

UNIVERSITY OF CAPE TOWN



**A Mixed Methods Study to explore the outcomes, experiences and perceptions of women who attended a New Counselling model for HIV-positive pregnant women accessing antenatal services in Khayelitsha, Cape Town, South Africa**

by

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# **Preamble**

## **Declaration**

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

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## **Dedication**

I give thanks to God for he is faithful. I dedicate this thesis to my children who are the sunshine in my life and give me a reason to smile and laugh every day.

## Overview of Dissertation

Two major problems that have been identified in the Prevention of mother-to-child transmission programme are, the high rate of loss to follow up of patients and the poor adherence to antiretroviral therapy. Literature has highlighted some of the barriers that result in poor adherence and poor retention in care of patients. Counselling is an intervention that has been used to address some of the barriers to poor adherence and poor retention in care in the general population. In this study we examined the outcomes of the women who accessed a new counselling model for HIV-positive pregnant women at a clinic in Khayelitsha, Cape Town and explored their experiences and perceptions of this intervention.

**Section A** of the thesis is the **proposal**. The proposal describes the methodology of the study. The study design that was employed was a mixed methods study comprising of quantitative and qualitative data. The **literature review** forms **Section B** of the thesis. In the review, literature on the PMTCT cascade and on the issues that affect the adherence and the retention in care (RIC) of patients is reviewed and discussed. In addition, the review describes how counselling can aid in adherence to treatment and the RIC of patients. The 'journal ready' **manuscript** forms **Section C** of the thesis. The manuscript is in keeping with the requirements of the PLoS One journal. A copy of the requirements is available in the **Appendix 5**. The referencing style for the journal is Vancouver and this style has been used throughout the thesis document to maintain consistency.

### Methods

A mixed methods study design was employed. The quantitative data collection involved using retrospective cohort quantitative data of women that were initiated on Option B+ during the period of 1 October 2013 to 30 June 2014. The variables of interest included maternal age, gravidity, date of ART start, viral load test result and number of counselling sessions attended. The qualitative data involved semi-structured interviews of patients and counsellors who had experienced the counselling model.

## **Results**

The number of women who completed a total of 1, 2, 3 or 4 counselling sessions was 25%, 26%, 48% and 1% respectively. The percentage of women that were retained in care for more than 8 weeks postnatal was 53%. Of the women with VL results, 92% were virally suppressed. The Fisher's exact test showed a P-value of 0.05 at a level of significance of  $P \leq 0.05$ . Therefore there is sufficient evidence to show that there is a positive association between the number of counselling sessions completed and number of postnatal days in care (RIC). The study also found that from the counselling, the women gained social support, knowledge about ART, HIV, side effects of ARVs and infant feeding.

## **Conclusion**

The findings suggest that when offering counselling interventions to pregnant women, a balance between psychosocial support, practical support and patient education needs to be struck. Counselling can be used to address some of the barriers to adherence but due to the fact that the causes of poor adherence and retention in care are multifactorial, it needs to be implemented in conjunction with other interventions that address other barriers to adherence.

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## List of Acronyms

AIDS	Acquired Immune Deficiency Syndrome
ANC	Antenatal care
ART	Antiretroviral therapy
ARV	Antiretroviral
AZT	Zidovudine
CITC	Client-initiated testing and counselling
DOH	Department of Health
EBF	Exclusive breastfeeding
FP	Family Planning
HCW	Health care worker
HIV	Human Immunodeficiency Virus
HR	Hazard ratio
HREC	Human Research Ethics Committee
IQR	Interquartile range
LTFU	Lost to follow-up
MDGs	Millennium Development Goals
MOU	Maternity Obstetric Unit
MSF	Médecins Sans Frontières
MTCT	Mother-to-Child Transmission
NIMART	Nurse initiation and management of antiretroviral therapy
PCR	Polymerase chain reaction
PITC	Provider-initiated testing and counselling
PMTCT	Prevention of Mother-to-Child Transmission
RIC	Retention in Care

VL	Viral load
UN	United Nations
UNAIDS	Joint United Nations Programme on HIV/AIDS
WHO	World Health Organisation

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## **Section A: Proposal**



# 1. Purpose of the study

The purpose of the study is to describe the outcomes of a cohort of women who have accessed a new counselling model for Human immunodeficiency virus (HIV) positive pregnant women at Site B Maternity Obstetric Unit (MOU) in Khayelitsha. The study will also explore the experiences and perceptions of women towards the new counselling model in order to understand how these experiences and perceptions influence adherence to HIV treatment.

## Objectives

1. To describe the cohort of HIV-positive pregnant women who experienced a new counselling model at Site B Maternity Obstetric Unit (MOU) during the period of 1 October 2013 to 30 June 2014.
2. To determine the number of patients in the cohort who are adherent to treatment based on Viral load  $< 40$  cells/mm<sup>3</sup> and remaining in care after 6 weeks delivery<sup>1</sup>.
3. To explore the experiences and perceptions of counsellors and patients towards a new counselling model for HIV-positive pregnant women at Site B MOU in Khayelitsha, Cape Town.
4. To explain how the experiences and perceptions of patients influence adherence to HIV treatment and follow-up.

## 2. Research Question

What are the outcomes of the women that have accessed the new counselling model for HIV-positive pregnant women at Site B MOU, Khayelitsha during the study period and what are their experiences and perceptions of this intervention?

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<sup>1</sup> Post-study note: Adherence to treatment was changed from 'remaining in care after 6 weeks post delivery' to 'remaining in care after 8 weeks post delivery'. This is because the baby's HIV test is done at 6 weeks of age and the mother receives the results 2 weeks later. After receiving the results, the mother and baby are referred to another clinic for on going follow up.

### **3. Background**

The vision of UNAIDS is that by 2015 there will be no children born with HIV and that HIV-positive mothers will not die from HIV, therefore giving them a chance to raise their children [1]. HIV remains an important cause of mortality in both women and children worldwide [2]. In the last decade there has been a global scale up of services to prevent HIV transmission from mother-to-child. This has led to a significant impact on decreasing child mortality, improving maternal health and the fight against HIV/AIDS epidemic: a positive move towards achieving Millennium Development Goals (MDG) 4, 5 and 6 [2].

In the absence of Prevention of mother-to-child transmission (PMTCT) interventions, the risk of transmission of HIV to the baby is 25-35 %, yet with PMTCT this risk can be reduced to below 2% [3]. For this reason there has been a global scale up of services providing antiretroviral therapy (ART) to pregnant women and as a result the number of pregnant HIV-positive women receiving antiretroviral treatment increased from 14% to 56% of the total number of women who needed treatment between the period of 2005 to 2011 [4]. In addition, the number of HIV infections in children living in lower and middle income countries has decreased gradually, from approximately 410 000 new infections in 1996 to approximately 290 000 new infections in 2012 [4]. Despite these successes, the PMTCT remains a global priority because elimination of paediatric HIV has not yet been achieved [5].

In 2010, the World Health Organisation (WHO) PMTCT Guidelines recommended ARV prophylaxis to prevent MTCT during pregnancy, delivery and breastfeeding for HIV-positive women who do not need ART [6]. Prophylaxis came in 2 options: Option A and Option B, where Option A was maternal Zidovudine (AZT) from 14 weeks gestation plus infant ARV prophylaxis and Option B was maternal triple ART prophylaxis which was to be stopped once risk of exposure ceased [6]. In 2013, a new guideline from WHO recommended Option B+, which provides all HIV-positive pregnant and breast-

feeding women with lifelong triple therapy [4]. These guidelines stress that the health of the mother is as important as the health of the baby.

Two major limitations which threaten the success of PMTCT programmes are the number of pregnant patients that are lost to follow-up (LTFU) and poor adherence to medication [2,7]. Evidence from antiretroviral (ART) programme data suggests that poor adherence to treatment among pregnant HIV-positive women, is a problem. The evidence also suggests that attrition among pregnant women is more common than in the general clinic population. A study conducted in a community HIV clinic in South Africa looked at patient characteristics related to LTFU 6 months after starting ART. Results showed that patients  $\leq 30$  years had a hazard ratio (HR) for LTFU at 6 months of 2.14, pregnant women had a HR of 3.75 and pregnant women with a CD4 count  $\leq 200$  had a HR of LTFU at 6 months 6.06 times that of men [8]. Hence there is a concern that pregnant women are at higher risk of LTFU compared to males and non-pregnant women [8]. A systemic review and meta-analysis of adherence to ART in pregnant women in low and middle-income countries showed that adherence levels were higher during pregnancy (75.7%) compared to the postnatal period (53%) [9]. Another study that supported the above findings was a study conducted in Malawi that looked at pregnant and breast feeding women on lifelong ART (Option B+) and found that 17% of patients were LTFU at 6 months and those who were on Option B+ were 5 times more likely to not return to clinic after their first visit compared to those with WHO stage III and IV disease or have CD4 < 350 [10].

South Africa started the PMTCT program in 2002 and since then there has been an up scaling of the programme towards achieving the MDGs 4, 5 and 6 by 2015 [11]. The PMTCT programme in South Africa has undergone several policy changes since the initial 2002 policy: in 2008, 2010, 2013 and in 2014. The 2013 National guidelines stated that all HIV-positive pregnant women were to be started on triple therapy, on the day of HIV diagnosis and this was to continue until after stopping breastfeeding (Option B). All the provinces adopted Option B except the Western Cape Province which adopted Option B+ (lifelong ART for all pregnant women irrespective of CD4 count) [12].

Nationally HIV prevalence amongst pregnant women was 29.5% in 2012, this had remained unchanged since 2004 [13]. In 2011, the Western Cape had an antenatal HIV seroprevalence of 18.2%, with Khayelitsha having an antenatal seroprevalence of HIV of 38% which was considerably higher than the national seroprevalence [13]. The new 2013/2014 PMTCT guidelines require that all pregnant HIV-positive women start ART on their first antenatal visit [12], meaning that an HIV-positive pregnant woman is faced with accepting a positive diagnosis of HIV, risk of HIV transmission to unborn baby and starting life long ART, all of which happen on the same day. It has been reported that this “triple burden” may put these women at risk of defaulting treatment and having poor adherence, suggesting the need for supportive counselling [14,15]. This problem in combination with the scaling up of the PMTCT programme makes it vital to address the causes of LTFU and poor adherence in order to improve the effectiveness of the programme.

In order to understand why the PMTCT programme is not as effective as it should be and why patients are LTFU, it is important to identify service gaps by looking at the PMTCT cascade [2]. The PMTCT cascade includes: attendance to antenatal clinic, receiving HIV results, receiving antiretroviral treatment during the antenatal period and labour, receiving of antiretroviral treatment during breastfeeding, counselling on infant feeding, early diagnosis of HIV-exposed new-borns, linking HIV-positive new-borns to treatment and survival of children living with HIV [2]. Patients can be lost at any point in the cascade; therefore interventions must address the relevant service issues at the different levels of the cascade.

Addressing the causes of LTFU and poor adherence is vital for the success of the PMTCT programme. Counselling has been an intervention used to try to improve adherence and decrease LTFU in ART services more generally. Counselling has been used to educate patients on HIV, the benefits of ART, adherence to treatment and its side effects, elements of a healthy lifestyle, breastfeeding and early HIV testing for the HIV-exposed baby. The South African Guidelines state that counselling is to be given in 2 to 3 sessions with the aim of starting the patient on treatment within 2 weeks following the first antenatal visit [16]. A study performed in Cape Town, assessed the

acceptability and difficulties of rapid initiation of patients on ART among pregnant women and found that 91% of the women in the study agreed to start treatment on the day of their first antenatal visit. However, the authors stressed the need for counselling to ensure good adherence and retention in care [15]. Another study that highlighted the need for counselling was a cross-sectional study conducted in Ghana that looked at the knowledge and perception of pregnant women about ART and PMTCT [17]. The authors found that adherence of mothers to HIV medication and PMTCT was dependent on their knowledge and understanding about HIV and PMTCT [17]. What is unknown, however, is evidence for optimal counselling models or interventions for HIV-positive pregnant women on Option B and B+, which target adherence in particular.

In October 2013, Médecins Sans Frontières (MSF) piloted a counselling model that was designed for women initiating ART as part of Option B+. The aim of the counselling model was to improve adherence and decrease LTFU of pregnant women on ART. The model is patient-centred and consists of 4 antenatal sessions and 6 postnatal sessions (Appendix 1). All the sessions are conducted on clinical visit days for the convenience of the patient. The design of the counselling model ensures that the counselling can be modified to cater for the needs of pregnant women presenting at the different stages of the PMTCT programme. Since it was implemented in Khayelitsha in 2013, there has not yet been a study conducted to examine this new counselling model.

## **4. Motivation for the study**

As mentioned above, the decrease in new HIV infections in children has been attributed to the scaling up of PMTCT programmes [13]. Despite this scaling up, South Africa is still behind in trying to meet the MDG 4, 5 and 6 targets to decrease child mortality, maternal mortality and reducing HIV infections by 2015 [13,18]. A problem highlighted in the literature is the high rate of LTFU and the poor adherence to treatment leading to increased MTCT, limiting the effectiveness of the PMTCT programme [8,9]. Interventions to address this problem are urgently needed especially in Khayelitsha, due to the high antenatal seroprevalence of HIV among pregnant women and in the general

population. The counselling model for Option B+ is one such intervention that aims to improve adherence and decrease LTFU, yet little is known about its effectiveness and whether it is acceptable or feasible. The results of the study will assist the MOU currently using the model on ways to optimise the effectiveness of the model. The information generated will also help inform the future implementation of the model as it may be rolled out to the rest of Western Cape and the rest of South Africa.

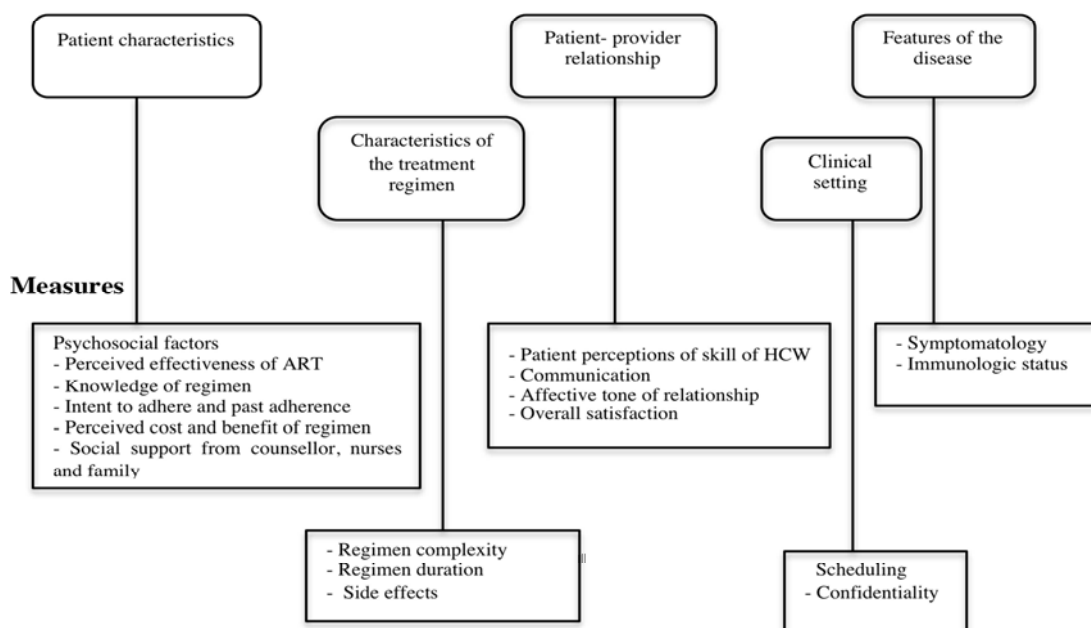
## **5. Conceptual framework**

One of the aims of the study is to examine the new counselling model by exploring the experiences and perceptions of women towards model in order to understand how these experiences and perceptions influence adherence to HIV treatment. From identified literature, a conceptual framework that currently appears appropriate to be used to inform data collection and data analysis in the qualitative study will be the framework by Ickovics & Meisler (1997) on “Adherence in AIDS clinical trials: a framework for clinical research and clinical care”. The conceptual framework, “ a model for recruitment, adherence and retention in AIDS clinical trials” was developed from previous studies on medical adherence (Figure 1) [20: p.386]. Factors that influence adherence in AIDS clinical trials were found to be the patient characteristics, the patient-provider relationship, characteristics of the treatment regimen, the clinical setting and the features of the disease [20: p.386]. Psychosocial factors such as the perceived effectiveness of treatment, knowledge of the regimen, intent to adhere and patient history of adherence, the perceived costs and benefits of the regimen and social support are all patient characteristics that can influence adherence [20: p.386]. Furthermore, characteristics of the trial and treatment regimen include: Allocation, length of the regimen, difficulty of the regimen and side effects. Elements of the patient-provider relationship such as patients perception of the health care practitioner’s technical skill, affective tone of the relationship, communication and the overall satisfaction of the patient-provider relationship were also found to influence adherence [20: p.386]. Features of the clinical setting that influence adherence include: clinical environment, scheduling, confidentiality and transportation. Lastly, features of the disease such as symptoms and the

immunological status influence adherence [20: p.386]. This framework has been adapted in order to assess what factors highlighted in the framework on adherence, are addressed by the new counselling model for HIV-positive pregnant women, thereby having a positive influence on adherence of patients, in a clinic setting.

**Fig. 1: Conceptual Framework on factors that influence adherence and retention in care in HIV-positive patients**

**Concepts**



Adapted from: Ickowics, J. R and Meisler AW. Adherence in AIDS Clinical Trials : A Framework for Clinical Research and Clinical Care. J Clin Epidemiol. 1997;50(4): 385–91.

## 6. Methods

### 6.1 Study design

The study design will employ mixed methods comprising of quantitative and qualitative data. Mixed methods studies are particularly useful to explore operational research, because they can provide information and understanding about a phenomenon that would not be obtained if the quantitative and qualitative studies were done independently [20]. Applied to this study, a mixed methods approach

will enable a wider scope of investigation into the new counselling model for HIV-positive pregnant women [21]. The quantitative study will be performed first and will provide a description of the patients in the cohort: generate information on the adherence of the patients to treatment and determine the number of counselling sessions each patient attended, adjusted for the gestational age at first presentation<sup>2</sup>. The qualitative study will follow the quantitative study in order to allow for some results from the quantitative study to be developed or clarified. This will comprise of a qualitative exploration of the experiences and perceptions of patients and counsellors of the new counselling model [21]. The third and fourth objectives are exploratory and explanatory in nature requiring a qualitative form of inquiry, all with the aim of providing a better understanding of the new counselling model for HIV-positive pregnant women on Option B+ and how it relates to adherence to treatment.

There will be a researcher (who is a Masters student) and a field worker conducting the study. The researcher will be responsible for the supervision of the fieldworker and management of the study.

## **6.2 Study setting**

The study will take place at Site B Maternity Obstetric Unit (MOU), which is in Khayelitsha, Cape Town. The MOU implemented nurse-initiated antiretroviral therapy (ART) in May 2013. Khayelitsha is 56km from the centre of Cape Town. The demographics in 2011 were: Population was 391 749, 45% of households reside in formal housing; the level of employment was 62% among those aged 15 to 64 years; Individuals (aged 20 years and older) who have completed Grade 12 or higher make up 36% of the population [22]. Khayelitsha had an antenatal seroprevalence of HIV of 38% in 2011 [13]. MSF assisted in the implementation of the new counselling model for HIV-positive pregnant women on Option B+ in October 2013 and it is still on going.

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<sup>2</sup> Post-study note: Data on gestational age was not obtained due to the data not being available on the DOH routine electronic health record platform (Ekapa), therefore it was not possible to determine the number of counselling sessions each patient attended, adjusted for gestational age.



## **6.3 Population**

The study population will include HIV-positive pregnant women attending Site B MOU for antenatal care (ANC), who have attended one or more counselling sessions from the Option B+ counselling model and the counsellors who use the counselling model.

## **6.4 Sampling**

### **Sampling for the quantitative study:**

The sample will comprise of all the patients who had counselling from the new counselling model for Option B+ and were initiated on ART at Site B MOU during the period of 1 October 2013 and 30 June 2014 and fulfil the inclusion criteria (refer to Table 1).

### **Sampling for the qualitative study:**

The sampling method will employ purposive sampling of counsellors and of HIV-positive pregnant women at Site B MOU. The model consists of 4 antenatal counselling sessions therefore the sample must include women who have had 1, 2, 3 and 4 counselling sessions respectively. This will ensure that information is gathered from a range of perspectives and experiences. Participants who have only 1 counselling session might be different from those who have all 4 counselling sessions and therefore both types of patients could provide different information about the counselling model. Due to their experience with the counselling model, their knowledge gained from interaction with the HIV-positive pregnant patients and their knowledge of the context, counsellors will be able to provide useful information. The fact that HIV is a sensitive topic and that people fear stigmatization if their status is known, it may be difficult to get a large number of patients to participate. The estimated number of study participants will be 15 participants, who include 3 counsellors and 12 HIV-positive pregnant women who have experienced the counselling model. Each participant will be interviewed individually. The researcher will select the participants based on the inclusion and exclusion criteria (refer to Table 1). Although the target sample size is 15, the number of participants will be guided by

data saturation, which is when there is a repetition of data from successive interviews and no new information is being generated.

**Table 1: Inclusion and exclusion criteria**

<b>Inclusion criteria</b>	<b>Exclusion criteria</b>
HIV-positive pregnant women	Postpartum mothers
Must have had 1 or more counselling session with Option B+ model	Patients who have not had counselling with Option B+ model
Must be older than 18 years	Individuals < 18 years old as not able to consent on their own
Must have signed informed consent to participate	

## 6.5 Recruitment

### **Counsellors:**

The counsellors, who are using the counselling model, will be invited to participate in the study by the researcher. They will be given an information sheet about the study and a copy of the consent form (refer to Appendix 2), both of which will be in English and isiXhosa. These will be given to the counsellor up to 2 to 5 days before the interview. The consent form will only be signed on the day of the interview.

### **HIV-positive pregnant women:**

The counsellors will assist the researcher in recruiting eligible HIV-positive pregnant women for the study from their list of follow-up patients for the day. The researcher will guide the counsellors on which participants to select based on the inclusion and exclusion criteria and depending on how many counselling sessions the participant has completed. The researcher will confirm the eligibility of the participants. The potential participants will be provided with an information sheet about the study and a copy of the consent form. The interview will be conducted on the same day as recruitment for those participants that are able to stay for the interview. Those who are unable to stay for the interview will

be given an appointment for a convenient time. Consent forms will be signed on the day of the interview.

## 6.6 Measurements

The data on the number of counselling sessions completed by each participant and date for each counselling session will be collected using Epidata 3.1. Data on patient viral load after 4 months on treatment, gestational age and retention in care (RIC) status will all be obtained from the Department of Health electronic health record (Ekapa), which is used for routine data monitoring.

