

**PREVALENCE AND RISK FACTORS ASSOCIATED WITH PREGNANCY INDUCED AND
POSTPARTUM HYPERTENSION AMONG OBESE WOMEN LIVING WITH HIV IN CAPE
TOWN, SOUTH AFRICA.**

NTHABISENG PHOHLO

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Master of Public Health (Epidemiology and Biostatistics)

Faculty of Health Science

School of Public Health and Family Medicine

UNIVERSITY OF CAPE TOWN

Supervisor: Doctor Hlengiwe Madlala

Faculty of Health Science

School of Public Health and Family Medicine

University of Cape Town

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PREAMBLE

DECLARATION

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Abstract

Aim: To find prevalence of pregnancy induced hypertension (PIH) and postpartum hypertension (PPH) in obese pregnant women living with HIV (WLHIV) and to identify risk factors associated with both PIH and PPH in pregnant WLHIV in Cape Town South Africa.

Background: In accordance with global hypertension practice guidelines, hypertension is defined as having systolic blood pressure ≥ 140 mm Hg and diastolic blood pressure ≥ 90 mm Hg in an office or clinic setting following repeated examination. Hypertension is one of the leading causes of morbidity and mortality in the world and it is a risk factor for many non-communicable diseases, particularly cardiovascular disease. In South Africa, management of hypertension remains suboptimal due to insufficient healthcare utilities. Roughly 8.22 million adult South Africans who do not have private insurance have hypertension and the direct healthcare costs associated with hypertension were projected to be around 10.1 billion. Consequently, proactive interventions need to be reinforced in order to combat this growing epidemic and factors associated with it need to be well defined. Coupled with escalating trends of obesity and high prevalence of HIV, hypertension poses more threat to South African health system. Globally, obesity has increased since 1975 to 2016 from 3% to 11% among men, from 6% to 15% among women and from less than 1% to 8% in children. Conversely in South Africa, prevalence of obesity in adult men and women was 9% and 27% in 2003. Additionally, about 21.7% of women of child bearing age are living with HIV. More research is therefore required in order to inform relevant stakeholders to incorporate effective measures that can control and prevent this disease.

Methods: A retrospective cohort study that used secondary data from previous studies was carried out. This data was for pregnant WLHIV, who presented themselves at Gugulethu community health facility from 2013 to 2018. The data was merged for analysis of hypertensive disorders of pregnancy (HDP) in association with body mass Index (BMI) and antiretroviral therapy (ART) initiation time. Women who were included in the study were those who were on ART before pregnancy (preconception) and those who initiated ART during pregnancy (post conception). Other risk factors associated with PIH and PPH were also determined. Hypertension was classified according to American

hypertension guidelines. Descriptive analysis of the whole sample included 1859 WLHIV, 752 WLHIV of these were included in the sub-analysis of PPH. Analytical analysis was done by multinomial ordinal proportional logistic regression because the outcome had four ordered levels (normal, high-normal, grade1 and grade2). This analysis was done using R programming version 4.2.2.

Ethical statement: Ethics approval was obtained from Human Research Ethics committee, Faculty of Health Sciences, University of Cape Town. Informed consent for parent studies, where data was collected from was obtained from the participants. In this study, no informed consent from the participants was required as these were already obtained from the parent studies.

Results: Overall PIH prevalence was 67.7 cases per 1000 population. Prevalence of PIH was 67.7 cases per 1000 population stratified by ART initiation timing (42% preconception and 58% post-conception) and 67.9 cases per 1000 population stratified by BMI (a proportion of obese women was 67%). Conversely, PIH prevalence in obese women was 43 cases per 1000 population in the overall sample. Association between PIH and ART initiation timing (preconception) was OR; 0.76, 95% CI; 0.59 to 0.97, with p-value of 0.03. Association between PIH and BMI in obese women was; OR; 3.49, 95% CI; 2.42 to 5.15, p-values; <0.001. Overall PPH prevalence was 155 cases per 1000 population. PPH prevalence was 155 cases per 1000 population stratified by ART initiation timing (44% preconception and 56% post-conception) and 158.6 cases per 1000 population stratified by BMI (a proportion of 64% was obese women). Overall PPH prevalence in obese women was 101 cases per 1000 population. ART initiation timing (preconception) and PPH association was (OR; 0.67, 95% CI; 0.47 to 0.95), p-value; 0.03. BMI and PPH association in obese women was; (OR; 2.41, 95% CI; 1.51 to 3.96), p-value; < 0.001. Obesity, old age (≥ 35) and late booking at antenatal clinic were risk factors that showed a positive association with hypertension, with ORs; 3.49, 2.21 and 1.56 respectively.

Conclusions: There is significantly high prevalence of PIH and PPH in women living with HIV in Cape Town. Obesity is the major risk factor for PIH and PPH. ART initiation timing (preconception) was negatively associated with PIH and PPH. Effective measures to manage and prevent hypertension in pregnant WLHIV need to be implemented to prevent PIH and PPH. Pregnant WLHIV need to be monitored for hypertension, particularly those above 35 years and those who are obese. Early booking at antenatal care should be encouraged to facilitate early monitoring of PIH.

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LIST OF ABBREVIATIONS

ANC	Anti-natal Care
ART	Anti-Retro viral Treatment
BMI	Body Mass Index
BMJ	British Medical Journal
BP	Blood pressure
CI	Confidence Interval
HDP	Hypertensive Disorders of Pregnancy
HIV	Human Immunodeficiency Virus
OR	Odds Ratio
PIH	Pregnancy-induced Hypertension
PLHIV	People Living with HIV
PPH	Post-partum hypertension
WLHIV	Women Living with HIV

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PART A: RESEARCH PROTOCOL

1. INTRODUCTION

According to global hypertension practice guidelines, hypertension is defined as having systolic blood pressure ≥ 140 mm Hg and diastolic blood pressure ≥ 90 mm Hg in an office or clinic setting, following repeated examination [1]. Hypertensive disorders of pregnancy (HDP) are considered to be presence of hypertension during pregnancy, either chronic hypertension or hypertension that develops at 20 weeks of pregnancy [2, 3]. Globally, HDP has incidence rate of approximately 10% [2]. In a review study carried out by Gemechu et al., pooled prevalence of HDP in Sub-Saharan Africa was 8% [4]. HDP proliferate risks associated with cardiovascular diseases (CVDs), stroke, postpartum chronic kidney disease, adverse birth outcomes, maternal and neonatal mortality. HDP contribute 14% of maternal deaths in the world and 16% in Sub-Saharan Africa [5]. In South Africa, HDP contributed to 18% of maternal deaths [6].

Excluding chronic hypertension in pregnancy, HDP or pregnancy induced hypertension (PIH), can be categorized into four types, preeclampsia, eclampsia, gestational hypertension and other forms of hypertension [7]. Gestational hypertension does not result in adverse birth outcomes in pregnancy, but it can develop into preeclampsia, which can lead to poor pregnancy outcomes. Preeclampsia is characterized by high levels of protein in the urine, onset of hypertension during pregnancy, poor placental perfusion in pregnant women and foetal growth restriction [2]. There is trophoblast invasion dysregulation resulting in reduction of blood flow. The placenta then releases pro-inflammatory factors which release excess oxygen factors in the blood. The whole process causes preeclampsia [8]. Annually, more than 500 000 foetal and neonatal deaths and 70 000 maternal deaths are caused by this condition [2]. Preeclampsia can further cause eclampsia, which is defined as development of seizures in people who already have preeclampsia [9]. Pregnancy outcomes of these conditions include pre-term labour, postpartum haemorrhage and abruption placenta [10]. Preeclampsia can further complicate pregnancy by damaging the liver and kidney functionality [7].

There are several risk factors associated with hypertension, including age and body weight amongst other factors. The association between body weight and hypertension has been recognized since 20th century when hypertension was first measured in a population. Later on, it was discovered that obesity is the major risk factor for hypertension [11]. Globally, obesity has increased since 1975 to 2016 from 3% to 11% among men, from 6% to 15% among women and from less than 1 % to 8 % in children [12]. South African public report published in 2019 revealed that about 41% of women and 11% of men aged 15 years and above were obese [13]. This becomes a concern with regard to prevalence of NCDs in the world today, especially in developing countries, where there is high prevalence of HIV.

Since obesity is a major risk factor of hypertension, these trends of obesity pose a public health threat to hypertension prevalence. Estimates from the Nurses' Health study indicate that worldwide, obesity was responsible for 40% of hypertension from 2001 to 2016 [14]. Conversely, a Framingham study showed that obesity was responsible for 78% of hypertension in men and 65% in women [15]. In the African continent, association between obesity and hypertension is still poorly characterized, nevertheless, a positive association between the two is still observed and the association strengthens with age [16]. Body mass index (BMI) is an index of weight for height and is commonly used to classify adults into different weight categories. It is defined as weight in kilograms divided by the square of height (Kg/m^2) [17]. Underweight is defined as BMI less than 18.5 Kg/m^2 , normal BMI ranges from 18.5 to 24.9 Kg/m^2 , overweight as 25 to 29.9 Kg/m^2 and obese as BMI Over 30 kg/m^2 . Increasing evidence suggests that over the years women of child-bearing age have an escalating trend in BMI [18], this increase in BMI could be problematic with regard to maternal mortality and morbidity. In a study carried out by Madhi et al. [19], it was revealed that in SSA countries with high obesity trends among women of child-bearing age, there was low fertility in comparison to countries with lower trends of obesity and overweight. Furthermore, these countries with high obesity trends also had higher mortality and morbidity rate.

Maternal mortality is one of the major public health threat worldwide, factors that increase the risk of maternal mortality include PIH, sepsis, unsafe abortion, severe anaemia and infections. [20], these account for approximately 70% of maternal deaths [21]. In addition, obese women have higher chances of death when they have CVDs, HDP and stroke in comparison to women with normal body weight [22].

HDP can be difficult to treat and it is important to manage it even though its etiology has not been fully explained [17]. Furthermore, HDP is also a major cause of fetal and neonatal mortality and morbidity [23]. Birth weight is an important indicator of a child's development and future health status, [24], it is associated with cognitive and neurological development of a child and these can have an impact on social and economic status in societies [25]. Among other factors like maternal age, maternal nutrition, multiple pregnancies and socio-economic status, HDP is a cause of low birth weight [25]. Globally, approximately 20 million children are born with low birth weight and this represents 15.5% of total births [26] and 96% of these children are born in developing countries [26]. In South Africa, neonatal mortality rate was 12 per 1000 births in 2017 and maternal hypertension was reported to be among factors that contributed to the mortality rate [27]. In a study carried out in South Africa, in Soweto between 2014 and 2015, it was discovered that among 350 women, 133 of them developed hypertension and 19% of these experienced still births [19]. Consequently, it is important to monitor pregnant women with HDP as they are likely to encounter complications during pregnancy as well as during delivery [10].

Globally, approximately two million HIV positive women become pregnant each year, majority of whom reside in SSA [28]. In South Africa, about 21.7 % of women of child bearing age are living with HIV [29]. As a results, South Africa is facing high prevalence of communicable and non-communicable diseases, particularly in this age group. It is not clear whether high burden of HIV has any association with high burden of NCDs, particularly CVDs [30], more research is still required. In earlier years, HIV was associated with wasting but with the introduction of antiretroviral therapy (ART), people living with HIV are now faced with obesity challenge [31], a risk factor for many NCDs including hypertension. In a cohort study conducted in South Africa [32], it was discovered that patients who were initiated on ART without hypertension had incidence rate of 5.4 per 100 person years of developing hypertension. It is also important to discover if ART initiation timing in pregnant women (before conception or after conception) has any association with HDP. In a study carried out in Zambia, Lusaka, it was discovered that WLHIV who were on ART had higher risk of PIH compared to women not receiving ART treatment. However, time of ART initiation was found not to have any association with hypertension development [33]. In addition, in a systematic review carried out by Premkumer et al. it was discovered that women living with HIV (WLHIV) who were on ART had higher risk developing HDP compared to women who were not on ART, timing of ART initiation was not considered in this study [34]. It was also discovered that people with higher BMI were more at risk of developing hypertension compared to people with lower BMI.

The impact that HIV has on HDP is not well established. It is important to study this association because HIV and preeclampsia are both inflammatory diseases and have common side effects like thrombocytopenia and elevated liver enzymes [35]. The mechanism that results in symptomatic clinical disease of HIV is poorly understood, the inflammatory changes associated with this condition are believed to arise from HIV trans-activator of transcription protein, this triggers inflammatory pathway to release cytokines and other adhesion molecules. Viral membrane stimulates production of proinflammatory mediators which target endothelial cells, causing a dysfunction of these cells hence inflammation [36]. The high burden of HIV in Sub Saharan Africa further makes it essential to study the association between HIV and PIH. Also, both diseases are leading causes of death in Sub Saharan Africa [37]. In normal pregnancy, maternal immune system reacts in a way that leads to protection of the fetus, however in the presence of preeclampsia, maternal immune response rejects the fetus. Contrariwise, in HIV infected mothers, immune response is suppressed hence a neutralizing immune response is expected, however, the effectiveness of ART predisposes HIV positive mothers to preeclampsia like HIV negative mothers [38].

Some women who develop PIH continue to have the condition postpartum. It is therefore essential to monitor women for PPH in order to further manage it and reduce the risk of CVDs postpartum [37]. In

a study conducted in Denmark for postpartum hypertension, it was discovered that a decade after first pregnancy, women who developed HDP were more likely to develop PPH than women who did not develop hypertension during pregnancy [39]. The risk of postpartum hypertension is further associated with the risk of CVDs and stroke [39]. Moreover, women who develop hypertension during pregnancy are at higher risk of developing other NCDs in later stages of life, these NCDs include diabetes mellitus and kidney disease [40], hence the importance of monitoring women for postpartum hypertension. In another retrospective cohort study carried out in South Africa, it was discovered that women less than 20 years and women greater than 35 years contributed higher percentage of maternal death caused by hypertension. In this study, it was discovered that out of 47 maternal deaths of women under the age of 20, 18 of them died postpartum [41]. This study also revealed that teenage pregnancy is a risk factor for hypertension hence CVDs and other related NCDs later in the life of affected women. Despite the influence of hypertension on adverse maternal and infant health, there is limited data on the burden of this condition in pregnancy and postpartum in a setting of high HIV and obesity prevalence.

