was used to classify harmful alcohol use, while a DUDIT score of 2 or more denoted harmful drug use. Of the four participants who were classified as having harmful drug use, DUDIT scores were well above the cut-off point, ranging from 16 to 29.

*Emotional distress* was measured using the Kessler-10 (K-10) scale [23], a 10-item measure regarding the extent to which participants deem their life to have been stressful in the last month. The Likert scale responses were summed, and a score of greater than or equal to 6 classified a participant as emotionally distressed.

Depression was quantified using the Edinburgh Postnatal Depression Scale (EPDS) [24], a 10-item questionnaire that asked about feelings of sadness and depression during the past week. Likertscale responses were summed to generate an overall depression score. A score greater than or equal to 13 classified participants as depressed.

Perceived availability of social support was a 12-item Likert scale questionnaire asking about the likelihood that participants would be supported or offered help by people in their lives should the need arise [25]. Responses were summed to get an overall score. If a participant scored above a 36 they were considered to perceive strong social support available to them.

#### **Ethics**

All data gathered for this study were obtained in a private setting, after participants gave informed consent and with due consideration for participants' rights to confidentiality. Participants found to be experiencing IPV were referred to a local NGO offering counseling services and to the South African Police Service should they want to open a criminal case. The University of Cape Town Faculty of Health Sciences Human Research Ethics Committee and the Columbia University Medical Center Institutional Review Board granted approval for the initial data collection. Ethical clearance for the secondary analysis of study data was obtained from the University of Cape Town Faculty of Health Sciences Human Research Ethics Committee.

#### **Data Analysis**

Descriptive statistics of the outcome of interest and all predictor variables were reported for the total sample. Bivariate analyses were conducted using Z-statistics for continuous predictor variables, and  $X^2$  or Fisher's Exact for binary predictor variables. All P-values were analyzed using a significance level of  $\langle =0.05$ . Crude logistic regression models tested the association between total violence- defined as the experience of any form or act of IPV in the last 12 months, and each predictor variable. Separate models were built to evaluate the association between IPV and relationship characteristics, and IPV and individual behavioral characteristics. A forward step-wise variable selection method was employed, using coefficient magnitude and significance levels to evaluate predictors. The process was then repeated in an analysis stratified by the time of participants' first positive HIV test and an analysis stratified by couples' pregnancy intentions prior to conception. All data analysis was done in Stata 12 (StataCorp. 2011. Stata

#### **Results**

Women in the sample were between 18 and 44 years old, with a median age of 28 years. More than 99.5% of participants identified as African and 97% reported isiXhosa as their home language. SES varied throughout the sample, with 35%, 31% and 34% reporting low, middle and high SES respectively. More than 97% of participants reported being in a current relationship, 25% were married and 41% were living with their partner. Over one third of participants (36%) had disclosed their HIV status to their partner. Relationship duration ranged from 3 months to 20 years, with a median duration of 3 years.

Overall, 21% of the sample (132 women) reported experiencing at least one act of IPV in the past 12 months. Specifically, 92 (15%) reported emotional violence, 96 (15%) reported moderate physical violence, of whom 43 (45% of those reporting any physical IPV and 7% of the overall sample) also reported severe physical violence, and 14 (2%) reported sexual violence. Of those who reported IPV 63 participants (10% of the overall sample, 48% of those who reporting any IPV) experienced multiple types of violence in the last year (Figure 1). Emotional and physical violence was most prevalent among the 18-24 year olds, while sexual violence was most commonly reported among 25-29 year olds.

Table 1 shows that women who reported IPV in the past year were less likely to be married ( $X^2$ = 7.95, p=0.005) more likely to use drugs and/or alcohol ( $X^2$ =44.32, p=0.000), report emotional distress ( $X^2$ =23.10, p=0.000) and be depressed ( $X^2$ =15.68, p=0.000). Those who experienced violence were also more likely to have not discussed pregnancy with their partners or not agreed with their partners to become pregnant prior to conception ( $X^2$ =4.79, p=0.029) compared to women who had not experienced violence.

A logistic regression model of relationship characteristics adjusted for age and SES presented in Table 2 found marriage and having a middle SES to be protective (OR=0.52 [0.30; 0.91], OR=0.61 [0.37;1.00] respectively). When modeling behavioral characteristics, being of middle SES (compared to low SES) was protective against IPV (OR=0.57 [0.34; 0.94]) however women of a high SES were not significantly less likely to experience IPV compared to those of a low SES (OR=0.70 [0.42; 1.16]). Those who experienced IPV in the last year were also more likely to use drugs and/or alcohol (OR=4.61[2.77; 7.69]), and report emotional distress (OR=2.37 [1.49; 3.76]) and depression (OR=2.07 [1.17; 3.69]).

Overall, time of first HIV+ test was not a significant predictor of violence in the past year when adjusted for age and SES (OR=0.92 [0.62; 1.36]) (Table 2). Age and SES adjusted models of relationship characteristics stratified by time of first HIV+ test found that among women who first tested positive before this pregnancy, those who did not discuss pregnancy intentions with their partner or did not agree on pregnancy intentions with their partner prior to conception had significantly greater odds of experiencing IPV (2.44 [1.12; 5.31]). Among women who first tested HIV+ in this pregnancy, marriage was found to be protective against experiencing IPV (OR=0.29 [0.12;0.67]). Relationship duration was also found to be significant, but the odds ratio was negligible (OR=1.01 [1.00;1.02).

Models of behavioral characteristics adjusted for age and SES and stratified by time of first HIV+test found that those who experienced IPV in the last year were more likely to use alcohol and/or drugs, however the odds was lower among those who first tested HIV+ before this pregnancy compared to those who first tested HIV+ during this pregnancy (OR=3.36 [1.55; 7.29] vs. OR=6.36 [3.13; 12.94] respectively). Women who first tested HIV+ before this pregnancy were statistically significantly older than women who first tested HIV+ in this pregnancy (median ages 29 and 27 respectively, p=0.0000). Emotional distress was also more commonly reported among women who experienced violence, however the odds among those who first tested HIV+ before this pregnancy was higher than those who first tested HIV+ during this pregnancy (OR=2.75 [1.39; 5.43] vs. OR=2.13 [1.12; 4.06] respectively). Depression

was crudely associated with IPV in both strata, however became insignificant in the adjusted models (OR=2.15 [0.88; 5.24] among women who first tested HIV+ before this pregnancy and OR=1.96 [0.91; 4.21] among women who first tested HIV+ in this pregnancy). Age was not significantly associated with experiences of IPV in any of the crude or adjusted models.