### Outcomes:

Completion of 4 counselling sessions

Definition of adherence is defined as:

- Viral load < 40
- Remaining in care 6 weeks post partum

**Table 2: Variables Table**

Variables	Type of variable	Option	Source
Age	Numerical/ continuous	-	Ekapa
Gestational age in weeks	Numerical/ discreet	-	Ekapa
Number of counselling sessions completed	Numerical /discreet	-	Epidata, folders & counselling register
Viral load < 40 prior to delivery	Binary/categorical	Yes/no	Ekapa
RIC after 6 weeks post partum	Binary/categorical	Yes/no	Ekapa

## 6.7 Data collection

### Quantitative study data collection:

The quantitative data on the number of counselling sessions completed will be captured from the patient folders and the counselling registers onto Epidata 3.1. Other quantitative data (refer to table 2) will be extracted from the routine electronic health record (Ekapa), onto an excel spreadsheet by the

researcher. Quality control on the database will be performed on a random 10% of the sample, by comparing with the data source.

### **Qualitative study data collection:**

The qualitative study will be performed using semi-structured interviews, which will be guided by the conceptual framework. Individual interviews will enable participants to describe what they see as important and provide insight about the topic in its context [23]. The questionnaire will be piloted on 3 patients at the study site before being used in data collection. This will enable questions to be refined, to ensure that the correct questions are asked in order to target the research question. The fieldworker will undergo training on how to use the questionnaire and how to conduct individual interviews.

A conceptual framework adapted from a framework by Ickovics & Meisler (1997) on “A multifactorial framework for adherence for HIV/AIDS patients”, will be used to guide the data collection. The semi-structured interview and the data analysis will be based on the different components of the framework: patient characteristics, patient-provider relationship, characteristics of treatment regimen, clinical setting and features of the disease [19]. The data collection will aim to find out how the different features of the new counselling model for Option B+ satisfy some of the elements in the framework which are important for adherence, thereby positively influencing patient adherence. Data collection will be in the form of semi-structured interviews. There will be 3 counsellors and 12 HIV-positive pregnant women participating in the semi-structured interviews. Individual interviews will be guided by a semi-structured questionnaire that will consist predominantly of open-ended questions, which will allow for individuals to give their own perspective (refer to Appendix 3). The questionnaire for the counsellors will be different from the questionnaire for the pregnant women and the questions will focus on the acceptability and feasibility of the counselling model (refer to Appendix 3). The semi-structured interview questionnaire guides the interviewer and ensures that all the important topics are discussed but also allows for new topics raised by the interviewee to be pursued therefore adding richness to the data. The semi-structured

interview questionnaire will originally be in English and will then be translated into isiXhosa (the mother tongue of the participants) in order to be used for the interview of the pregnant women and the counsellors.

A trained fieldworker, under the supervision of the researcher will conduct the individual interviews. Supervision will ensure consistency and quality of the data. The individual interviews will be anonymised to ensure patient confidentiality. The interviews will be digitally recorded and additionally, the field worker will write notes of relevant information. The interviews will take place in a private closed room and should last approximately 60 to 90 minutes.<sup>3</sup> There will be a debriefing at the end of each day between the fieldworker and the researcher, which will enable the data collection process to be refined. The recordings will be translated from Xhosa to English and then transcribed verbatim by a trained person. The transcript of each interview will be read and analysed until there is no new information obtained from successive interviews and data saturation has been reached. The hand written interview notes will be typed at the end of each day to aid in memory recall of the interviewer. For respondent validation, the transcripts for the counsellors will be given to them to confirm that they are consistent with what was said in order to increase the validity of the results.

## **6.8 Data safety and monitoring**

### **Quantitative study:**

After extracting the data from Ekapa and Epidata, the data set will be anonymised, with the identifiers being replaced by independently derived patient identification numbers. This will be done before the data set is analysed. The file containing the data will be encrypted in order to maintain privacy and confidentiality. Only the principle investigator and the researcher will have access to the data file.

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<sup>3</sup> The interview lasted for 30- 40 minutes, which was shorter than the 60- 90 minutes initially estimated in the proposal.

**Qualitative study:**

To protect privacy and confidentiality, no names will be on the data collection tools. The interview notes (field notes) will be dated and kept in chronological order in an arch lever file labelled “qualitative study”. The notes will be filed away daily as the data is collected. The recordings of the interviews will be labelled as interview 1, 2, 3 etc. depending on the chronological order that they were performed and will be saved under the date on which the interview was conducted. The recordings of the interviews and the translated recordings will be kept in audio files on the researcher’s computer. The transcribed notes will also be kept on the researcher’s computer in a file in MS word. The hard copies of each transcript will also be filed in the arch lever file. Only the researcher will have access to the data on the computer and the files. The original signed consent forms; a copy of the information sheet and the original semi-structured interview questionnaire will also be filed. For quality assurance, an audit trail of all the study tools (protocol, digital recordings, translations, transcripts and notes) will be kept in case an independent researcher is interested in replicating the study to check that the statements made at the end of the study are not biased. An audit trail will also increase the reliability of the study results.

**6.9 Data analysis**

The quantitative data will be analysed using STATA version 12 (Statacorp, Texas, 2011). The numerical data will be explored using histograms, box-and-whisker plots and the Shapiro-Wilk test for normality. Data that is normally distributed will be described using means and standard deviations. Data that is not normally distributed will be described using medians and quartile ranges. The categorical data will be explored using frequency tables and bar graphs. The descriptive statistics will be presented in tables showing summary of frequencies and percentages. The variables of interest include maternal age; gestational age at antenatal booking; gravidity/parity; year of HIV diagnosis; date of ART start, viral load test results and the number of counselling sessions attended.

The data from the individual interviews will be analysed using thematic analysis. A thematic analysis involves the examination of the whole data set in order to find themes and interpret them. The data analysis will be guided by a framework adapted from the conceptual framework by Ickovics & Meisler (1997) on “A multifactorial framework for adherence for HIV/AIDS patients”, mentioned earlier. The data analysis will start with the researcher reading and re-reading the data to get familiar with the data (Robinson & Tolley 2005). This will be done after each new interview has been translated and transcribed. One interview can help inform the next interview (deductive then inductive). Once a number of transcripts are available from the individual interviews the researcher will code them in order to identify emerging themes (Robinson & Tolley 2005). The coded sections from the different interviews will be combined into a single report. The coding will be arranged into themes, which will be based on the abovementioned conceptual framework that will include: patient characteristics, patient-provider relationship, characteristics of treatment regimen, clinical setting and features of the disease. Interviews from the different pregnant women and counsellors will be used for data triangulation.

## **7. Ethics**

### **Ethical Approval**

Ethical clearance for the quantitative data for this study has been granted through the research protocol “Enhanced routine surveillance of an HIV clinic population in Khayelitsha” (HREC Ref: 395/2005). This approval, has on going clearance until 8 April, 2015, and covers all patients enrolled in Khayelitsha ART services (including maternity-based ART patients), in collaboration with UCT, MSF and the Khayelitsha sub-district health authority.

The study protocol will be submitted to University of Cape Town, Faculty of Health Sciences Human Research Ethics Committee for approval (HREC) for an amended protocol approval to include the qualitative interviews. Approval will also be obtained from the Provincial Department of the Western Cape to conduct interviews at Site B MOU. Throughout the period of the study the ethical principles

stated by the Declaration of Helsinki, for medical research involving human subjects will be adhered to [24]. This declaration states that the welfare of the study participant must take priority over all other interests. In addition the ethical principles and guidelines set out by the Belmont report for the protection of human subjects will also be observed. The principles include: respect for persons, beneficence and justice [25].

## **7.1 Potential risks and discomforts**

There is a potential risk that participants may feel pressured to participate in the study. This risk is minimal. To minimise this risk, the fieldworker who is not employed at the MOU and therefore less likely to pressure the participants into consenting to participate, will obtain the informed consent. The fieldworker will explain to the participants the importance of voluntary participation and clarify that their refusal to take part in the study will not affect their clinical care at the MOU.

There is a risk of emotional distress that could occur during the interview, due to discussing sensitive issues related to the counselling model. The risk of this occurring is minimal. To minimise this risk participants will be informed that they can refuse to answer any questions that they find uncomfortable. The field worker and the researcher will be instructed on how to be aware of the needs of the participants during the interview and respond accordingly, and they will provide emotional support where required. If the emotional support is not sufficient then the participant will be referred to the clinic HIV counsellor for support and to the operational manager for further referral if necessary.

There is a minimal to moderate potential risk to the counsellors of highlighting weaknesses in how they perform their job as counsellors and therefore it may have negative implications involving themselves and their line managers. To minimise this risk the data collection is anonymised to ensure that no individual is singled out and the final report at the end of the study will have recommendations, where relevant, on addressing some of the weaknesses highlighted.



There is a risk of accidental disclosure of the HIV status of the participant to other patients attending the clinic. This could happen during recruitment of the participant or during the data collection process. The risk of this happening is minimal. In order to minimise the risk of accidental disclosure, participants will be recruited by the researcher, a field worker and the counsellors (working at the clinic), all of who will be aware of the importance of protecting the confidentiality of the participants. The recruitment and interviews will all take place behind a closed door, in the privacy of the counsellors' office to ensure that other people in the clinic do not see the participant. The data sheets and interviews will be anonymised to protect the identity of participants. Lastly, all the data collected will be stored safely in order to maintain confidentiality.

Data will be collected by a trained fieldworker and researcher to ensure that data collected is rich, hence an efficient use of the participants' time and contribution.

## **7.2 Potential benefits**

The participants will not benefit directly from the study but some participants may find that the interview provides them with an opportunity to discuss some issues relating to their HIV diagnosis and treatment that they may not have had a chance to discuss and therefore derive some benefit. The potential benefit of the study to the health services is that the study can inform the current implementation of the model at Site B MOU in order to improve the effectiveness of the model. This will help future patients who will need counselling. The aim of improving the effectiveness of the model for the community of Khayelitsha is to improve adherence to HIV treatment and hence improving the health outcomes of HIV-positive mothers and their babies. The study will also help inform future implementation of the counselling model in similar clinics in the Cape Town Metro District Health Service and the rest of the Western Cape.

**Harm: Benefit ratio**

The potential risk of harm to the participant is minimal in this study. The potential benefit for the community of Khayelitsha, which is, improved adherence to HIV treatment by patients justifies the minimal risk involved.

## **7.3 Informed consent process**

**Qualitative study:**

Only participants that are 18 years and older will be recruited for the study because they are able to give their own consent. The counsellor will recruit participants after they have completed their routinely scheduled counselling session. The recruitment will take place in the counsellor's office. The field-worker, who will be fluent in both English and Xhosa, will have training on how to obtain informed consent prior to the start of the study. The fieldworker will obtain consent from the counsellors and the pregnant women. Informed consent will be obtained in the privacy of the counsellor's consulting room, which has a door. The information sheet and the consent forms provided about the study will be in English and the local language, isiXhosa. This is to ensure that participants who speak Xhosa fully understand what the study is about and what is involved. The fieldworker will read through the information sheet with the participant and will then obtain the informed consent.

The participants will be informed of the aim of the study, why they are being asked to take part, what their role will be, how long their involvement will be and how the results will be disseminated. They will also be informed that the research is contributing to the researcher's Masters in Public Health thesis, which has been approved by the Provincial Department of Health. There will not be any information about the study that is withheld from the participant. The fieldworker will emphasise the importance of their participation being voluntary, the researcher maintaining the anonymity of participants, the ability to withdrawal from the study at any time and the maintenance of confidentiality through out the study. The benefits and risks of the study will be explained to the

participant. The pregnant mothers who agree to participate will be asked to come back on the same day, after their clinical visit, in order to sign the consent form and to do the interview. This will give them time to decide about participation. For those who have had the clinical visit and agree to participate, informed consent will be obtained and the interview conducted following recruitment. If participants are not able to stay for the interview, then an appointment will be made for a convenient time in 2 to 5 days. The contact details of the supervisor, researcher and HREC will be given to all the participants.

**Quantitative data:**

Informed consent is not required for the cohort because it is routine data that is already collected for programme management.

## **7.4 Privacy and confidentiality**

For the quantitative study the data from Ekapa and Epidata will be stored in a file on a computer belonging to the thesis researcher, which is password protected. Only the Supervisor and the researcher have access to the data. Only patient information that is needed for the study will be extracted from the patient folders and Ekapa. In addition, no information will be added or removed from the dataset or folders.

For the qualitative study, all the data collected during the interviews (recordings and written notes) will be anonymised. No names will be written or recorded during data collection. All transcripts and interview notes will be stored in arch lever files and stored in a locked cupboard for maximum confidentiality. All the digital recordings and electronic copies of transcripts will be kept in a file on the researcher's computer, which is password protected. Only the Supervisor and the researcher have access to the data.

## 7.5 Reimbursement for participation

All participants will be given refreshments during the interviews; this will be done to thank the participant for their contribution. In addition, because most patients present to the MOU early for their appointments, refreshment given at anytime in the day will be helpful. Participants who return to the MOU for scheduled interviews will be reimbursed for their travel expenses.

## 8. Study duration

The study will take a period of 7 months from the time ethics approval is granted. Table 3 shows the detail of how the study will progress.<sup>4</sup>

**Table 3: Project Timeline**

	2015						
	Feb	March	April	May	June	July	Aug
Departmental and ethics approval							
Department of health approval							
Data collection – Qualitative & quantitative							
Data analysis							
Write-up							
Proof reading and finalising							
Submit thesis							

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<sup>4</sup> The study period was 11 months instead of 7 months because the data collection and data analysis took longer than had been expected in the proposal.

## 9. Budget

The total amount of money needed to conduct the study will be R8100. Table 4 shows detail of the budget.

**Table 4: Budget for the proposed study**

Item	Cost /unit	Number of units	Total cost
Fieldworker	60/hour	30	R1800
Translation consent forms	R60/hour	4	R240
Transcription of recordings in Xhosa	R60/hour	60	R3600
Translation from Xhosa to English	R60/hour	30	R 1800
Photocopy	R0.30/page	200	R60
Refreshments for participants	R 300	15	R450
Travel reimbursement for participants	R10	15	R150
Total			R8100

\* Each 1-hour of recording will take 4 hours to transcribe.

## 10. Dissemination of findings

The proposed study will be submitted to University of Cape Town as a requirement for partial fulfilment of Master in Public Health (General). The study findings will be reported back to the study participants, clinic staff, the operational manager at the MOU, facility manager and to relevant members of MSF. A copy of the results will be given to the PMTCT co-ordinator for Khayelitsha Sub district, Department of Health because the Counselling model has been implemented at all the MOUs in Khayelithsa. The researcher will also avail herself to present the results of the study at the monthly Sub-district management meetings.

The study will be submitted to a relevant research journal for publication.

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## **Section B: Literature Review**



**A Mixed Methods Study to explore the outcomes, experiences and perceptions of women who attended a New Counselling model for HIV-positive pregnant women accessing antenatal services in Khayelitsha, Cape Town, South Africa**

## **1. Introduction**

The elimination of new HIV infections in children continues to be a global priority [1]. In 2013, there were 1.3 million HIV-positive pregnant women worldwide and this number had remained relatively unchanged since 2009 [2]. In addition, there were approximately 199 000 children who acquired HIV in low and middle-income countries [2]. The high prevalence of HIV in pregnant women worldwide and the ongoing mother-to-child transmission (MTCT) of HIV have led to a global scale up of prevention of mother-to-child transmission (PMTCT) programmes. The scale up has targeted high prevalence populations in Sub-Saharan Africa (home to approximately 90% of HIV-positive pregnant women) and India [1]. As a result, progress has been seen in the PMTCT programmes, which is evidenced by the increase in coverage of pregnant HIV-positive women receiving antiretroviral treatment (ART) for PMTCT from 47% in 2009 to 67% in 2013 [1]. In addition, the MTCT rate has dropped from 26% to 16% during the same period. [2].

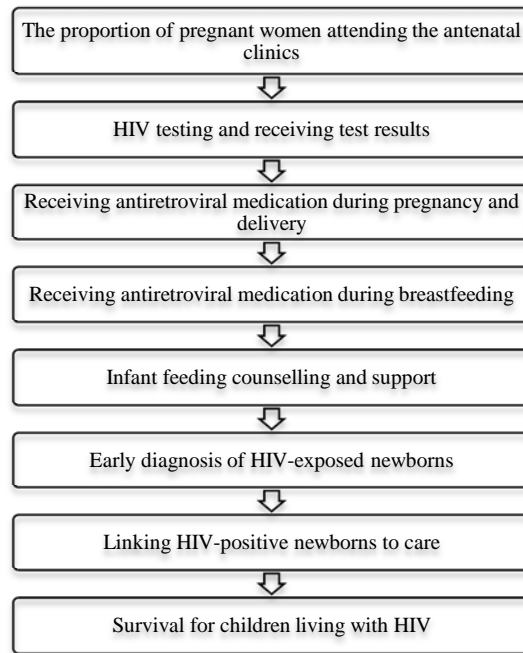
HIV testing in pregnancy is a gateway to PMTCT interventions and lifelong maternal ART [3,4]. HIV testing and counselling enables pregnant women to know their HIV status and thereafter, access antiretroviral therapy (ART) in order to prevent MTCT [1]. In 2013 there was an increase in the number of pregnant women who underwent HIV testing and counselling from 8% to 44 % in low and middle-income countries [1]. This increase has been attributed to the implementation of new policies and guidelines [1]. In 2013, the WHO released new Antiretroviral Treatment (ART) Guidelines. The key recommendations of these guidelines included the initiation of all pregnant and breastfeeding women on ART regardless of CD4 count or clinical stage (Option B and Option B+) and lifelong antiretroviral therapy (Option B+)[5]. The rationale behind Option B+ (lifelong ART to all pregnant women) is: to further decrease the rate of MTCT, to maintain the health of the HIV-positive mothers, to improve adherence, to prevent MTCT of further pregnancies and to prevent further transmission of

HIV [5]. Worldwide, there has been a quick move to adopt the 2013 guidelines in line with the global target of eliminating MTCT, with more countries choosing to implement B+ especially in Sub-Saharan Africa [1].

The national antenatal HIV seroprevalence in South Africa was 29.5% in 2012 [6]. The rate of MTCT of HIV decreased from 3.5% in 2010 to 2.4% in 2012, showing progress within the South African PMTCT programme [7]. In March 2013, South Africa adopted the 2013 PMTCT Guidelines for Option B then changed to Option B+ in January 2015, all with the aim of further decreasing the rate MTCT to 0% [8].

Despite the progress that has been made in the PMTCT programme globally, some challenges still remain [2,9,10]. To identify challenges and missed opportunities within the programme, the PMTCT cascade may be examined by analysing the following aspects: the proportion of pregnant women attending the antenatal clinics, HIV testing and receiving test results, receiving antiretroviral medication during pregnancy and delivery, receiving antiretroviral medication during breastfeeding, infant feeding counselling and support, early diagnosis of HIV-exposed newborns, linking HIV-positive newborns to care, and survival for children living with HIV (Fig. 1) [11]. Two major problems that have been identified are; the high rate of loss to follow up (LTFU) of patients and the poor adherence to ART [11]. A study conducted in Malawi on retention in care (RIC) of patients on Option B+ found that LTFU postpartum ranged between 0 and 58% depending of the health facility [12]. Retention rates for women in the first year of Option B+ have been found to be lower in pregnant women initiating ART compared to non-pregnant adults [13]. Another study conducted in South Africa on missed opportunities along the PMTCT service cascade found that 35% of the women were LTFU [14]. Women who started ART on the same day as the HIV diagnosis had the highest rate of LTFU. In addition, adherence during pregnancy has been found to be better than after delivery, leaving the baby at risk of HIV transmission during breastfeeding [15,16]. Poor adherence post-delivery was found in a study conducted in 24 South African townships among Mothers living with HIV, which found that at 36 months post-delivery only 53% of women were on ART [17].

**Fig. 1. Prevention of Mother-to-child transmission cascade**



Adapted from: UNAIDS, United Nations Children's Fund (UNICEF), World Health Organisation (WHO). Global Report: UNAIDS report on the global AIDS epidemic 2013. Geneva; 2013. Available: [http://www.unaids.org/sites/default/files/media\\_asset/UNAIDS\\_Global\\_Report\\_2013\\_en\\_1.pdf](http://www.unaids.org/sites/default/files/media_asset/UNAIDS_Global_Report_2013_en_1.pdf). Accessed 2014 Aug.

Factors that have been identified as linked to poor adherence and LFTU are; poor knowledge about ART and PMTCT, side effects of drugs, stigma resulting in fear of disclosing, weak social support, cultural traditions, poor relationships between patient and staff, shortage of staff and not being able to access services at the health facility [18]. Counselling is an intervention that has been used to address LTFU and poor adherence in the general population [19]. Counselling can also be used to address some of the problems at the different levels of the PMTCT cascade [20–22].

## 2. Objectives of the Literature Review

- A. To describe the PMTCT cascade and highlight the issues that affect the adherence and retention in care (RIC) of patients.
- B. To describe how counselling can aid in adherence to treatment and the RIC of patients at the different levels of the PMTCT cascade.

### **3. Literature search strategy**

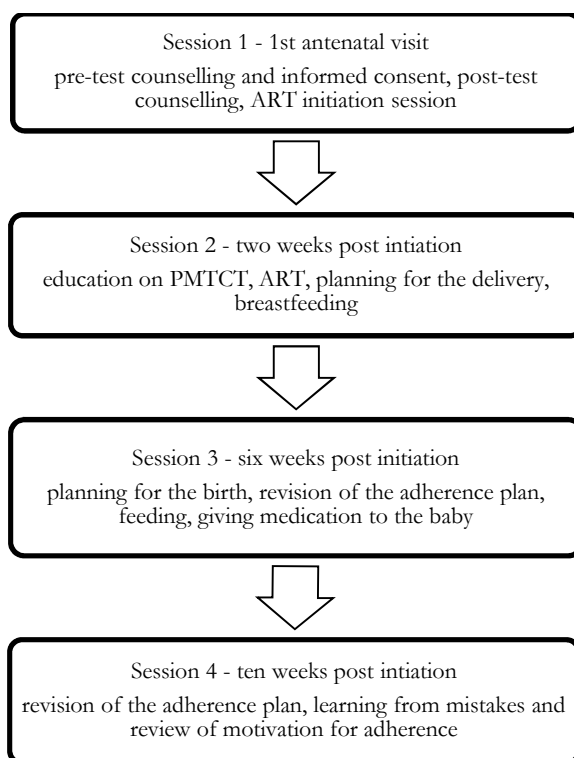
This literature review involved a search for studies from peer-reviewed articles. An electronic search of databases such as PubMed, Medline, CINAHL, EBSCO (Academic Search Premier) and Google Scholar was performed in order to find relevant studies on PMTCT. The period for the search was for literature published from 2005 to 2015 to enable the most current literature available to be obtained. Only one article from 2003 was included as it was found to be relevant to the topic. Only articles published in English were selected. Qualitative and quantitative studies were included. The key words and terms used were: “pregnancy and HIV (testing or screening)”, “HIV counselling AND pregnancy”, “timing of Antiretroviral Therapy initiation in pregnancy”, “patient (education or counselling) AND HIV treatment readiness”, “ART initiation in pregnancy”, “task shifting AND pregnancy”, “task shifting AND lay health workers”, “adherence HIV treatment in pregnancy”, “adherence counselling in pregnancy”, “HIV diagnosis and grief”. Further articles and one book were found by looking through the bibliographies of selected articles. Apart from databases, searches were made on websites of international organisations such as World Health Organisation (WHO) and Joint United Nations Programme on HIV/AIDS (UNAIDS). Lastly, national and provincial websites were searched to obtain reports, policies and guidelines relevant to the topic.