Rationale: Hypertensive disorders of pregnancy are among the leading causes of poor pregnancy outcomes and they further contribute to high mortality and morbidity in the world. Increasing trends of obesity pose a threat to women of child bearing age as obesity is a well-known risk factor for hypertension. Additionally, pregnancy increases the risk of development of hypertension as women are likely to gain weight during this time. Moreover, PIH increases the risk of PPH. Women face the highest burden of HIV, with introduction of ART, PLHIV do not face wasting anymore, instead, like general population, they are faced with obesity challenge. Since the recent trend of coexistence of HIV and obesity, the influence of these on the burden of PIH is not well understood. This study aims to examine prevalence of PIH and PPH and the risk factors associated in pregnant WLHIV, who are on ART.

2. AIMS AND OBJECTIVES

2.1 Aim

The aim of this study is to find prevalence of pregnancy induced hypertension and postpartum hypertension in obese pregnant women living with HIV and to identify risk factors associated with both PIH and PPH in pregnant WLHIV in Cape Town South Africa.

2.2 Objectives

- To describe the prevalence of hypertension in pregnancy and during the postpartum period in the Overall sample
- To describe the prevalence of hypertension in pregnancy and during the postpartum period by ART initiation timing and BMI status
- To examine the risks factors associated with hypertension

3. METHODOLOGY

3.1 Study design

A retrospective cohort study about pregnant women living in Cape Town, South Africa will be carried out, the women were recruited from Gugulethu community health centre. The women will be followed retrospectively throughout their pregnancy and postpartum to monitor if they developed hypertension during their pregnancy and postpartum. This study will use a combination of four different study cohorts' data for pregnant women who received antenatal care at Gugulethu community health centre.

The first parental study that will be included is a prospective cohort study entitled: "Maternal and Child Health-Antiretroviral Therapy (MCH-ART) study". The aim of this study was to examine the strategies for providing HIV care and treatment to HIV-infected women who initiate ART during pregnancy and their HIV-exposed infants. This study includes women who were enrolled between March 2013 and August 2015. A total of 1116 women were included, 529 of these women were HIV negative and 587 were WLHIV. For the purpose of this study, data for WLHIV from first antenatal visit to 12 months postpartum in this study will be used.

The second parental study is entitled: “The Prematurity Immunology in HIV-infected Mothers and their infants Study (PIMS)”. The overall aim of the parent study was to quantify the association between ART use in pregnancy and adverse birth outcomes in Cape Town, South Africa. A total of 3 254 pregnant women aged 18 years and above were enrolled into the parent study between April 2015 and October 2016. A subset of 550 women who booked early (≤ 24 weeks) were enrolled into the prospective cohort and they were prospectively followed via face-to-face study visits at Gugulethu community health centre. Similar to the first parental study, data from this study will be used in the proposed study from first ANC visit to 12 months postpartum.

The third parental study is entitled “Expanded ART access in pregnancy under Option B+ policy (BPositive)’. The aim of this study was to assess ART access during pregnancy at a population level and its impact on birth outcomes in South Africa. In this prospective cohort study, 479 WLHIV and 510 HIV uninfected women were enrolled between January 2017 and July 2018 at Gugulethu community health centre. This study will provide data for WLHIV about PIH in pregnant women at specified period of time, but it will not provide any data on these women postpartum since they were followed up until delivery.

The fourth parental study is ‘Cardio-metabolic complications in pregnancy’ (CAMP). The aim of this parental study was to evaluate the burden and impact of NCDs in pregnancy and NCD outcomes in women and children through 6 months postpartum and to examine if investigated associations differ by HIV status. 400 pregnant women were recruited, 200 HIV negative women and 200 WLHIV from the Gugulethu community health centre in Cape Town, South Africa. Data for these women was abstracted from their first ANC visit until 6 months postpartum. In this study, data for 200 WLHIV will be used to describe PIH and postpartum hypertension. Combining all these four observational cohort studies, a total of 1859 pregnant WLHIV will be included in this prospective study. These women were enrolled in different studies between March 2013 and July 2018.

3.2 Study setting

As mentioned from parental studies, participants in this study will be from Gugulethu community health centre. In 2011, population of Gugulethu was approximately 98 468, of this, 51% were women

[42]. This is a community health facility that offers primary healthcare services like child health, antiretroviral services, basic antenatal care, family planning, general HIV care and STI assessment and treatment. This health facility is located at an area where majority of the residents are of low socioeconomic status and about 60% of the residents live in informal housing. About 360 000 population is served by this facility and about 4800 women receive antenatal services at this facility [43]. Patients from this facility are referred to secondary and tertiary hospitals nearby for more advanced health services.

3.3 Study population

Women who were enrolled in four parental studies between 2013 and 2018 at Gugulethu community health centre will be included in this study. These will be pregnant women who presented at health facility during this period up until delivery, at 6 months postpartum and at 12 months postpartum.

The first parental study had a total of 1116 pregnant women, the exposure of interest was blood pressure at first ANC visit. Other exposures were pre-pregnancy BMI and HIV. The association between Blood pressure at enrolment, pre-pregnancy BMI and HIV status were analyzed. The association of blood pressure at first ANC visit and HIV exposures with birth outcomes were analyzed. The birth outcomes of interest were caesarian, low birth weight, pre-term delivery, small for gestational age and large for gestational age. From this cohort, prevalence of pregnancy induced hypertension in WLHIV will be determined. Postpartum hypertension sub analysis on subset of women will be performed.

In the second parental study, 505 WLHIV were enrolled. The exposure of interest was the point of ART initiation, pre pregnancy or during pregnancy. Association of the ART exposure categories with neurodevelopment outcome was determined. From this cohort study, the participants will be included in the proposed study to determine PIH and postpartum hypertension.

The third parental study enrolled 989 pregnant women, 479 WLHIV and 510 HIV uninfected women. Exposures of interest were dietary intake and HIV and the outcomes of interest were maternal obesity and gestational weight gain. Only WLHIV will be included in the prospective study.

The fourth parental study includes 400 pregnant women, 200 WLHIV and 200 HIV uninfected women. In this study prevalence of Non-communicable diseases in pregnancy and postpartum, stratified by HIV status was evaluated. Data of 200 WLHIV will be used to assess prevalence of PIH and postpartum hypertension.

3.4 Evaluation questions

- Does timing of ART initiation have an impact on development of PIH?
- Does BMI have any impact on development of PIH and PPH?
- What are the risk factors associated with development of PIH and PPH?

3.5 Exclusion and Inclusion criteria

3.5.1 Inclusion criteria

- ≥ 18 years pregnant women
- Known HIV status
- Reside in Cape Town
- Singleton birth
- Received health services at Gugulethu community health center during the study period.

3.5.2 Exclusion criteria

- Not pregnant at the time of the start of the study
- Twin birth
- Unknown HIV status

- Not initiated ART before or during pregnancy

3.6 Data collection

3.6.1 Exposures of interest

Maternal BMI and ART initiation timing status are the major exposures of interest in the proposed study. In the parental studies, BMI at enrolment was calculated from weight and height measured at enrolment. Pre-pregnancy weight was estimated by using an international gestational weight gain standard. This involves subtraction of gestational median weight gained per week based on weight measured at enrolment. Pre-pregnancy BMI was then estimated from this weight. Pre-pregnancy BMI was categorized into the following categories according to WHO weight classification;

Underweight (<18.5)

Normal weight (18.5–24.9)

Overweight (25–29.9)

Obese (≥ 30)

In parental studies, HIV and ART status together with other demographic information were collected at enrolment into ANC services from medical records. Gestational age at first ANC visit was obtained by ultrasound, last menstrual period or fundal height depending on the time that women presented themselves for ANC services. Socioeconomic status was determined from a composite socioeconomic score developed based on employment status, housing type and other factors. This was categorized into the following levels;

High

Medium

Low

ART timing will be categorized as;

Preconception and Post-conception

3.6.2 Outcomes of interest

Primary outcomes of interest are PIH and PPH.

Normal hypertension is regarded as systolic blood pressure less than 130 mmHg and diastolic blood pressure less than 85 mmHg and normal-high hypertension is defined as systolic blood pressure between 130 and 139 mmHg and diastolic blood pressure between 85 and 89 mmHg. Grade 1 hypertension is systolic blood pressure between 140 and 159 mmHg and diastolic blood pressure between 90 and 99 mmHg. Grade 2 hypertension is systolic blood pressure above 160 and diastolic blood pressure above 160 mmHg [1]. From parental studies, blood pressure was measured at first ANC visit and during preceding visits. An automated blood pressure reading was taken on seated women using a general use Edan M3A Vital Signs Monitor. Patients with higher blood pressure were relaxed and a repeat blood pressure measure was taken in the right lateral position with the appropriate sized cuff and auscultation of the 4th Korotkoff sound for the diastolic reading. Blood pressure readings were abstracted from medical records into study abstraction form. From the three visits, three blood pressure readings were used to calculate final individual blood pressure used in this study. This was done by taking the highest recorded reading of systolic and diastolic blood pressure. Hypertension was classified according to American Hypertension guidelines. Table 1 below shows all the exposures and outcomes that will be included in this study.

Table 1: Outcome and exposure variables to be included in the study

Variable	Scale	Categories
Age (years)	Numerical (Continuous)	-
Gravidity	Numerical (Continuous)	-
BMI (Kg/m ²)	Categorical (Ordinal)	Underweight
		Normal weight
		Overweight
		Obese
ART initiation timing	Categorical (binary)	Preconception
		Postconception
Socio-economic status	Categorical (Ordinal)	Low
		Middle
		High
Pregnancy-induced hypertension	Categorical (Ordinal)	Normal
		Normal-high
		Grade 1
		Grade 2
Postpartum hypertension	Categorical (Ordinal)	Normal
		Normal-high
		Grade 1
		Grade 2
Gestational age at first visit (weeks) Categories	Cartegorical (Odinal)	1 st trimester
		2 nd trimester
		3 rd trimester
Gestational age at first visit (weeks)	Numerical (Continuous)	-
Employment status	Categorical (binary)	Yes
		No
Pregnancy systolic blood pressure	Numerical (continuous)	-
Pregnancy diastolic blood pressure	Numerical (continuous)	-
Postpartum systolic blood pressure	Numerical (continuous)	-

Postpartum diastolic blood pressure	Numerical (continuous)	-
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3.7 Data management and analysis plan

3.7.1 Data safety

A database will be created in Microsoft access to capture all the required data from parental studies. This data will be password protected to limit access by non-study personnel. Confidentiality of the participants will not be compromised since Identification numbers will be used instead of the names. To ensure that the data is not lost, a daily back up will be enabled.

3.7.2 Data analysis

Data analysis will be performed using R version 3.3.3. Continuous variables will be summarized using mean (standard deviation) or median (interquartile range). On the other hand, categorical variables will be summarized using proportions.

Proportional (ordinal) odds regression model will be used to determine the association between hypertension and BMI and ART initiation timing. To determine other risk factors associated with hypertension, the proportional odds regression will be used.

Overall prevalence of hypertension will be determined by counting all hypertension cases and this will be reported as hypertension cases per 1 000 population. Similarly, prevalence of hypertension stratified by ART status and BMI will be determined by calculating cases within each strata and these will be reported as hypertension cases per 1000 population. P-value less than 0.05 will be considered significant and 95% confidence interval (CI) will be used to determine precision of the results.

4. ETHICAL CONSIDERATIONS

The parent studies were approved by Ethics Committees of the faculty of health science, University of Cape Town. Similarly, for this study, ethical approval will be obtained from Ethics Committees of the faculty of health science, University of Cape Town.

4.1 Informed consent

Informed consent for parent studies, where data was collected from participants was obtained from the participants. In this study, no informed consent from the participants will not be required as these were already obtained from the parental studies.

4.2 Privacy and confidentiality

Confidentiality and privacy will not be compromised because the data does not have identity of the participants from clinical records. The assigned study identities from parental studies will be used in this study. The data that will be used will be kept private by ensuring that it is password protected.

4.3 Risks and benefits

There are no risks associated with this study as the data that will be used will be from parental studies, where study IDs were used to identify participants. Similarly, study IDs will be used to identify the participants in the proposed study. The data will be kept under password protected device to eliminate

accessibility by non-study personnel. There are also no direct benefits associated with this study, however, the findings of the study will help to improve ANC services in South Africa in the near future.

4.4 Reporting and implementation

The proposed study will have important implications on policies related to hypertension in pregnancy, HIV, obesity and maternal and child care programs. The findings of the study will contribute to the knowledge that can be used to facilitate implementation of improved strategies for prevention and management of hypertension in pregnant women and postpartum. The findings of the study will further provide awareness of the impact of hypertension on maternal and child health.

4.5 Logistics

Table 2: study timeline

	Time				
	Oct	Nov	Dec	Jan	Feb
Submission of protocol to Ethics					
Merge and clean data					
Data analysis					
Thesis writeup					
Submit thesis for marking					

4.6 Budget

There is no budget for this study since it is part of MPH degree.

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PART B: Manuscript

PREVALENCE AND RISK FACTORS ASSOCIATED WITH PREGNANCY INDUCED AND POSTPARTUM HYPERTENSION AMONG OBESE WOMEN LIVING WITH HIV IN CAPE TOWN, SOUTH AFRICA.

Nthabiseng Phohlo¹

Author Affiliation

¹Division of Epidemiology and Biostatistics, School of Public Health and Family Medicine, University of Cape Town, South Africa.

Keywords: Prevalence, hypertensive disorders of pregnancy, post-partum, hypertension, body mass index, anti-retro-viral therapy, HIV

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Tables: 6

Figures: 2

ABSTRACT

Aim and the objectives:

The aim of this study was to find prevalence and risk factors associated with pregnancy induced hypertension (PIH) and postpartum hypertension (PPH) in obese pregnant women living with HIV (WLHIV). The objectives were to describe overall prevalence of hypertension in pregnancy and postpartum, to describe prevalence of hypertension by antiretroviral therapy (ART) initiation timing and body mass index (BMI) and to examine the risks factors associated with PIH and PPH.