Table 3 shows bivariate relationships according to pregnancy intention. Women who discussed pregnancy with their partners prior to conception and agreed to become pregnant were significantly less likely to experience violence overall ( $X^2$ =4.79, p=0.029) and physical violence ( $X^2$ =6.68, p=0.010). They were more likely to be in a relationship (p=0.030) for longer (Z=3.76, p=0.0002), and to be cohabitating with their partner ( $X^2$ =45.62, p=0.000) but less likely to be married ( $X^2$ =7.95, p=0.005) compared to women who had either not discussed or not agreed to become pregnant with their partners prior to conception.

Logistic regression models of relationship characteristics stratified by pregnancy intention (Table 4) show that among women who discussed and agreed to become pregnancy prior to conception, those who reported violence n the past year had lower odds of being married (OR=0.22 [0.08;0.61). Among women who did not discuss or disagreed there were not statistically significant predictors of experiencing IPV in the last 12 months.

Models of behavioral characteristics show that among women who discussed and agreed to become pregnant with their partner, those who reported violence were significantly more likely to be substance users (OR=5.31 [1.95;14.43]) compared to those who did not report violence. Among women who did not discuss or disagreed on pregnancy intentions prior to conception, those who reported IPV were significantly more likely to use substances (OR=4.98 [2.66;9.31]), report emotional distress(OR=2.52 [1.47;4.31]) and depression (OR=2.08 [1.06;4.09]).

#### **Discussion**

These data show a significant burden of IPV in this population, with 21% reporting IPV in the past 12 months, 15% reporting physical and emotional violence respectively and 2% reporting sexual violence. Of those who reported violence, 48% experienced multiple types, most often physical and emotional violence together (37% of those who reported any IPV and 8% of overall sample). Women who experienced violence were more likely to be unmarried, substance users, emotionally distressed and depressed. Women who reported pregnancy intention discord with their partner were more likely to experience violence, and among those who experienced violence substance use, emotional distress and depression were reported more often.

The estimated prevalence of overall IPV in this sample (21%) is the same as a previously reported study of IPV during pregnancy [26], and only slightly lower than the 24.75% prevalence reported among pregnant women in Durban [14]. It is, however, markedly higher than the most recent population-based data gathered in the 1998 South African Demographic and Health Survey (SADHS), in which 4% of women reported IPV during pregnancy [6]. It is worth noting, however, that underestimation has been noted in these data, and a study conducted in the Eastern Cape using the same enumeration area used in the SADHS reported a prevalence of 27% of everpartnered women reporting physical IPV, compared to the 9% found in the same area by the SADHS [6]. Furthermore, underreporting is common in this field of research [6], and thus it is plausible that the true prevalence of IPV in this population is higher than the estimates produced by these data.

The reported prevalence of sexual IPV in this sample was markedly lower than the other types of IPV (2%), however consistent with previous research in which 3% of women in South Africa

reported sexual IPV during pregnancy [26]. A multi-country study published by the WHO reported that in most sites, between 4% and 12% of women experience IPV during pregnancy [27]. Although these estimates are slightly lower than those reported in previous South African settings [26], they still represent a significant burden of disease in this population.

Overall, demographic and relationship characteristics did not appear to be strong predictors of IPV, as is consistent with past systematic reviews from the region which have reported mixed findings on the role of such variables on the, if any, on the risk of IPV [26]. Age was not statistically significant in any adjusted regression models presented, and SES was insignificant in nearly all presented models. While age has been noted as a significant predictor in some past research, in many cases it does not significantly predict IPV [28]. Poverty has been consistently associated with IPV in past research [28]. However, in a setting such as this in which there is such a high prevalence of IPV, and in which the vast majority are relatively impoverished, we hypothesize that there is not enough SES variability to see the association that may exist between poverty and IPV in these data.

Similarly, relationship characteristics were non-predictive across most models, with no more than two individual factors ever being significantly associated with the reported experience of IPV in any particular model, and no specific relationship characteristic remaining statistically significant across all models. Behavioral characteristics, however, were consistently predictive. Substance use was statistically significantly associated with an increased risk of IPV in all six models presented, and emotional distress and depression were often associated with reported experiences of IPV, as consistent with previous research [14, 29–31].

These data showed no major differences in the associated behavioral characteristics among women who first test HIV positive before this pregnancy compared to those who first tested HIV positive during this pregnancy. While there were differences in the associated relationship characteristics between the two groups, we do not believe they represent a fundamental difference in the risk profile of women who were previously aware of their HIV status compared to those who have recently been diagnosed.

Results show that women who reported IPV in the last 12 months are more likely to have either not discussed or not agreed with their partners to become pregnant prior to conception.

Additionally, logistic regression models show that among women who do not discuss or agree with their partners regarding pregnancy, those who experience IPV are significantly more likely to also report substance use, emotional distress and depression. All of these factors are known to impede ART adherence among pregnant women [17], and are thus a major barrier in optimizing care in this population. Local research has shown that IPV screening and identification in primary care settings in South Africa is very low [32], however IPV survivors participating in a study to evaluate an IPV screening and management protocol reported significant improvements in their mental health, substance use, partner relationships as a result of screening and referrals [33]. Therefore, querying women's pregnancy intentions within the context of a maternal health-focused ART program is a potentially important screening tool for both IPV and other comorbidities which can have an adverse effect on women's ART care, and thus on the health of both mothers and children.

This analysis is subject to a number of important limitations. This is a cross-sectional study and therefore cannot establish temporality between IPV and associated risk factors. In order to better

understand the cycle of violence and how it manifests in this population, one must understand whether specific relationship and behavioral factors increase the risk of IPV, or vice versa. From these data it is not possible, for instance, to know if experiences of IPV lead to depression, or if depression increases a woman's risk of IPV. Furthermore, the nature of the WHO questionnaire used to measure IPV does not allow researchers to establish the frequency of violence acts, nor the time period in relation to current pregnancy. More detailed information regarding violence before, during and after pregnancy specifically would shed more light on the effects of pregnancy on the risk of IPV. In addition, underreporting is a common bias in this type of research, due to the sensitivity and stigma often associated with violence [6, 26]. However, reports of sexual violence appear drastically lower than many previous findings. Although pregnancy has been shown to be protective against IPV in some settings [11] this discrepancy is more than likely a result of methodological issues or biases. It is well documented that IPV, especially of a sexual nature, is a major source of shame and stigma that may be a barrier to reporting [6].