### **4. The counselling model**

In this study, we examine a counselling model for pregnant women enrolled on Option B+, which was piloted by Médecins Sans Frontières (MSF). It is an adapted ART preparation approach for ART initiation in pregnancy and follows the PMTCT guidelines set out for counselling by the WHO and the South African National Department of Health [23,24]. The counselling model is patient-centred and offers individualised practical support by focusing on assisting patients to find solutions to specific barriers to adherence faced by HIV-positive women during pregnancy and during the postnatal period [25]. Patient-centred refers to treating patients as individuals who need to be respected, heard, informed and their wishes honoured through the entire counselling process [26]. In

contrast, a study conducted in Cape Town, South Africa evaluated the counselling performed by lay counsellors to patients on ART for adherence support and found that the counselling sessions were not patient-centred and mainly involved the counsellor giving information and strategies to try address reasons for non-adherence [27]. The counselling and education activities enable pregnant women to be initiated on ART on the same day as receiving a positive HIV diagnosis. Ongoing support after ART initiation and during postnatal period is a vital component for the counselling model which also allows for experiential learning for patients while on ART [25]. The goal is to examine each patient's unique situation. The counselling model consists of four antenatal sessions (Fig. 2) [25]. Women attend the maternal obstetric unit (MOU) until approximately eight weeks post-delivery, when they receive the HIV test results of the baby. An important part of the counselling includes defining life goals, the motivation for treatment and developing strategies for adherence [25].

**Fig. 2. Sequence and timing of counselling sessions in the Option B+ counselling model**



Adapted from: Médecins Sans Frontières. Patient Education & Counseling Guide: Preventing Mother To Child Transmission Option B+. 2013. Available: <http://samumfsf.org/download/pec-guide-pmtct-b-en-final-may-2013-pdf/>. Accessed 2014 Oct.

## 5. The PMTCT Cascade

### 5.1 HIV Testing

When the PMTCT programme was first introduced in South Africa, client-initiated testing and counselling (CITC) (also known as ‘opt in’ counselling) was the main way in which HIV testing was performed. In 2004, due to the low rates of testing and poor knowledge about HIV, the WHO and UNAIDS recommended including provider-initiated testing (PITC) (also known as ‘opt out’ counselling) as another way to offer HIV testing. Provider-initiated testing and counselling (PITC) is defined as HIV testing and counselling that is offered by health care workers to all individuals attending health care facilities as part of routine care [23]. This change did not result in a dramatic increase in testing therefore, in 2007 new recommendations stated that provider-initiated testing and

counselling was to be the main intervention in which HIV testing is offered, with the view that this would increase the number of people testing for HIV [23].

Provider-initiated testing and counselling (PITC) has led to an increase in the number of people tested for HIV [1]. A study conducted in Uganda looked at the increase in rates of HIV testing in women attending the antenatal clinic at a regional hospital, after a change in policy from CITC to routine PITC between the period of 2002 to 2009 [28]. The results showed an increase in the number of people testing from 22% during the period of CITC to 88% following the change to PITC [28]. Similar results were found in a Zambian study, which looked at the rate of increase in HIV testing following the introduction of PITC to supplement the existing CITC [22]. The findings showed that there was a mean increase in the monthly HIV testing of 97% with PITC compared to CITC alone [22]. The increase in the number of people tested for HIV after PITC has been introduced, has led to its implementation in a majority of low and middle-income countries [1].

As PITC has been implemented in many countries and HIV testing has become part of routine care, HIV testing and counselling has become generally acceptable to pregnant women [4,28]. Knowing one's status provides women with an opportunity to protect their baby from acquiring HIV by using ART [29]. As PITC has become the routine standard of care in antenatal clinics, concerns have arisen regarding coercion of patients into having an HIV test [30]. A mixed methods study conducted in Kenya, Tanzania and Zambia that looked at the perceptions and experiences of PITC in adults, found that some pregnant women thought that testing was a requirement and that they had no choice [31]. These findings were supported by similar results from a qualitative study conducted in Uganda about patient experiences with PITC, which found that some women thought that testing for HIV was a requirement and that the test was mandatory [30]. Women suggested that they believed they had been strong-armed into taking the HIV test and this has highlighted the need to protect informed consent [30]. Obtaining informed consent during the individual pre-test counselling is part of the first session in the counselling model.

Another challenge to the implementation of PITC is the poor quality of pre- and post-test counselling [31]. A qualitative study in Uganda showed that pregnant women who had undergone counselling and testing found the post-test counselling to be lacking [4]. Participants in the study expressed appreciation for the education and the support that they received during the post-test counselling. Insufficient pre and post-test counselling can result in missed opportunities to further educate and support HIV-positive women and missed opportunities to educate HIV-negative women on preventative measures [4,31,32].

The information that counselling provides can address the missed opportunities that have been highlighted by the studies above: opportunities to further educate and support HIV-positive women and to educate HIV-negative women on preventative measures. This results in more pregnant women and their partners knowing their status, and an increased awareness of PMTCT. Counselling can aid in disclosure to close relatives, which has been linked to improved adherence [33–35]. Education about HIV and PMTCT, assistance with accepting a positive HIV diagnosis and disclosure are all vital to patient adherence [33–35].

## **5.2 HIV diagnosis in pregnancy: psychosocial challenges**

A positive HIV diagnosis in pregnancy can be associated with psychological and social stress [36]. Feelings such as shock, guilt, anxiety, fear and denial can be associated with a positive HIV diagnosis [37,38]. A study conducted in South Africa, that explored the experiences of HIV-positive pregnant women found that feelings of guilt and anxiety, felt by the women were often due to the possibility of transmitting HIV to their unborn baby [37].

Non-disclosure, stigma and partner relationships have been found to be important obstacles to women accessing PMTCT [39]. Fear of rejection, abandonment or harm can result in failure to disclose to relatives and friends [36,40]. Stigma related to HIV has been shown to negatively impact all levels of the PMTCT cascade [38]. Stigma can be experienced from the health care worker, the community, the



family and the individual themselves. It can result in feelings of guilt and fear and has been shown to negatively affect access to health care, adherence to treatment, the health of those with HIV and can become an obstacle to HIV prevention behaviour and HIV testing [38].

HIV related stigma may result in the fear to disclose. Disclosure is important in order to get social support. Social support plays a key role in decreasing the risk of HIV transmission to the partner, and the baby, and in adherence to treatment and in decreasing stress [41]. A study conducted in Ethiopia and Uganda, looked at the adherence of HIV patients to treatment and found that, support from health care workers was important in creating an environment where patients did not feel stigmatized [40]. As a result, the patients were more likely to adhere to treatment and follow-up [40]. Support from family was also highlighted as important and this could be in the form of emotional support or financial support. Lastly, support from peer groups consisting of HIV-positive women were found to be helpful, as women could discuss similar issues and support each other [40].

Emotional support for the patient is one of the components of all the sessions in the counselling model. A supportive relationship established between the patient and the counsellor can assist in alleviating the fear of stigma [40,41]. Counselling can help alleviate the anxiety and fear that women feel about the possibility of transmitting HIV to the baby and can also aid in accepting the diagnosis and disclosure [42]. Stigma is related to the negative ideas that people have about certain behaviour risks for acquiring HIV, therefore information obtained through counselling can also help alleviate stigma [36,39]. Accepting the diagnosis, stigma and disclosure all influence adherence to treatment and follow-up.

## **5.3 Antiretroviral therapy initiation**

### **5.3.1 The triple burden**

The purpose of the PMTCT programme is to minimise missed opportunities for coverage by initiating all HIV-positive women on ART, following a positive HIV test. There has been a debate about the

right time to start an individual on ART, with the latest evidence from the START (Strategic Timing of Antiretroviral Treatment) study demonstrating that earlier ART initiation provides substantial health benefits irrespective of the individual's immune status [43]. Currently, the South African 2014 PMTCT guidelines recommend starting all HIV-positive pregnant women on lifelong ART, on the same day that they test positive [8]. However, for the HIV-positive pregnant woman the challenge of dealing with being pregnant, the positive HIV diagnosis, and starting life-long ART, all at once (the triple burden) may result in a desire to delay treatment [37]. The concern is whether these women can commit to starting life-long ART while still having to accept their new HIV status and how it will impact them and their unborn baby [37,44].

The HIV-positive mother experiences a range of emotions: denial, anger, bargaining, depression and acceptance [44]. Not all women reach the stage of acceptance and ultimately, the women have to think about the well-being of the baby [44]. These emotions occur in a culture where more value is placed on the well being of the baby than the mother [45]. Therefore, while the Option B+ guidelines recommending same day initiation of lifelong ART for all HIV-positive pregnant women, aims to prioritise the health of the mother as it is inextricably linked to the well being of her child [5], the triple burden of being HIV-positive in pregnancy and same day initiation of lifelong ART highlights the issue of when the right time to start ART is, for the mother. In addition it highlights the need for ongoing counselling post initiation.

### **5.3.2 When to start ART**

The right time to start ART is defined as the time when the patient is “ready” to take ART and to stay adherent to treatment [46]. The preparation for readiness for ART usually involves patient education and counselling and this usually occurs over three to four sessions spread over weeks to several months. Studies have not shown any tools or guidelines that are useful to assist clinicians in deciding whether a patient is “ready” to start ART [46]. A cohort study conducted in South Africa looked at whether delaying ART until completion of counselling was related to improved outcomes in HIV-

positive pregnant women [47]. The findings showed that 22% of the pregnant women did not start ART before giving birth, one of the reasons being failure to complete the counselling sessions. This highlights a gap in the PMTCT cascade where pregnant women who enter the PMTCT programme fail to start ART to prevent MTCT of HIV. The study also found that in women who started ART, there was no association between improved patient outcomes and delaying starting ART for patient preparation [47].

In an attempt to address the delays in starting ART, a pilot programme was developed in Cape Town, South Africa that involved the rapid initiation of pregnant women [48]. All pregnant women who were eligible for ART were started on ART on the same day as the HIV diagnosis. Ninety-one per cent of those eligible to start ART accepted to start on the same day [48]. A qualitative study conducted on patients in the pilot programme found that the main incentive for starting treatment on the same day as HIV diagnosis was to protect the unborn baby [49]. Some women started for their own health. The women saw the counselling and support as vital in helping them accept their HIV status and starting treatment [47,49]. An issue that some women struggled with was accepting that they would be on lifelong ART. The rapid initiation in the face of the 'triple burden' stresses the importance of ongoing counselling and support post initiation [49].

Option B+ guidelines recommend the initiation of ART regardless of immunological status. Yet starting ART when the CD4 count is high and the patient is well can be difficult for patients advised to start lifelong ART. This has been shown in other settings in the subcontinent. A qualitative study was conducted in Kenya that explored the attitudes of HIV serodiscordant couples towards starting ART early [50]. Most of the participants were interested in starting ART early and their motivation was to stay healthy and to prevent HIV transmission to the partner. They felt that staying healthy prevented their status from being revealed to the community [50]. Some of the concerns expressed by the participants included; adherence to lifelong ART, the side effects of the treatment and stigma [50,51].

## **5.4 Pregnancy care and Delivery**

Following treatment initiation, adherence to antenatal care is particularly important to ensure that both mother and baby are healthy and that the mother is adhering to treatment. This is achieved through clinical follow-up with nurses and continued counselling with lay counsellors. The quality of the antenatal care can be influenced by factors such as a shortage of staff and overcrowded clinics resulting in less time for clinicians to see patients and long waiting times, all of which can impact on patient adherence [9]. The delivery of the baby is important because of the increased risk of HIV transmission during the process of delivery. Preparation for this period is vital especially for women who have not given birth before or have no experience of PMTCT.

## **5.5 Adherence and Retention in care**

Poor adherence to treatment and poor retention in care (RIC) within the PMTCT programme has been widely documented in the literature since the programme's inception [12,34]. In addition, it has also been documented after the implementation of Option B+ [12]. A study conducted in Kenya that examined the rate of disengagement from prenatal ART between the period of 2006 to 2009 found that of the women who had initiated treatment, 67% had received uninterrupted treatment and were still retained in care [52]. Another study conducted in South Africa also examined the disengagement of HIV-positive pregnant and postpartum women from antiretroviral treatment services [16]. The findings showed that at 6 months postpartum, 24% of women had missed one or more clinic visits and 32% had defaulted from treatment. Poor adherence and disengagement from treatment in the prenatal or postnatal period increases the risk of HIV transmission to the baby. Women who initiate ART in pregnancy are vulnerable to developing poor adherence in the postnatal period [16]. This highlights the importance of addressing some of the barriers to good adherence and RIC.

Some of the barriers to good adherence and RIC are lack of knowledge about the benefits of ART, drug side effects, treatment fatigue, institutional stigma, discrimination, poor support outside immediate relatives, lack of disclosure, poor relationships with health care providers, lack of male

involvement, domestic violence and limited access to transport [33–35,53]. Counselling can be used to address some of the barriers to good adherence and RIC.

Adherence to ART during the postnatal period is poor [54]. Mothers who know the benefits of postnatal PMTCT and have access to PMTCT services are more likely to adhere to treatment and remain in care [54]. Adherence to exclusive breastfeeding (EBF) is important as it lowers the risk of MTCT of HIV and mortality compared to mixed feeding in the first 6 months of life [55]. The global estimate for EBF is low, this previously being reported as 34% in 2006, while the rate of EBF in Sub-Saharan Africa was 30% [56]. A Ugandan study examined the factors that influenced adherence to EBF among HIV-positive women [21]. Some factors that influenced adherence were, knowledge that EBF decreased the risk of HIV transmission, attending counselling sessions before and after delivery, commencement of breastfeeding within one hour of giving birth, being able to consult health care workers about problems with EBF, mothers believing that they have enough milk and support from fathers and family [21].

Another study conducted in Kenya examined the rate of adherence to EBF by participants who had been exposed to a counselling intervention to support EBF [57]. The results showed that the rate of EBF was 84% at 5.25 months. Counselling on EBF initiated in the antenatal period and continued during the postnatal period can increase adherence to EBF [57].

## **5.6 Service delivery approaches to HIV counselling in pregnancy and post-delivery**

The scale up of antiretroviral treatment (ART) programmes in Sub-Saharan Africa has required the implementation of task shifting, in order to address the shortages in the health work force [58]. The goal of task shifting is to increase access to ART by increasing the efficiency of the existing health workforce and in addition improve the quality of care provided [58]. Task shifting involves the

reallocation of tasks from highly qualified health care worker to a lower-level cadre of staff with shorter training and less qualifications [58].

Literature has shown that staff shortages, delays due to counselling are some of the causes of missed opportunities to initiate HIV-positive pregnant women eligible for ART, on treatment [18,47]. To address these challenges, lay counsellors have been employed to increase the rate of HIV testing and counselling in antenatal clinics (ANC) and Nurse initiation and management of ART (NIMART) has been implemented in ANC in South Africa in order to increase the ART coverage [59]. Lastly, mentor mothers have been integrated as part of PMTCT care in an effort to close some of the gaps in the PMTCT cascade such as poor adherence to treatment, missing early PCR testing and failure to link HIV infected babies to care early [60].

‘Task shifting’ from doctor to nurse, from nurse to lay counsellors, nurses to mentor mothers, lay workers becoming pharmacy assistants and lay workers becoming adherence supporters, have been implemented in various countries in Sub-Saharan Africa [61]. Task shifting from doctor to nurse has been implemented in the form of NIMART, in order to increase the coverage of ART. A study conducted in South Africa on a large scale implementation of NIMART found that NIMART was feasible and acceptable to patients and health care workers within the different cadres [62]. Nurses reported an increase in their workload due to ART patients requiring more time during consultation, while doctors reported a decrease in their workload, giving them more time to see complicated patients. A concern has been whether nurses provide a similar quality of care to doctors. The outcomes of a nurse managed ART service such as virological failure, loss to follow up and death, have been found to be similar to those of a doctor run service [63]. A study conducted in Khayelitsha, South Africa examined the clinical mentorship of nurse-initiated ART and reported similar findings regarding the workload for nurses and doctors [64]. In addition mentoring was found to be important in increasing the confidence of nurses in their clinical skills and improving the quality of care received by patients [64].

Task shifting from clinical staff to lay counsellors has also been implemented in order to ease the work pressure on clinical staff, therefore giving clinical staff more time to spend with the patients. Lay counsellors have been employed to supplement the work of clinical staff in offering HIV counselling and testing [65]. A Zambian study examined the effectiveness of lay counsellors in providing HIV testing and counselling and in addressing the shortage of staff [65]. The findings showed that lay counsellors decreased the workload of clinical staff, increased the number of people screened for HIV, provided a quality service and had fewer errors in data entry [65]. The experience that a woman has of her pregnancy can be influenced by the service that she receives during her antenatal care. This can in turn influence adherence to treatment and RIC [66]. Compared to the midwives, lay counsellors have more time to spend with women, enabling the process of giving information about antenatal care, which they may not have received from the midwife due to time constraints. Counselling can help enhance a woman's experience of pregnancy.

Lay-Counsellors can also assist in improving adherence and RIC of women and infants during the postnatal period. A randomised control trial was conducted in Kenya, which involved the implementation of a Lay-Counsellors led intervention in order to improve retention of mother-infant pairs [67]. The intervention involved the administration of individualized health education, home visits, phone and short message service appointment reminders, physical tracing immediately after missed clinic visits, and individualized retention and adherence support all conducted by Lay-counsellors compared to routine postnatal HIV care. The findings showed that the intervention improved retention in care of mother-infant pairs [67].

In pregnancy, counselling programmes use mentor mothers in another form of task shifting, in order to provide peer support. Mentor mothers are HIV-positive women who have been through the PMTCT programme and are employed then trained to augment and support existing PMTCT interventions [60]. They provide comprehensive peer education and psychosocial support to pregnant women and new mothers who are in the PMTCT programme. The involvement of mentor mothers in antenatal and postnatal care has been shown to increase the retention in care of women [68]. The aim of the

mentor mothers programme is to increase the number of women accessing the PMTCT programme, to eliminate HIV related stigma and to empower women [60].

In resource limited settings, providing an effective counselling service can have several challenges. Poorly resourced settings usually struggle with overflowing clinics and lack of human resources to attend to patients. Task shifting the role of counselling from clinical staff to lay counsellors decreases the workload of the clinical staff but usually increases the workload of the counsellors [65,69,70]. The increased workload in combination with overflowing clinics and shortage of staff due to absenteeism can limit the time that a counsellor has with the patient. Lack of human resources and staff shortages can result in counsellors being asked to perform work in other areas of the clinic, further limiting the time available to give counselling to patients [71].

Insufficient resources such as lack of HIV testing kits, gloves and office space to offer private counselling can limit the ability of the counsellors to perform their duties [69]. Supportive supervision and ongoing training has been found to be necessary for successful task shifting [61]. This can be difficult to achieve in an environment of heavy work loads and staff absenteeism [69]. Counselling can be emotionally and psychologically challenging for counsellors. A study conducted in Botswana, evaluated a task shifting initiative involving lay counsellors [69]. The counsellors reported feeling stressed and burnt-out as a result of the work that they do. This was a result of not having services in place to provide regular support such as debriefing sessions for the counsellors.

## **5.7 Family Planning post-delivery**

Family planning (FP) is an important part of PMTCT because it reduces unplanned pregnancies and MTCT. Women with planned pregnancies are more likely to present for antenatal care earlier and to adhere to ART (UNAIDS 2014). There is still an unmet need for family planning in some countries that have high prevalence rates of HIV and this unmet need for family planning has been found to be as high as 25% (UNAIDS 2014). A study conducted in Kenya on attitudes of HIV-positive women



towards FP found that 59% of the women had unplanned pregnancies [72]. In addition, the findings showed that the uptake of FP was influenced by whether the partner supported the use of FP or not. Lack of counselling on FP has been found to limit access to FP [73,74]. The integration of FP services to HIV services can help improve the access of women to FP [75].

The available literature shows the possible benefits of counselling in addressing adherence and most importantly retention in care for mothers and their unborn babies. What is unknown, however, is evidence for optimal counselling models or interventions for HIV-positive pregnant women on Option B and B+, which target adherence in particular. It is therefore imperative to examine the counselling model intervention in order to inform its implementation with the aim of improving health outcomes.

## **6. Conclusion**

This literature review gives a wide view of the issues that relate to the PMTCT programme and reflect the literature currently available. The Global priority to eliminate new HIV infections in children highlights the need to look at interventions to address barriers to the effectiveness of the PMTCT programme. The literature available from developing countries on counselling as one such intervention has shown the benefit of counselling for HIV-positive pregnant and postnatal women in the pre and post-testing period, post ART initiation and during the postnatal period. Existing literature on counselling interventions is mostly for HIV-positive adults in the general population and there is limited literature on counselling interventions in HIV-positive pregnant women. With the adoption of Option B+ by a majority of developing countries and the existing literature on poor adherence and poor retention in care with Option B+, it is important to examine the new counselling model for patients on Option B+ in order to see how it can aid in improving poor adherence and poor retention in care and hence improve the effectiveness of the PMTCT programme.

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## **Section C: Manuscript**

**Note:** In line with MPH dissertation guidelines, co-authors are not listed in the journal ready manuscript but are listed in the acknowledgements. This article was prepared according to the instructions for authors of the PLoS One journal (Appendix 5). The exception is that the tables and figures have been put in the text as per MPH dissertation guidelines. According to the PLoS One guidelines, all the tables and each figure are supposed to be uploaded as individual files and not embedded in the manuscript file.

**A Mixed Methods Study to explore the outcomes, experiences and perceptions of women who attended a New Counselling model for HIV-positive pregnant women accessing antenatal services in Khayelitsha, Cape Town, South Africa**

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# **Abstract**

## **Objectives**

The aim of this study was to explore the experiences and perceptions of counsellors and patients towards a new counselling model for HIV-positive pregnant women on Option B+ at an antenatal clinic in South Africa and to describe the cohort of HIV-positive pregnant women who experienced the new counselling model.

## **Methods**

A mixed methods study design was employed. The quantitative data collection involved using retrospective cohort quantitative data of women that were initiated on Option B+ during the period of 1 October 2013 to 30 June 2014. The variables of interest included: age, gravidity, antiretroviral therapy initiation date, viral load result and number of counselling sessions completed. These were obtained from patient folders and from the Department of Health patient electronic health record. The data was analysed using STATA 12. The qualitative data involved semi-structured interviews of patients and counsellors who had experienced the counselling model.