Study design: Retrospective cohort study.

Setting: The study was conducted using secondary data collected in previous studies from a primary healthcare facility in a peri-urban area in Cape Town.

Participants: 1859 pregnant WLHIV from four parent studies were included. Enrolment was from March 2013 to July 2018. A subset of these women (752) was followed postpartum.

Outcome measures: Pregnancy induced hypertension and postpartum hypertension.

Results: Overall prevalence of PIH was 67.7 cases per 1000 population. Prevalence of PIH was 67.7 and 67.9 cases per 1000 population stratified by ART initiation timing and BMI status. Conversely, overall PIH prevalence in obese women was 43 cases per 1000 population. Association between PIH and ART initiation timing was OR; 0.76, 95% CI; 0.59 to 0.97, p-value; 0.03. Association between PIH and BMI in obese women was; OR; 3.49, 95% CI; 2.42 to 5.15, p-values; <0.001. Overall prevalence of PPH was 155 cases per 1000 population. PPH prevalence was 155 and 158.6 cases per 1000 population stratified by ART initiation timing and BMI status. PPH prevalence in obese women was 101 cases per 1000 population. ART initiation timing and PPH association was (OR; 0.67, 95% CI; 0.47 to 0.95), p-value; 0.03. BMI and PPH association in obese women was; (OR; 2.41, 95% CI; 1.51 to 3.96), p-value; < 0.001.

Obesity, old age (≥ 35) and late booking at antenatal clinic were risk factors that showed positive association with hypertension, with Odds ratios; 3.49, 2.21 and 1.56 respectively.

Conclusions: There is high prevalence of hypertension in pregnant WLHIV in Cape Town. Most women continue to have the condition postpartum. Obesity, old age and late booking at antenatal clinic were risk factors positively associated with hypertension. ART initiation timing was negatively associated with PIH and PPH.

Strengths and limitations of this study

- Large sample size for pregnancy induced hypertension analysis.
- Many risk factors were included for assessment of hypertension association.
- Many variables had missing data.
- Sub-analysis of post-partum hypertension had smaller sample size and the size was reduced further by missing data.

1. INTRODUCTION

In accordance with global hypertension practice guidelines, hypertension is defined as having systolic blood pressure ≥ 140 mm Hg and diastolic blood pressure ≥ 90 mm Hg in an office or clinic setting, following repeated examination [1]. Hypertensive disorders of pregnancy (HDP) are considered to be presence of hypertension during pregnancy, either chronic hypertension or hypertension that develops at 20 weeks of pregnancy [2, 3]. HDP are often part of a placental syndrome which is associated with a number of factors including dyslipidemia, insulin resistance, oxidative stress, inflammatory activation, and endothelial dysfunction, all of which may remain in the postpartum period and contribute to an increase in the risk of cardiovascular diseases (CVDs) [4].

Excluding chronic hypertension in pregnancy, HDP or pregnancy induced hypertension (PIH), can be categorized into four types, preeclampsia, eclampsia, gestational hypertension and other forms of hypertension [5]. Gestational hypertension does not result in adverse birth outcomes in pregnancy, but it can develop into preeclampsia, which can lead to poor pregnancy outcomes. Preeclampsia is characterized by high levels of protein in the urine, poor placental perfusion in pregnant women and foetal growth restriction [2]. There is trophoblast invasion dysregulation resulting in reduction of blood flow. The placenta then releases pro-inflammatory factors which release excess oxygen factors in the blood. The whole process causes preeclampsia [6]. Preeclampsia can further cause eclampsia, which is defined as development of seizures in people who already have preeclampsia [7]. Pregnancy outcomes of these conditions include pre-term labour, postpartum haemorrhage and abruption placenta [8]. Preeclampsia can further complicate pregnancy by damaging the liver and kidney functionality [5].

There is an increase in incidence of HDP in the world and this is one of the major public health problems. Globally, HDP has incidence rate of approximately 10% [2]. In the United States of America, onset of new cases of HDP has almost doubled from 2007 to 2019, from 48.6 to 83.9 per 1000 live births in the urban areas [4] and the highest incidence of HDP was found in the older age group (40-44). In Ethiopia, a systematic review study showed a prevalence of 6% of HDP [9]. Conversely, in a review study carried out by Gemechu et al., pooled prevalence of HDP in Sub-Saharan Africa was 8% [10]. Annually, more than 500 000 foetal and neonatal deaths and 70 000 maternal deaths are caused by this condition [2]. In addition, HDP contribute 14% of maternal deaths in the world and 16% in Sub-Saharan Africa [11]. In South Africa, HDP contributed to 18% of maternal deaths [12]. It has been discovered that HDP have major implications for cardiovascular diseases later in the lives of both the mother and the infant [13] and the offspring further stand the risk of hypertension and obesity at later stages of life [13].

Globally, approximately two million HIV positive women become pregnant each year, majority of whom reside in SSA [14]. In South Africa, about 21.7 % of women of child bearing age are living with HIV [15]. As a result, South Africa is facing high prevalence of communicable and non-communicable diseases, particularly in this age group. It is not clear whether high burden of HIV has any association with high burden of NCDs,

particularly CVDs [16], more research is still required. In earlier years, HIV was associated with wasting but with the introduction of antiretroviral therapy (ART), people living with HIV are now faced with obesity challenge [17], a risk factor for many NCDs including hypertension. In a cohort study conducted in South Africa [18], it was discovered that patients who were initiated on ART without hypertension had incidence rate of 5.4 per 100 person years of developing hypertension.

Hypertensive disorders of pregnancy are among the leading causes poor pregnancy outcomes and they further contribute to high mortality and morbidity in the world. Increasing trends of obesity pose a threat to women of child bearing age as obesity is a well-known risk factor for hypertension. Pregnancy increases the risk of development of hypertension as women are likely to gain weight during this time. Moreover, HDP increases the risk of postpartum hypertension (PPH). Women face the highest burden of HIV, with introduction of ART, PLHIV do not face wasting anymore, instead, like general population, and they are faced with obesity challenge. Since the recent trend of coexistence of HIV and obesity, the influence of these on the burden of PIH and PPH is not well understood. There is limited data on the burden of this condition in pregnancy and postpartum in a setting of high HIV and obesity prevalence. This study aims to examine prevalence of PIH and PPH and the risk factors associated in pregnant WLHIV, who are on ART.

2. METHODOLOGY

2.1 Study design

This was a retrospective cohort study, where secondary data was analysed to describe prevalence of PIH and PPH in WLHIV with respect to BMI. Factors associated with PIH and PPH were also defined and association of ART initiation timing and hypertension was examined. The data used was from four parent studies of pregnant women.

2.2 Study settings

Participants in this study were from Gugulethu community health centre, which has a population of approximately 98 468. This is a community health facility that offers primary healthcare services. This health facility is located at an area where majority of the residents are of low socio-economic status and about 60% of the residents live in informal housing. About 360 000 population is served by this facility and about

4800 women receive antenatal services at this facility. Patients from this facility are referred to secondary and tertiary hospitals nearby for more advanced health services.

2.3 Inclusion and Exclusion Criteria

This study included pregnant WLHIV 18 years and above, who went for antenatal services at Gugulethu community health centre between 2013 and 2018 and were enrolled in one of the four parent studies from which the data was derived. The women included were those who initiated ART before pregnancy (preconception) and during pregnancy (post conception). Median gestational age at first visit was 18 weeks. Women who were underweight, aged below 18 and who were pregnant with more than one child were excluded from the study as these characteristics were likely to confound the study outcomes. Also women with missing essential variables like BMI, HIV status and hypertension results were not included in the study. Figure 1 below shows included women.

2.4 Ethical statement

Ethics approval was obtained from Human Research Ethics committee, Faculty of Health Sciences (appendix 1) and Ethics approval from department of health is also attached (appendix 2). University of Cape Town. Informed consent for parent studies, where data was collected from participants was obtained from the participants. In this study, no informed consent from the participants was required as these were already obtained from the parent studies.

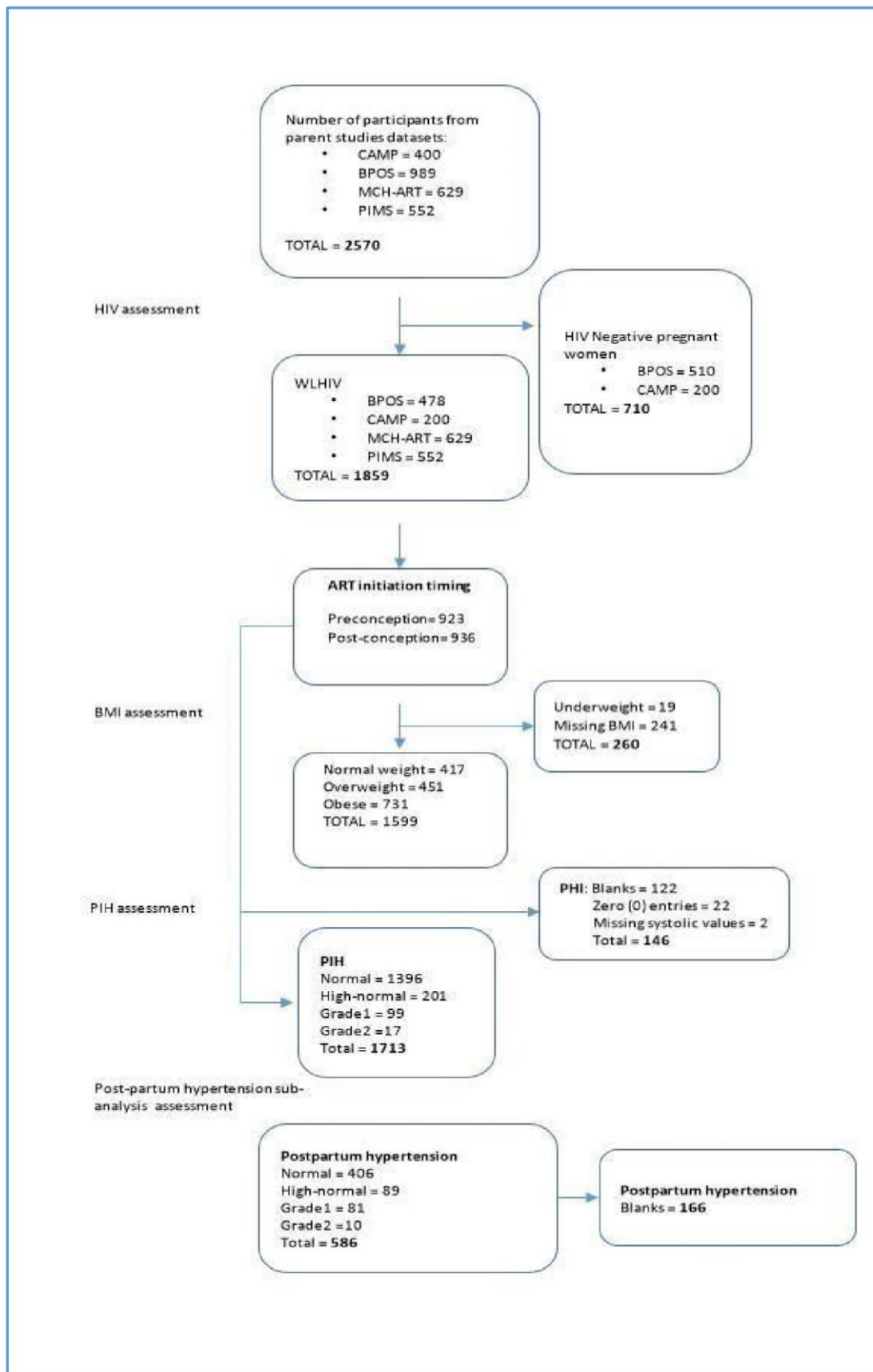


Figure 1: Flow diagram of women included in the study in both pregnancy induced hypertension and post-partum hypertension.

2.5 Data analysis

Since secondary data was used, data collection was not performed in this study. Available data was cleaned, merged and relevant categories created. Data collection instruments used in parent studies are attached in appendix section (appendix 3 to 8). Data collection Data was analysed using R version 4.2.2. Numerical variables were presented as median (IQR). Categorical variables were presented as proportions (%). Ordinal proportional logistic regression was used to study the association between hypertension and included risk factors. Proportional odds assumption was tested using Brant Wald test and all the p-values obtained were higher than 0.05, an indication that the model was applicable for this analysis. Lipsitz goodness of fit test for ordinal response models was done and p-value above 0.05 was obtained, indicating that the model was fit for this analysis. 95% confidence interval was used to determine the precision of the results and p-value was used to determine statistical significance of the results (≤ 0.05). The analysis focused on the description of PIH/PPH stratified by

- BMI status and
- ART initiation time

Other socio-demographic and obstetric factors were described by these variables. The analysis also looked at the association between hypertension and BMI as well as ART initiation time. Associations between other factors and PIH and PPH were also explored. From parental studies, blood pressure was measured at first ANC visit and during preceding visits. An automated blood pressure reading was taken on seated women using a general use Edan M3A Vital Signs Monitor. Patients with higher blood pressure were relaxed and a repeat blood pressure measure was taken in the right lateral position with the appropriate sized cuff and auscultation of the 4th Korotkoff sound for the diastolic reading. Blood pressure readings were abstracted from medical records into study abstraction form. From the three visits, three blood pressure readings were used to calculate final individual blood pressure used in this study. This was done by taking the highest recorded reading of systolic and diastolic blood pressure. Hypertension was classified according to American Hypertension guidelines. Figure 2 below shows blood pressure (BP) and hypertension classification. Gestational median age at first visit for PIH analysis was 19 weeks and for PPH sub-analysis was 17 weeks.