However, while there are limitations, this is also the first known research looking at IPV risk profiles specifically among women with two previously established risk factors of IPV-pregnancy and HIV-infection. The high prevalence estimates garnered from these data suggest that IPV is a significant burden on this population, and warrants further research. Prospective studies are necessary to establish temporality between IPV and predictive factors, and to estimate the incidence of IPV. Furthermore, prospective studies will allow further assessment of the effects of pregnancy and HIV-infection on IPV, and the role of IPV in ART adherence and retention.

Future research also must place an emphasis on programs and practices for IPV prevention, and further research into the possible role of pregnancy intention agreement as a screening tool for IPV is warranted. While screening alone does not reduce IPV risk, screening and paired interventions have be shown to significantly lower future risk of IPV [26], including one program showing efficacy in South Africa [34]. It is estimated that 87% of pregnant women in South Africa attend at least four antenatal visits [26], thus interventions in maternal health settings, specifically those geared towards HIV-infected women, offer an ideal point of access to this highly vulnerable population.

This research has number of implications for changing policies and public health programs in South Africa. Health care workers, especially those working in HIV- and pregnancy-related fields, need to be adequately trained in identifying and referring IPV survivors to appropriate services. Information regarding IPV and local support services should be integrated into all maternal health and HIV pamphlets and educational materials, and be kept readily available in health centers. Local support services must be supported and expanded in order to meet the increased burden of disease identified through screening efforts. Furthermore, interdisciplinary stakeholders must be mobilized on a national level to become more involved raising awareness, supporting prevention programs and adapting IPV policies and programs nationally. Finally, screening and support services for IPV must be integrated into ART programs across South Africa in order to directly target and support HIV-infected women.

### **Conclusions**

In summary, these data demonstrate a high prevalence of IPV- specifically physical and emotional violence - in this population of HIV-infected pregnant women. The prevalence of IPV in this study suggests that this is a high-risk population accessing health services requiring continued efforts to further understand and optimize care. While the potential impact of IPV and related factors on ART adherence over time require further research, IPV-related screening and appropriate support services need to be considered as part of the package of care for ART in pregnancy.

#### List of abbreviations

IPV Intimate Partner Violence

HIV Human Immunodeficiency Virus

ART Antiretroviral Therapy

MCH-ART Maternal and Child Health Antiretroviral Treatment Study

WHO World Health Organization

LMIC Low- and Middle-Income Countries

SES Socioeconomic Status

AUDIT Alcohol Use Disorders Identification Test

DUDIT Drug Use Disorders Identification Test

K-10 Kessler-10 Scale of Emotional Distress

EPDS Edinburgh Postnatal Depression Scale

NGO Non-Governmental Organization

OR Odds Ratio

SADHS South African Demographic & Health Survey

## **Competing interests**

The author declares that they have no competing interests.

#### **Authors' contributions**

MB completed background research on the topic, carried out the statistical analysis, prepared all tables and figures, and wrote article.

# **Authors' information**

MB is a final year student at the University of Cape Town earning a Masters of Public Health (MPH) degree in Epidemiology. She has an interest in issues of sexual and reproductive health and gender and health.

# Acknowledgements

Many thanks to all who participated in this study, all staff members who aided in data collection, entry and cleaning, and all who reviewed and provided feedback on earlier drafts.

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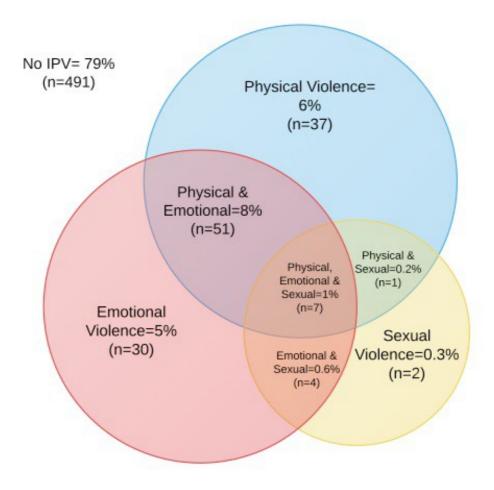
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# **Figures**

Figure 1: Venn diagram of types of violence experienced in past 12



# **Tables**

Table 1: Bivariate analysis of socioeconomic, relationship and behavioral characteristics by IPV in past 12 months

	Total (n=623) Med (IQR) OR n (%)	Reported violence in past 12 months (n=132)  Med (IQR) OR n (%)	Did not report violence in past 12 months (n=491) Med (IQR) OR n (%)	Z-Stat OR X2/Fisher's	P-Value
	00 (150()				
Emotional Violence	92 (15%)				
Physical Violence	96 (15%)				
Sexual violence	14 (2%)				
Age	28 (24-32)	28 (24-31)	28 (25-32)	1.180	0.237
SES Global Measure (3 levels)				3.17	0.205
Low	184 (30%)	46 (35%)	138 (28%)		
Middle	230 (37%)	41 (31%)	189 (39%)		
High	209 (34%)	45 (34%)	164 (33%)		
Currently in a relationship	606 (97%)	125 (95%)	481 (98%)		0.064
Duration of relationship (years)(n=623)	3 (2-5)	2.25 (1.63-5)	3 (2-5)	1.09	0.275
HIV status disclosure to partner (n=606)	217 (36%)	44 (35%)	173 (36%)	0.03	0.870
Married to partner (n=606)	151 (25%)	19 (15%)	132 (28%)	7.95	0.005
Cohabitating with partner (n=606)	246 (41%)	44 (35%)	202 (42%)	1.90	0.168
Confirmed concurrency in past 12 months	55 (9%)	13 (10%)	42 (9%)	0.22	0.642
Boyfriend	36 (6%)	9 (7%)	28 (6%)		
Casual partner	19 (3%)	5 (4%)	14 (3%)		
HIV status disclosure to concurrent partners (n=55)	16 (16%)	4 (16%)	12 (16%)		0.59
AUDIT/DUDIT					
# reporting harmful drug or alcoholuse	81 (13%)	40 (30%)	41 (8%)	44.32	0.000
Kessler-10 scale					
# reporting distress	132 (21%)	48 (36%)	84 (17%)	23.10	0.000
EPDS scale					
# reporting depression	68 (11%)	27 (20%)	41 (8%)	15.68	0.000
PAS scale (n=621)					
# reporting perceived social support	515 (83%)	113 (86%)	402 (82%)	1.30	0.254
Pregnancy intention agreement with partner (n=614)				5.82	0.055
Discussed, agreed to become pregnant	185 (30%)	29 (22%)	156 (32%)		
Did not discuss or disagreed	429 (70%)	101 (78%)	328 (68%)	4.79	0.029