## **Results**

The number of women who completed a total of 1, 2, 3 or 4 counselling sessions was 25%, 26%, 48% and 1% respectively. The percentage of women that were retained in care for more than 8 weeks postnatal was 53%. Of the women with VL results, 92% were virally suppressed. The Fisher's exact test showed a P-value of 0.05 at a level of significance of  $P \leq 0.05$ . Therefore there is sufficient evidence to show that there is a positive association between the number of counselling sessions completed and number of postnatal days in care. The study also found that from the counselling, the women gained social support, knowledge about: antiretroviral therapy, HIV, drug side effects and infant feeding.

## **Conclusion**

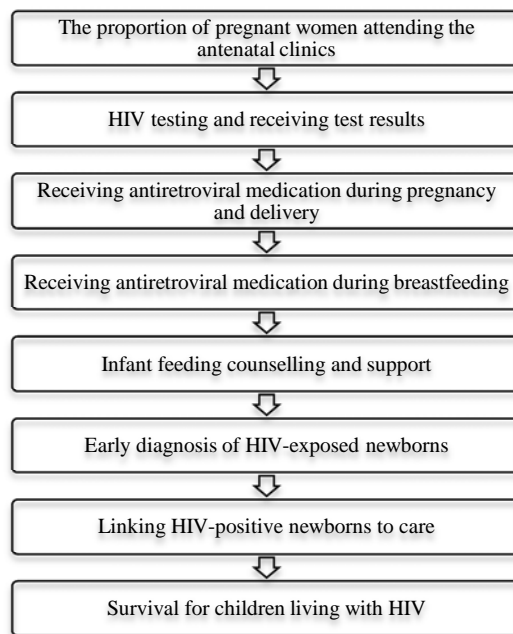
The reasons for the poor uptake of the counselling intervention include, poor communication, service delivery challenges and social factors. The main motivation for initiating ART and maintaining adherence to treatment was to protect the baby and as a result, some women maintained adherence despite not completing the counselling. Women valued the education that they received during the counselling sessions and this influenced their adherence. Psychosocial support from the counsellors and peers was found to be vital to the women and this highlighted the need to incorporate a support group for the pregnant women, as part of the intervention. The findings also suggest that when offering counselling interventions to pregnant women, a balance between psychosocial support, practical support and patient education needs to be struck. Finally, education of the community on the importance of counselling is important in order to improve the uptake of the counselling because interventions aimed at mothers do not always take into account the influence of the social environment on the uptake of the intervention.

Key words: adherence, counselling, HIV, Prevention of mother-to-child transmission (PMTCT), retention, South Africa

## **Introduction**

The elimination of new HIV infections in children continues to be a global priority [1]. Worldwide, there has been a quick move to adopt the Option B+ 2013 guidelines recommended by the WHO, with more countries choosing to implement Option B+ especially in Sub-Saharan Africa [1]. South Africa adopted Option B+ in January 2015, all with the aim of further decreasing the rate MTCT to 0% [2]. Despite the progress in the implementation and scale up of Option B+ worldwide, PMTCT programme challenges still remain [3–5]. Two major problems that have been identified are; the high rate of loss to follow up (LTFU) of patients and the poor adherence to ART [6–9]. This highlights the importance of addressing some of the barriers to good adherence and retention in care (RIC). Some of the barriers to good adherence and RIC are: lack of knowledge about the benefits of ART, drug side effects, treatment fatigue, institutional stigma, discrimination, poor support outside immediate relatives, lack of disclosure, poor relationships with health care providers and lack of male involvement [10–13]. Counselling is an intervention that has been used to address LTFU and poor adherence in the general population [14]. Counselling can be used to address some of the barriers to good adherence and good RIC, at the different levels of the PMTCT cascade (Fig. 1) [15–17].

**Fig. 1. Prevention of Mother-to-child transmission cascade**



Adapted from: UNAIDS, United Nations Children's Fund (UNICEF), World Health Organisation (WHO). Global Report: UNAIDS report on the global AIDS epidemic 2013. Geneva; 2013. Available: [http://www.unaids.org/sites/default/files/media\\_asset/UNAIDS\\_Global\\_Report\\_2013\\_en\\_1.pdf](http://www.unaids.org/sites/default/files/media_asset/UNAIDS_Global_Report_2013_en_1.pdf). Accessed 2014 Aug.

Adherence of mothers to HIV medication and PMTCT has been found to be dependent on their knowledge and understanding about HIV and PMTCT [18]. A qualitative study in Uganda interviewed pregnant women who had undergone counselling and testing as part of HIV screening [19]. Participants in the study expressed appreciation for the education and the support that they had received during the post-test counselling. Insufficient pre and post-test counselling can result in missed opportunities to further educate and support HIV-positive women and missed opportunities to educate HIV-negative women on preventative measures [19,20].

Counselling and support has been identified by HIV-positive pregnant women as vital in helping them accept their HIV status and starting treatment [21,22]. Receiving both antenatal and postnatal counselling has also been shown to positively influence adherence and RIC [16]. While current South African PMTCT guidelines recommend starting all HIV-positive pregnant women on lifelong ART on the same day that they test positive (Option B+), the challenge of dealing with being pregnant, the

positive HIV diagnosis, and starting life-long ART, all at once (the triple burden) may result in a desire to delay treatment [23] [2]. A study conducted in Malawi examined the levels and determinants of LTFU under Option B+ and found that LTFU was greatest in pregnant women on Option B+ who were initiated on ART on the day of the HIV diagnosis [24]. The concern is whether these women can commit to starting life-long ART while still having to accept their new HIV status and how it will impact them and their unborn baby [23,25].

The literature available from developing countries on counselling as an intervention has shown the benefit of counselling for HIV-positive pregnant and postnatal women in the pre- and post-testing period, post ART initiation and during the postnatal period. What is unknown, however, is evidence for optimal counselling models or interventions for HIV-positive pregnant women on Option B and B+, which target adherence in particular. In October 2013, Médecins Sans Frontières (MSF) piloted a counselling model that was designed for women initiating ART as part of Option B+. The goal of the counselling model was to improve adherence and RIC of pregnant women newly diagnosed and initiated on ART. The aim of this study was to explore the experiences and perceptions of counsellors and patients towards a new counselling model for HIV-positive pregnant women on Option B+ at a clinic in Cape Town, South Africa and to describe the cohort of HIV-positive pregnant women who experienced the new counselling model.

## **Methods**

### **Study setting**

The study was conducted at Site B Maternity Obstetric Unit (MOU), in Khayelitsha, Cape Town. The MOU implemented nurse-initiated antiretroviral therapy (ART) in May 2013 in order for HIV-positive pregnant women to be initiated on ART at the MOU. Khayelitsha is 56km from the centre of Cape Town. The population in 2011 was 391 749, with 45% of households residing in formal housing [26]. The level of employment was 62% among those aged 15 to 64 years. Individuals aged 20 years and older who have completed Grade 12 or higher make up 36% of the population [26]. In 2011,



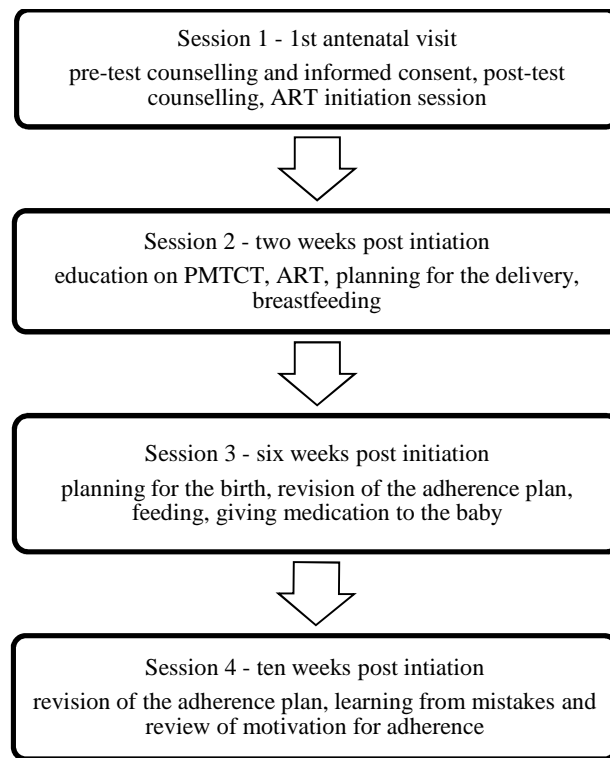
Khayelitsha had a higher antenatal seroprevalence of HIV as compared to the national average rate, 38% and 29% respectively [27]. In October 2013, MSF implemented a new counselling model for HIV-positive pregnant women on Option B+, in Khayelitsha, which is still ongoing.

## **The Option B+ counselling model**

The counselling model is made up of four antenatal and six postnatal counselling sessions, the former of which are conducted at the MOU (Fig. 2). No postnatal counselling sessions from the model are conducted on site; mothers receive counselling from nurses when they attend the scheduled visits for the baby's routine health check and vaccination. Due to the fact that only antenatal sessions are conducted at the MOU, the study will only focus on the antenatal component of the counselling model. The women are transferred out to other clinics after obtaining the baby's six-week HIV test result at about eight weeks postnatal. The antenatal counselling sessions are conducted on the date of the clinical visit at the MOU, for the convenience of the patient.

The counselling model is patient-centred and offers individualised practical support by focusing on assisting patients to find solutions to specific barriers to adherence faced by HIV-positive women during pregnancy and during the postnatal period [28]. The counselling and education activities enable pregnant patients to be initiated on ART on the same day as receiving a positive HIV diagnosis. The first antenatal session consists of a pre-test session, a post-test session and ART initiation [28] (Fig. 2). The second antenatal session consists of education on PMTCT, ART, planning for the delivery, breastfeeding and treatment of the baby. The third session involves planning for the birth, revision of the adherence plan, feeding, giving medication to the baby and motivation for adherence [28]. The fourth session involves revision of the adherence plan, learning from mistakes and review of motivation for adherence. The third and fourth sessions are sometimes grouped together depending on the needs of the patient.

**Fig. 2. Sequence and timing of counselling sessions in the Option B+ counselling model**



Adapted from: Médecins Sans Frontières. Patient Education & Counseling Guide: Preventing Mother To Child Transmission Option B+. 2013. Available: <http://samumsf.org/download/pec-guide-pmtct-b-en-final-may-2013-pdf/>. Accessed 2014 Oct.

## Study design

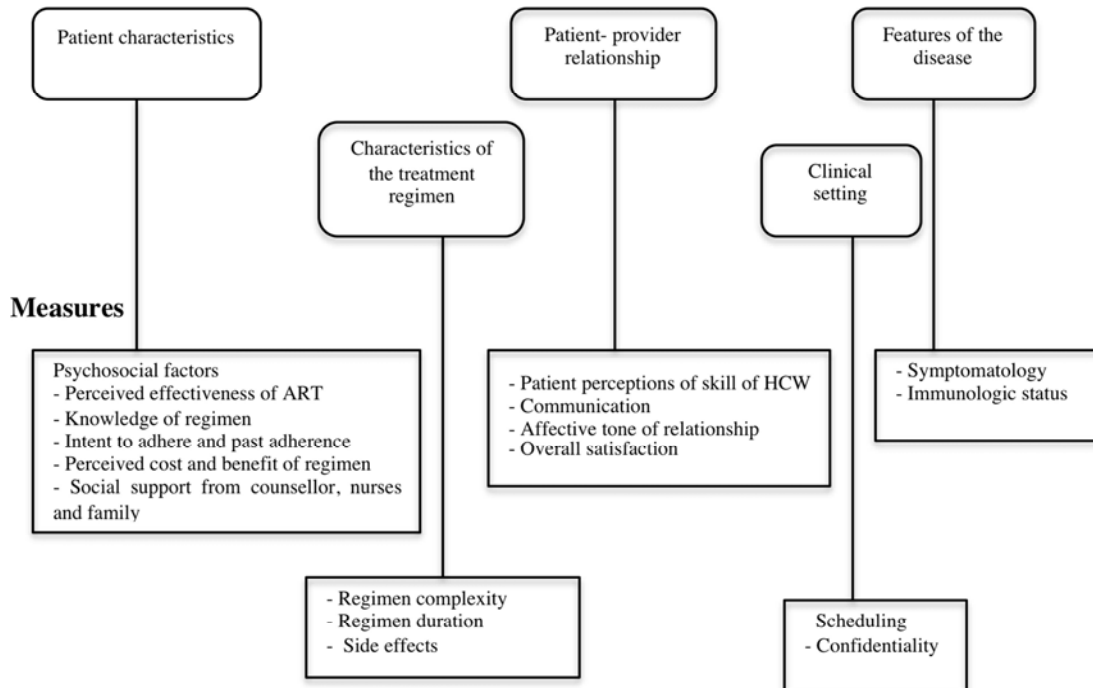
A mixed methods study design comprising of quantitative and qualitative data collection was employed. The study was conducted between March 2015 and January 2016. The quantitative data provided a description of the patients in the cohort, including information on the adherence of the patients to treatment and the number of counselling sessions attended. The qualitative data allowed for some results from the quantitative study to be clarified. The study population included HIV-positive pregnant women who were attending Site B MOU for antenatal care (ANC). The pregnant women also had to have attended one or more counselling sessions from the Option B+ counselling model. Included in the study population were the counsellors who were using the counselling model.

## **The conceptual framework**

The aim of the counselling model was to improve adherence of patients to treatment and to improve RIC [28]. The conceptual framework by Ickovics and Weisler on “factors that affect recruitment, adherence and retention in care in AIDS Clinical trials” was adapted to be used in the data collection and analysis of this study [29: p.386]. The conceptual framework was developed from previous medical research on adherence (Fig. 3) [29: p.386]. This framework lists the factors that have been found to influence adherence and RIC. Four categories of the framework (patient characteristics, patient provider relationship, treatment regime and clinical setting) out of the five categories were used to develop the questions and to analyse the data because they are still relevant in HIV treatment adherence in Sub-Saharan countries as seen in the literature review. A study conducted in Kenya and South Africa that examined the reasons for non-adherence in women taking pre-exposure HIV prophylaxis also used this framework in their qualitative data analysis [30]. Due to the fact that the counselling model aims to influence adherence and RIC, the framework appeared appropriate to use in examining whether the counselling model has some of the factors that can positively influence adherence and RIC. Themes from the conceptual framework were used to develop the questions and to analyse the data.

**Fig. 3. Conceptual Framework on factors that influence adherence and retention in care in HIV-positive patients**

**Concepts**



Adapted from: Ickowics, J. R and Meisler AW. Adherence in AIDS Clinical Trials : A Framework for Clinical Research and Clinical Care. J Clin Epidemiol. 1997;50(4): 385–91.

**Sampling**

In the quantitative study, the sample size comprised of 448 out of 578 (130 missing) treatment naïve HIV-positive pregnant women who had been initiated on ART at Site B MOU during the period of 1 October 2013 and 30 June 2014 and had also received counselling from the new counselling model for Option B+. Treatment naïve patients were selected from the Western Cape Provincial electronic health record (Ekapa).

The sampling method employed for the qualitative study was purposive sampling of HIV-positive pregnant women and counsellors at Site B MOU. The pregnant women were selected depending on the number of counselling sessions that they had completed (ranging from 1 to 4), in order to get a range of perspectives. Counsellors provided useful information based on their experience of the model

and knowledge of the context. The number of study participants was 12, consisting of 2 counsellors and 10 HIV-positive pregnant women who had experienced the counselling model. The number of participants was guided by data saturation.

## **Data collection**

The quantitative data collection was on the number of antenatal counselling sessions completed and was captured from the patient folders onto Epidata 3.1. Other quantitative data was extracted from the Department of Health routine electronic health record (Ekapa), onto an excel spreadsheet by the researcher. In order to find all the women who had experienced the counselling model within the study period, an electronic linkage was done on a provincial data set to map all women who may have attended a clinic outside of the district. Data on postnatal counselling sessions was not available from MSF or from the MOU because the model implementation only covered antenatal sessions. We were able to quantify RIC by using provincial data on clinical visits.

The qualitative study was performed using semi-structured interviews, which was guided by a conceptual framework. The interview guide for the pregnant women was piloted on three patients at the MOU. The questions on the patient interview guide were based on the different components of the framework: patient characteristics, patient-provider relationship, characteristics of treatment regimen and clinical setting (Fig. 3) (Appendix 3) [29]. Two interviews from the pilot were included in the total number (N) of people interviewed because the interviews yielded useful data. The third interview was not used because the participant's responses were monosyllabic and not informative. Changes were made to some of the questions that were closed-ended or leading. Some questions were reworded in order for participants to better understand the question. Probing questions were also added to the questionnaire in order to improve the richness of the data. The provider interview guide focused on the acceptability and feasibility of the counselling model. The fieldworker interviewed each participant individually. The counsellors, who were using the counselling model, were invited to participate in the study by the researcher. The fieldworker obtained the consent. All participants were

given an information sheet about the study and a copy of the consent form, which were both in isiXhosa (the local language). The counsellors assisted the researcher in recruiting eligible HIV-positive pregnant women for the study from their list of follow-up patients for the day. The researcher guided the counsellors on which participants to select based on the inclusion and exclusion criteria and depending on how many counselling sessions the participant had completed. The researcher confirmed the eligibility of the participants. There was a potential risk that the pregnant women may feel pressured to participate in the study by the counsellors. To minimise this risk, the fieldworker who was not employed at the MOU and therefore was less likely to pressure the participants into consenting to participate, obtained the consent. The fieldworker also explained to the participants the importance of voluntary participation and clarified that their refusal to take part in the study would not affect their clinical care at the MOU. Written consent was obtained prior to the interview and participants were reassured of anonymity. The semi-structured interviews were performed in isiXhosa (the mother tongue of the participants). The interviews lasted approximately 30 – 40 minutes and were digitally recorded. An experienced translator translated the recordings from isiXhosa to English. To improve the reliability of the results, a second translator checked the accuracy of the transcribed and the translated documents. The interviews of the pregnant women continued until data saturation had been reached. Data saturation was reached when there was no new data gathered after subsequent interviews and sufficient information was obtained to answer the research questions. Data saturation for the counsellors was not reached due to their limited availability and number. An audit trail of all the study tools was kept.

## **Data analysis**

The quantitative data were analysed using STATA version 12 (Statacorp, Texas, 2011). The variables of interest included maternal age, gravidity, date of ART start, viral load test result and number of counselling sessions attended at the MOU (the maximum being 4 sessions). The Shapiro-Wilk test confirmed that the data for age, gravidity and total sessions completed was not normally distributed, therefore the descriptive statistics for the numerical data have been reported in the form of medians

and interquartile ranges (IQR). The Fisher's exact test was used to determine the association between number of counselling sessions attended and retention in care. Since women are retained in the antenatal service for ART care for two months postpartum, retention in care was measured as a binary variable with a cut off of 60 days, with successful retention in care being denoted as  $\geq 60$  days. This threshold takes into account the need for women to transfer to another facility for ART care, hence illustrating a critical point in the PMTCT cascade where failure can occur.

The qualitative data were analysed using thematic analysis. The data analysis was guided by the conceptual framework [29]. Atlas.ti 5.1 software was used to code the data. The data analysis started with the researcher reading and re-reading the data to get familiar with the data (Robinson & Tolley 2005). This was done after each interview had been translated and transcribed. Each interview helped inform the next interview (deductive then inductive process). The researcher coded the transcripts. After the researcher coded the data an independent researcher reviewed the coding. The coding was arranged into themes and subthemes, which were based on the conceptual framework. The themes included: patient characteristics, patient-provider relationship, characteristics of treatment regimen and clinical setting.

### **Quality control measures**

The interviews were conducted in the local language to ensure that participants could fully express their views and therefore improve the richness of the data. There was continuous peer debriefing between the researcher and a senior researcher after each day of interviews to discuss issues that arose during the interviews. The debriefing sessions also served as a platform to discuss emerging ideas. After the researcher coded the data an independent researcher reviewed the coding. The preliminary list of codes was based on the themes and subthemes from the framework. External validation was obtained by giving participants a copy of their translated interviews in order to confirm that they agreed that it reflected their comments and views. The researcher had a prolonged engagement (7 months) in the field that allowed the researcher to become familiar with the context. Quantitative data

combined with interviews from the counsellors were used to validate the data gathered from the women.

Ethical approval was obtained from University of Cape Town, Faculty of Health Sciences Human Research Ethics Committee for approval (HREC) and from the Provincial Department of the Western Cape.

## **Results**

### **Quantitative results**

The cohort included 448/578 patients, with the balance (n= 130, 22%) being excluded due to complete missing paper and electronic data. These patients with missing data were randomly distributed throughout the study period. The median age was 28 years (IQR 24-32 years) (99% of 448 had data for age) and the median gravidity was 2 (IQR 2-3) (Table 1). The median number of completed counselling sessions was 2 (IQR 1-3). The number of women who completed a total of 1, 2, 3 or 4 counselling sessions was 25%, 26%, 48% and 1% respectively. Of the 448 women in the cohort, 402 (90% of the 448) had data on their retention status. The percentage of women that were retained in care for more than 8 weeks postnatal was 53%. There were 311/448 (69%) of women with VL results. Of those with VL results, 92% were virally suppressed. The Fisher's exact test was used to determine if there was an association between number of postnatal days in care and the number of counselling sessions completed because more than 20% of the expected frequencies were less than 5 (< 5). The Fisher's exact test showed a P-value of 0.05 at a level of significance of  $P \leq 0.05$ . Therefore there is sufficient evidence to show that there is a positive association between the number of counselling sessions completed and number of postnatal days in care (RIC).



**Table 1.** Descriptive characteristics of the cohort of pregnant women initiated on Option B+ at Site B MOU between 1 July 2013 – 30 June 2014

	Median/n	IQR/ %
<b>Patient characteristics (N= 448)</b>		
Age in years (n= 444)	28	24- 32
Gravidity (number of pregnancies)(n= 353)	2	2-3
<b>Number of Counselling Sessions completed by each woman (n= 448)</b>		
1 session	115	25
2 sessions	116	26
3 sessions	214	48
4 sessions	4	1
<b>Retention in care (RIC) (n=402)</b>		
Antenatal	134	33
Postnatal	268	67
Postnatal > 8 weeks	215/268	80
<b>Viral load (VL) (n=311)</b>		
VL < 40 (suppressed)	285	92
VL ≥ 40	26	8
<b>Counselling sessions completed for women retained in Postnatal care (RIC) <sup>a</sup></b>		
<b>≤ 60 days postnatal (n= 53)</b>		
1 session	14	26
2 sessions	16	30
3 sessions	22	42
4 sessions	1	2
<b>&gt; 60 days postnatal (n= 215)</b>		
1 session	39	18
2 sessions	45	21
3 sessions	130	60
4 sessions	1	0.47

<sup>a</sup>Fisher's exact P-value = 0.05 for the association between number of postnatal days in care and the number of counselling sessions completed.