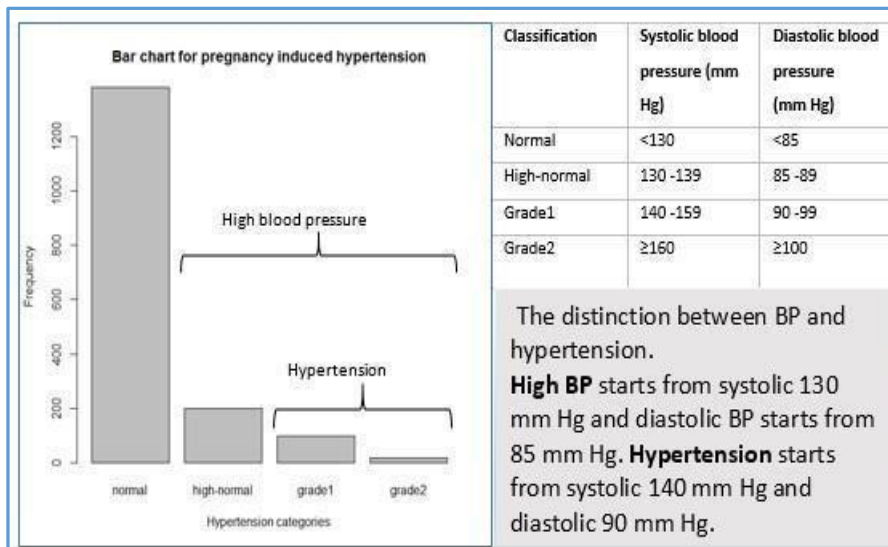


Figure 2: Illustration of the difference between high blood pressure and hypertension.

3. RESULTS

3.1 Prevalence of PIH described by ART initiation timing

The analysis included 1859 pregnant WLHIV. For stratification by ART initiation timing, 146 women were eliminated. Out of 1713 women remaining, 317 had high BP and 116 had hypertension. Overall PIH prevalence was 67.7 cases per 1000 population. Prevalence of PIH was 67.7 cases per 1000 population stratified by ART initiation timing, 42% initiated ART preconception and 58% post-partum. On the other hand, pregnancy high BP prevalence was 185 cases per 1000 population stratified by ART initiation timing. Median systolic and diastolic BP were higher for post-conception than preconception. Larger proportion of participants was unemployed. Most participants came in the second trimester and the median gestational age was 18 and 19 weeks in the two groups. The three categories of SES did not vary a lot as they all ranged around 30%. The median gravidity was 2 and post-conception had lower median age of 28 compared to 31 in preconception (Table 1).

The last column shows p-values for groups' comparison. Chi-square test was used for categorical variables and t-test for two samples was used for mean comparison between the two groups (preconception and postconception). PIH, age, gestational age and gravidity categories had p-values <0.05, an indication that there is a relationship between these groups and ART initiation timing groups. Employment and socio-economic status categories had p-values greater than 0.05, an indication that there is no relationship between this groups and ART time initiation groups. Further, pregnancy systolic, diastolic and age variables

p- values were less than 0.05. The difference in means between these groups and ART time initiation groups was not zero, indicating that preconception mean is significantly different from postconception mean in these groups. On the other hand, gestational age variable had p-value greater than 0.05, an indication that preconception mean and postconception means were not significantly different.

Table 1: Baseline characteristics of pregnant WLHIV stratified by ART initiation timing (n = 1713)

Variables		Preconception n = 923 (49.7)	Postconception n = 936 (50.3)	p-values
Pregnancy-induced hypertension n (%)	Total n = 1713	n = 850	n = 863	0.037
	Normal	709 (83.41)	687 (79.60)	
	High-normal	92 (10.83)	109 (12.63)	
	Grade 1	38 (4.47)	61 (7.07)	
	Grade 2	11 (1.29)	6 (0.70)	
	Missing	146		
<hr/>				
Pregnancy systolic blood pressure Median (IQR)		113.00 (106.00 – 123.00)	118.00 (109.00 – 126.00)	<0.001
<hr/>				
Pregnancy diastolic blood pressure Median (IQR)		69.50 (63.00 -76.00)	70 (64.69 – 77.00)	0.006
<hr/>				
Age groups (years) n (%)	Total n = 1859	n = 923	n = 936	<0.001
	≤24	99 (10.73)	240 (25.64)	
	25-29	232 (25.13)	320 (34.19)	
	30-34	322 (34.88)	244 (26.07)	

	≥35	270 (29.25)	132 (14.10)	
Age median (IQR)				
		31.86 (27.68 – 35.00)	28.00 (24.37 – 32.00)	<0.001
Employment status n (%)				
	Total n = 1842	n = 915	n = 927	
	Yes	360 (39.34)	379 (40.88)	0.705
	No	555 (60.66)	548 (59.12)	
	Missing	17		
Gestational age category at first visit (weeks) n (%)				
	Total n = 1812	n = 905	n = 907	
	1st trimester	264 (29.17)	209 (23.04)	0.016
	2nd trimester	564 (62.32)	616 (67.92)	
	3rd trimester	77 (8.51)	82 (9.04)	
	Missing	47		
Gestational age at first ANC visit (weeks) median (IQR)				
		18 (13 – 24)	19 (14 – 24)	0.289
Socio-economic status n (%)				
	Total n = 1722	n = 850	n = 872	
	High	324 (38.12)	316 (36.24)	0.242
	Medium	258 (30.35)	288 (33.03)	
	Low	268 (31.53)	268 (30.73)	
	Missing	137		

Gravidity groups n (%)	Total	n = 826	n = 893	
	n = 1719			
	1	267	174	<0.001
	2	272	268	
	≥3	287	451	
Missing	140			
Gravidity median (IQR)		2 (2 -3)	2 (1 – 3)	<0.001

3.2 Prevalence of PIH described by BMI

Out of a total sample of 1859, 299 women were eliminated because of missing data from PIH variable and BMI categories. 298 women had high BP and 106 had hypertension. Prevalence of PIH stratified by BMI was 67.9 cases per 1000 population and a proportion of obese women was 67%. PIH prevalence in obese women was 45.5 cases per 1000 population. Prevalence of high BP stratified by BMI was 191 cases per 1000 population. In the total sample stratified by BMI, prevalence of high BP in obese women was 119 cases per 1000 population. Other included covariates were also stratified by BMI based on the number of women without missing data as shown in (Table 2). Median systolic and diastolic BP increased from normal to obese. Median age increased from normal weight to obese. Most women who were unemployed were obese. Median gestational age ranged from 18 to 19.

The last column shows p-values for group comparisons. Chi-square test, Fisher's Exact test and Chi-square test for trend were used to test for independence between the groups. On the other hand, Kruskal- Wallis tests was used for median comparison between the groups. Unlike Chi-square test, Chi-square test for trend gave proportion p-values, as a result, multiple p-values were observed under one variable. The multiple p-values enabled observation of individual category contribution to the relationship between variables under investigation. Chi-square test for trend was used in large contingency tables, where Chi-square test was limited.

Table 2: Baseline characteristics of pregnant WLHIV stratified by BMI (n = 1560)

Variables		Normal weight	Overweight	Obese	p-value
Pregnancy induced hypertension n (%)	Total n = 1560	n = 405	n = 440	n = 715	
	Normal	368 (90.86)	365 (82.95)	529 (78.99)	0.006
	High-normal	24 (5.93)	53 (12.05)	115 (16.04)	0.010
	Grade 1	8 (1.98)	21 (4.77)	63 (8.81)	0.115
	Grade 2	5 (1.23)	1 (0.23)	8 (1.12)	0.110
	Missing	299			
Pregnancy systolic blood pressure Median (IQR)		111 (103 – 120)	114 (106 – 123)	120 (111 – 129)	<0.001
Pregnancy diastolic blood pressure Median (IQR)		68 (61 – 73)	70 (64 – 76)	72 (65 – 79)	<0.001
Age groups (years) n (%)	Total n = 1699	n = 517	n = 451	n = 731	
	≤24	109 (21.08)	82 (18.18)	100 (13.68)	<0.001
	25 -29	148 (26.63)	132 (29.27)	196 (26.81)	0.446
	30 -34	115 (22.24)	127 (28.16)	245 (33.52)	<0.001
	≥35	145 (28.05)	110 (24.39)	190 (25.99)	0.472
	Missing	160			
Age (years) median (IQR)		27.58 (24.07 - 32)	30 (26 -34)	31 (27 – 35)	<0.001
Employment status n (%)	Total n = 1593	n = 415	n = 451	n = 727	
	Yes	146 (35.18)	199 (44.12)	307 (42.23)	0.039
	No	269 (64.82)	252 (55.88)	420 (57.77)	

	Missing	266			
Gestational age category at first visit					
n (%)	Total n = 1569	n = 409	n = 445	n = 715	
	1 st Trimester	110 (26.89)	107 (24.04)	209 (29.23)	<0.001
	2 nd Trimester	261 (63.81)	295 (66.29)	451 (63.08)	<0.001
	3 rd Trimester	38 (9.29)	43 (9.66)	55 (7.69)	<0.001
	Missing	290			
Gestational age at first ANC visit (weeks) median (IQR)					
		18 (13 – 24)	19 (14 – 24)	18 (13 -24)	0.177
Socio-economic status					
n (%)	Total n = 1583	n = 413	n = 449	n = 721	
	High	135 (32.69)	165 (36.75)	270 (37.45)	<0.001
	Medium	138 (33.41)	155 (34.52)	205 (28.42)	<0.001
	Low	140 (33.90)	129 (28.73)	246 (34.12)	<0.001
	Missing	276			
Gravidity groups					
n (%)	Total n = 1494	n = 383	n = 420	n = 691	
	1	122 (31.85)	93 (22.14)	164 (23.73)	<0.001
	2	115 (30.03)	155 (36.90)	201 (29.09)	0.290
	≥3	146 (38.12)	172 (40.95)	326 (47.18)	0.106
	Missing	365			
Gravidity median (IQR)					
		2 (1 -3)	2 (1- 3)	2 (1-3)	<0.001

3.3 Prevalence of PPH stratified by ART initiation timing and other risk factors

In sub-analysis, 752 women from the total sample (1859) were followed postpartum for 6 to 12 months. Table 3 shows descriptive statistics of the included women. Due to missing data, 586 women were included in postpartum sub analysis stratified by ART initiation timing. 180 women had high BP and 91 had PPH. Overall prevalence of PPH was 155 cases per 1000 population. Prevalence of PPH was 155 cases per 1000 population stratified by ART initiation and 44% initiated ART preconception and 56% postconception. Prevalence of postpartum high BP stratified by ART initiation timing was 307 cases per 1000 population (Table 3). Other baseline characteristics results stratified by ART initiation timing are also shown in table 3 below. More participants were unemployed, none of the participants came in the third trimester and majority came in the second trimester. Median gestational age at first visit was higher in post-conception category than in preconception category. Median age was higher in preconception group than post-conception group. Median systolic and diastolic BP was higher in postconception group than preconception category. Last column shows p-values for groups' comparison. Suitable tests were used to generate the p-values and the relationships between ART initiation timing groups were established based on the p-values.

Table 3: Baseline postpartum characteristics of WLHIV stratified by ART initiation time (n = 586)

Variables		Preconception n = 349	Postconception n = 403	p-value
Post-partum hypertension n (%)	Total n = 586	n = 278	n = 308	0.093
	Normal	206 (74.10)	200 (64.94)	
	High-normal	32 (11.51)	57 (18.51)	
	Grade 1	35 (12.59)	46 (14.94)	
	Grade 2	5 (1.80)	5 (1.62)	
	Missing	166		
Post-partum systolic blood pressure Median (IQR)		114 (102 – 126)	117 (98.62 – 129)	0.032
Post-partum diastolic blood pressure		71.25 (61 -79)	72 (58.25 – 81.00)	0.007

Median (IQR)				
Pregnancy-induced hypertension n (%)	Total n = 730	n = 340	n = 390	
	Normal	287 (84.41)	320 (82.05)	0.743
	High-Normal	32 (9.41)	36 (9.23)	
	Grade 1	17 (5)	30 (7.69)	
	Grade 2	4 (1.18)	4 (1.03)	
	Missing	22		
Pregnancy systolic blood pressure Median (IQR)		114 (106 -122)	117 (109 -125.20)	0.007
Pregnancy diastolic blood pressure Median (IQR)		69.50 (64 – 75)	70.25 (65 – 77)	0.036
Age groups (years) n (%)	Total n = 752	n = 349	n = 403	
	≤24	26 (7.45)	92 (22.83)	<0.001
	25-29	72 (20.63)	129 (32.01)	
	30-34	121 (34.67)	123 (30.52)	
	≥35	130 (37.25)	59 (14.64)	
Age (years) median (IQR)		33 (29 -36)	29 (25 -33)	<0.001
Employment status n (%)	Total n = 736	n = 341	n = 395	
	Yes	151 (44.28)	167 (42.28)	0.376
	No	190 (55.72)	228 (57.72)	
	Missing	16		

Gestational age category at first visit	Total	n = 348	n = 400	
n (%)	n = 648			
	1 st Trimester	134 (38.51)	120 (30)	0.016
	2 nd Trimester	214 (61.49)	280 (70)	
	3 rd Trimester	0	0	
	Missing	104		
Gestational age at first ANC visit (weeks) median (IQR)				
		15 (12 -24)	17 (12 -24)	0.090
Socio-economic status				
n (%)	Total	n = 313	n = 340	
	n = 653			
	High	119 (38.02)	121 (35.59)	0.385
	Medium	85 (27.16)	112 (32.94)	
	Low	109 (34.84)	107 (31.47)	
	Missing	99		
Gravidity groups				
n (%)	Total	n = 338	n = 390	
	n = 728			
	1	33 (9.76)	80 (20.51)	<0.001
	2	103 (30.47)	137 (35.13)	
	≥3	202 (59.76)	173 (44.36)	
	Missing	24		
Gravidity median (IQR)				
		3 (2 - 4)	2 (2 - 3)	<0.001

3.4 Prevalence of PPH stratified by BMI status

Prevalence of PPH was 158.7 cases per 1000 population (a proportion of 64% was obese women) and overall prevalence of PPH in obese women was 101 cases per 1000 population stratified by BMI status. Additionally, 166 women had high BP and 83 had PPH. Prevalence of high BP stratified by BMI was 317.4 cases per 1000 population. High BP prevalence in obese women stratified by BMI was 196.9 cases per 1000 population (Table 4). Median systolic and diastolic BP increased from normal weight category to obese category. Median age ranged between 28 and 31 in the three BMI groups. P-values on the last column were included using appropriate statistical tests as mentioned in table 2 to establish relationships between the groups.