Table 2: Logistic regression of the risk of experiencing IPV in past 12 months stratified by time of first HIV+ test

	TOTAL (n=623)			TESTED HIV+ BEFORE THIS PREGNANCY (n=281)				FIRST TESTED HIV+ IN THIS PREGNANCY (n=342)			
					11	CEGIVITIVE I (II	201)			REGIVER (II	342)
	Al	DJUSTED									
	OR	95% CI	P-value								
Testing HIV+ in this	0.92	(0.62-1.36)	0.670								
pregnancy											
		DJUSTED	1		4.0	JUSTED	<u> </u>			DJUSTED	T
	OR	95% CI	P-value		OR	95% CI	P-value		OR	95% CI	P-value
_	UK	95% CI	r-value		UK	95% CI	r-value	l l	UK	95% CI	r-value
			Rela	atio	nship cha	aracteristics					
Age	0.99	(0.95-1.03)	0.548		0.98	(0.92-1.04)	0.471		0.96	(0.91-1.02)	0.175
SES											
Low											
Middle	0.63	(0.39-1.03)	0.065		0.74	(0.36-1.54)	0.422		0.53	(0.27-1.03)	0.061
High	0.76	(0.47-1.25)	0.284		1.17	(0.57-2.42)	0.668		0.60	(0.31-1.15)	0.125
Duration									1.01	(1.00-1.02)	0.008
Marriage	0.52	(0.30 - 0.90)	0.020						0.29	(0.12-0.67)	0.004
Pregnancy intention											
Discussed, agreed					-						
Did not discuss or	1.33	(0.82-2.15)	0.244		2.44	(1.12-5.31)	0.025				
disagreed											
		T (0.05.1.05)		hav		racteristics				T co o d d o o o	
Age	0.99	(0.95-1.03)	0.528		1.00	(0.94-1.07)	0.994		0.99	(0.94-1.03)	0.602
SES											
Low											
Middle	0.57	(0.3-0.94)	0.029		0.53	(0.24-1.16)	0.110		0.62	(0.31-1.24)	0.177
High	0.70	(0.42-1.16)	0.162		0.76	(0.36-1.64)	0.492		0.65	(0.33-1.29)	0.219
Alcohol/Drugs	4.61	(2.77-7.69)	0.000		3.36	(1.55-7.29)	0.002		6.36	(3.13-12.94)	0.000
Distress	2.37	(1.49-3.76)	0.000		2.75	(1.39-5.43)	0.004		2.13	(1.12-4.06)	0.022
Depression	2.07	(1.17-3.69)	0.013		2.15	(0.88-5.24)	0.092		1.96	(0.91-4.21)	0.086

Table 3: Bivariate analysis of IPV experiences, socioeconomic, relationship and behavioral characteristics by pregnancy intention prior to conception

	Total (n=614) Med (IQR) OR n (%)	Discussed with partner, agreed to become pregnant (n=185) Med (IQR) OR n (%)	Did not discuss and/or agree with partner to become pregnant (n=429) Med (IQR) OR n (%)	Z-Stat OR X2/Fisher's	P-Value
	(7 <b>0)</b>	OR II (70)	OR II (70)	712/1 131101 3	
Pregnancy intention agreement with partner prior to conception (n=614)					
Discussed, agreed to become pregnant	185 (30%)				
Did not discuss or disagreed	429 (70%)				
T ( IXC )	120 (210()	20 (1(0))	101 (249/)	4.70	0.020
Total Violence	130 (21%)	29 (16%)	101 (24%)	4.79	0.029
Emotional Violence	90 (15%)	21 (11%)	69 (16%)	2.31	0.128
Physical Violence	95 (15%)	18 (10%)	77 (18%)	6.68	0.010
Sexual Violence	14 (2%)	3 (2%)	11 (3%)		0.569
Age	28 (24-32)	28 (24-31)	28 (24-32)	0.25	0.804
SES Global Measure (3 levels)				1.78	0.410
Low	184 (30%)	50 (27%)	134 (31%)		
Middle	226 (37%)	67 (36%)	159 (37%)		
High	204 (33%)	68 (37%)	136 (32%)		
Currently in a relationship	597 (97%)	184 (99%)	413 (96%)		0.030
Duration of relationship (years)	3 (2-5)	4 (2-6)	3 (1.17-5)	3.76	0.0002
HIV status disclosure to partner (n=597)	213 (36%)	72 (39%)	141 (34%)	1.38	0.240
Married to partner (n=597)	150 (25%)	19 (15%)	132 (28%)	7.95	0.005
Cohabitating with partner (n=597)	242 (41%)	112 (61%)	130 (32%)	45.62	0.000
Confirmed concurrency in past 12 months	52 (8%)	20 (11%)	32 (7%)	1.87	0.171
Boyfriend	34 (6%)	11 (2%)	23 (4%)		
Casual partner	18 (3%)	9 (1%)	9 (1%)		
HIV status disclosure to concurrent partners (n=52)	6 (12%)	1 (5%)	5 (16%)		0.387
AUDIT/DUDIT					
# reporting harmful drug or alcohol use	79 (13%)	25 (14%)	54 (13%)	0.10	0.753
Kessler-10 scale					
# reporting distress	129 (21%)	32 (17%)	97 (23%)	2.20	0.138
EPDS scale					
# reporting depression	65 (11%)	14 (8%)	51 (12%)	2.55	0.110
PAS scale (n=612)					
# reporting perceived social support	507 (83%)	151 (82%)	356 (83%)	0.28	0.598

Table 4: Logistic regression of the risk of experiencing IPV in past 12 months stratified by pregnancy intention