## Qualitative results

The data was arranged according to themes and subthemes from four out of the five categories in the framework on adherence. The first theme was patient characteristics, which consisted of the subthemes: social support, disclosure and stigma, intent to adhere and perceived effectiveness of ART. The second theme was characteristics of treatment regimen, which included the following subthemes: knowledge of regimen and regimen complexity and side effects to treatment. The third theme was patient-provider relationship, which consisted of the following subthemes: tone of the

relationship and communication. The last theme was clinical setting, which included the subtheme privacy and confidentiality.

## **Theme - Patient characteristics**

### **Social Support**

The provision of social support in the form of encouragement, reassurance, acceptance, friendship, advice, providing information and assistance with solving problems, was unanimously recognised as an important component of the counselling model. More than half the women reported feeling afraid, stressed and alone after being diagnosed HIV-positive. Some women feared that they would die prematurely and that the baby would become infected with HIV. Several women, who had been diagnosed on the first antenatal visit, reported that they had felt better after receiving the first counselling session and subsequently, some were able to disclose (Table 2). This was because they had been told that being HIV-positive was not the end of their life and that they could still live a long life. Lastly, the women were told that there were many other people living with HIV. Participants reflected that knowing that there were other pregnant women with HIV helped them not feel as alone and afraid.

*'It was better when she (the counsellor) counselled me, because I always heard that HIV was the end of life, then when she counselled me, I felt better, and when she took me to the group that lives with HIV (support group with mentor mothers), people like me then I was ok that I am not alone, like she had said. Then again I met with people who have the virus and they are alive, like I mean they are healthy.'* (27-year-old woman)

**Table 2.** Quotes obtained from interviews and arranged into themes and subthemes

Theme	Quote
<b>Patient characteristics</b>	
Subtheme - social support	<i>'When I went to that side for my HIV test, I was diagnosed Positive. Then the counsellor encouraged me and I was not prepared to disclose, then I end up disclosing to my partner, my cousin and my friends they now know that I am HIV-positive' (26 year old woman)</i>
	<i>'Because the people I stay with they know I am sick, I live with HIV, so that they can support me and motivate me every day, so that I can go to the clinics and get my treatment' (33-year-old woman)</i>
Subtheme - Disclosure and stigma	<i>'I mean, I wanted to be on treatment but I couldn't go to the clinic in case someone saw me, maybe I will get sick until I can't walk and be bed ridden... When I started it, I realised that there is nothing wrong with it.'</i> (27-year-old woman)
Subtheme - Intent to adhere and perceived effectiveness of ART	<i>In the first one (counselling session), I didn't understand, I had to ask why I was to start on ARVs now. They said it's not like when it was the AZT, because they were protecting the baby, but it was discovered that it protects the baby fine, they deliver a HIV-negative baby, but the mother then dies. So now we protect the mother and the baby. That's why we must take ARVs' (30-year-old woman)</i>
<b>Patient-provider relationship</b>	
Subtheme - Tone of the relationship	<i>'They need to be connected, so to bond with her (the Patient)... then you must understand her and not judge, also don't ask why you didn't come fetch your pills, even when they didn't come for the sessions, when you see them come fetch their pills, you must not shout at them' (Counsellor)</i>
Subtheme - Communication and patient's perception of skill of HCW	<i>'Yes she (the counsellor) was friendly because she doesn't talk about what she studied only. She talks about what you know, she asks you questions that you must answer yourself, and then she will counsel you where she needs to counsel you. She doesn't read what she sees (not only reading the information to the woman)' (30-year-old woman)</i>
	<i>I am comfortable, because she is the one with knowledge of HIV, she is the one who is more educated, I might know but I don't know more than she know.'</i> (30-year-old woman)
<b>Clinic setting</b>	
Subtheme - Privacy and confidentiality	Interviewer: <i>'Were you comfortable to ask questions?'</i> <i>'Yes, because you sit together with her, she does not ask you questions in front of other people. If you were sitting with other people you would not be comfortable with your answers. However if it's just the two of you, in privacy you can answer just about anything, you can ask whatever you want to ask' (30-year-old woman)</i>

Some of the women reported receiving advice and encouragement from nursing staff. Others reported getting support from family members, which the women felt was important for their adherence. Several women had attended the MOU on the insistence of family members. Women expressed an appreciation for a support group in the facility, which they voluntarily joined during pregnancy. They expressed the relief they had felt at seeing other HIV-positive pregnant women and healthy looking HIV-positive women who had given birth to HIV-negative babies. The women revealed that they had liked the support groups because they were interactive and educational. Several women also revealed that the support group facilitators were willing to assist them in certain domestic issues such as problems with a partner. The women found this support helpful and therefore continued to attend the support groups. The counsellor who had been trained in the counselling model mentioned that the support group assisted them in making sure that the women complete the counselling sessions. She reported that some women seemed to have a better understanding about the importance of completing counselling after attending the support group. One of the counsellors assisted the support group facilitators in running a chat forum using mobile phones, which enabled the women to ask questions out of work hours.

### **Disclosure and Stigma**

Nearly all the women had disclosed. Several women had disclosed to their partners only, while the rest had disclosed to two or more people, most of whom were family members; mother, father, siblings and cousins. These women gave several reasons for disclosing (Table 3). However, one participant explained that despite having had several counselling sessions, she was not ready to disclose. She confirmed that despite this, she was still taking her treatment in order to protect the baby. According to the counsellor, some women were not ready to disclose after the first session but usually after the second session the women were able to come up with their own plans on how they would disclose.

*'I told him (husband) because I didn't want maybe, how can I put it, it's not that he will hear it from someone else because he will never hear from it someone else. I told him because I wanted him to trust me.'* (30-year-old woman)

**Table 3.** Reasons stated by pregnant women for disclosing their HIV status

	% no. of women
1. To get support from family in order to stay adherent to treatment	10
2. To be able to speak freely about being HIV-positive	10
3. To get support while living with HIV	30
4. To maintain trust in the relationship	50
5. To be able to use condoms in the marriage	10
6. To avoid the stress related to keeping the diagnosis a secret	20

Several women expressed fear of experiencing stigma at the clinic and in the community due to their HIV status (Table 2). The women remarked that the counsellors had not treated them differently and that the counselling helped them to speak freely about their status and about HIV to other people. Interviews with the counsellors revealed that some patients defaulted treatment because they had not disclosed to family members.

*'It is that before I used to think you couldn't sit with positive people and now since I have met her (the counsellor) I talk to other people about it unlike before I used to think I will not share it with anyone. So ever since I received counselling I feel free to talk about my status.'* (26-year-old woman)

### **Intent to adhere and perceived effectiveness of ART**

All the women stated that the reason for initiating ART and staying adherent was because they believed that the ARVs would prevent their unborn baby from becoming HIV-positive (Table 2). Several women also stated that they had started ART to maintain their own health. Other motivations for maintaining adherence were: not wanting to die prematurely, having the responsibility of being the breadwinner in the family, having other young children to bring up and fear of becoming ill. One participant acknowledged that because it was her life, she had to take responsibility for her adherence. The support that some women experienced at the clinic, from the counsellor and support groups motivated them to start treatment.

When the women were asked about how they felt about taking lifelong ART, the responses ranged from some women willingly accepting it, some women being resigned to the idea and some women being reluctant to take lifelong treatment.

*'I never thought I would take them (ARVs). It hurts me but it helps, in the end it's my health, what can I say... I never saw myself taking medication for the rest of my life.'* (30-year-old woman)

### **Knowledge of regimen and regimen complexity**

All the women understood how they were supposed to take their treatment and were aware of what to do if they missed a dose or were late in taking the medication. A participant expressed relief at the fact that the medication consisted of a single pill taken once a day instead of three pills. In contrast, another participant commented that she would have preferred medication that was taken once a week.

## **Theme - Characteristics of treatment regimen**

### **Side effects to treatment**

Most women had been informed of the possible side effects of the medication and had also been told to report to the clinic if they had any side effects. Several women reported that they had experienced some side effects after starting treatment. However, these women continued to take the medication because they wanted to protect the baby. Some women felt that the information on side effects had helped them stay adherent to ART.

## **Theme - Patient-provider relationship**

### **Tone of the relationship**

Throughout the interviews, the women were happy with their relationship with the counsellors. The women described the counsellors as friendly, easy to talk to, patient, supportive, approachable, warm, respectful and non-judgemental. This helped build trust within the relationship. The women appreciated the fact that the counsellor was never angry and always spoke politely to them. In fact,

one lady remarked that anger from staff at the clinic would deter women from attending the clinic. Some women likened the interaction with the counsellor to that of talking to a friend or a caring parent. Since women saw the same counsellor most of the time, it allowed for continuity of care and enabled the women to develop a relationship with the counsellor. Some women reported that because the counsellor was approachable and easy to talk to, they felt that they could go to the counsellor for help if they had a problem. In addition, separate counselling rooms provided privacy and confidentiality needed for women to feel safe (Table 2). The counsellors, who felt that the women needed warmth, understanding, non-judgement and respect, supported these statements (Table 2). The counsellors believed it was important to connect and bond with the women. One woman stated:

*'The first time I met the counsellor it was difficult ... it was like I was hallucinating, but the counsellor spoke to me and counselled me, that it is not the end of the world, life must go on, but it was nice. You see what I mean? I was stressed, but she made me feel at ease when she spoke to me, I felt human and all right. I was lost, when I was counselled I was comfortable'* (33-year-old woman)

### **Communication**

Women felt comfortable asking questions, and felt that their questions were answered to their satisfaction. In addition, several women reported that the counselling sessions involved a dialogue between the counsellor and the woman, whereby the woman was free to express her views and the counsellor responded to what the woman said to her. This finding was supported by the opinion of the counsellor, who felt that a positive aspect of the counselling model was that it engaged the patient and therefore put more responsibility on the woman to adhere to treatment.

*'It (the counselling model) looks like it involves the patient a lot and that means it also makes them understand their responsibility'* (Counsellor)

Counsellors articulated that they informed most of the patients about the number of counselling sessions that they needed to complete and about the next counselling session. On the contrary, most of

the women reported not getting this information. One participant remarked that because she had no written date for the counselling session she had forgotten to go back to the counsellor on her clinical visit.

## **Additional themes that emerged from the interviews**

### **Knowledge gained from counselling**

Some women expressed feeling shocked, hurt and fear after receiving a positive HIV diagnosis. When the women were asked about how they felt after having received their counselling, nearly all the women said that they had felt motivated to take their treatment. Several women reported that without the counselling, they would not have known that HIV can be treated with ARVs, that HIV-positive people can live a long healthy life on treatment, that ARVs can prevent transmission of HIV to the baby, the importance of being adherent to treatment and the importance of using condoms in pregnancy. Furthermore, most of the women acknowledged the importance of accessing their antenatal care early in the pregnancy. The reason being that it enabled women to get tested and start ART early in pregnancy therefore reducing the risk of HIV transmission. Most of the women felt that they had understood the information that had been given to them during counselling.

Surprisingly, one woman stated that even after receiving counselling and starting ARVs, she did not understand why she had to be on lifelong ART. She argued that if her CD4 count was still high, why did she need lifelong ART yet people who were not pregnant and had a high CD4 count did not have to be on ART. As a result of this lack of an explanation, she had not been satisfied with the counselling that she had received. Despite this, the lady continued her treatment in order to protect the baby.

*'I didn't see why I had to take treatment. She didn't explain to me why I had to take ARVs. She didn't explain to me why I had to start with the treatment, because my sister has had the virus for a long*



*time but she is not treating, but I just find out (diagnosed HIV-positive) and she (the counsellor) just said I must start.'* (23-year-old woman)

## **Reasons for not completing the counselling sessions**

The counsellors believed that a reason for some women not completing the counselling sessions was because some women thought that the education that they received during the mentor mothers support group was also counselling and therefore they felt that there was no need to go back to the counsellor. The counsellors also believed that some patients thought that going to the counsellor for follow-up counselling would disclose their HIV status to other patients and therefore they did not return for further counselling. Some reasons given by the women for not completing the counselling sessions included, forgetting to go to the counsellor on the day of the clinical visit, having waited at the clinic for a long time and therefore the woman could not wait to see the counsellor, not being told to return to the counsellor for another session, not being given a written follow up appointment by the counsellor and believing the education received at the mentor mothers support group was counselling. One of the participants commented that after the first counselling session, she felt confident about how to take her treatment and knew the importance of being adherent and therefore felt that she had no further need for counselling. The counsellor expressed the difficulty of counselling women who initially commit to taking the treatment but later default both counselling and treatment.

## **Feasibility and acceptability of the model**

The counsellors were of the opinion that early initiation of pregnant women on lifelong ART on the same day as an HIV diagnosis was beneficial to both the mother and baby. Therefore, they were happy to provide counselling and support to the women. The counselling was provided on the day of the clinical visit, which made it more convenient for the women. According to the counsellors, the tools used in the counselling such as the guide, the flip chart and the adherence plan made it easier for them to give all the information during the sessions because they followed the tools. In addition, the

flip chart also aided the patient who could use it to follow the session as the counsellor talked. The counsellors also stated that the adherence plan was very helpful in engaging the patient during the session, because it provided a list of questions for the patient on motivation for adherence and how they would address challenges to taking their treatment. As a result, it put more responsibility on the patient to adhere to treatment.

The counsellors highlighted some of the challenges of using the model. They explained that due to the amount of content needing to be covered in the first and second sessions, there were times when they did not complete the sessions. This would usually happen if a woman had just been diagnosed HIV-positive and due to the stress of the diagnosis, they would have to spend part of the session comforting her, leaving less time to cover all the content such as the adherence plan. Similar statements were made by some of the women who remarked that on the day of their diagnosis, they were very stressed during the counselling session and therefore had difficulty concentrating. As a result, they had forgotten some of the information that had been given to them during the first session. Busy clinic days also affected completion of the sessions.

Less than half of the women admitted to having seen the adherence plan during their counselling sessions. Several women could remember some of the issues discussed in the adherence plan but remarked that the counsellor had filled the form in for them and that was why they had difficulty recognising the form. The counsellors remarked that it was challenging to always get all the paper work filled in during the counselling session.

## **Discussion**

Studies have shown that counselling can positively influence adherence to ART in HIV-positive pregnant women [18,31]. This study examined a new counselling model for Option B+, the goal of which was to ensure uptake of ART in pregnancy and promote retention in care (RIC). The findings showed that retention in care was 53% at 8 weeks and this was lower than the findings in a similar

study conducted in South Africa on missed opportunities along the PMTCT service cascade that found RIC was 65% [32]. A Malawian study found that RIC of women on Option B+ could be as low as 42% in some hospitals [24]. The viral load results showed that 92% of women were virally suppressed, which is high, considering that only 311/448 (69%) of women had VL results. This was despite only 48% of patients completing 3 counselling sessions. This suggests that the motivation for taking the treatment and the knowledge of how to take the treatment may be important factors for good adherence despite not having received all the education from completing the counselling sessions. The Fisher's exact test revealed a P-value of 0.05, which showed that there is a positive association between the number of counselling sessions completed and number of postnatal days in care (RIC). The results also show features of the model that have been shown to positively influence adherence and RIC.

### **Knowledge gained from counselling**

The study findings show that the main motivation for starting ART was to protect the baby. This finding has been seen in other studies [19,22,23,31]. Some women started ART for their own health. Women valued the education that they had received from the counselling. The counselling provided the women with information about HIV and ART that was important to change incorrect preconceived ideas. After receiving counselling, women had a better understanding about living with HIV and the benefit of ART for the baby and their own health. Poor knowledge about HIV and ART can result in poor adherence and RIC [33]. This information served in motivating the women to take their ART and also helped them understand the importance of being adherent after delivery of the baby. These findings are similar to those found in a study in Togo, where the choice to participate in the PMTCT programme and stay adherent was correlated with the education the women received from the health care workers and peer-to-peer interaction about the effectiveness of ART in helping them have an HIV-negative baby [31].

Lack of clarity on why patients are taking treatment can lead to poor adherence especially during the postnatal period [34]. The difference in guidelines for initiation of ART for the general population and in pregnant women can cause confusion for the public. This issue highlights a need for policy makers to clearly motivate to the public and to health care workers (HCW) the reason for the different guidelines for treating the same illness, depending on the individual circumstances [35]. It also shows how the prospect of lifelong ART can be a daunting one for some patients [33,36].

## **Patient characteristics**

An important component of the counselling model was the psychosocial support provided to the women by the counsellors. Support from counsellors has been found to improve adherence [13]. The counselling provided women with the support that they needed as they faced the burden of being pregnant and HIV-positive.. Studies have shown the importance of having a supportive relationship between the patient and the counsellor, which can help to increase the trust the patient has in the treatment and decrease worry, blame and fear that can arise following diagnosis [13,20,37]. Family support was identified as important for women to stay adherent to treatment. This emphasises the need for family members to be involved in the antenatal and postnatal period. Family support has been found to come in the form of financial, logistical and emotional support all with the aim to help the woman be adherent to treatment [31,38].

The women voluntarily joined a support group independent of the counselling model, which was held at the health facility, for pregnant women on the PMTCT programme. The support that was received from the support group motivated the women to adhere to treatment [31]. These support groups help women not to feel alone and enabled them to discuss issues relating to the pregnancy with their peers [13,39,40]. The women valued the practical support offered to them by the facilitators of the support group, in solving some of their personal problems. Mentor mothers have assisted women with disclosure by acting as mediators and creating an environment that enables disclosure [40]. This

emphasizes the need that the women have for assistance in finding practical solutions to address barriers to adherence and the practical support to execute the plans to address the barriers [12].

The motivation for taking treatment is important because even when women do not complete counselling or get all the information that is relevant to their pregnancy and the baby, their reason for taking the treatment can keep them adherent. This was supported by the fact that only 48% of patients completed 3 counselling sessions and 1% completed all 4 sessions, yet the percentage of women that were virally suppressed was high at 92% (69% of 448 women had VL results). All the women were motivated to start treatment in order to protect the baby because they believed in the effectiveness of the ART. This was knowledge that they had gained from the first and second counselling sessions. Belief in the effectiveness of the treatment motivates patients to initiate and adhere to treatment [31,41]. Family responsibility and personal responsibility for her own health were also found to be reasons for maintaining adherence. The social environment in which a woman lives plays an important role in adherence.

Starting lifelong ART was a challenge for some women. For all the women, protecting the baby was of utmost importance and therefore they took the treatment [23]. The challenge for the women with difficulties in taking lifelong treatment is most likely during the postnatal period when their primary motivation for taking ART is gone. The rapid initiation in the face of the 'triple burden' (pregnancy, positive HIV status and starting lifelong ART) stresses the importance of ongoing counselling and psychosocial support post initiation to assist women in coping with these weighty issues [9,22,42]. The counselling model provided psychosocial support but it appears not to have been sufficient, as shown by the appreciation that the women had for the support group at the facility.

Non-disclosure and stigma have been found to be impediments to women accessing PMTCT [22,44]. Stigma adversely affects all levels of the PMTCT cascade [44]. HIV related stigma may lead to fear to disclose. In this study, the women voiced fear of stigma from the clinic staff and the community. Counselling played a critical role in allaying the anxiety women felt and assisted women with

disclosure. Some disclosed to their partners only and others also disclosed to other family members. Disclosure is the first step towards getting social support, which plays a key role in adherence to treatment and in decreasing stress [40]. Non-disclosure can be due to fear of rejection, abandonment or harm [45,46]. The period between diagnosis and acceptance of an HIV diagnosis differs between people and that can affect the decision to disclose. One of the study participants reported not being ready to disclose to anyone despite having completed all four counselling sessions. In spite of this, she was still adherent to her treatment in order to protect her baby. This suggests that disclosure is a facilitator to good adherence, not a prerequisite. A study conducted in Cape Town found that non-disclosure did not affect the acceptance of rapid ART initiation in pregnant women [22]. In addition it highlights the importance of the motivation for taking treatment, as a facilitator to good adherence. The motivation for taking the treatment and maintaining adherence was a main focus in all the counselling sessions.

### **Characteristics of treatment regimen**

Lack of clarity on how to take treatment especially on issues such as missed doses has been found to influence adherence. In addition, the frequency of dosage and the pill burden also influence adherence [22]. The findings showed that all the women clearly understood how to take their treatment, which indicates the benefit from the counselling they received. The fear of side effects and the experience of side effects due to treatment is one of the causes of poor adherence and defaulting of treatment [22,23,37]. The information received about the side effects gave the women an idea of what to expect and enabled the women to monitor themselves and come to the clinic for help when necessary. This helped alleviate some of the anxiety related to taking the treatment and therefore encouraged adherence to treatment. A study on adherence to ART in patients found that overcoming the fear of side effects and the difficulties of experiencing side effects was best achieved with support from providers [37]

## **Patient-provider relationship**

The patient–provider relationship has been identified as important for adherence [47]. The ability to establish a relationship of trust between the patient and the counsellor, facilitates a trust in the treatment [37]. The fact that the women saw the same counsellor for all their sessions enabled a relationship of trust to develop [47]. In general, the women spoke positively about their relationship with the counsellor. An important feature of the model was that it was interactive, which enabled the patient to be involved in the decisions made about how to take their treatment, disclosure and how to address barriers to adherence, all of which is important in patient-centred counselling [48]. In addition, it put more responsibility on the patient to maintain her adherence. The women appreciated the polite manner in which the counsellor always spoke to them. Rudeness by staff towards patients has been shown to deter patients from returning to clinics resulting in missed opportunities to prevent MTCT [47,49].

Unclear information from the health care workers can be a barrier to adherence and RIC [39]. Most women articulated that they had not been informed about the counselling sessions or when the next appointment was. Suggesting a need to review how this information is communicated.

## **Clinic setting**

Fear of disclosure of their HIV status is of real concern for patients especially in an environment where stigma exists. The privacy and confidentiality provided during the counselling, allowed the women to feel safe and engage freely with the counsellor. Women feared disclosure of their status to other patients in the clinic if they were seen returning to the counselling room. This further highlights the negative impact of stigma, which can result in patients not realising the full value of the counselling intervention.

## **Reasons for not completing the counselling sessions**

Non-completion of counselling sessions was problematic in this cohort with only 1% of women completing all 4 sessions. The study revealed several reasons why this may have occurred. Confusion

about the role of the mentor mothers support group led some women to think that the support group was also considered counselling and therefore they did not return to the counsellor. This stresses the need for counsellors and clinical staff to clarify information given to patients [39]. Other reasons were, forgetting to go to the counsellor, long waiting times, not being told to return to the counsellor for another session, not having a written follow up appointment, fear of disclosure and feeling confident about taking ART after one counselling session. Some of which show weaknesses in communication to patients. In a similar fashion, long waiting times and forgetting have previously been given by patients as reasons for defaulting treatment and follow up [49].

### **Feasibility and acceptability of the model**

The counsellors were in support of early initiation of pregnant women onto ART and of the counselling model. A negative attitude of health care workers (HCW) towards the implementation of a service can affect the optimal implementation of the service [35]. The counselling sessions were conducted on the same day as the clinical visit, which saved the women from experiencing issues such as incurring extra financial costs from travelling, dealing with child care issues and the possibility of lost income from missing work; which have previously been found to affect adherence [50]. Another strength of the model is the flip chart and the adherence plan which aided the counsellors in the provision of patient-centred counselling [48]. Thus, assisting women with finding solutions to individual barriers to adherence is important for good adherence and RIC [12].