Table 4: Baseline characteristics of WLHIV stratified by BMI for postpartum analysis (n = 523)

Variables		Normal weight	Overweight	Obese	p-value
Postpartum hypertension n (%)	Total n = 523	n = 134	n = 131	n = 258	
	Normal	104 (77.61)	98 (74.81)	155 (60.08)	<0.001
	High-normal	15 (11.19)	18 (13.74)	50 (19.38)	0.028
	Grade 1	10 (7.46)	12 (9.16)	50 (19.38)	<0.001
	Grade 2	5 (3.73)	3 (2.29)	3 (1.16)	0.092
	Missing	299			
Postpartum systolic blood pressure Median (IQR)		113 (103 – 123)	115 (107.5 -125.1)	120 (108 – 132)	0.001
Postpartum diastolic blood pressure Median (IQR)		71 (63 – 77.25)	71.75 (64 – 79.50)	74 (64 – 82)	0.004

Pregnancy induced hypertension	Total	n = 159	n = 151	n = 305	
n (%)	n = 615				
	Normal	144 (90.57)	128 (84.77)	236 (77.38)	<0.001
	High-normal	6 (3.77)	17 (11.26)	38 (12.46)	<0.001
	Grade 1	6 (3.77)	5 (3.31)	29 (9.51)	<0.001
	Grade 2	3 (1.89)	1 (0.66)	2 (0.66)	0.528
	Missing	137			
Pregnancy systolic blood pressure Median (IQR)		113 (106 -120)	113.8 (106 - 121.5)	120 (111 -128)	<0.001
Pregnancy diastolic blood pressure Median (IQR)		69 (63 – 74.75)	69.75 (64.25 - 74.88)	72 (66.78)	0.001
Age groups (years)	Total	n = 161	n = 151	n = 309	
n (%)	n = 621				
	≤24	42 (26.09)	19 (12.58)	37 (11.97)	<0.001
	25-29	51 (31.68)	42 (27.81)	76 (24.60)	0.100
	30-34	46 (28.57)	48 (31.79)	107 (34.63)	0.179
	≥35	22 (13.66)	42 (27.81)	89 (28.80)	<0.001
	Missing	131			
Age (years)		28 (24 – 32)	31 (26 – 35)	31 (28 -35)	<0.001

median (IQR)					
Employment status n (%)	Total	n = 160	n = 151	n = 305	
		n = 616			
	Yes	68 (42.5)	73 (48.34)	131 (42.95)	0.921
	No	92 (57.5)	78 (51.66)	174 (57.05)	
Missing	136				
Gestational age category at first visit n (%)	Total	n = 159	n = 150	n = 309	
		n = 618			
	1st Trimester	57 (35.84)	50 (33.33)	116 (37.54)	0.936
	2nd Trimester	102 (64.15)	100 (66.67)	193 (62.46)	
Missing	134				
Gestational age at first ANC visit (weeks)		16 (12 - 20)	17 (12 – 22)	15 (12 -21)	0.652
median (IQR)					
Socio-economic status n (%)	Total	n = 158	n = 149	n = 299	
		n = 606			
	High	55 (34.81)	54 (36.24)	106 (35.45)	0.921
	Medium	57 (36.08)	52 (34.90)	80 (26.76)	0.028
	Low	46 (29.11)	43 (28.86)	113 (37.79)	0.039
Missing	146				

Gravidity groups n (%)	Total	n = 160	n = 151	n = 306	
	n = 617				
	1	42 (26.25)	21 (13.04)	36 (11.76)	<0.001
	2	56 (35)	58 (38.41)	95 (31.05)	0.288
	≥3	62 (38.75)	72 (47.68)	175 (57.19)	<0.001
Missing	135				
Gravidity median (IQR)		2 (1 – 3)	2 (2 – 3)	3 (2 – 3)	<0.001

3.5 Association between PIH and other risk factors

Adjusted and unadjusted ordinal proportional models were used for this analysis, as a result, only one value of odds ratio was obtained for all levels of BP (similar slope but different intercepts). Proportional odds assumption was tested using Brant Wald test and all the p-values obtained were higher than 0.05, an indication that the model was applicable for this analysis. The odds of moving across the levels of BP (from lower level to higher level) in obese women were 3.49 times higher than in normal weight women in unadjusted model. On the other hand, adjusted for other covariates, the odds of moving across BP levels in obese women were 1.33 times higher in comparison to women of normal weight. In both models, obesity was positively associated with PIH and the results were statistically significant in unadjusted model.

In age group category, for women of age 35 years and above, the odds of moving across the levels of hypertension were 1.13 times higher than in women of age less or equal to 24 years. Older age was positively associated with hypertension but the results obtained were not statistically significant as p-values were above 0.05.

A slightly positive association of PIH was obtained in employment covariate in both models but the results were not statistically significant. ART initiation timing showed a negative association with statistically significant results in unadjusted model. High SES showed higher odds of association with PIH than medium SES with reference to low SES. Women who came in third trimester showed increased odds of association compared to women who came in the second trimester and in unadjusted model, the results were statistically significant. Under gravidity group, adjusted model gave slightly positive association and unadjusted model gave negative results with statistically significant results in group three and above. (Table 5). Continuous variables, age, 1st visit gestational age, BMI and gravidity showed no association in both models, this clearly illustrates the importance of creating categorical variables with sensible cut-offs (Table 5).

Table 5: Risk factors associated with pregnancy induced hypertension: proportional odds ratios

Pregnancy induced hypertension				
(normal, high-normal, grade1, grade2)				
	Adjusted OR (95% CI)	p-value	Unadjusted OR (95%)	p-value
Age groups (n = 1716)				
25-29	0.65 (0.37 – 1.18)	0.15	0.95 (0.66 – 1.38)	0.80
30-34	0.64 (0.27 – 1.56)	0.32	0.95 (0.66 – 1.38)	0.80
≥35	0.66 (0.18 – 2.47)	0.53	1.13 (0.77 – 1.65)	0.54
BMI categories (n = 1563)				
Overweight	1.57 (0.97 – 2.58)	0.07	2.01(1.33 – 3.08)	0.001
Obese	1.37 (0.74 – 2.55)	0.32	3.49 (2.42 – 5.15)	<0.001

ART timing				
Preconception	0.77 (0.59 – 1.03)	0.08	0.76 (0.59 – 0.97)	0.03
Employment status (1714)				
Yes	1.09(0.80 – 1.49)	0.57	1.22 (0.96 – 1.57)	0.11
Socio economic status (1631)				
High	1.06 (0.74 – 1.54)	0.74	1.22 (0.90 -1.65)	0.19
Medium	0.95 (0.66 – 1.37)	0.78	1.12 (0.82 – 1.54)	0.47
Gestational age group (1673)				
2nd trimester	0.91 (0.55 – 1.51)	0.73	0.87 (0.65 – 1.16)	0.32
3rd trimester	1.53(0.57 – 4.07)	0.40	1.56 (1.00 – 2.42)	0.05
Gravidity group (1607)				
2	1.06 (0.65 – 1.72)	0.83	0.83 (0.60 – 1.15)	0.27
≥3	1.04 (0.45 – 2.50)	0.93	0.71 (0.52 – 0.97)	0.03
Age	1.03 (0.95 – 1.11)	0.48	1.01 (0.99 – 1.03)	0.33
Gravidity	0.84 (0.60 – 1.14)	0.30	0.91 (0.82 – 1.00)	0.05
1st visit gestational age	1.00 (0.96 – 1.04)	0.99	1.01 (0.99 – 1.02)	0.54
BMI	1.08 (1.04 – 1.11)	<0.001	1.08 (1.06 – 1.10)	<0.001

3.6 Association between postpartum hypertension and the risk factors

Missing data was removed and 515 participants were included in analytical analysis of PPH. PIH was strongly associated with PPH in all 3 hypertension categories in unadjusted model with statistically significant in two categories. An increase in age showed an increase in association with hypertension in unadjusted model. The greatest association was found in unadjusted model in age equal or above 35, with statistically significant results. BMI categories also had positive association with PPH, obese group in unadjusted model

showing stronger association with statistically significant results. ART initiation timing showed a negative association with statistically significant results in unadjusted model. Employment showed a negative association in unadjusted model and no association in adjusted model.

Under SES, high SES showed positive association in adjusted model and no association in unadjusted model. Gestational age category showed positive association in adjusted model and no association in unadjusted model, however, the results were not statistically significant. Gravity categories showed positive associations with PPH in unadjusted model with statistically significant results. Continuous variables also showed little to no associations. Age, gestational age at 1st visit, BMI, pregnancy systolic and diastolic showed no association with PPH. Gravity showed positive association in unadjusted model with statistically significant results (Table 6).

Table 6: Risk factors association with postpartum hypertension: proportional odds ratios

	Postpartum hypertension (normal, high-normal, grade1, grade2)			
	Adjusted OR (95% CI)	p-value	Unadjusted OR (95% CI)	p-value
Pregnancy-induced hypertension				
High-normal	0.56 (0.26 – 1.18)	0.13	3.65 (2.10 – 6.31)	<0.001
Grade1	0.47 (0.17 – 1.31)	0.15	11.80 (6.20 - 22.97)	<0.001
Grade2	0.01 (0.0009 – 0.18)	0.01	2.06 (0.28 – 10.93)	0.41
Age groups				
25-29	0.63 (0.25 – 1.61)	0.34	0.92 (0.51 -1.70)	0.79
30-34	0.61 (0.16 – 2.37)	0.47	1.46 (0.84 – 2.60)	0.19
≥35	0.96 (0.13 – 7.01)	0.97	2.21 (1.26 – 4.00)	0.007
BMI categories				
Overweight	1.06 (0.54– 2.10)	0.87	1.24 (0.70 – 2.21)	0.46
Obese	1.40 (0.58 – 3.38)	0.46	2.41 (1.51 – 3.96)	0.003
ART timing				

Preconception	0.70 (0.44 – 1.09)	0.12	0.67 (0.47 – 0.95)	0.03
Employment status				
Yes	1.00 (0.63 – 1.61)	0.99	0.89 (0.63 -1.27)	0.52
Socio economic status				
High	1.32 (0.77 – 2.28)	0.32	1.00 (0.66 – 1.54)	0.98
Medium	1.03 (0.60 – 1.78)	0.91	0.82 (0.52 – 1.29)	0.39
Gestational age group				
2nd trimester	1.37 (0.69 – 2.75)	0.37	0.99 (0.69 – 1.43)	0.94
Gravidity group				
2	1.00 (0.44 – 2.29)	0.99	1.23 (0.60 – 1.90)	0.85
≥3	1.27 (0.37 – 4.48)	0.70	1.63 (1.00 – 2.82)	0.07
Age	1.05 (0.93 – 1.19)	0.40	1.07 (1.03 – 1.10)	<0.001
Gravidity	1.03 (0.67– 1.58)	0.88	1.22 (1.04 – 1.44)	0.01
1st visit gestational age	0.96 (0.91 – 1.02)	0.17	1.00 (0.97 – 1.03)	0.95
BMI	0.99 (0.95 – 1.05)	0.84	1.06 (1.04 – 1.09)	<0.001
Pregnancy systolic blood pressure	1.09 (1.06 – 1.13)	<0.001	1.09 (1.07 – 1.10)	<0.001
Pregnancy diastolic blood pressure	1.05 (1.01 – 1.09)	0.01	1.11 (1.09 – 1.14)	<0.001

4. DISCUSSION

4.1 Key findings

Significantly high prevalence of pregnancy-induced hypertension (PIH) and post-partum hypertension (PPH) in the overall sample were found. Further, higher prevalence of both PIH and PPH was found in obese groups compared to other BMI categories. Obesity, older age (≥35 years) and late booking at antenatal clinic were associated with high risk of PIH and PPH. On the other hand, ART initiation timing (preconception) was associated with low risk of PIH and PPH.

4.2 PIH and PPH prevalence

Overall prevalence of PIH was 67.7 cases per 1000 population and overall prevalence of PPH was 155 cases per 1000 population. These findings are in agreement with what other literature has discovered. Global incidence of PIH has been estimated to be around 10% [2]. Furthermore, in a province-wide study carried out in South Africa by Slogrove et al. [19], 7.6% of pregnant women had hypertensive disorders of pregnancy and 18.8% of these were WLHIV. In addition, Behrens et al. [20] discovered that there is high risk of PPH in women who developed PIH and this risk can continue for more than 20 years postpartum. The results further illustrate that there was higher prevalence of PIH and PPH in obese women than in other BMI categories. This was not a surprise as obesity is a known risk factor for hypertension.

4.3 Association between BMI and hypertension

Obesity was strongly associated with both PIH and PPH compared to the other risk factors. This was in agreement with what most literature reveal about obesity and hypertension [21, 22, and 23]. Erasmus et al. [24] showed that highest prevalence of PIH was found in overweight and obese women.

4.4 Association between ART initiation timing and hypertension

The results indicated that Initiating ART before pregnancy reduces the odds of PIH in comparison to initiating ART during pregnancy. The results agree with what Slogrove et al. [19] had found, where long term ART initiation was proved to be protective. However, this results are still in contradiction with other literature, one article showed no association between ART timing and PIH [25]. Conversely, in another article by Wimalasundera et al [26], it was discovered that due to immune reconstitution of ART, PLHIV who were on ART were at higher risk of PIH than PLHIV that were not on ART. The findings of this study with regard to ART initiation timing are very important and this is a very under researched area and further research is necessary to reach conclusive results.

4.5 Association between age and hypertension

Older women showed stronger association with PIH compared to younger women. These finding agree with what most literature indicate about association between age and hypertension [27], HDP is more predominant among older women than younger women. Also Berhe et al. [9] discovered that pregnant women above 35 years of age were more likely to develop hypertensive disorders of pregnancy.