	TOTAL (n=614)			DISCUSSED AND AGREED (n=185)			DISAGREED OR DID NOT DISCUSS (n=429)			
		ADJUSTE	<u> </u>	l						
	OR	95% CI	P-value							
Pregnancy Intention		70,002	1				1			
Discussed, agreed										
Did not discuss or	1.65	(1.04-2.60)	0.032							
disagreed		,								
					1					
		ADJUSTE				ADJUSTED			ADJUSTEI	
	OR	95% CI	P-value		OR	95% CI	P-value	OR	95% CI	P-value
		1		tion		acteristics	, ,	-		,
Age	0.99	(0.95-1.03)	0.535		0.97	(0.90-1.05)	0.503	0.98	(0.94-1.03)	0.436
SES										
Low										
Middle	0.61	(0.37-1.00)	0.048		0.42	(0.13-1.31)	0.33	0.73	(0.42-1.26)	0.252
High	0.74	(0.45-1.22)	0.243		1.02	(0.39-2.72)	0.962	0.68	(0.38-1.22)	0.198
Disclosure to Partner								1.26	(0.78-2.04)	0.338
Marriage	0.52	(0.30-0.91)	0.022		0.22	(0.08-0.61)	0.004			
			Bel	avio	oral chara	ecteristics				
Age	0.99	(0.95-1.03)	0.528		1.01	(0.93-1.09)	0.861	0.99	(0.94-1.03)	0.531
SES		(01,00)				(01,00 1,11)			(4.7)	
Low										
Middle	0.58	(0.35-0.97)	0.039		0.40	(0.13-1.29)	0.125	0.60	(0.34-1.08)	0.090
High	0.69	(0.42-1.15)	0.157		1.12	(0.42-2.96)	0.825	0.57	(0.31-1.04)	0.067
Alcohol/Drugs	4.66	(2.78-7.80)	0.000		5.31	(1.95-14.43)	0.001	4.98	(2.66-9.31)	0.000
Distress	2.29	(1.44-3.64)	0.000					2.52	(1.47-4.31)	0.001
Depression	2.03	(1.13-3.66)	0.018					2.08	(1.06-4.09)	0.033

# Part IV

# Appendices

# I. UCT human research ethics committee approval letter



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



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

05 March 2015

HREC REF: 063/2015

**Prof L Myer**Public Health & Family Medicine
Falmouth Building

Dear Prof Myer

PROJECT TITLE: INTIMATE PARTNER VIOLENCE AMONG HIV-INFECTED PREGNANT WOMEN INITIATING ANTIRETROVIRAL THERAPY IN SOUTH AFRICA- (LINKED TO 451/2012) - Masters candidate- Molly Bernstein

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

The reviewer would firstly like to apologise to the PI and his colleagues for the unnecessary delay in returning this review. Circumstances beyond the reviewer's control impacted on the timely submission of this review.

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

Approval is granted for one year until the 30th March 2016.

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

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

Please quote the HREC REF in all your correspondence.

We acknowledge that the student, Molly Bernstein will also be involved in this study.

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

Yours sincerely

PROFESSOR M BLOCKMAN

CHAIRPERSON, FHS HUMAN RESEARCH ETHICS COMMITTEE

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

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

# II. Protocol appendices

# **Appendix P1: Phase 2 informed consent form**

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

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

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

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

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

## 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 and health care.
- Have 5mLs (1 teaspoon) of blood drawn from your arm

Page 1 of 5 Version 3.1, 10 January 2014



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

## Follow-up of missed visits

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

#### Contact for future study

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

### WHAT ARE THE POTENTIAL RISKS?

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

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 your usual care at the MOU.

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#### WHAT ABOUT CONFIDENTIALITY?

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

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

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

## WILL I BE GIVEN ANYTHING FOR TAKING PART?

At the end of each visit, you will be given R20 in cash to cover the transport cost to your next scheduled study visit, and anR80grocery voucher. You will also receive a small gift for the first visit after birth and refreshments will be provided at all visits.

## 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:**

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

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

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

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## Phase 2 Informed Consent Form

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

_(initial) I <u>agree</u> to have my <u>blood stored for future research.</u>
_(initial) I <u>agree</u> to have my <u>blood stored for future research</u> related to this study ONLY.
_(initial) I do NOT agree to the storage of my blood for future use.

## 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

Dr Elaine Abrams ICAP, Columbia University Mailman School of Public Health College of Physicians and Surgeons

Tel: +1 212 342 0543 Email: eja1@columbia.edu

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

Prof Marc Blockman Chair, Human Research Ethics Committee Faculty of Health Sciences, University of Cape

Town

Tel: 021 406 6338

Columbia University Medical Center IRB

Tel: +1 212 305 5883

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# **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 w	vith your signature.	
Volunteer's name		
Signature of Volunteer Da	ate	
Staff member's name		
Signature of study staff	Date	
If the volunteer is unable to re by an independent witness who consent.		elling process must be observed edure once the she has given
Fingerprint of volunteer:		
Witness: I confirm that I am independent counselling process in the home		sed the entire informed consent
Name:		
Signature:		
Date:		
Thank you.		
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# Appendix P2: WHO violence against women questionnaire

WH	O VAWQUESTIONNAIRE Visit Date:	1	1
Siza	kubuza imibuzo embalwa malunga nokuhlukunyezwa kwako liqabane lako.		
We a	re going to ask you a few questions relating to partner violence.		
Kwe	zi nyanga zi-12 zidlulileyo ukhe wafunyanwanzezi zilandelayo		
In the	last 12 months, have you experienced any of the following?		
	UKUMEZO LWENGQON	Ewe	Hayi
Psvo	phological Violence	Yes	No
1.	Iqabane lakho likhe lakuthuka okanye wasiva ungalunganga?	1	0
	Has your partner insulted you or made you feel bad about yourself?		
•	Likhe lakwenza wasifumanisa ukuba usithobile isidima sakho phambi	4	
2.	kwabanye abantu?	1	0
	Has he belittled or humiliated you in front of other people?		
3.	Likhe laoyikisa lakuphatha kakubi ngabom	1	0
	Has he done things to scare or intimidate you on purpose?		
1 4	Likhe lakugrogrisa ngokonzakalisa okanye umntu omnakekelayo?	4	0
4.	Has he threatened to hurt you or someone you care about?	1	0
UHL	UKUMEZO LOMZIMBA	Ewe	Hayi
Phys	sical Violence	Yes	No
	Likhe lakuqhwaba ngempama okanye wakugibisela ngento		
5.	enokwenzakalisa?	1	0
	Has he slapped you or thrown something at you that could hurt you?		
6.	Likhe lakutyhala okanye lakunyola?	1	0
	Has he pushed or shovedyou?		
7.	Likhe lakubetha ngenqindi okanyengento enokonzakalisa?	1	0
	Has he hit you with a fist or with something else that could hurt you?		
8.	Likhe likukhabe,likurhuqe okanye likubethe?	1	0
	Has he kicked you, dragged you or beaten you up?		
9.	Likhe likukrwitshe okanye likutshise ngabom?  Has he choked or burnt you on purpose?	1	0
	Likhe likugrogrise okanye lisebenzise umpu,imela okanye nasiphi		
10.	isixhobo kuwe?	1	0
	Has he threatened to use or actually used a gun, knife or other weapon against you?		
UHL	UKUNYEZO NGOKWABELANA NGOCANTSI	Ewe	Hayi
Sexu	ial Violence	Yes	No
11.	Likhe likunyanzele ngokwabelana ngocantsi wena ungafuni?	1	0
	Has he physically forced you to have sexual intercourse when you didn't want to?	<u> </u>	,
	Wakhe wabelana naye ngocantsi ungafuni kuba uloyika umazi		
12.	angenza ntoni?	1	0
	Did you ever have sexual intercourse when you didn't want because you were afraid of what he might do?		
	Likhe likunyanzele ngokwebelana ngocantsi ngendlela ofumanisa ukuba		
13.	ukuthathela phantsi okanye uyakwenyelisa?	1	0
	Has he forced you to do something sexual that you found degrading or humiliating?		
С	ate completed: /_ / Signed counsellor completing CRF		
E	ate of QC: /_ /_ Signed measurement nurse:		