There were challenges to using the counselling model. Completing session one and session two was sometimes a challenge due to the amount of content to be covered. This problem was usually encountered when offering emotional support to a newly diagnosed woman, which required more time, leaving less time to cover all the content such as the adherence plan. Less than half of the women admitted to having seen the adherence plan during their counselling sessions. Other reasons for not covering all the content in the sessions was lack of time due to a heavy workload as a result of shortage of staff due to absenteeism or due to a large number of patients for the day. Midwives do not



have the time to cover all the content in the counselling session during the clinical visit therefore the counsellor plays a vital role in providing information and assistance to the women thereby improving their experience of pregnancy and delivery. Shortage of staff and overcrowded clinics result in less time for counsellors to see patients and long waiting times, which can influence the quality of the counselling and can impact on patient adherence [4,51]. Less time to conduct the counselling sessions could pose a potential threat to the feasibility of the individual counselling sessions; the structure of the sessions may not have lent itself to being effectively implemented due to time constraints.

Overall, the counselling model provided women with psychosocial support and knowledge about ART, HIV, side effects of ARVs and infant feeding. Furthermore, women were assisted by counsellors in finding solutions to overcome their individual barriers to adherence. The counselling model addressed some of the causes of poor adherence that were highlighted in the framework but unfortunately due to poor communication, service delivery challenges and social factors, the uptake of the counselling intervention was suboptimal.

## **Limitations of the study**

There were several limitations in the study. The missing quantitative data from patient folders and the electronic health record resulted in an incomplete data set. This may have resulted in the finding of an association between the number of postnatal days in care (RIC) and the number of counselling sessions completed, when there may have been no association. Similarly, the results may be an underestimate of the retention in this study. To mitigate this, an electronic linkage was done on a provincial data set to map all women who may have attended a clinic outside of the district. Due to the nature of the study design it cannot be inferred that having more counselling sessions resulted in better adherence in women during the postnatal period. Some women may have had a predisposition to be adherent.

No parallel study of the "additional" support group was done to evaluate it: the importance of this support group only emerged while the study was underway. The support group was offered by a separate organisation and considered not part of the scope of the evaluation, however, it seemed to have importance in the qualitative interviews. Social desirability bias may have resulted in women over reporting some of the positive experiences of the counselling model that are related to good adherence due to fear of being penalised by clinic staff. In order to reduce this bias, participants were informed that the clinic staff would not be involved in the research and the interviews were conducted in a private room. In addition the participants were informed that the interviews would be anonymised and the clinic staff would not have access to the interview data.

The sample size of the number of pregnant women interviewed was small but data saturation was reached and sufficient information was obtained to answer the reach questions. We were only able to get two counsellors to participate in the study due to their lack of availability and acknowledge that this was a limitation, which has implications for the breadth of the perspectives generated from this participant group. Since the counsellors were positive about the intervention they may have been more inclined to give positive responses about the intervention, hence a limitation. To mitigate this, data triangulation between the interviews of both counsellors and pregnant women was done. To improve the credibility of the results, the author had a prolonged engagement in the field, which allowed the researcher to gain a better understanding of the context and to build relationships with the clinic staff. Based on professional experience and the literature review the researcher started the research with the belief that counselling is beneficial to HIV-positive patients and this may have led to some bias in the analysis and interpretation of the results. Due to the fact that the sampling included only women who experienced the counselling model at one clinic in an informal settlement, this limited the generalizability of the findings to other areas. However, the findings were similar to findings in other studies on women on the PMTCT programme in Sub-Saharan African.

The study was formative research and did not include a measure of fidelity to the intervention. This represents a potential limitation because poor implementation of the intervention could have affected

the data collected and hence the results. The counsellors had mentoring to ensure that they were delivering the counselling model correctly. This included monitoring how the counselling sessions were conducted and checking that all the counselling tools were being used correctly. Lastly, it included ensuring correct completion of the counselling register, which documented the number of counselling sessions completed by each woman. The mentor also performed monthly audits on the implementation of the counselling model. This information was not a component of the study but could be used as part of a larger study to evaluate the intervention.

## **Recommendations**

There needs to be a review of the amount of content in session one and two to enable the counsellors to complete the sessions on busy days. This may involve a second modified version of session one and two, which the counsellor can use in the counselling session on busy days. This will allow for consistency of the information given and ensure that all the important information is given to patients. Communication to patients about how many counselling sessions need to be completed and on what information will be discussed at the next session would be helpful for patients as some patients may assume that the next session is a repeat of the one they have just completed and therefore not return. Giving patients written appointments would act as a reminder for patients and in future, mobile texting would be a useful intervention. The start of a support group facilitated by the counsellor will give the women a platform to discuss issues with their peers in a relaxed environment and enable the counsellors to support the women further. In the setting where another service provider provides a support group, collaboration between the two service providers needs to be initiated to enable the counsellors to assist in facilitating the support groups and prevent duplication of services.

## **Conclusion**

The reasons for the poor uptake of the counselling intervention include, poor communication, service delivery challenges and social factors. The main motivation for initiating ART and maintaining

adherence to treatment was to protect the baby and as a result, some women maintained adherence despite not completing the counselling. Women valued the education that they received during the counselling sessions and this influenced their adherence. Psychosocial support from the counsellors and peers was found to be vital to the women and this highlighted the need to incorporate a support group for the pregnant women, as part of the intervention. The findings also suggest that when offering counselling interventions to pregnant women, a balance between psychosocial support, practical support and patient education needs to be struck. Finally, education of the community on the importance of counselling is important in order to improve the uptake of the counselling because interventions aimed at mothers do not always take into account the influence of the social environment on the uptake of the intervention.

## **Acknowledgements**

I would like to thank the study participants and the counsellors, nurses and reception staff at Site B MOU, Khayelitsha Community Health Centre.

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## **Section D: Appendices**

## Appendix 1: Women testing HIV-Positive Counselling guide for Option B+



## **Appendix 2: Information Sheet and Consent Forms**

### **A. Information Sheet and Consent Form for Pregnant women**



University of Cape Town

Information Sheet and Consent Form for Pregnant women

**A study to explore the experiences and opinions of women towards a new counselling model for HIV-positive pregnant women at Site B clinic in Khayelitsha, Cape Town**

#### **What is the University of Cape Town?**

The University of Cape Town is a tertiary academic institution based in Cape Town. The Centre of Infectious Disease, Epidemiology and Research, which is a centre within the School of Public Health at University of Cape Town, conducts research on various health related issues. The University of Cape Town has a Human Research Ethics Committee that has to approve all research before it is started. The Ethics committee ensures that the research is justified, that ethical principles are followed and that participant's rights and safety are protected.

#### **What is this research about?**

In this study we would like to learn about your experiences and thoughts about the new counselling model for HIV-Positive pregnant women. We would like to invite 12 participants who like you, have attended the counselling sessions at this clinic.

#### **Why are you being asked to take part?**

You have been selected to take part in the study because you have experienced the new counselling model and will therefore be able to tell us about your experiences and thoughts about the counselling model.

We think that your experiences and thoughts about the counselling model will help us understand how the counselling model can improve how participants take their treatment. It will also help us find out how we can improve how well the counselling model is delivered to patients.

**What will be involved in taking part?**

My colleague will ask you some questions about your experiences and thoughts about the counselling model and your responses will be written down and recorded on a digital recorder. The questions will be in Xhosa. You are free to refuse to answer any question that you do not want to answer. Your name will not be recorded or written down therefore your answers to the questions will be kept private and confidential. Only the researchers in the study will see your answers. The interviewer will be the only person in the room with you unless you will need another person there.

The interview will take approximately 60 to 90 minutes.

**What are the risks and discomforts of taking part?**

You may find that some of the questions about your experience of the counselling model may make you uncomfortable and may be difficult to answer. You may be worried that the information that you give will have a bad affect on how you are treated at the clinic. There will be no change in how you are treatment at the clinic in any way.

There will be not delay in your appointment or in your treatment if you agree to take part. There will be no names recorded or written down therefore there is no chance of any information being connected back to you.

**Are there any benefits to me for taking part?**

In answering the questions, you will not personally benefit from the study. The study will help us understand how the counselling model can improve how participants take their treatment and it will also help us find out how we can improve how well the counselling model is delivered to patients.

**What will happen to the results of the study?**

The results of the study will be presented in the form of a report to the staff at the clinic and the facility manager in order that the most benefit is gained from the study. A copy of the report will be given to a member of Department of Health and to the relevant member of Médecins Sans Frontières (MSF). Lastly, the study will be submitted to a relevant research journal for publication.

**Who will see the information that has been collected about me?**

We will not give any information about you or other participants to anyone apart from people involved in conducting the study. The recordings and electronic documents will be kept in files on computers that are password protected. Documents and interview sheets will be kept in files that will be stored safely in a locked cupboard.

**What will happen if I refuse to participate?**

Agreeing to take part in the study is voluntary. You are free to agree to take part or refuse to take part. There will be no punishment for refusing to take part. Even after you agree, you are free to change your mind any time after without any penalties.

**Will I receive any reward for taking part?**

You will not receive any reward for taking part.

**Who do I speak to if I have questions?**

You can ask me any questions. If you have more questions about the study, contact the research team using the information below:

Principal investigator's name and contact:

Dr. Kathryn Stinson (Epidemiologist)  
Centre for Infectious Diseases, Epidemiology and Research  
School of Public Health and Family Medicine  
Falmouth Building, Level 5  
University of Cape Town  
Observatory, Cape Town  
Phone: 021-406-6760

Researcher – Dr Viola Kirya  
Cell: 0732727842  
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Department of Health contact person:  
Charlene Roderick: +27 021 4836857

Email: [health.research@westerncape.gov.za](mailto:health.research@westerncape.gov.za)

**Who do I contact if I want to ask someone independent anything about this research?**

If you have any problems or questions about this study please contact the Ethics committee directly.

Human Research Ethics Committee Faculty of Health Sciences, University of Cape Town.

Telephone number: 021 406 6338

**CONSENT FORM - For Pregnant Women**

**A study to explore the experiences and opinions of women towards a new counselling model for HIV-positive pregnant women at Site B clinic in Khayelitsha, Cape Town**

The study has been explained to me. I have understood what has been read to me. I have been given the chance to ask questions about the study and I am satisfied that the questions have been answered.

**Yes (please tick) I agree to be interviewed**

I understand that I can change my mind at any time and it will not affect how I am treated at the clinic.

**Participant's signature** \_\_\_\_\_ **Date:** \_\_\_\_\_

**Participant's name** \_\_\_\_\_ **Date** \_\_\_\_\_  
**(Please print name)**

**Thumbprint of the participant as named above if they are not able to write:**

\_\_\_\_\_

I certify that I have followed the informed consent SOP to obtain consent from the participant. S/he has understood the type and the reason for the study and agrees to take part in the study. S/he has been given a chance to ask questions which have been answered adequately.

**Signature** \_\_\_\_\_ **Date:** \_\_\_\_\_

**Designee/investigator's name** \_\_\_\_\_ **Time** \_\_\_\_\_  
**Name** **(Please print name)**



## **Participants' FAQs and Some Answers**

### **What is a research study?**

A research study is a very careful way of looking at something and collecting information about what is being looked at. It can be as simple as asking a few questions such as in a survey or in an interview. Or it can be more difficult and may look at a particular sickness or testing new treatments for a particular sickness.

### **What is a research participant?**

A research participant is a person who agrees to take part in a research study. This is completely voluntary. As a research participant you will be helping the researcher to answer the questions in the study. You can decide you no longer want to be in the study at any time.

### **What is a protocol?**

A research protocols helps a researcher to carry-out the research. A protocol is like a cookbook. It tells the researcher what can and cannot happen during the research. It includes information the researcher must follow to protect participants from harm. This protocol must be reviewed by a Human Research Ethics Committee before the research can begin.

### **Can anyone be in a research study?**

Each study has a list of who can and cannot be in the research. This is written in the protocol. In order to protect research participants, only people who qualify can be in a study.

### **What is a principal investigator?**

The principal investigator or PI is the person who is in charge of the research study. The PI has to make sure that everything is done properly. There may also be other people who help with the research study. There may be people who help to translate the questions into a participant's home language, there may be people who ask for informed consent and people who make sure that participants' personal information is kept confidential.

### **What is a Human Research Ethics Committee?**

The Human Research Ethics Committee is a group of people such as doctors, scientists, dieticians, physiotherapists and some community people. This Committee must look at every protocol before a research study can begin and it watches what happens during a study. This is to protect participants and to make sure that researchers keep any risks as low as possible.

**What is informed consent?**

If you decide you would like to be in a research study, the facts about the research will be given to you in an information sheet or consent form. This is to help you understand what will happen to you in the research study so that you can make up your mind. You will be told about all the risks, if there are any benefits and any other options to the study. You will be able to ask any questions about the study and you may be able to speak to your family or friends before making your decision. You are also able to ask questions during the study.

**Investigators**

Investigators should ask questions to make sure that you understand what you are consenting to.

## B. Information Sheet and Consent Form for Counsellors



### University of Cape Town

### Information Sheet and Consent Form for Counsellors

#### **A study to explore the experiences and opinions of women towards a new counselling model for HIV-positive pregnant women at Site B clinic in Khayelitsha, Cape Town**

#### **What is the University of Cape Town?**

The University of Cape Town is a tertiary academic institution based in Cape Town. The Centre of Infectious Disease, Epidemiology and Research, which is a centre within the School of Public Health at University of Cape Town, conducts research on various health related issues. The University of Cape Town has a Human Research Ethics Committee that has to approve all research before it is started. The Ethics committee ensures that the research is justified, that ethical principles are followed and that participant's rights and safety are protected.

#### **What is this research about?**

In this study we would like to learn about your experiences and thoughts about the new counselling model for HIV-positive pregnant women. We would like to invite 3 participants who like you, have experience with using the new counselling model at this clinic.

#### **Why are you being asked to take part?**

You have been selected to take part in the study because you have experience with using the new counselling model and will therefore be able to tell us about your experiences and thoughts about the counselling model.

We think that your experiences and thoughts about the counselling model will help us understand how the counselling model can improve how participants take their treatment. It will also help us find out how we can improve how well the counselling model is delivered to patients.

**What will be involved in taking part?**

My colleague will ask you some questions about your experiences and thoughts about the counselling model and your responses will be written down and recorded on a digital recorder. The questions will be in Xhosa or English. You are free to refuse to answer any question that you do not want to answer. Your name will not be recorded or written down therefore your answers to the questions will be kept private and confidential. Only the researchers in the study will see your answers. The interviewer will be the only person in the room with you unless you will need another person there. The interview will take approximately 60 minutes.

**What are the risks and discomforts of taking part?**

You may find that some of the questions about your experience with using the counselling model may make you uncomfortable and may be difficult to answer. You may be worried that the information that you give will have a negative effect on your relationship with your managers. There will be no names recorded or written down therefore there is no chance of any information being connected back to you.

**Are there any benefits to me for taking part?**

In answering the questions, you will not personally benefit from the study. The study will help us understand how the counselling model can improve how participants take their treatment and it will also help us find out how we can improve how well the counselling model is delivered to patients.

**What will happen to the results of the study?**

The results of the study will be presented in the form of a report to the staff at the clinic and the facility manager in order that the most benefit is gained from the study. A copy of the report will be given to a member of Department of Health and to the relevant member of Médecins Sans Frontières (MSF). We may present the results to you in a meeting at the facility if you wish. Lastly, the study will be submitted to a relevant research journal for publication.

**Who will see the information that has been collected about me?**

We will not give any information about you or other participants to anyone apart from people involved in conducting the study. The recordings and electronic documents will be kept in files on computers that are password protected. Documents and interview sheets will be kept in files that will be stored safely in a locked cupboard.

**What will happen if I refuse to participate?**

Agreeing to take part in the study is voluntary. You are free to agree to take part or refuse to take part. There will be no punishment for refusing to take part. Even after you agree, you are free to change your mind any time after without any penalties.

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Centre for Infectious Diseases, Epidemiology and Research

School of Public Health and Family Medicine

Falmouth Building, Level 5

University of Cape Town

Observatory, Cape Town

Phone: 021-406-6760

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vkirya@hotmail.com

Department of Health contact person:

Charlene Roderick: +27 021 4836857

Email: [health.research@westerncape.gov.za](mailto:health.research@westerncape.gov.za)

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Telephone number: 021 406 6338

**CONSENT FORM - FOR CONSELLORS**

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The study has been explained to me. I have understood what has been read to me. I have been given the chance to ask questions about the study and I am satisfied that the questions have been answered.

**Yes (please tick) I agree to be interviewed**

I understand that I can change my mind at any time and it will not affect how I am treated at the clinic.

**Participant's signature** \_\_\_\_\_ **Date:** \_\_\_\_\_

**Participant's name** \_\_\_\_\_ **Date** \_\_\_\_\_  
**(Please print name)**

I certify that I have followed the informed consent SOP to obtain consent from the participant. S/he has understood the type and the reason for the study and agrees to take part in the study. S/he has been given a chance to ask questions which have been answered adequately.

**Signature** \_\_\_\_\_ **Date:** \_\_\_\_\_

**Designee/investigator's name** \_\_\_\_\_ **Time** \_\_\_\_\_  
**Name** **(Please print name)**

## **Participants' FAQs and Some Answers**

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Each study has a list of who can and cannot be in the research. This is written in the protocol. In order to protect research participants, only people who qualify can be in a study.

### **What is a principal investigator?**

The principal investigator or PI is the person who is in charge of the research study. The PI has to make sure that everything is done properly. There may also be other people who help with the research study. There may be people who help to translate the questions into a participant's home language, there may be people who ask for informed consent and people who make sure that participants' personal information is kept confidential.

### **What is a Human Research Ethics Committee?**

The Human Research Ethics Committee is a group of people such as doctors, scientists, dieticians, physiotherapists and some community people. This Committee must look at every protocol before a research study can begin and it watches what happens during a study. This is to protect participants and to make sure that researchers keep any risks as low as possible.

**What is informed consent?**

If you decide you would like to be in a research study, the facts about the research will be given to you in an information sheet or consent form. This is to help you understand what will happen to you in the research study. It will explain the kinds of things that you can expect will happen at each visit so that you can make up your mind. You will be told about all the risks, if there are any benefits and any other options to the study. You will be able to ask any questions about the study and you may be able to speak to your family or friends before making your decision. You are also able to ask questions during the study.

**Investigators**

Investigators should ask questions to make sure that you understand what you are consenting to.



### Appendix 3: Samples of interview guides for Semi-structured interviews

Original interview guides, prior to piloting.

#### A. Sample of interview guide for Semi-structured interview for HIV-positive women

Participant number .....

Age? .....

First pregnancy (Y/N)?

How many weeks pregnant are you? .....

Previous HIV diagnosis (Y/N)?

Number of counselling sessions completed? .....

<b>Questions</b>	
1.	Can you tell me about your first counseling session? <b>Probe:</b> When was it? Were you diagnosed HIV-positive that day? How did you feel in that moment when you got the results?
2.	Did you feel supported? Who did you feel supported by? If you did not feel supported, who would you have liked to support you?
3.	I want to take you back to that first session. Did you understand why you had to start ARV at the first session?  Did you get all the information you needed to understand how to take your treatment? If no, why?  Was the information easy to understand? What would have helped you?
4.	May I ask about your experience with the counsellor? How did you find them? <b>Probe:</b> Was the counsellor patient, kind? Did the counsellor explain the information? How did this affect you?
5.	Did you feel free to ask questions? Were your questions answered?
6.	Do you think that pregnant women should start ARVs? Why?
7.	Why do you think you need to start ARVs in pregnancy?
8.	Why do you think the government and the clinic want women to book early and deliver in a clinic?
9.	Is there anything that would prevent you from delivering at this clinic?
10.	After the counselling session, which words best describe how you felt about taking the treatment? (Circle appropriate answer) C. I felt more motivated D. I did not see the point of taking the treatment E. I am still unsure about taking the treatment

	<p><i>F.</i> It made no difference</p> <p>Why?</p>
11.	Do you think it is important to stay on treatment? Why?
12.	<p>What do you think about the adherence plan? Why?</p> <p>What was discussed in your adherence plan?</p>
13.	What would make it easier for you to stay on treatment?
14.	<p>How could the counsellor help you with this?</p> <p>Do you feel that the counsellor has supported you with this?</p>
15.	<p>Have you told anyone about your diagnosis?</p> <p>If yes, what helped you?</p> <p>If no, why have you not been able to tell anyone?</p>
16.	Do you think it will be helpful to see the counsellor for support after the baby is born? Why?
17.	<p>What do you think about your relationship with the counsellor? Why?</p> <p><b>Probe:</b></p> <p>Is she friendly?</p> <p>Does she make you feel comfortable?</p> <p>Can you share your secrets?</p> <p>Can you tell her everything?</p> <p>Do you feel comfortable asking questions?</p>
18.	How do you think your relationship with the counsellor affects your staying on treatment now and in the future?
19.	How do you feel about taking ARVs for the rest of your life when you do not feel ill? Why?
20.	Why is it important to take lifelong treatment for yourself?
21.	<p>Has the counselling helped you?</p> <p>If yes, How?</p> <p>If no, Why?</p>
22.	What do you think was most helpful about the counselling?
23.	What do you think are the positive things about the type of counselling you received?
24.	What would you add to improve it?
25.	<p>What is your experience of privacy and confidentiality during the counselling sessions?</p> <p><b>Probe:</b></p> <p>Do you think other people could hear? Why?</p> <p>Do you think other people could see you? Why?</p> <p>How did you feel while you were waiting outside the counselling room? Why?</p>

Interview guide after piloting.

**B. Sample of interview guide for Semi-structured interview for HIV-positive women**

Participant number _ recording number	
How old are you?	
How many pregnancies have you had?	
When did you give birth to your last baby?	
How many weeks pregnant were you when you booked?	
How many weeks pregnant are you now?	
How long have you had HIV?	
Have you had PMTCT before?	
How many counselling sessions have you completed?	