4.6 Association between time of first antenatal visit and hypertension

Women who came for antenatal care during third trimester showed a positive association with PIH in both adjusted and unadjusted models with statistically significant results. This results show that attending antenatal services at later stages of pregnancy is associated with high risk of PIH as this prevents early monitoring and management of HDP. The results agree with what Hinkosa et al. [28] discovered in a study conducted in Ethiopia, where lack of ANC follow up was associated with high risk of hypertensive disorders of pregnancy.

4.7 Strengths and limitations

The results obtained should be interpreted with consideration of some limitations. This was a retrospective study where secondary data was used, therefore certain aspects of the study could not be altered for improvement of the outcome. Different types of PIH could not be distinguished, as a result, it is not clear which hypertensive disorder had greater association with the mentioned risk factors. Missing data had to be removed before analysis, as a result, the power of the study was reduced. However, remaining sample size was large enough to make sensible inferences. In the sub-analysis, the sample size was smaller and this could have led to non-significant results for the association of PPH and other risk factors. Also, there was limitation in the choice of risk factors since different studies were used and only common risk factors had to be selected. Nonetheless, combination of common risk factors increased the power of the study hence more precise results.

4.8 Public health implications of the study

The high prevalence of PIH and PPH found in this study is a clear indication that management and prevention of hypertension in pregnancy need to be improved, particularly in obese WLHIV. Women should also be monitored for PPH, specifically those who developed PIH as this condition is likely to continue post delivery. Regarding ART initiation timing, PLHIV should be encouraged to start ART as earlier ART initiation showed lower association with PIH than initiating during pregnancy, however, these findings are not generalizable and they conflict with what other literature say about ART and hypertension but they lay a foundation for further research. Further, Older pregnant WLHIV need to be monitored for PIH, specifically those above 35

years. Early booking at antenatal care should be encouraged to facilitate early monitoring and treatment of PIH.

In conclusion, high prevalence of PIH and PPH was obtained and risk factors associated with these were obesity, old age and late booking at antenatal clinic. Further, women who developed PIH are at high risk of developing PPH. PIH management in WLHIV should be given a priority to prevent maternal mortality and morbidity and to prevent PPH.

Competing interests

The author declares that there are no competing interests.

Acknowledgements

None

Funding information

There was no funding for this study as it is part of Masters in Public Health degree.

Ethics approval

Ethics approval was obtained from Human Research Ethics committee, Faculty of Health Sciences, University of Cape Town (Appendix 1). Ethics letter from the department of Health is also attached (Appendix 2). Informed consent for parent studies, where data was collected from participants was obtained from the participants. In this study, no informed consent from the participants will not be required as these were already obtained from the parent studies.

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Part C: Appendices

1. Ethics approval letter



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



Room 45 E-52-E-Floor- Old Main Building
Groote Schuur Hospital
Observatory 7925
Telephone [021] 406 6492
Email: hrec-submissions@uct.ac.za
Website: www.health.uct.ac.za/home/human-research-ethics

12 December 2022

HREC REF: 792/2022

Dr H Madlala

Epidemiology & Biostatistics
Public Health & Family Medicine
FHS
Email: Hlengiwe.madlala@uct.ac.za
Student: PHHNTH001@myuct.ac.za

Dear Dr Madlala

PROJECT TITLE: PREVALENCE OF PREGNANCY AND POSTPARTUM HYPERTENSION IN OBESE WOMEN LIVING WITH AND WITHOUT HIV AND ASSOCIATIONS WITH ADVERSE BIRTH OUTCOMES IN CAPE TOWN, SOUTH AFRICA-SUB-STUDY LINKED TO 451/2012; 739/2014; 541/2015; 505/2020-MASTERS' CANDIDATE-MS NTHABISENG PHOHLLO

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

It is a pleasure to inform you that the HREC has **formally approved** the above-mentioned study, subject to updating HREC.REF 505/2020.

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

Please submit a progress form, using the standardised Annual Report Form (FHS016) if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period.

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

The HREC acknowledge that the student: Ms Nthabiseng Phohlo will also be involved in this study.

Please quote the HREC REF 792/2022 in all your correspondence.

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

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

HREC/ref 792.2022

Yours sincerely

PROFESSOR M BLOCKMAN
CHAIRPERSON FACULTY OF HEALTH SCIENCES HUM RESEARCH E CS COMMITTEE

Federal Wide Assurance Number: FWA00001637. Institutional Review Board (IRB) number:
IRB00001938 NHREC-registration number: REC-210208-007

This serves to confirm that the University of Cape Town Human Research Ethics Committee complies to the Ethics Standards for Clinical Research with a new drug in patients, based on the Medical Research Council (MRC-SA), Food and Drug Administration (FDA-USA), International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use: Good Clinical Practice (ICH GCP), South African Good Clinical Practice Guidelines (DoH 2020), based on the Association of the British Pharmaceutical Industry Guidelines (ABPI), and Declaration of Helsinki (2013) guidelines. The Human Research Ethics Committee granting this approval is in compliance with the ICH Harmonised Tripartite Guidelines E6: Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) and FDA Code Federal Regulation Part 50, 56 and 312.

2. Department of Health Ethics approval letter



STRATEGY & HEALTH SUPPORT

Health.Research@westerncape.gov.za
tel: +27 21 483 0866; fax: +27 21 483 6058
5th Floor, Norton Rose House., 8 Riebeeck Street, Cape Town, 8001
www.capegateway.gov.za

REFERENCE: WC_202011_024
ENQUIRIES: Dr Sabela Petros

University of Cape Town
Anzio Road
Observatory
Cape Town
7925

For attention: Prof Landon Myer, Dr Hlengiwe Madlala

Re: Addressing the dual burden of HIV and non-communicable disease in pregnancy in South Africa

Thank you for submitting your proposal to undertake the above-mentioned study. We are pleased to inform you that the department has granted you approval for your research.

Please contact the following people to assist you with any further enquiries in accessing the following sites:

Gugulethu CHC

Lunga Makamba

021 633 0020

Kindly ensure that the following are adhered to:

1. Arrangements can be made with managers, providing that normal activities at requested facilities are not interrupted.
2. Researchers, in accessing provincial health facilities, are expressing consent to provide the department with an electronic copy of the final feedback (**annexure 9**) within six months of completion of research. This can be submitted to the provincial Research Co-ordinator (Health.Research@westerncape.gov.za).
3. In the event where the research project goes beyond the *estimated completion date* which was submitted, researchers are expected to complete and submit a progress report (**Annexure 8**) to the provincial Research Co-ordinator (Health.Research@westerncape.gov.za).
4. The reference number above should be quoted in all future correspondence.

Yours sincerely

DR M MOODLEY
DIRECTOR: HEALTH IMPACT ASSESSMENT
DATE:
CC

A handwritten signature in black ink, appearing to be 'M Moodley', written over a white background.

PWID: _____ - ____

STUDY VISIT QUESTIONNAIRE

**This CRF applies to ALL enrolled CAMP Participants
 Complete during 24-28 weeks (V1) Study Visit**

Visit Date								
D	D	M	M	M	Y	Y	Y	Y

Visit Code	
V	1

SECTION A: SOCIODEMOGRAPHIC INFORMATION

1.	Uzelwe Nini? <i>What is your date of birth?</i>	_____ / _____ / _____ DD MMM YYYY
2.	Bangaphi abantu abahlala endlini yakho kuquka nawe? (kuquka abantu abahleli ngaphezu kwenyanga ezintandathu zonyaka) <i>How many people (adults and children) normally live in your household, including yourself? (Include people who live there for more than 6 months of the year)</i>	Inani labantu _____ <i>Number of people</i>
3.	Bangaphi abantu abadala kuquka nawe (abaneninyaka elishumi elinesithandathu okanye ngaphezulu) abahlala endlini yakho? <i>How many adults (aged 16 or older), including you, live in your house?</i>	Inani _____ <i>Number of adults</i>
4.	Bangaphi abantwana (abaneminyaka elishumi elinesihlanu nangaphantsi) abahlala endlini yakho? <i>How many children (aged 15 and under) live in your house?</i>	Inani lababantwana _____ <i>Number of children</i>
5.	Ingaba buthini ubudlelwane bakho naye nawuphi umntu omdala okanye umntwana ohlala nabo endlini yakho? (Nceda khetha ZONKE ezifanelekileyo) <i>What is your relationship to each adult or child living with you at home? (Please tick ALL that apply)</i>	<input type="checkbox"/> Umlingane/ Iqabane <i>Spouse/partner</i> <input type="checkbox"/> Unyana/Intombi <i>Son/Daughter</i> <input type="checkbox"/> Umzukulwane <i>Grandchild</i> <input type="checkbox"/> Umzali <i>Parent</i> <input type="checkbox"/> Umntakwenu/Udadewenu <i>Brother/Sister</i> <input type="checkbox"/> Umthsana <i>Nephew/Niece</i> <input type="checkbox"/> Umzali womnyeni <i>Parent-in-law</i> <input type="checkbox"/> Umkhwenyana/Umolokazana <i>Son-in-law/Daughter-in-law</i> <input type="checkbox"/> Umntwana ongazalwa nguwe <i>Adopted/foster/step-child</i> <input type="checkbox"/> Okunye <i>Other</i> Cacisa <i>Specify:</i> _____
6.	Uthetha oluphi ulwimi ekhaya? <i>What language do you speak at home?</i>	<input type="checkbox"/> IsiXhosa <input type="checkbox"/> IsiZulu <input type="checkbox"/> Isingesi <i>English</i> <input type="checkbox"/> Isibhulu <i>Afrikaans</i>

		<input type="checkbox"/> Okunye <i>Other</i> Cacisa <i>Specify</i> : _____
7.	Wazalelwaphi? <i>Where were you born?</i>	<input type="checkbox"/> Ntshonakoloni <i>Western Cape</i> <input type="checkbox"/> Empumakoloni <i>Eastern Cape</i> <input type="checkbox"/> KwaZulu-Natal <input type="checkbox"/> Erhawutini <i>Gauteng</i> <input type="checkbox"/> Okunye <i>Other</i> Cacisa <i>Specify</i> : _____
8.	Leliphi elona banga liphezulu oliphumeleleyo esikolweni? <i>How far did you get in school?</i>	<input type="checkbox"/> Andinasikolo <i>No education</i> <input type="checkbox"/> Ndiqibe ibanga lokuqala ukuya kwibanga lesithathu <i>Complete Grade 1 (Sub A) to Grade 5 (Standard 3)</i> <input type="checkbox"/> Ndiqibe ibanga lwesine ukuya kwibanga lesihlanu <i>Completed Grade 6 (Standard 4) to Grade 7 (Standard 5)</i> <input type="checkbox"/> Ndiqibe ibanga leshumi <i>Completed Grade 12 (Standard 10) i.e. high school with matriculating</i> <input type="checkbox"/> Ndithatha maqaphapha edyunivesithi/collegi <i>Part of university/college/post-matric education</i> <input type="checkbox"/> Ndiqibe idyunivesithi <i>Completed university/college/post-matric education</i>
9.	Ngoku uyasebenza okanye uyafunda <i>Are you currently working and /or studying?</i>	<input type="checkbox"/> Ewe <i>Yes</i> <input type="checkbox"/> Hayi <i>No</i> → Gqithela ku Q11 SKIP to Q11
10.	Ukuba nguEwe, yeyephi kwezi zilandelayo echaza, bhetele ukuba wenza ntoni? Khetha ibenye <i>If yes, which of one the following best describes what you do? Choose one only</i>	<input type="checkbox"/> Ndiphangela isigxina <i>Employed full-time</i> <input type="checkbox"/> Ndiphangela mangqaphangqapha <i>Employed part-time</i> <input type="checkbox"/> Ndiphangela izingxungxo/ndingumatheng'ethengisa <i>Informal job/hawker</i> <input type="checkbox"/> Uhamba isikolo/ ungumfundi <i>Attending school/learner</i> <input type="checkbox"/> Uhamba isikolo semfundo enomsila <i>Attending tertiary education facility</i>
11.	Ingaba lukhona naluphi na uhlobo lwesibonelelo sika rhulumente olufumanayo? <i>Do you currently receive any social assistance in the form of government grants?</i>	<input type="checkbox"/> Ewe <i>Yes</i> <input type="checkbox"/> Hayi <i>No</i> → Gqithela ku Q13 SKIP to Q13
12.	Loluphi uhlobo lwesibonelelo sika rhulumente olufumanayo? <i>Which type of government grant do you receive?</i>	<input type="checkbox"/> Isibonelelo sabantwana <i>Children's grant</i> <input type="checkbox"/> Isibonelelo sokukhubazeka <i>Disability grant</i> <input type="checkbox"/> Isibonelelo sokukhathalela <i>Care Dependency grant</i> <input type="checkbox"/> Okunye <i>Other</i> Cacisa <i>Specify</i> : _____
13.	Ingaba wamnkela malini ngenyanga (umlinganiselo womvuzo wakho kwezinyanga zintandathu zidlulileyo)? <i>What is your own average income per month (i.e. average over the past 6 months)?</i>	<input type="checkbox"/> Ngaphantsi kwe waka lerandi ngenyanga <i>Less than R1 000 per month</i> <input type="checkbox"/> Iwaka ukuya kumawaka amahlanu erandi ngenyanga <i>R1 000 to R5 000 per month</i>