Columbia University IRB
IRB-AAAK8959
IRB Approval Date: 12/16/2013
for use until: 11/26/2014

Page 1 of 1

# III. Manuscript appendices

Appendix M1: Reported experiences of IPV in the past 12 months

	n (%)
Total Violence	132 (21%)
Emotional violence	92 (15%)
Insulted you	69 (11%)
Belittled/humiliated you	48 (8%)
Scared/intimidated you on purpose	30 (5%)
Threatened to hurt you or someone you care about	24 (%)
Physical violence	96 (15%)
Moderate Physical Violence	
Slapped or thrown something at you	85 (14%)
Pushed/shoved you	57 (9%)
Hit you with a fist or something else that could hurt you	27 (4%)
Severe Physical Violence	43 (7%)
Kicked you, dragged you or beaten you up	28 (5%)
Chocked or burned you on purpose	18 (3%)
Threatened to use or used a gun, knife or other weapon against you	8 (1%)
Sexual Violence	14 (2%)
Physically forced you to have sexual intercourse when you didn't want to	14 (2%)
Unwanted sexual intercourse because you were afraid of what he might do	8 (1%)
Forced to do something sexual you found degrading or humiliating	5 (1%)

Appendix M2: Reported experiences of IPV by age

Age	All (18- 44)	18-24 (n=159	25-29 (n=221	30-34 (n=170	35+ (n=73)
	(n=623	)		)	, ,
	N(%) or	N(%) or	N(%) or	N(%) or	N(%) or
	Median(I	Median(I	Median(I	Median(I	Median(I
	QR)	QR)	QR)	QR)	QR)
Total Violence	132 (21%)	40 (25%)	45 (20%)	33 (19%)	14 (19%)
					( 1 1 1 )
<b>Emotional violence</b>	92 (15%)	28 (18%)	30 (14%)	23 (14%)	11 (15%)
Insulted you/made you feel bad	69 (11%)	23 (14%)	20 (9%)	17 (10%)	9 (12%)
Belittled/humiliated you	48 (8%)	14 (9%)	17 (8%)	11 (6%)	6 (8%)
Scared/intimidated you on purpose	30 (5%)	8 (5%)	7 (3%)	10 (6%)	5 (7%)
Threatened to hurt you or someone you care about	24 (4%)	5 (3%)	7 (3%)	8 (5%)	4 (6%)
Physical violence	96 (15%)	31 (20%)	30 (14%)	25 (15%)	10 (14%)
Moderate Physical Violence					
Slapped or threw something at you	85 (14%)	26 (17%)	26 (12%)	23 (14%)	10 (14%)
Pushed/shoved you	57 (9%)	19 (12%)	18 (8%)	14 (8%)	6 (8%)
Hit you with a fist or something	27 (4%)	6 (4%)	8 (4%)	9 (5%)	4 (5%)
else that could hurt you					
Severe Physical Violence	43 (7%)	14 (9%)	13 (6%)	11 (6%)	5 (7%)
Kicked you, dragged you or beaten you up	28 (5%)	11 (7%)	8 (4%)	7 (4%)	2 (3%)
Chocked or burned you on purpose	18 (3%)	5 (3%)	6 (3%)	6 (4%)	1 (1%)
Threatened to use or used a gun, knife or other weapon against you	8 (1%)	4 (3%)	1 (0.5%)	3 (2%)	0
Sexual Violence	14 (2%)	1 (1%)	9 (4%)	3 (2%)	1 (1%)
Physically forced you to have sexual intercourse when you didn't want to	14 (2%)	1 (1%)	9 (4%)	3 (2%)	1 (1%)
Unwanted sexual intercourse because you were afraid of what he might do	8 (1%)	0	5 (2%)	2 (1%)	1 (1%)
Forced to do something sexual you found degrading or humiliating	5 (1%)	1 (1%)	3 (1%)	0	1 (1%)

Appendix M3: Bivariate analysis of relationship characteristics by types of reported IPV

	Reported	Did not report	Total		
	violence in	violence in	(n=623)		
	past 12 months (n=132)	past 12 months (n=491)			
	Median (IQR)	Median (IQR)	Mean (SD)	Z-Stat OR	P-Value
	OR n (%)	OR n (%)	OR n (%)	X2/Fisher's	1 value
Duration of relationship (years) (n=623)					
Total IPV	2.25 (1.63-5)	3 (2-5)	3 (2-5)	1.09	0.275
Physical IPV	2 (1.63-5)	3 (2-6)	3 (2-5)	1.57	0.12
Emotional IPV	3 (1.04-6)	3 (2-5)	3 (2-5)	0.46	0.65
HIV status disclosure to partner (n=606)					
Total IPV	44 (35%)	173 (36%)	217 (36%)	0.03	0.870
Physical IPV	36 (41%)	181 (35%)	217 (36%)	0.98	0.32
Emotional IPV	27 (31%)	190 (37%)	217 (36%)	0.85	0.36
Married to partner (n=606)					
Total IPV	19 (15%)	132 (28%)	151 (25%)	7.95	0.005
Physical IPV	13 (15%)	138 (27%)	151 (25%)	5.93	0.02
Emotional IPV	17 (20%)	134 (26%)	151 (25%)	1.42	0.23
Cohabitating with partner (n=606)					
Total IPV	44 (35%)	202 (42%)	246 (41%)	1.90	0.168
Physical IPV	29 (33%)	217 (42%)	246 (41%)	2.78	0.10
Emotional IPV	35 (41%)	211 (41%)	246 (41%)	0.00	0.98
Confirmed Concurrency in last 12 months (n=623)					
Total IPV	13 (10%)	42 (9%)	55 (9%)	0.22	0.642
Physical IPV	10 (10%)	45 (9%)	55 (9%)	0.36	0.551
Emotional IPV	9 (10%)	46 (9%)	55 (9%)	0.12	0.727
Pregnancy Intention Agreement (n=614)					
Total IPV	29 (22%)	156 (32%)	185 (30%)	4.79	0.029
Physical IPV	18 (19%)	167 (32%)	185 (30%)	6.68	0.010
Emotional IPV	21 (23%)	164 (31%)	185 (30%)	2.31	0.128