<b>Questions</b>	
1.	<p>Can you tell me about your first counseling session? <b>Wait for a response</b></p> <p><b>Probe individually:</b></p> <ul style="list-style-type: none"> <li>a) When was it? Wait for response</li> <li>b) Were you diagnosed HIV-positive on that day?</li> <li>c) How did you feel in that moment when you got the results?</li> </ul>
2.	<ul style="list-style-type: none"> <li>• Did you feel supported? <b>Wait for a response</b></li> <li>• Who did you feel supported by? <b>Wait for a response</b></li> <li>• How did they support you?</li> <li>• If you did not feel supported, who would you have liked to support you?</li> </ul>
3.	<ul style="list-style-type: none"> <li>a) I want to take you back to that first session. Did you understand why you had to start ARV at the first session?</li> <li>b) Did you get all the information you needed to understand how to take your treatment? Why do you say that?</li> <li>c) Were you told about the side effects of the medication? If yes: Did this help you when deciding about starting your treatment? How? If no: Do you know about the side effects of the treatment? Who told you? Did this help you when deciding about starting your treatment? How?</li> <li>d) Was the information easy to understand? If no, why not? If yes, how so?</li> <li>e) What would have helped you get more from the counselling?</li> </ul>
4.	<ul style="list-style-type: none"> <li>• I would like to know more about your experience with the counsellor. Tell me how it was?</li> </ul> <p><b>Probe individually:</b></p> <ul style="list-style-type: none"> <li>• Was the counsellor patient, kind? Why do you say that?</li> <li>• Did the counsellor explain the information? Why do you say that?</li> <li>• How did your relationship with the counsellor affect you?</li> </ul>
5.	<ul style="list-style-type: none"> <li>• Did you feel free to ask questions? Can you explain why?</li> </ul>

	<ul style="list-style-type: none"> <li>Were your questions answered? Why do you say that?</li> </ul>
6.	<ul style="list-style-type: none"> <li>Tell me what you know about being pregnant and ARVs.</li> <li>Do you think that pregnant women should start ARVs? Why?</li> </ul>
7.	<ul style="list-style-type: none"> <li>What do you understand about why pregnant women should book early?</li> <li>What do you understand about why pregnant women should deliver in a clinic?</li> </ul>
8.	What do you think would prevent a pregnant woman from delivering at a clinic?
9.	<p>After the counselling session, which words best describe how you felt about taking the treatment? (Give the paper to participant to answer) (Circle appropriate answer)</p> <p>G. I felt more motivated H. I did not see the point of taking the treatment I. I am still unsure about taking the treatment J. It made no difference</p> <p>Why?</p>
10.	Do you think it is important to stay on treatment? Why?
11.	<ul style="list-style-type: none"> <li>Tell me about the adherence plan? <b>Wait for a response</b></li> </ul> <p>Interviewer: Show the participant the adherence plan and ask if they have seen or heard about it before.</p> <ul style="list-style-type: none"> <li>Tell me, what do you think about the adherence plan.</li> <li>What was discussed in your adherence plan.</li> </ul>
13.	<p>a) At home, what are some of the things that would help you to stay on treatment?</p> <p>b) How could the counsellor help or support you with this?</p> <p>c) At the clinic, what are some of the things that would help you to stay on treatment?</p> <p>d) How could the counsellor help or support you with this?</p>
14.	Do you feel that the counsellor has supported you with this?
15.	<ul style="list-style-type: none"> <li>Have you told anyone about your diagnosis?</li> <li>If yes: what helped you?</li> <li>If no: why have you not been able to tell anyone?</li> </ul>
16.	<ul style="list-style-type: none"> <li>How do you think the counselling has helped you prepare for the baby?</li> <li>Do you think that mothers should come to the counsellor after the baby is born? Why?</li> </ul>
17.	<p>What do you think about your relationship with the counsellor? Why?</p> <p><b>Probe individually:</b></p> <p>a) Is she friendly? Why do you say that?</p> <p>b) Does she make you feel comfortable? If yes: why? If no: Why?</p> <p>c) Can you share your secrets? Why do you say that?</p> <p>d) Can you tell her everything? Why do you say that?</p> <p>e) Do you feel comfortable asking questions? Why do you say that?</p>
18.	How do you think your relationship with the counsellor affects your staying on treatment now and in the future?
19.	How long do you have to take the ARVs for? Why Question 19 and 20 have been changed and swapped around
20.	How do you feel about taking ARVs for the rest of your life when you do not feel ill? Why?
21.	<p>Has the counselling helped you?</p> <p>If yes, How has it helped?</p> <p>If no, Why has it not been helpful?</p>
22.	What do you think was most helpful about the counselling?

23.	What do you think are the positive things about the type of counselling you received?
24.	Lets pretend that I am a new patient and you are the counsellor, trying to educate me about HIV and ARVs. How would you change the counselling to make it more helpful to be, the patient?
25.	<p>What is your experience of privacy and confidentiality during the counselling sessions?</p> <p><b>Probe individually:</b></p> <ul style="list-style-type: none"> <li>a) Do you think other people could hear? Why?</li> <li>b) Do you think other people could see you? Why?</li> <li>c) How did you feel while you were waiting outside the counselling room? Why?</li> </ul>
26.	<ul style="list-style-type: none"> <li>• At the start of the counselling sessions, what were you told about the number of counselling sessions you were supposed to have?</li> <li>• Were you told about what was going to be discussed in all the counselling sessions, before you started the counselling?</li> </ul>
27.	<p>What made you complete all the counselling sessions?</p> <p>Why did you only complete # counselling sessions instead of all 4 sessions?</p>

**1. Table on the Measures used to assess the different categories of the Framework on Adherence and Retention in care**

Theme	Subtheme	Question number on questionnaire
Patient characteristics	Social support	2, 15
	Disclosure and Stigma	1c, 15
	Intent to adhere	9, 10, 13, 20
	Perceived effectiveness of ART	3a
Characteristics of treatment regimen	Knowledge of regimen regimen and regimen complexity	3a, 3b
	Side effects to treatment	3c
Patient-provider relationship,	Tone of the relationship and communication	4, 5, 17, 26
Clinical setting	Privacy and confidentiality	25

### C. Sample of interview guide for Semi-structured interview for the counsellors

Participant .....

How long have you been using the counselling model? .....

<b>Questions</b>	
1.	<p>What was counselling like before this new model?</p> <p><b>Probe:</b>                      Was it Structured?                      Did each counsellor do his or her own thing?                      Were there forums/feedback meetings to discuss and share ideas?</p>
2.	<p>How do you feel about pregnant women starting ARVs on the first clinic visit? Why?</p>
3.	<p>Have you found the model simple to use? Why?</p>
3.	<p>What are the strengths of the model?</p>
4.	<p>What are the challenges of the model?</p> <p><b>Probe:</b>                      Is there enough time to complete the sessions?                      Is there space for privacy?                      Are you able to fill in all the paperwork (folder, adherence plan and counselling register)?                      Do you feel confident using the model?                      Do you need mentorship or coaching?</p>
5.	<p>How have the patients responded to the counselling model?</p>
6.	<p>Do you have any examples of patients who have shown that counselling has been beneficial?</p>
7.	<p>What do you think patients need from you as a counsellor?</p>
8.	<p>How are you trying to help them with this?</p>
9.	<p>How can the model be improved?</p>

**D. Sample of interview guide for Semi-structured interview for HIV-positive women translated to isiXhosa**

iSampuli yolandelo lodliwano ndlebe lwesimiselo sodliwanondlebe kumabhinqa akhulelweyo.

**Isimiselo sodliwano ndlebe lusakufumaneka ngeSingesi nangesiXhosa**

Inombolo yomthathi nxaxheba bhala inombolo	
Uneneminyaka emingaphi?	
Kukangaphi ukhulelwa ?	
Ubumzele nini umntwana wakho wokugqibela?	
Ubuneveki ezingaphi ukhulelwe ngoku ubuzobhalisa?	
Uneveki ezingaphi ukhulelwe ngoku?	
Kulixesha elingakanani ngoku unentsholongwane kaGawulayo?	
Wakhe wafumana iPMTCT ngaphambili?	
Zingaphi iseshoni zocebiso ozigqibileyo?	

<b>Iimibuzo</b>	
1.	<p>Ungandixelela malunga neseshoni yakho yokuqala yocetyiswa? Linda impendulo</p> <p><b>Buzisisa:</b></p> <ul style="list-style-type: none"> <li>• Kwakunini ngoku? Linda impendulo</li> <li>• Wawuyazi ukuba unentsholongwane kaGawulayo ngalomini?</li> <li>• Waziva unjani ngalamzuzu xa wawufumana iziphumo zakho?</li> </ul>
2.	<ul style="list-style-type: none"> <li>• Wawuziva uxhasiwe na? Linda impendulo</li> <li>• Waziva uxhasiwe ngubani? Linda impendulo</li> <li>• Bakuxhasa njani?</li> <li>• Ukuba waziva ungaxhasekanga, wawunothanda uxhaswa ngubani?</li> </ul>
3.	<ul style="list-style-type: none"> <li>• Ndifuna ukubuyisela umva kulaseshoni yokuqala. Wawuyiqonda kakhle ukuba kutheni kufuneka uqale iARV kulaseshoni yokuqala?</li> <li>• Walifumana lonke ulwazi malunga nokuba lutyiwa njani unyango lwakho? Kutheni usitsho njalo?</li> <li>• Wawuxelelwe malunga neziphumela zalamayeza? Ukuba Ewe: Ingaba oku kwakunceda ekubeni uthathe isigqibo ukuba uqala unyango lwakho? njani? Ukuba Hayi: Ingaba uyawazi amaphumela olunyango.? Wawuxelelwe ngubani? Ingaba oko kwakunceda ukuba uthathe isigqibo sokuqala unyango? njani?</li> <li>• Ingaba ulwazi olo kwakulula ukuba uliqonde? Ukuba Hayi, kwakutheni? Ukuba Ewe, kanjani?</li> <li>• Yintoni eyayi nokunceda ufumane banzi kolucebiso?</li> </ul>
4.	<ul style="list-style-type: none"> <li>• Ndingathanda ukukwazi banzi malunga namava akho kunye nomcebisi? Khandixelelw kwakunjani?</li> </ul> <p><b>Buzisisa mbuzo ngamnye:</b></p> <p>a) Ingaba umcebisi waye nomonde? Kutheni usitsho?</p>



	<p>b) Ingaba umcebisi wakucacisela ngolwazi? Kutheni usitsho?</p> <p>c) Yakuchaphazela njani into yobudlelwane bakho kunye nomcebiso?</p>
5.	<ul style="list-style-type: none"> <li>• Waziva ukhululekile ukubuza imibuzo? Ungandicacisela ngoba?</li> <li>• Yaphendeleka imibuzo yakho? Kutheni usitsho njalo?</li> </ul>
6.	<ul style="list-style-type: none"> <li>• Khandixelele yintoni oyaziyo ngokukhulelwa kunye neARV's.</li> <li>• Ucinga ukuba amabhinqa akhulelweyo angaqala iARVs? Ngoba?</li> </ul>
7.	<ul style="list-style-type: none"> <li>• Yintoni oyiqonda malunga nokuba kutheni amabhinqa akhulelweyo funeka ayobhalisa kwamsinyane?</li> <li>• Yintoni oyiqonda malunga nokuba kutheni amabhinqa akhulelweyo funeka abelekele ekliniki?</li> </ul>
8.	Ucinga yintoni enokunqanda amabhinqa akhulelweyo ukuba angabelekeli ekliniki?
9.	<p>Emveni kweseshoni yengcebiso, ngawaphi amagama acacisa indlela oziva ngayo malunga nokuthatha unyango? (nika umthathi nxaxheba iphepha aphendule)</p> <p>( beka isangqa kwimpendulo efanelekileyo)</p> <ol style="list-style-type: none"> <li>Ndaziva ndikhuthazeke kakhulu</li> <li>Zange ndibone ukuba kutheni mandithathe unyango</li> <li>Kuba andikaqiniseki ukuba kutheni mandithathe unyango</li> <li>Ayizange yenze mahluko</li> </ol> <p>Ngoba?</p>
10.	Ucinga ukuba kubalulekile ukuba uhlale kunyango? Ngoba?
11.	<ul style="list-style-type: none"> <li>• Khandixelele ngesicwangciso sokuncelela ipilisi? Linda impendulo</li> </ul> <p>Umbuzi: Bonisa umthathi nxaxheba esicwangciso sokuncelela ipilisi kwaye umbuze ukuba wakhe bayibona okanye wava ngayo ngaphambili.</p> <ul style="list-style-type: none"> <li>• Khandixelele, ucinga ntoni wena ngesicwangciso sokuncelela ipilisi?</li> <li>• Yintoni ibixoxiwe kwisicwangciso sokuncelela ipilisi?</li> </ul>
12.	<ol style="list-style-type: none"> <li>Ekhaya, zeziphi izinto ezinothi zikunceda uhlale kolunyango?</li> <li>Umcebisi angakunceda okanye akuxhase njani ngalo mba?</li> <li>Apha ekliniki, zeziphi izinto ezinothi zikunceda uhlale kolunyango?</li> <li>Umcebisi angakunceda okanye akuxhase njani ngalo mba?</li> </ol>
14.	Ucinga ukuba umcebisi ukuxhasile ngalonto?
15.	<ul style="list-style-type: none"> <li>• Ukhona umntu omxeleleyo ngokufunyanisiweyo kuwe?</li> <li>• Ukuba ewe, yintoni ekuncedileyo?</li> <li>• Ukuba Hayi, kutheni ungekakwazi ukuxelela noba ngubani?</li> </ul>
16.	<ul style="list-style-type: none"> <li>• Ucinga ukuba umcebisi ukuncedile ekulungiseleleni umntwana wakho?</li> <li>• Ucinga ukuba omama baze kubacebisi emveni koba abantwana bezelwe? Ngoba?</li> </ul>
17.	<p>Ucinga ntoni malunga nobudlelwane bakho kunye nomcebisi? Ngoba?</p> <p><b>Buzisisa umbuzo ngamnye:</b></p> <ol style="list-style-type: none"> <li>Unobuhlobo na? kutheni usitsho?</li> <li>Ukwenza uzive ukhululekile? Ukuba ewe, ngoba? Ukuba hayi, ngoba?</li> <li>Ungathetha ngemfihlelo zakho? Kutheni usitsho?</li> <li>Ungamxelela ngento yonke? Kutheni usitsho?</li> <li>Uziva ukhululekile ukubuza imibuzo? Kutheni usitsho?</li> </ol>

18.	Ucinga njani ubuhlobo bakho nomcebisi ingaba buyachaphazela ukuba uhleli kunyango ngoku kunye nakwilixesha elizayo?
19.	Kufuneka uzisebenzisa ixesha elingakanani iARV's? Ngoba?
20.	Uziva njani ngokuthatha iARV's ubomi bakho bonke kodwa awuziva ugula? Ngoba?
21.	Ingaba umcebisi ukuncedile? Ukuba ewe, ukuncede njani? Ukuba hayi, kutheni ingakhange ikuncede?
22.	Yintoni ocinga yakunceda malunga nocetyiswa?
23.	Ucinga zintoni ezazibalulekile malunga nendlela owayifumana ngayo ingcebiso?
24.	Masenze ingathi mna ndisigulane esitsha, wena ungumcebisi uzama ukundifundisa malunga nentsholongwane kaGawulayo kunye neARV's , Yintoni onoyintshintha wena pha kucebiso ukuyenza ibeluncedo olukhulu kum njengesigulane?
25.	Ngawaphi amava onawo malunga nobucala nemfihlelo ngexesha leseshoni yengecebiso? <b>Buzisisa umbuzo ngamnye:</b> a) Ucinga abanye abantu babesiva? Ngoba? b) Ucinga abanye abantu babekubona? Ngoba? c) Wawuziva njani ngoku wawulinde ngaphandle kwegumbhi locebiso? Ngoba?
26.	a) Ekuqaleni kweseshoni yocebiso, wawuxelelwe ntoni malunga noba zingaphi iseshoni zocebiso oku mele ubenazo? b) Wawuxelelwe ukuba yintoni ezakuxoxwa kuzozonke eseshoni zocebiso, phambi kokuba uqale ucebiso?
27.	Yintoni eyakwenza ugqibe iseshoni zocebiso? Yintoni eyakwenza ugqibe iseshoni zocebiso ezi# endaweni yazozo4 iseshoni?

**E. Sample of interview guide for Semi-structured interview for the counsellors translated to isiXhosa**

iSampuli yolandelo lodliwano ndlebe lwesimiselo sodliwanondlebe sabacebisi.

**Interview guide will be available in English and Xhosa**


Inombolo yomthathi nxaxheba bhala inombolo	
Unexesha elingakanani usebenzisa lendlela yencebiso?	

<b>Imibuzo</b>	
1.	<p>Kwakunjani ukucebisa phambi kwale indlela intsha?</p> <p><b>Buzisisa umbuzo ngamnye:</b></p> <p>Yayinto elungiselelwe kakuhle?</p> <p>Umcebisi ngamnye wenze oku okanye into yakhe?</p> <p>Kwakukhona iforums okanye intlangano apho bekukuxoxwa okanye kusherishwe malunga nembono ?</p>
2.	Uziva njani malunga namabhinqa akhulelweyo aqala iARV's kutyelelo lokuqala ekliniki? Ngoba
3.	wayifumane kulula ukuyisebenzisa lemodel ? kungoba kutheni usitsho njalo?
3.	Yintoni engamandla kulemodel?
4.	<p>Zintoni ezinobunzima kulemodel?</p> <p><b>Buzisisa umbuzo ngamnye:</b></p> <p>a) ingaba ixesha lanele ukugqiba iseshoni? kutheni usitsho njalo?</p> <p>b) Ingaba likhona igumbi lemfihlelo? kutheni usitsho njalo?</p> <p>c) Ukwazile ukubhala yonke into ephepheni( kwifolder, kwisigwangciso sokuncekelela kunye neregister yengcebiso)?</p> <p>d) Ingaba usebenzisa isicwangciso soncekelela ipilisi kwizigulane zakho zonke?</p> <p>e) Uziva uzithembile ngokusebenziseni lemodel? Ngoba?</p> <p>f) Ingaba uyaku dinga ukufundiswa okanye ukuboniswa ?Ngoba</p>
	<p>Kutheni ucinga amanye amabhinqa enza iseshoni enye qha yocebiso?</p> <p>Ucinga ntoni ngoba kuthen amabhinqa engabuyeli uzogqiba iseshoni zocebiso?</p> <p>Ucinga zeziphi ingxaki ezichaphazela isigcwanciso sepilisi kumabhinqa akhulelweyo.</p> <p>Bakhe babekhona omama ababuyayo kucebiso emveni koba abantwana bezelwe? Ukuba Ewe, ibazintoni izidingo zabo? Ukuba Hayi, kutheni uncinga kunjalo?</p> <p>Amabhinqa ayazi njani ukuba kufuneka babuye nini kwiseshoni yocebiso?</p> <p>Loluphi ulwazi olunika ibhinqa elikhulelweyo malunga neseshoni zocebiso?</p>
5.	Zikuphendule njani izigulane kulemodel yengcebiso?
6.	Unayo imizekelo yezigulane ezithe zakubonisa ukuba banengenelo ngezingcebiso?
7.	Ucinga izigulane zidinga ntoni kuwe njengomcebisi?

8.	Uzama ukubanceda njani ngalomba?
9.	Ingaphuchulwa njani lemodel?

## Appendix 4: Ethics approval forms

### A. Ethical approval letter for primary study

 UNIVERSITY OF CAPE TOWN		HUMAN RESEARCH ETHICS COMMITTEE 24 JUN 2014		FACULTY OF HEALTH SCIENCES Human Research Ethics Committee	
<b>FHS017: Annual Progress Report / Renewal</b>					
Record Reviews/Audits/Collection of Biological Specimens/Repositories/Databases/Registries					
HREC office use only (FWA00001637; IRB00001938)					
This serves as notification of annual approval, including any documentation described below.					
<input checked="" type="checkbox"/> Approved	Annual progress report	Approved until/next renewal date	8.4.2015		
<input type="checkbox"/> Not approved	See attached comments				
Signature Chairperson of the HREC		Signed		Date Signed	26/6/2014
Principal Investigator to complete the following:					
<b>1. Protocol information</b>					
Date form submitted	5 May 2014				
HREC REF Number	395/2005	Current Ethics Approval was granted until	8/04/2014		
Protocol title	Enhanced routine surveillance of an HIV clinic population in Khayelitsha				
Principal Investigator	A/Professor Andrew Boule				
Department / Office Internal Mail Address	Centre for Infectious Disease Epidemiology & Research Level 5, Falmouth Building School of Public Health & Family Medicine, Faculty of Health Sciences Anzio Road, Observatory, 7925				
1.1 Does this protocol receive US Federal funding?				<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
<b>2. Protocol status (tick ✓)</b>					
<input checked="" type="checkbox"/>	Research-related activities are ongoing				
<input type="checkbox"/>	Data collection is complete, data analysis only				
<b>3. Protocol summary</b>					
Total number of records or specimens collected, reviewed or stored since the original approval					34 000
Total number of records or specimens collected, reviewed or stored since last progress report					4 000
Have any research-related outputs (e.g. publications, abstracts, conference presentations) resulted from this research? If yes, please list and attach with this report.	<input checked="" type="checkbox"/> Yes				<input type="checkbox"/> No

B. Ethical approval letter for this study

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

**Room E52-24 Old Main Building**  
**Groote Schuur Hospital**  
**Observatory 7925**

**Telephone [021] 406 6492 • Facsimile [021] 406 6411**

**Email: Sumayah.ariefdien@uct.ac.za**

**Website: [www.health.uct.ac.za/fhs/research/humanethics/forms](http://www.health.uct.ac.za/fhs/research/humanethics/forms)**



Human

**30 January 2015**

**HREC/REF: 046/2015**

**A/Prof A Boule**

Falmouth Building  
FHS

Dear A/Prof Boule

**Project Title: ENHANCED ROUTINE SURVEILLANCE OF AN HIV CLINIC POPULATION IN KHAYELITSHA (SUB-STUDY LINKED TO 395-2005) (Masters candidate- V Kirya)**

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

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

**Approval is granted for one year until the 30 January 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.

***We acknowledge that the following student:-Viola Kirya is also involved in this project.***

The Participant FAQ's and some answers document is excellent and the HREC love to consider placing this on our website if you agree.

Please note that the on-going ethical conduct of the study remains the responsibility of principal investigator.

**Please quote the HREC correspondence.**

Yours sincerely

REF in all your

Signed

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Level 5 Human the s would the C

**PROFESSOR M BLOCKMAN**

**CHAIRPERSON, HSF HUMAN ETHICS Hrec/ref:046/2015**

Federal Wide Assurance Number: FWA00001637.

Institutional Review Board (IRB) number: IRB00001938

This serves to confirm that the University of Cape Town 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) and Declaration of Helsinki guidelines.

The 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, and 312.

Pr 1 56 Hrec/ref:046/2015

## Appendix 5: PLoS One Journal Instructions to Authors

Available: <http://journals.plos.org/plosone/s/submission-guidelines>

### Submission Guidelines

#### Style and Format

**File format** Manuscript files can be in the following formats: DOC, DOCX, RTF, or PDF. Microsoft Word documents should not be locked or protected. LaTeX manuscripts must be submitted as PDFs. [Read the LaTeX guidelines.](#)

**Length** Manuscripts can be any length. There are no restrictions on word count, number of figures, or amount of supporting information. We encourage you to present and discuss your findings concisely.

**Font** Use any standard font and a standard font size.

**Headings** Limit manuscript sections and sub-sections to 3 heading levels. Make sure heading levels are clearly indicated in the manuscript text.

**Layout** Manuscript text should be double-spaced. Do not format text in multiple columns.

**Page and line number** Include page numbers and line numbers in the manuscript file.

**Footnotes** Footnotes are not permitted. If your manuscript contains footnotes, move the information into the main text or the reference list, depending on the content.