		<input type="checkbox"/> Amawaka amahlanu ukuya kumawaka alishumi erandi ngenyanga <i>R5 000 to R10 000 per month</i> <input type="checkbox"/> Ngaphezu kwamawaka alishumi erandi ngenyanga <i>More than R10 000 per month</i> <input type="checkbox"/> Akukho nanye <i>None</i>				
14.	<p>Ingaba yimalini oyisa endlini ngenyanga (kwinyanga ezintandathu ezidlulileyo)? <i>What is your average household income per month (i.e. average over the past 6 months)?</i></p>	<input type="checkbox"/> Ngaphantsi kwe waka lerandi ngenyanga <i>Less than R1 000 per month</i> <input type="checkbox"/> Iwaka ukuya kumawaka amahlanu erandi ngenyanga <i>R1 000 to R5 000 per month</i> <input type="checkbox"/> Amawaka amahlanu ukuya kumawaka alishumi erandi ngenyanga <i>R5 000 to R10 000 per month</i> <input type="checkbox"/> Ngaphezu kwamawaka alishumi erandi ngenyanga <i>More than R10 000 per month</i>				
15.	<p>Uya thandana ngoku? <i>Are you currently in a relationship?</i></p>	<input type="checkbox"/> Ewe <i>Yes</i> <input type="checkbox"/> Hayi <i>No</i> → Gqithela ku Q17 <i>SKIP to Q17</i>				
16.	<p>Ungaluchaza njani uthando lwakho? <i>How would you describe your current relationship?</i></p>	<input type="checkbox"/> Utshatile <i>Married, living together</i> <input type="checkbox"/> Anditshatanga, ndiya hlalisana <i>Not married, living together</i> <input type="checkbox"/> Nditshatile, asihlali kunye <i>Married, not living together</i> <input type="checkbox"/> Anditshatanga, asihlali kunye <i>Not married, not living together</i> <input type="checkbox"/> Okunye <i>Other</i> Cacisa <i>Specify</i> : _____				
17.	<p>Unexesha elingakanani uhlala kuledilesi uhlala kuyo? <i>How long have you lived at your current address?</i></p>	Inani _____ iminyaka years <i>Number</i>				
18.	<p>Kwezi ezilandelayo yeyiphi echaza betele ikhaya lakho? <i>Which of the following best describes your home (type of dwelling)?</i></p>	<input type="checkbox"/> Ityotyombe <i>Shack</i> <input type="checkbox"/> Indlu yamaplanga okanye uluhlu olungahlelwanga ngasemva emzini <i>Wendy house or backyard dwelling</i> <input type="checkbox"/> Indlu yesitena <i>Formal House</i> <input type="checkbox"/> Efletini <i>Flat</i> <input type="checkbox"/> Andinandawo yokuhlala <i>Refugee centre/homeless shelter</i> <input type="checkbox"/> Okunye <i>Other</i> Cacisa <i>Specify</i> : _____				
19.	<p>Yonke imihla, bangaphi abantu owabelana nabo Ngegumbi lokulala? <i>On a daily basis, how many people share your bedroom?</i></p>	Inani _____ <i>Number</i>				
20.	<p>Zeziphi kwezi zilandelayo onazo ekhayeni lakho? (Nceda khetha ZONKE ezifanelekileyo)</p>	<table border="0" style="width: 100%;"> <tr> <td style="width: 50%;"> a. Indlu yangasese A toilet inside </td> <td style="width: 50%;"> <input type="checkbox"/> Ewe <i>Yes</i> <input type="checkbox"/> Hayi <i>No</i> </td> </tr> <tr> <td style="width: 50%;"> b. Amanzi abalekayo empompo Running water inside </td> <td style="width: 50%;"> <input type="checkbox"/> Ewe <i>Yes</i> <input type="checkbox"/> Hayi <i>No</i> </td> </tr> </table>	a. Indlu yangasese A toilet inside	<input type="checkbox"/> Ewe <i>Yes</i> <input type="checkbox"/> Hayi <i>No</i>	b. Amanzi abalekayo empompo Running water inside	<input type="checkbox"/> Ewe <i>Yes</i> <input type="checkbox"/> Hayi <i>No</i>
a. Indlu yangasese A toilet inside	<input type="checkbox"/> Ewe <i>Yes</i> <input type="checkbox"/> Hayi <i>No</i>					
b. Amanzi abalekayo empompo Running water inside	<input type="checkbox"/> Ewe <i>Yes</i> <input type="checkbox"/> Hayi <i>No</i>					

Which of the following do you have in your home? (Please tick ALL that apply)	c. Umbane Electricity inside	<input type="checkbox"/> Ewe Yes <input type="checkbox"/> Hayi No	d. Isikhenkcisi A refrigerator	<input type="checkbox"/> Ewe Yes <input type="checkbox"/> Hayi No
	e. Umnxeba A telephone	<input type="checkbox"/> Ewe Yes <input type="checkbox"/> Hayi No	f. Umabona kude A television	<input type="checkbox"/> Ewe Yes <input type="checkbox"/> Hayi No

SECTION B: CLINICAL INFORMATION

21.	<p>Ingaba wakhe waxelelwa ngugqirha ukuba unayo nayiphi na kwezimeko zilandelayo? (nceda khetha ZONKE ezifanelekileyo)</p> <p><i>Has a doctor ever told you that you have any of the following conditions? (tick ALL that apply)</i></p>	<input type="checkbox"/> Utyebekakhulu <i>Obesity</i> <input type="checkbox"/> Isifo sephepha <i>Tuberculosis</i> <input type="checkbox"/> Isifuba/isifo sombefu <i>Asthma</i> <input type="checkbox"/> Isigulo/imeko yokuphefumla ngaphandle kwesifuba/isifo sombefu <i>A respiratory condition other than asthma</i> Cacisa: _____ <i>Specify</i> <input type="checkbox"/> Isifo sokuwa <i>Epilepsy</i> <input type="checkbox"/> Isifo sezintso <i>Renal/Kidney disease</i> <input type="checkbox"/> Intsholongwane enobungozi echaphazela igazi enokwenza umkhuhlane omandla <i>Hepatitis B</i> <input type="checkbox"/> Isifo sentliziyo <i>A heart or cardiac condition</i> Cacisa: _____ <i>Specify</i> <input type="checkbox"/> Akukho nanye <i>None</i>
22.	<p>Kwiveki ezimbini ezidlulileyo ingaba ubukhe wanayo neyiphi na kwezizinto zilandelayo? (khetha ZONKE ezifanelekileyo)</p> <p><i>In the past 2 weeks, have you experienced any of the following symptoms? (tick ALL that apply)</i></p>	<input type="checkbox"/> Ukhohlokhohlo ngaphezu kweveki ezimbini <i>Cough > 2 weeks</i> <input type="checkbox"/> Ukwehla emzimbeni <i>Weight loss</i> <input type="checkbox"/> Umkhuhlane <i>Fever</i> <input type="checkbox"/> Ukubila ebusuku <i>Night Sweats</i> <input type="checkbox"/> Ukukhohlela igazi <i>Coughing up blood</i> <input type="checkbox"/> Ukudinwa <i>Fatigue</i> <input type="checkbox"/> Akukho nanye <i>None</i>
23.	<p>Koku kukhulelwa kwakho <u>kwangoku</u>, ingaba ufumana unyango lwe-TB?</p> <p><i>During your <u>current</u> pregnancy, are you currently taking TB treatment?</i></p>	<input type="checkbox"/> Ewe Yes <input type="checkbox"/> Hayi No <p style="text-align: right;">→ Gqithela ku Q27 SKIP to Q27</p>
24.	<p>Wafumanisa nini ukuba une TB?</p> <p><i>When did you receive this TB diagnosis?</i></p>	<p style="text-align: center;">____ / ____ / ____ DD MMM YYYY</p>

25.	<p>Wafumanisa phi ukuba une TB? <i>Where did you receive this TB diagnosis?</i></p>	<input type="checkbox"/> Nzame Zabantu <input type="checkbox"/> Mzamomhle <input type="checkbox"/> Hannan <input type="checkbox"/> Nyanga <input type="checkbox"/> Vuyani <input type="checkbox"/> Masincedane <input type="checkbox"/> Okunye <i>Other</i> Cacisa <i>Specify</i> : _____
26.	<p>Yayiphi emzimbeni wakho le TB (e.g. kwimiphunga, kwenye indawo)? <i>Where in your body was the TB (e.g., lungs, other location)?</i></p>	Indawo emzimbeni: _____ <i>Place in body</i>
27.	<p>Ngaphambi koku kukhulelwa, ingaba wakhe wafumana unyango lweTB? <i>Before this pregnancy, did you ever take TB treatment?</i></p>	<input type="checkbox"/> Ewe <i>Yes</i> <input type="checkbox"/> Hayi <i>No</i> <p style="text-align: right;">→ Gqithela ku Q32 <i>SKIP to Q32</i></p>
28.	<p>Wafumanisa nini ukuba une TB eku Q27 (hayi koku ukukhulelwa)? <i>When did you receive this TB diagnosis from Q27 (not during this pregnancy)?</i></p>	<p style="text-align: center;">____ / ____ / ____ <small>DD MMM YYYY</small></p>
29.	<p>Ngamaxesha amangaphi ewonke owathi wafumana ngawo unyango lweTB? <i>How many times in total have you been treated for TB?</i></p>	Inani lamaxesha: _____ <i>Number of times</i>
30.	<p>Yaba lixesha elingakanani ufumana unyango lweTB ngexesha lokugqibela eyathi yafunyaniswa ngalo? <i>How long was your TB treatment the last time you were diagnosed?</i></p>	<input type="checkbox"/> Inyanga ezintandathu <i>6 months</i> <input type="checkbox"/> Inyanga ezisibhozo <i>8 months</i> <input type="checkbox"/> Inyanga ezilithoba <i>9 months</i> <input type="checkbox"/> Iyaqhubeleka <i>On-going</i> <input type="checkbox"/> Andazi <i>Don't know</i> <input type="checkbox"/> Okunye <i>Other</i> Cacisa <i>Specify</i> : _____
SECTION C: OBSTETRIC INFORMATION		
31.	<p>Ingaba uyaqala ukukhulelwa? <i>Is this your first pregnancy?</i></p>	<input type="checkbox"/> Ewe <i>Yes</i> <input type="checkbox"/> Hayi <i>No</i> <p style="text-align: right;">→ Gqithela ku Q39 <i>SKIP to Q39</i></p>
C1: PREVIOUS PREGNANCY		
32.	<p>Kukangaphi ukhulelwa, kuuqka noku ukukhulelwa? <i>How many times have you been pregnant before, including this pregnancy?</i></p>	_____ amatyeli okukhulelwa <i>pregnancies</i>
33.	<p>Bangaphi abantwana obazeleyo? <i>How many times have you given birth to a baby?</i></p>	_____ amatyeli okubeleka <i>deliveries</i>
34.	<p>Bangaphi abantwana abaphilayo onabo? <i>How many living children do you have?</i></p>	_____ abantwana abaphilayo <i>living children</i>

35.	<p>Nceda ukhethe uhlobo ngalunye obeleke ngalo <i>Please indicate the number of each type of delivery</i></p>	<p>_____ ndizibelekele <i>vaginal deliveries</i></p> <p>_____ ndibeleke ngesikere (sikiwe) <i>cesarean deliveries</i></p> <p>_____ saphuma <i>miscarriage</i></p> <p>_____ ndasikhupha <i>abortion (TOP)</i></p> <p>_____ Okunye <i>Other</i> Cacisa <i>Specify</i>: _____</p>
36.	<p>Kumatyeli okukhulelwa kwakho adlulileyo ingaba wakhe wafumana naziphi na <u>iziphumo</u> kwezi zilandelayo? (khetha ZONKE ezifanelekileyo) <i>During any of your previous pregnancies, have any of the following <u>outcomes</u> occurred (tick ALL that apply)</i></p>	<p><input type="checkbox"/> Wakhupha isisu <i>Abortion (TOP)</i></p> <p><input type="checkbox"/> Wambeleka engasaphili. <i>Stillbirth</i></p> <p>Cacisa isizathu esisuka kugqirha <i>Specify reason from Dr:</i> _____</p> <p><input type="checkbox"/> Waphuncukelwa sisisu <i>Miscarriage</i></p> <p><input type="checkbox"/> Wabeleka phambi kwexesha <i>Preterm birth (baby born before 37 weeks gestation)</i></p> <p><input type="checkbox"/> Umntwana onobunzima obuncinci (ngaphantsi ko2.5kg) <i>Low birthweight baby (birthweight < 2.5 kg)</i></p> <p><input type="checkbox"/> Umntwana onobunzima obukhulu (ngaphezu kuka 4kg) <i>High birthweight baby (birthweight >4 kg)</i></p> <p><input type="checkbox"/> Umntwana ophile ixeshana emva kokuba umbelekile <i>Neonatal death</i></p> <p><input type="checkbox"/> Akukho nanye <i>None</i></p>
37.	<p>Ukukhulelwa kwakho <u>okungaphambili</u>, ingaba ukhe wafumana ezinye zezimpawo? <i>During any of your <u>previous</u> pregnancies, did you experience any of these symptoms? (tick ALL that apply)</i></p>	<p><input type="checkbox"/> Ukuchama okungaphezulu <i>Excessive urination</i></p> <p><input type="checkbox"/> Ukunxanwa kakhulu <i>Extreme thirst</i></p> <p><input type="checkbox"/> Akukho nanye <i>None</i></p>
38.	<p>Kumatyeli okukhulelwa kwakho angaphambili, ukhe <u>wanezingxaki</u> zilandelayo? (khetha ZONKE ezifanelekileyo) <i>During any of your previous pregnancies, have any of the following <u>complications</u> occurred? (tick ALL that apply)</i></p>	<p><input type="checkbox"/> Unxinizelelo lwegazi <i>High blood pressure (or hypertension) during pregnancy</i></p> <p><input type="checkbox"/> Xinizelelo lwegazi olwenzeka xa ukhulelwe lubengaphezu kweqondo elifanelekileyo kubekho neproteyini <i>Pre-eclampsia</i></p> <p><input type="checkbox"/> Isigulo esenzeka xa ukhulelwe esinokwenza ukuba uxhuzule <i>Eclampsia</i></p> <p><input type="checkbox"/> Ukufunyaniswa kweswekile ngexesha usakhulelweyo <i>Gestational diabetes</i></p> <p><input type="checkbox"/> Ukopha kakhulu ngexesha usakhulelweyo <i>Heavy bleeding during pregnancy</i></p> <p><input type="checkbox"/> Ukopha kakhulu emva kokubeleka <i>Heavy bleeding during or following delivery</i></p> <p><input type="checkbox"/> Ukuphazamiseka kokubeleka (umntwana angezi ngendlela</p>

	<p>efanelekileyo) <i>Obstructed labor (baby could not come out through the birth canal)</i></p> <p><input type="checkbox"/> Ukungahambi kwegazi ngenxa yehlwili elisemithanjeni <i>Thromboembolism (e.g. stroke)</i></p> <p><input type="checkbox"/> Akukho nanye <i>None</i></p>
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C2: CURRENT PREGNANCY