# Appendix M4: Analysis of age by time of first HIV+ test

	Tested HIV+	First tested	Total (n=623)		
	before this	HIV+ in this			
	pregnancy	pregnancy			
	(n=281)	(n=342)			
	Med (IQR)	Med (IQR)	Med (IQR)	Z-Stat	P-value
Age	29 (26-32)	27 (23-31)	28 (24-32)	-4.448	0.0000

# Appendix M5: Relationship characteristics associated with experiences of IPV in the past 12 months among those who perceive strong social support

	Adjuste d for Age and		Adjuste d for all variable	
	OR	95% CI	OR	95% CI
Age			0.97	(0.93;1.02)
SES				
Low				
Middle			0.72	(0.42;1.23)
High			0.80	(0.47;1.36)
Disclosure	1.06	(0.68;1.66)		
Duration	1.00	(1.00;1.01)	1.01	(1.00;1.00)
Marriage	0.48	(0.27;0.86)	0.41	(0.22;0.75)
Cohabitation	0.75	(0.47;1.19)		
Concurrency	0.97	(0.48;1.98)		
Pregnancy intention				
Discussed, agreed				
Did not discuss or disagreed	1.61	(0.98;2.63)		

# Appendix M6: Relationship characteristics associated with experiences of IPV in the past 12 months among those who perceive weak social support

	Adjuste d for Age and		Adjuste d for all variable	
	OR OR	95% CI	OR	95% CI
Age			1.00	(0.90;1.10)
SES				
Low				
Middle			0.27	(0.07;1.02)
High			0.77	(0.23;2.62)
Disclosure	0.77	(0.26;2.31)		
Duration	0.98	(0.96;1.00)	0.98	(0.96;1.00)
Marriage	0.40	(0.10;1.57)		
Cohabitation	0.60	(0.18;1.94)		
Concurrency	2.35	(0.37;15.03)		
Pregnancy intention				
Discussed, agreed				
Did not discuss or disagreed	1.98	(0.57;6.87)		

# Appendix M7: Behavioral characteristics associated with experiences of IPV in the past 12 months among those who perceive strong social support

	Adjuste d for Age and		Adjuste d for all variable	
	OR	95% CI	OR	95% CI
Age			0.99	(0.95;1.04)
SES				
Low				
Middle			0.67	(0.39;1.17)
High			0.70	(0.40;1.23)
Alcohol/Drugs	6.27	(3.62;10.85)	5.83	(3.32;10.25)
Distress	2.72	(1.70;4.35)	2.12	(1.27;3.54)
Depression	2.91	(1.61;5.27)	2.41	(1.27;4.60)

# Appendix M8: Behavioral characteristics associated with experiences of IPV in the past 12 months among those who perceive weak social support

	Adjuste d for Age and		Adjuste d for all variable	
	OR	95% CI	OR	95% CI
Age			0.98	(0.89;1.08)
SES				
Low				
Middle			0.33	(0.09;1.28)
High			0.80	(0.23;2.75)
Alcohol/Drugs	1.58	(0.37;6.71)		
Distress	3.12	(1.05;9.32)	3.12	(1.05;9.32)
Depression	2.09	(0.54;8.08)		

# IV. Journal submission guidelines

3/6/2015

BMC Women's Health | Instructions for Authors | Research articles



### **Instructions for authors**

#### Research articles

Criteria | Submission process | Preparing main manuscript text | Preparing illustrations and figures | Preparing tables | Preparing additional files | Style and language

Assistance with the process of manuscript preparation and submission is available from BioMed Central customer support team. See 'About this journal' for information about policies and the refereeing process. We also provide a collection of links to useful tools and resources for scientific authors on our page.

#### Criteria

Research articles should report on original primary research, but may report on systematic reviews of published research provided they adhere to the appropriate reporting guidelines which are detailed in our Editorial Policies. Please note that non-commissioned pooled analyses of selected published research will not be considered.

#### Submission process

Manuscripts must be submitted by one of the authors of the manuscript, and should not be submitted by anyone on their behalf. The submitting author takes responsibility for the article during submission and peer review.

Please note that BMC Women's Health levies an article-processing charge on all accepted Research articles; if the submitting author's institution is a <u>BioMed Central member</u> the cost of the article-processing charge may be covered by the membership (see <u>About</u> page for detail). Please note that the membership is only automatically recognised on submission if the submitting author is based at the member institution.

To facilitate rapid publication and to minimize administrative costs, BMC Women's Health prefers online submission.

Files can be submitted as a batch, or one by one. The submission process can be interrupted at any time;; when users return to the site, they can carry on where they left off.

See below for examples of word processor and graphics file formats that can be accepted for the main manuscript document by the online submission system. Additional files of any type, such as movies, animations, or original data files, can also be submitted as part of the manuscript.

During submission you will be asked to provide a cover letter. Use this to explain why your manuscript should be published in the journal, to elaborate on any issues relating to our editorial policies in the 'About BMC Women's Health' page, and to declare any potential competing interests. You will be also asked to provide the contact details (including email addresses) of potential peer reviewers for your manuscript. These should be experts in their field, who will 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 research institution. Suggested reviewers will be considered alongside potential reviewers recommended by the Editorial team, Editorial Advisors, Section Editors and Associate Editors.

Assistance with the process of manuscript preparation and submission is available from BioMed Central customer support team.

We also provide a collection of links to useful tools and resources for scientific authors on our Useful Tools page.