**Language** Manuscripts must be submitted in English. You may submit translations of the manuscript or abstract as supporting information. [Read the supporting information guidelines.](#)

**Abbreviations** Define abbreviations upon first appearance in the text. Do not use non-standard abbreviations unless they appear at least three times in the text. Keep abbreviations to a minimum.

**Reference style** PLOS uses “Vancouver” style, as outlined in the [ICMJE sample references](#). See [reference formatting examples and additional instructions below](#).

**Equations** We recommend using MathType for display and inline equations, as it will provide the most reliable outcome. If this is not possible, Equation Editor is acceptable. Avoid using MathType or Equation Editor to insert single variables (e.g., “ $a^2 + b^2 = c^2$ ”), Greek or other symbols (e.g.,  $\beta$ ,  $\Delta$ , or ' [prime]), or mathematical operators (e.g.,  $\times$ ,  $\geq$ , or  $\pm$ ) in running text. Wherever possible, insert single symbols as normal text with the correct Unicode (hex) values.



Do not use MathType or Equation Editor for only a portion of an equation. Rather, ensure that the entire equation is included. Avoid “hybrid” inline or display equations, in which part is text and part is MathType, or part is MathType and part is Equation Editor.

**Nomenclature** Use correct and established nomenclature wherever possible.

Units of measurement	Use SI units. If you do not use these exclusively, provide the SI value in parentheses after each value. <a href="#">Read more about SI units.</a>
Drugs	Provide the Recommended International Non-Proprietary Name (rINN).
Species names	Write in italics (e.g., <i>Homo sapiens</i> ). Write out in full the genus and species, both in the title of the manuscript and at the first mention of an organism in a paper. After first mention, the first letter of the genus name followed by the full species name may be used (e.g., <i>H. sapiens</i> ).
Genes, mutations, genotypes, and alleles	Write in italics. Use the recommended name by consulting the appropriate genetic nomenclature database (e.g., <a href="#">HUGO</a> for human genes). It is sometimes advisable to indicate the synonyms for the gene the first time it appears in the text. Gene prefixes such as those used for oncogenes or cellular localization should be shown in roman typeface (e.g., v-fes, c-MYC).

### **Manuscript Organization**

Manuscripts should be organized as follows. Instructions for each element appear below the list.

**Beginning section** The following elements are required, in order:

- Title page: List title, authors, and affiliations as first page of manuscript
- Abstract
- Introduction

**Middle section** The following elements can be renamed as needed and presented in any order:

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

**Ending section** The following elements are required, in order:

- Acknowledgments
- References
- Supporting information captions (if applicable)

## Other elements

Figure captions are inserted immediately after the first paragraph in which the figure is cited. Figure files are uploaded separately.  
Tables are inserted immediately after the first paragraph in which they are cited.  
Supporting information files are uploaded separately.

Please refer to our downloadable sample files to make sure that your submission meets our formatting requirements:

[Download sample title, author list, and affiliations page \(PDF\)](#)

[Download full manuscript sample \(PDF\)](#)

## Parts of a Submission

### Title

Include a full title and a short title for the manuscript.

Title	Length	Guidelines	Examples
<b>Full title</b>	250 characters	Specific, descriptive, concise, and comprehensible to readers outside the field	Impact of Cigarette Smoke Exposure on Innate Immunity: A Caenorhabditis elegans Model Solar Drinking Water Disinfection (SODIS) to Reduce Childhood Diarrhoea in Rural Bolivia: A Cluster-Randomized, Controlled Trial
<b>Short title</b>	50 characters	State the topic of the study	Cigarette Smoke Exposure and Innate Immunity SODIS and Childhood Diarrhoea

Titles should be written in title case (all words capitalized except articles, prepositions, and conjunctions). Avoid specialist abbreviations if possible. For clinical trials, systematic reviews, or meta-analyses, the subtitle should include the study design.

### Author list

#### Who belongs on the author list

All authors must meet the criteria for authorship as outlined in the authorship policy. [Read the policy](#). Those who contributed to the work but do not meet the criteria for authorship can be mentioned in the Acknowledgments. [Read more about Acknowledgments](#).

#### Author names and affiliations

Enter author names on the title page of the manuscript and in the online submission system.

On the title page, write author names in the following order:

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

Each author on the list must have an affiliation. The affiliation includes department, university, or organizational affiliation and its location, including city, state/province (if applicable), and country. If an author has multiple affiliations, enter all affiliations on the title page only. In the submission system, enter only the preferred or primary affiliation.

Author names will be published exactly as they appear in the manuscript file. Please double-check the information carefully to make sure it is correct.

#### Corresponding author

One corresponding author should be designated in the submission system as well as on the title page. One corresponding author should be designated in the submission system. However, this does not restrict the number of corresponding authors that may be listed on the article in the event of publication. Whoever is designated as a corresponding author on the title page of the manuscript file will be listed as such upon publication.

Include an email address for each corresponding author listed on the title page of the manuscript.

#### Consortia and group authorship

If a manuscript is submitted on behalf of a consortium or group, include the consortium or group name in the author list, and include the full list of members in the Acknowledgments or in a supporting information file.

The corresponding author is responsible for making sure all authors approve the final manuscript before submission. *PLOS ONE* will contact all authors by email at submission to ensure that they are aware of the submission

#### **Cover letter**

Upload a cover letter as a separate file in the online system. The length limit is 1 page.

The cover letter should include the following information:

- Summarize the study's contribution to the scientific literature
- Relate the study to previously published work
- Specify the type of article (for example, research article, systematic review, meta-analysis, clinical trial)
- Describe any prior interactions with PLOS regarding the submitted manuscript
- Suggest appropriate Academic Editors to handle your manuscript ([see the full list of Academic Editors](#))
- List any opposed reviewers

**IMPORTANT:** Do not include requests to reduce or waive publication fees in the cover letter. This information will be entered separately in the online submission system.

[Read about publication fee assistance.](#)

#### **Title page**

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

[Download sample title, author list, and affiliations page \(PDF\)](#)

#### **Abstract**

The Abstract comes after the title page in the manuscript file. The abstract text is also entered in a separate field in the submission system.

The Abstract should:

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

Abstracts should not include:

- Citations
- Abbreviations, if possible

## **Introduction**

The introduction should:

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

## **Materials and Methods**

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

We encourage authors to submit detailed protocols for newer or less well-established methods as supporting information. [Read the supporting information guidelines.](#)

### Human or animal subjects and/or tissue or field sampling

Methods sections describing research using human or animal subjects and/or tissue or field sampling must include required ethics statements. [See the reporting guidelines for human research, clinical trials, animal research, and observational and field studies for more information.](#)

### Data

PLOS journals require authors to make all data underlying the findings described in their manuscript fully available without restriction, with rare exception.

Large data sets, including raw data, may be deposited in an appropriate public repository. [See our list of recommended repositories.](#)

For smaller data sets and certain data types, authors may provide their data within [supporting information files](#) accompanying the manuscript. Authors should take care to maximize the accessibility and reusability of the data by selecting a file format from which data can be efficiently extracted (for example, spreadsheets or flat files should be provided rather than PDFs when providing tabulated data).

For more information on how best to provide data, read our [policy on data availability](#). PLOS does

not accept references to “data not shown.”

#### Cell lines

Methods sections describing research using cell lines must state the origin of the cell lines used. [See the reporting guidelines for cell line research for more information.](#)

#### New taxon names

Methods sections of manuscripts adding new taxon names to the literature must follow the [reporting guidelines below for a new zoological taxon, botanical taxon, or fungal taxon.](#)

### **Results, Discussion, Conclusions**

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

Together, these sections should describe the results of the experiments, the interpretation of these results, and the conclusions that can be drawn.

Authors should explain how the results relate to the hypothesis presented as the basis of the study and provide a succinct explanation of the implications of the findings, particularly in relation to previous related studies and potential future directions for research.

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

### **Copyediting manuscripts**

Prior to submission, authors who believe their manuscripts would benefit from professional editing are encouraged to use language-editing and copyediting services. Obtaining this service is the responsibility of the author, and should be done before initial submission. These services can be found on the web using search terms like “scientific editing service” or “manuscript editing service.”

*Submissions are not copyedited before publication.*

Submissions that do not meet the [PLOS ONE publication criterion for language standards](#) may be rejected.

### **Acknowledgments**

Those who contributed to the work but do not meet our authorship criteria should be listed in the Acknowledgments with a description of the contribution.

Authors are responsible for ensuring that anyone named in the Acknowledgments agrees to be named. Do not include funding sources in the Acknowledgments or anywhere else in the manuscript file. Funding information should only be entered in the financial disclosure section of the online submission system.

### **References**

Any and all available works can be cited in the reference list. Acceptable sources include:

- Published or accepted manuscripts
- Manuscripts on pre-print servers, if the manuscript is submitted to a journal and also

publicly available as a pre-print

Do not cite the following sources in the reference list:

- Unavailable and unpublished work, including manuscripts that have been submitted but not yet accepted (e.g., “unpublished work,” “data not shown”).
- Instead, include those data as supplementary material or deposit the data in a publicly available database.
- Personal communications (these should be supported by a letter from the relevant authors but not included in the reference list)

References are listed at the end of the manuscript and numbered in the order that they appear in the text. In the text, cite the reference number in square brackets (e.g., “We used the techniques developed by our colleagues [19] to analyze the data”). PLOS uses the numbered citation (citation-sequence) method and first six authors, et al.

Do not include citations in abstracts or author summaries.

Make sure the parts of the manuscript are in the correct order *before* ordering the citations.

### Formatting references

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

PLOS uses the reference style outlined by the International Committee of Medical Journal Editors (ICMJE), also referred to as the “Vancouver” style. Example formats are listed below. Additional examples are in the [ICMJE sample references](#).

A reference management tool, EndNote, offers a current [style file](#) that can assist you with the formatting of your references. If you have problems with any reference management program, please contact the source company's technical support.

Journal name abbreviations should be those found in the [National Center for Biotechnology Information \(NCBI\) databases](#).

Source	Format
<b>Published articles</b>	Hou WR, Hou YL, Wu GF, Song Y, Su XL, Sun B, et al. cDNA, genomic sequence cloning and overexpression of ribosomal protein gene L9 (rpL9) of the giant panda ( <i>Ailuropoda melanoleuca</i> ). Genet Mol Res. 2011;10: 1576-1588. Devaraju P, Gulati R, Antony PT, Mithun CB, Negi VS. Susceptibility to SLE in South Indian Tamils may be influenced by genetic selection pressure on TLR2 and TLR9 genes. Mol Immunol. 2014 Nov 22. pii: S0161-5890(14)00313-7. doi: 10.1016/j.molimm.2014.11.005  <i>Note: A DOI number for the full-text article is acceptable as an alternative to or in addition to traditional volume and page numbers.</i>
<b>Accepted,unpublished articles</b>	Same as published articles, but substitute “In press” for page numbers or DOI
<b>Web sites or online articles</b>	Huynen MMTE, Martens P, Hilderlink HBM. The health impacts of globalisation: a conceptual framework. Global Health. 2005;1: 14. Available: <a href="http://www.globalizationandhealth.com/content/1/1/14">http://www.globalizationandhealth.com/content/1/1/14</a> .
<b>Books</b>	Bates B. Bargaining for life: A social history of tuberculosis. 1st ed.

	Philadelphia: University
<b>Book chapters</b>	Hansen B. New York City epidemics and history for the public. In: Harden VA, Risse GB, editors. AIDS and the historian. Bethesda: National Institutes of Health; 1991. pp. 21-28.
<b>Deposited articles (preprints, e-prints, or arXiv)</b>	Krick T, Shub DA, Verstraete N, Ferreiro DU, Alonso LG, Shub M, et al. Amino acid metabolism conflicts with protein diversity; 1991. Preprint. Available: arXiv:1403.3301v1. Accessed 17 March 2014.
<b>Published media (print or online newspapers and magazine articles)</b>	Fountain H. For Already Vulnerable Penguins, Study Finds Climate Change Is Another Danger. The New York Times. 29 Jan 2014. Available: <a href="http://www.nytimes.com/2014/01/30/science/earth/climate-change-taking-toll-on-penguins-study-finds.html">http://www.nytimes.com/2014/01/30/science/earth/climate-change-taking-toll-on-penguins-study-finds.html</a> . Accessed 17 March 2014.
<b>New media (blogs, web sites, or other written works)</b>	Allen L. Announcing PLOS Blogs. 2010 Sep 1 [cited 17 March 2014]. In: PLOS Blogs [Internet]. San Francisco: PLOS 2006-. [about 2 screens]. Available: <a href="http://blogs.plos.org/plos/2010/09/announcing-plos-b">http://blogs.plos.org/plos/2010/09/announcing-plos-b</a>
<b>Masters' theses or doctoral dissertations</b>	Wells A. Exploring the development of the independent, electronic, scholarly journal. M.Sc. Thesis, The University of Sheffield. 1999. Available: <a href="http://cumincad.scix.net/cgi-bin/works/Show?2e09">http://cumincad.scix.net/cgi-bin/works/Show?2e09</a>
<b>Databases and repositories (Figshare, arXiv)</b>	Roberts SB. QPX Genome Browser Feature Tracks; 2013. Database: figshare [Internet]. Accessed: <a href="http://figshare.com/articles/QPX_Genome_Browser_Feature_Tracks/701214">http://figshare.com/articles/QPX_Genome_Browser_Feature_Tracks/701214</a>
<b>Multimedia (videos, movies, or TV shows)</b>	Hitchcock A, producer and director. Rear Window [Film]; 1954. Los Angeles: MGM

### Supporting Information

Authors can submit essential supporting files and multimedia files along with their manuscripts. All supporting information will be subject to peer review. All file types can be submitted, but files must be smaller than 10 MB in size.

Authors may use almost any description as the item name for a supporting information file as long as it contains an “S” and number. For example, “S1 Appendix” and “S2 Appendix,” “S1 Table” and “S2 Table,” and so forth.

Supporting information files are published exactly as provided, and are not copyedited.

#### Supporting information captions

List supporting information captions at the end of the manuscript file. Do not submit captions in a separate file.

The file number and name are required in a caption, and we highly recommend including a one-line title as well. You may also include a legend in your caption, but it is not required.

### Example caption

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

### In-text citations

We recommend that you cite supporting information in the manuscript text, but this is not a requirement. If you cite supporting information in the text, citations do not need to be in numerical order.

Read the [supporting information guidelines](#) for more details about submitting supporting information and multimedia files.

### **Figures and tables**

#### Figures

Do not include figures in the main manuscript file. Each figure must be prepared and submitted as an individual file.

Cite figures in ascending numeric order upon first appearance in the manuscript file.

[Read the guidelines for figures.](#)

#### Figure captions

Figure captions must be inserted in the text of the manuscript, immediately following the paragraph in which the figure is first cited (read order). Do not include captions as part of the figure files themselves or submit them in a separate document.

At a minimum, include the following in your figure captions:

A figure label with Arabic numerals, and “Figure” abbreviated to “Fig” (e.g. Fig 1, Fig 2, Fig 3, etc). Match the label of your figure with the name of the file uploaded at submission (e.g. a figure citation of “Fig 1” must refer to a figure file named “Fig1.tif”).

A concise, descriptive title

The caption may also include a legend as needed.

[Read more about figure captions.](#)

#### Tables

Cite tables in ascending numeric order upon first appearance in the manuscript file.

Place each table in your manuscript file directly after the paragraph in which it is first cited (read order). Do not submit your tables in separate files.

Tables require a label (e.g., “Table 1”) and brief descriptive title to be placed above the table. Place legends, footnotes, and other text below the table.

[Read the guidelines for tables.](#)

### **Data reporting**

All data and related metadata underlying the findings reported in a submitted manuscript should be deposited in an appropriate public repository, unless already provided as part of the submitted article.

[Read our policy on data availability.](#)

Repositories may be either subject-specific (where these exist) and accept specific types of structured data, or generalist repositories that accept multiple data types. We recommend that authors select repositories appropriate to their field. Repositories may be subject-specific (e.g., GenBank for sequences and PDB for structures), general, or institutional, as long as DOIs or accession numbers are provided and the data are at least as open as CC BY. Authors are encouraged to select repositories that meet accepted criteria as trustworthy digital repositories, such as criteria of the Centre for Research Libraries or Data Seal of Approval. Large, international databases are more likely to persist than small, local ones.

[See our list of recommended repositories.](#)

To support data sharing and author compliance of the PLOS data policy, we have integrated our



submission process with a select set of data repositories. The list is neither representative nor exhaustive of the suitable repositories available to authors. Current repository integration partners include [Dryad](#) and [FlowRepository](#). Please contact [data@plos.org](mailto:data@plos.org) to make recommendations for further partnerships.

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

- Deposit data in the integrated repository of choice.
- Once deposition is final and complete, the repository will provide you with a dataset DOI (provisional) and private URL for reviewers to gain access to the data.
- Enter the given data DOI into the full Data Availability Statement, which is requested in the Additional Information section of the PLOS submission form. Then provide the URL passcode in the Attach Files section.

If you have any questions, please [email us](#).

### **Accession numbers**

All appropriate data sets, images, and information should be deposited in an appropriate public repository. [See our list of recommended repositories](#).

Accession numbers (and version numbers, if appropriate) should be provided in the Data Availability Statement. Accession numbers or a citation to the DOI should also be provided when the data set is mentioned within the manuscript.

In some cases authors may not be able to obtain accession numbers of DOIs until the manuscript is accepted; in these cases, the authors must provide these numbers at acceptance. In all other cases, these numbers must be provided at submission.

### Identifiers

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

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

Identifiers should be provided in parentheses after the entity on first use.

### **Striking image**

You can choose to upload a “Striking Image” that we may use to represent your article online in places like the journal homepage or in search results.

The striking image must be derived from a figure or supporting information file from the submission, i.e., a cropped portion of an image or the entire image. Striking images should ideally be high resolution, eye-catching, single panel images, and should ideally avoid containing added details such as text, scale bars, and arrows.

If no striking image is uploaded, we will designate a figure from the submission as the striking image. Striking images should not contain potentially identifying images of people. [Read our policy on identifying information](#).

The PLOS content license also applies to striking images. [Read more about the content license](#).

## **Additional Information Requested at Submission**

### **Funding statement**

This information should not be in your manuscript file; you will provide it via our submission system. This information will be published with the final manuscript, if accepted, so please make sure that this is accurate and as detailed as possible. You should not include this information in your manuscript file, but it is important to gather it prior to submission, because your financial disclosure statement cannot be changed after initial submission.

Your statement should include relevant grant numbers and the URL of any funder's web site. Please also state whether any individuals employed or contracted by the funders (other than the named authors) played any role in: study design, data collection and analysis, decision to publish, or preparation of the manuscript. If so, please name the individual and describe their role.

[Read our policy on disclosure of funding sources.](#)

### **Competing interests**

This information should not be in your manuscript file; you will provide it via our submission system. All potential competing interests must be declared in full. If the submission is related to any patents, patent applications, or products in development or for market, these details, including patent numbers and titles, must be disclosed in full.

[Read our policy on competing interests.](#)

### **Manuscripts disputing published work**

For manuscripts disputing previously published work, it is *PLOS ONE* policy to invite input from the disputed author during the peer review process. This procedure is aimed at ensuring a thorough, transparent, and productive review process.

If the disputed author chooses to submit a review, it must be returned in a timely fashion and contain a full declaration of all competing interests. The Academic Editor will consider any such reviews in light of the competing interest.

Authors submitting manuscripts disputing previous work should explain the relationship between the manuscripts in their cover letter, and will be required to confirm that they accept the conditions of this review policy before the manuscript is considered further.

### **Related manuscripts**

Upon submission, authors must confirm that the manuscript, or any related manuscript, is not currently under consideration or accepted elsewhere. If related work has been submitted to *PLOS ONE* or elsewhere, authors must include a copy with the submitted article. Reviewers will be asked to comment on the overlap between related submissions.

We strongly discourage the unnecessary division of related work into separate manuscripts, and we will not consider manuscripts that are divided into “parts.” Each submission to *PLOS ONE* must be written as an independent unit and should not rely on any work that has not already been accepted for publication. If related manuscripts are submitted to *PLOS ONE*, the authors may be advised to combine them into a single manuscript at the editor's discretion.

## **Guidelines for Specific Study Types**

### **Human subjects research**

All research involving human participants must have been approved by the authors' Institutional Review Board (IRB) or by equivalent ethics committee(s), and must have been conducted according to the principles expressed in the [Declaration of Helsinki](#). Authors should be able to submit, upon request, a statement from the IRB or ethics committee indicating approval of the research. We reserve

the right to reject work that we believe has not been conducted to a high ethical standard, even when formal approval has been obtained.

Subjects must have been properly instructed and have indicated that they consent to participate by signing the appropriate informed consent paperwork. Authors may be asked to submit a blank, sample copy of a subject consent form. If consent was verbal instead of written, or if consent could not be obtained, the authors must explain the reason in the manuscript, and the use of verbal consent or the lack of consent must have been approved by the IRB or ethics committee.

All efforts should be made to protect patient privacy and anonymity. Identifying information, including photos, should not be included in the manuscript unless the information is crucial and the individual has provided written consent by completing the [Consent Form for Publication in a PLOS Journal \(PDF\)](#). More information about patient privacy, anonymity, and informed consent can be found in the [International Committee of Medical Journal Editors \(ICMJE\) Privacy and Confidentiality guidelines](#).

Manuscripts should conform to the following reporting guidelines:

- Studies of diagnostic accuracy: [STARD](#)
- Observational studies: [STROBE](#)
- Microarray experiments: [MIAME](#)
- Other types of health-related research: Consult the [EQUATOR](#) web site for appropriate reporting guidelines

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

**The name of the approving institutional review board or equivalent committee(s).** If approval was not obtained, the authors must provide a detailed statement explaining why it was not needed

**Whether informed consent was written or oral.** If informed consent was oral, it must be stated in the manuscript:

- Why written consent could not be obtained
- That the Institutional Review Board (IRB) approved use of oral consent
- How oral consent was documented

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

- Explicitly describe their methods of categorizing human populations
- Define categories in as much detail as the study protocol allows
- Justify their choices of definitions and categories, including for example whether any rules of human categorization were required by their funding agency
- Explain whether (and if so, how) they controlled for confounding variables such as socioeconomic status, nutrition, environmental exposures, or similar factors in their analysis

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

For papers that include identifying, or potentially identifying, information, authors must download the [Consent Form for Publication in a PLOS Journal \(PDF\)](#), which the individual, parent, or guardian must sign once they have read the paper and been informed about the terms of PLOS open-access

license. The signed consent form should not be submitted with the manuscript, but authors should securely file it in the individual's case notes and the methods section of the manuscript should explicitly state that consent authorization for publication is on file, using wording like:

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

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Qualitative research studies use non-quantitative methods to address a defined research question that may not be accessible by quantitative methods, such as people's interpretations, experiences, and perspectives. The analysis methods are explicit, systematic, and reproducible, but the results do not involve numerical values or use statistics. Examples of qualitative data sources include, but are not limited to, interviews, text documents, audio/video recordings, and free-form answers to questionnaires and surveys.

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