#### File formats

The following word processor file formats are acceptable for the main manuscript document:

Microsoft word (DOC, DOCX)
Rich text format (RTF)
Portable document format (PDF)
TeX/LaTeX (use <u>BioMed Central's TeX template</u>)
DeVice Independent format (DVI)

TeX/LaTeX users: Please use <u>BioMed Central's TeX template</u> and BibTeX stylefile if you use TeX format. During the TeX submission process, please submit your TeX file as the main manuscript file and your bib/bbl file as a dependent file. Please also convert your TeX file into a PDF and submit this PDF as an additional file with the name Reference PDF. This PDF will be used by internal staff as a reference point to check the layout of the article as the author intended. Please also note that all figures must be coded at the end of the TeX file and not inline.

If you have used another template for your manuscript, or if you do not wish to use BibTeX, then please submit your manuscript as a DVI file. We do not recommend converting to RTF.

For all TeX submissions, all relevant editable source must be submitted during the submission process. Failing to submit these source files will cause unnecessary delays in the publication procedures.

## **Publishing Datasets**

Through a special arrangement with <u>LabArchives</u>, LLC, authors submitting manuscripts to BMC Women's Health can obtain a <u>complimentary subscription to LabArchives</u> with an allotment of 100MB of storage. LabArchives is an Electronic Laboratory Notebook which will enable scientists to share and publish data files in situ;; you can then link your paper to these data. Data files linked to published articles are assigned digital object identifiers (DOIs) and will remain available in perpetuity. Use of LabArchives or similar data publishing services does not replace preexisting data deposition requirements, such as for nucleic acid sequences, protein sequences and atomic coordinates.

Instructions on assigning DOIs to datasets, so they can be permanently linked to publications, can be found on the LabArchives website. Use of LabArchives' software has no influence on the editorial decision to accept or reject a manuscript.

http://www.biomedcentral.com/bmcwomenshealth/authors/instructions/researcharticle

Authors linking datasets to their publications should include an Availability of supporting data section in their manuscript and cite the dataset in their reference list.

#### Preparing main manuscript text

General guidelines of the journal's style and language are given below.

#### Overview of manuscript sections for Research articles

Manuscripts for Research articles submitted to BMC Women's Health should be divided into the following sections (in this order):

Title page

Abstract

Kevwords

Background

Methods

Results and discussion

Conclusions

List of abbreviations used (if any)

Competing interests

Authors' contributions

Authors' information

Acknowledgements

Endnotes

References

Illustrations and figures (if any)

Tables and captions

Preparing additional files

The Accession Numbers of any nucleic acid sequences, protein sequences or atomic coordinates cited in the manuscript should be provided, in square brackets and include the corresponding database name; for example, [EMBL:AB026295, EMBL:AC137000, DDB]:AE000812, GenBank:U49845, PDB:1BFM, Swiss-Prot:Q96KQ7, PIR:S66116].

The databases for which we can provide direct links are: EMBL Nucleotide Sequence Database (EMBL), DNA Data Bank of Japan (DDBJ), GenBank at the NCBI (GenBank), Protein Data Bank (PDB), Protein Information Resource (PIR) and the Swiss-Prot Protein Database (Swiss-Prot).

For reporting standards please see the information in the About section.

#### Title page

The title page should:

provide the title of the article

list the full names, institutional addresses and email addresses for all authors  $\frac{1}{2}$ 

indicate the corresponding author

#### Please note:

the title should include the study design, for example "A versus B in the treatment of C: a randomized controlled trial X is a risk factor for Y: a case control study" abbreviations within the title should be avoided

#### Abstract

The Abstract of the manuscript should not exceed 350 words and must be structured into separate sections: **Background**, the context and purpose of the study; **Methods**, how the study was performed and statistical tests used;; **Results**, the main findings;; **Conclusions**, brief summary and potential implications. Please minimize the use of abbreviations and do not cite references in the abstract. **Trial registration**, if your research article reports the results of a controlled health care intervention, please list your trial registry, along with the unique identifying number (e.g. **Trial registration**: Current Controlled Trials ISRCTN73824458). Please note that there should be no space between the letters and numbers of your trial registration number. We recommend manuscripts that report randomized controlled trials follow the <u>CONSORT</u> extension for abstracts.

#### Kevwords

Three to ten keywords representing the main content of the article.

#### Background

The Background section should be written in a way that is accessible to researchers without specialist knowledge in that area and must clearly state - and, if helpful, illustrate - the background to the research and its aims. Reports of clinical research should, where appropriate, include a summary of a search of the literature to indicate why this study was necessary and what it aimed to contribute to the field. The section should end with a brief statement of what is being reported in the article.

#### Methods

The methods section should include the design of the study, the setting, the type of participants or materials involved, a clear description of all interventions and comparisons, and the type of analysis used, including a power calculation if appropriate. Generic drug names should generally be used. When proprietary brands are used in research, include the brand names in parentheses in the Methods section.

For studies involving human participants a statement detailing ethical approval and consent should be included in the methods section. For further details of the journal's editorial policies and ethical guidelines see 'About this journal'.

For further details of the journal's data-release policy, see the policy section in 'About this journal'.

#### Results and discussion

http://www.biomedcentral.com/bmcwomenshealth/authors/instructions/researcharticle

The Results and discussion may be combined into a single section or presented separately. Results of statistical analysis should include, where appropriate, relative and absolute risks or risk reductions, and confidence intervals. The Results and discussion sections may also be broken into subsections with short, informative headings.

#### Conclusions

This should state clearly the main conclusions of the research and give a clear explanation of their importance and relevance. Summary illustrations may be included.

#### List of abbreviations

If abbreviations are used in the text they should be defined in the text at first use, and a list of abbreviations can be provided, which should precede the competing interests and authors' contributions.

#### Competing interests

A competing interest exists when your interpretation of data or presentation of information may be influenced by your personal or financial relationship with other people or organizations. Authors must disclose any financial competing interests;; they should also reveal any non-financial competing interests that may cause them embarrassment were they to become public after the publication of the manuscript.

Authors are required to complete a declaration of competing interests. All competing interests that are declared will be listed at the end of published articles. Where an author gives no competing interests, the listing will read 'The author(s) declare that they have no competing interests'.

When completing your declaration, please consider the following questions:

Financial competing interests

In the past three years have you received reimbursements, fees, funding, or salary from an organization that may in any way gain or lose financially from the publication of this manuscript, either now or in the future? Is such an organization financing this manuscript (including the article-processing charge)? If so, please specify.

Do you hold any stocks or shares in an organization that may in any way gain or lose financially from the publication of this manuscript, either now or in the future? If so, please specify.

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