39.	<p>Uneveki ezingaphi ukhulelwe? <i>How many weeks pregnant are you?</i></p> <p>_____iveki weeks</p>	
40.	<p>Ingaba ufuna ukubelekela kweliphi icandelo lezempilo okanye isibhedlele? <i>In which facility do you plan to deliver your baby?</i></p>	<p><input type="checkbox"/> Gugulethu MOU</p> <p><input type="checkbox"/> Mowbray Maternity Hospital</p> <p><input type="checkbox"/> Groote Schuur Hospital</p> <p><input type="checkbox"/> Okunye <i>Other</i> Cacisa <i>Specify</i>: _____</p>
41.	<p>Kokukukhulelwa <u>kwangoku</u>, ingaba ukhe wafumana ezinye ezimpawo? <i>In the <u>current</u> pregnancy, have you experienced any of these symptoms?</i></p>	<p><input type="checkbox"/> Ukuchama okungaphezulu <i>Excessive urination</i></p> <p><input type="checkbox"/> Ukunxanwa kakhulu <i>Extreme thirst</i></p> <p><input type="checkbox"/> Akukho nanye <i>None</i></p>
42.	<p>Cinga ngendlela oziva ngayo ngoku. Yeyiphi kwezi zilandelayo echaza kakhulu ngendlela ocinga ngayongokuba nomntwana kwixesha elilandelayo. <i>Think about how you feel right now. Which of the following statements best describes your own thinking about having a child in the future?</i></p>	<p><input type="checkbox"/> Ndingafuna ukuba nomntwana kwiinyanga ezilishumi elinesibini elizayo. <i>I may want to have a child <u>in the next 12 months</u>.</i></p> <p><input type="checkbox"/> Ndingafuna ukuba nomntwana kwixesha elilandelayo kodwa hayi kwiinyanga ezilishumi elinesibini elizayo <i>I may want to have a child <u>sometime in the future</u> but not in the next 12 months.</i></p> <p><input type="checkbox"/> Ndithathe isigqibo sokuba ndingabinamntwana kwixesha elilandelayo. <i>I have decided that I <u>do not</u> want to have a child in the future.</i></p> <p><input type="checkbox"/> Andiqinisekanga ukuba ndiyafuna ukuba nomntwana okanye hayi kwixesha lilandelayo. <i>I am unsure about whether or not I want to have a child in the future.</i></p> <p><input type="checkbox"/> Okunye <i>Other</i> Cacisa <i>Specify</i>: _____</p>

SECTION D: The London Measure of Unplanned Pregnancy (LMUP)

Ngezantsi kunemibuzo ebuza ngemeko kunye nezimvo zakho ngeli xesha umithe. Nceda cinga ngolu mitho lwangoku xa uphendula lemibuzo ingezantsi. Below are some questions that ask about your circumstances and feelings around the time you became pregnant. Please think of your current pregnancy when answering the questions below.

43.	<p>Kwinyanga endimithe ngayo _____ (Nceda tikisha intetha engqamelene nawe kakhulu):</p> <p><i>In the month that I became pregnant _____</i> <i>(Please tick the statement which most applies to you):</i></p>	<p><input type="checkbox"/> Mna/besingalu sebenzisi ucwangciso. <i>I/we were not using contraception</i></p> <p><input type="checkbox"/> Mna/besilusebenzisa ucwangciso, kodwa hayi lonke ixesha <i>I/we were using contraception, but not on every occasion</i></p> <p><input type="checkbox"/> Mna/besilusebenzisa rhoqo ucwangciso, kodwa sisazi ukuba uhlobo alusebenzi(igqabhukile, ishenxile, iphumile, iphumile ngaphandle, ayisebenzi) kwankanje nje. <i>I/we always used contraception, but knew that the method had failed (i.e. broke, moved, came off, came out, not worked etc) at least once</i></p>
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		<input type="checkbox"/> Mna/besilusebenzisa rhoqo ucwangciso. <i>I/we always used contraception</i>
44.	<p>Kwindima yokuba ngumama (okokuqala, okanye ndiphinde) ndiziva ukuba umitho lwenzeke _____</p> <p>(Nceda tikisha intetha engqamelene nawe kakhulu):</p> <p><i>In terms of becoming a mother (first time or again), I feel that my pregnancy happened at the _____</i></p> <p><i>(Please tick the statement which most applies to you):</i></p>	<input type="checkbox"/> Lixesha elilungileyo <i>Right time</i> <input type="checkbox"/> Kulungile, kodwa ayilo xesha elulingileyo <i>Ok, but not quite right time</i> <input type="checkbox"/> lixesha elingalunganga <i>Wrong time</i>
45.	<p>Nje phambi kokuba ndimithe _____</p> <p>(Nceda tikisha intetha engqamelene nawe kakhulu):</p> <p><i>Just before I became pregnant _____</i></p> <p><i>(Please tick the statement which most applies to you):</i></p>	<input type="checkbox"/> Bendizimisela ukumitha <i>I intended to get pregnant</i> <input type="checkbox"/> Iingcinga zam bezintshintsha <i>My intentions kept changing</i> <input type="checkbox"/> Bendingazimisele ukumitha <i>I did not intend to get pregnant</i>
46.	<p>Nje phambi kokuba ndimithe _____</p> <p>(Nceda tikisha intetha engqamelene nawe kakhulu):</p> <p><i>Just before I became pregnant _____</i></p> <p><i>(Please tick the statement which most applies to you)</i></p>	<input type="checkbox"/> Bendifuna ukuba nosana <i>I wanted to have a baby</i> <input type="checkbox"/> Imizwa yam ibibethabethana ngokuba nosana <i>I had mixed feelings about having a baby</i> <input type="checkbox"/> Bendingafuni ukuba nomtwana <i>I did not want to have a baby</i>
47.	<p>Phambe kokuba ndimithe _____</p> <p>(Nceda tikisha intetha engqamelene nawe kakhulu):</p> <p><i>Before I became pregnant _____</i></p> <p><i>(Please tick the statement which most applies to you)</i></p>	<input type="checkbox"/> Iqabane lam, nam sivumelene ukuba ndimithe <i>My partner and I had agreed that we would like me to be pregnant</i> <input type="checkbox"/> Iqabane lam, nam sixotile ukuba sibenantwana sobabini kodwa asavumelana ukuba mna ndimithe <i>My partner and I had discussed having children together, but hadn't agreed for me to get pregnant</i> <input type="checkbox"/> Asikhange sixoxe ngokuba nabantwana sobabini <i>We never discussed having children together</i>
48.	<p>Phambi kokuba imithe, ikho into oyenzileleyo ukuphucula impilo yakho ulungiselela umitho? (Nceda tikisha zonke engqamelene nawe)</p> <p><i>Before you became pregnant, did you do anything to improve your health in preparation for pregnancy? (Please tick all that apply)</i></p>	<input type="checkbox"/> Ndiyey Folic Acid <i>took folic acid</i> <input type="checkbox"/> Ndiyey okanye ndabuyise unyawo ekutshayeni <i>Stopped or cut down smoking</i> <input type="checkbox"/> Ndiyey okanye ndabuyise unyawo ekuseleni <i>Stopped or cut down drinking alcohol</i> <input type="checkbox"/> Ndiyey ukutya okusempilweni <i>Ate more healthily</i> <input type="checkbox"/> Ndiyey ndafuna amacebisa empilo <i>Sought medical/health advice</i> <input type="checkbox"/> Ndiyey ndathethe amanje amanyathelo nceda chaze: <i>Took some other action, please describe:</i> Cacisa Specify: _____ <input type="checkbox"/> Akukho nenye endiyenzileyo kwezi zisentla phambi ndimithe <i>I did not do any of the above before my pregnancy</i>
SECTION E: HIV CARE AND MEDICATION ADHERENCE		
49.	<p>Zithini iziphumo zakho zentsholongwane kagawulayo?</p> <p><i>What is your HIV status?</i></p>	<input type="checkbox"/> Ndiphila nentsholongwane kagawulayo <i>Positive</i> <input type="checkbox"/> Andinayo intsholongwane kagawulayo → Gqithela ku Q69 <i>Negative</i> SKIP to Q69

50.	<p>Kwakunini ukufumanisa kwakho ukuba uphila nentsholongwane kagawulayo? <i>When did you test HIV positive?</i></p>	<p><input type="checkbox"/> Phambi koku ukukhulelwa, kodwa kokunye ukukhulelwa <i>Before this pregnancy, but during another pregnancy</i></p> <p><input type="checkbox"/> Phambi koku ukukhulelwa, kodwa hayi ndikhulelwe <i>Before this pregnancy, but NOT during another pregnancy</i></p> <p><input type="checkbox"/> Koku ukukhulelwa <i>During this pregnancy</i></p> <p><input type="checkbox"/> Phambi kokuba ndikhulelwe <i>Perinatally infected</i></p>
51.	<p>Kwakunini ukufumanisa kwakho ukuba unentsholongwane? <i>How long ago was it when you were diagnosed with HIV?</i></p>	<p><input type="checkbox"/> Kulenyanga idlulileyo <i>In the last month</i></p> <p><input type="checkbox"/> Kwinyanga ezimbini ezidlulileyo ukuya kwezintlanu <i>In the last 2-5 months</i></p> <p><input type="checkbox"/> Kwinyanga ezintandathu ezidlulileyo ukuya kunyaka <i>In the last 6 months to 1 year</i></p> <p><input type="checkbox"/> Ngaphezu konyaka <i>More than 1 year ago</i></p>
52.	<p>Waqala nini ukuthatha amachiza kagawulayo? <i>When did you initiate ART?</i></p>	<p><input type="checkbox"/> Phambi kokukhulelwa, kodwa kokunye ukukhulelwa <i>Before this pregnancy, but during another pregnancy</i></p> <p><input type="checkbox"/> Phambi kokukhulelwa, kodwa hayi kokunye ukukhulelwa <i>Before this pregnancy, but NOT during another pregnancy</i></p> <p><input type="checkbox"/> Kokukhulelwa <i>During this pregnancy</i></p>
53.	<p>Uqale nini ukuwatya lamachiza uwathathayo ngoku okuthomalalisa intsholongwane kagawulayo? <i>When did you start taking the ART that you are currently taking?</i></p>	<p>_____ / _____ / _____ DD MMM YYYY</p>
54.	<p>Yintoni igama lamachiza owatyayo ngoku? <i>What are the names of the ART that you are currently taking?</i></p>	<p><input type="checkbox"/> TDF-XTC-EFV (Tribuss/Odimune/Atripla/Atrioza/Efaverenz)</p> <p><input type="checkbox"/> TDF-3TC-DTG</p> <p><input type="checkbox"/> Okunye <i>Other</i> Cacisa <i>Specify</i>: _____</p>
55.	<p>Ingaba wakhe wathatha amachiza entsholongwane ka gawulayo ukukhusela ukosuleleka komntwana ngexesha elidlulileyo obukhulelwe ngalo? (dlula ukuba umbuzo 31 ngu EWE) <i>Have you ever taken antiretroviral drugs to prevent mother-to-child HIV transmission ONLY while you were pregnant? (skip if Q31 is YES)</i></p>	<p><input type="checkbox"/> Ewe <i>Yes</i></p> <p><input type="checkbox"/> Hayi <i>No</i></p>
56.	<p>Ingaba iqabane lakho ulixelele ngesimo sakho sentsholongwane kagawulayo? <i>Have you disclosed your HIV status to your partner?</i></p>	<p><input type="checkbox"/> Ewe <i>Yes</i></p> <p><input type="checkbox"/> Hayi <i>No</i></p>
57.	<p>Ingaba umhlobo wakho okanye amalungu osapho lwakho uwaxelele ngesimo sakho sentsholongwane kagawulayo? <i>Have you disclosed your HIV status to a friend or family member?</i></p>	<p><input type="checkbox"/> Ewe <i>Yes</i></p> <p><input type="checkbox"/> Hayi <i>No</i></p>
58.	<p>Kwezintsuku zine zidlulileyo, kukangaphi apho uthu walibala ukuthatha onke amachiza wakho? <i>During the past 4 days, on how many days have you missed taking ALL of your doses?</i></p>	<p><input type="checkbox"/> Akukho nalunye usuku <i>None</i></p> <p><input type="checkbox"/> Lusuku olunye <i>One day</i></p> <p><input type="checkbox"/> Zintsuku ezimbini <i>Two days</i></p> <p><input type="checkbox"/> Zintsuku ezintathu <i>Three days</i></p> <p><input type="checkbox"/> Zintsuku ezine <i>Four days</i></p>

59.	<p>Kwakunini apho wathi walibala ukuthatha amachiza akho? <i>When was the last time you miss any of your medications?</i></p>	<input type="checkbox"/> Kuleveki iphelileyo <i>Within the past week</i> <input type="checkbox"/> Iveki ukuya kwiveki ezimbini ezidlulileyo <i>1-2 weeks ago</i> <input type="checkbox"/> Iveki ezimbini ukuya kwiveki ezine ezidlulileyo <i>2-4 weeks ago</i> <input type="checkbox"/> Inyanga ukuya kwinyanga ezintathu ezidlulileyo <i>1-3 months ago</i> <input type="checkbox"/> Ngaphezu kwenyanga ezintathu ezidlulileyo <i>More than 3 months ago</i> <input type="checkbox"/> Azange ndawalibala ukuwathatha amachiza wam <i>Never skip medications</i>
60.	<p>Kwintsuku ezingamashumi amathathu adlulileyo, kukanganani apho uthe wathatha amachiza entsholongwane kagawulayo ngendlela ebekumele uwathatha ngayo? <i>In the last 30 days, how often did you take your HIV medication in the way you were supposed to?</i></p>	<input type="checkbox"/> Azange <i>Never</i> <input type="checkbox"/> Ibingaxhaphakanga <i>Rarely</i> <input type="checkbox"/> Ngamanye amaxesha <i>Sometimes</i> <input type="checkbox"/> Ngesiqhelo <i>Usually</i> <input type="checkbox"/> Phantse oko <i>Almost always</i> <input type="checkbox"/> Oko oko <i>Always</i>
61.	<p>Kwintsuku ezingamashumi amathathu ezidlulileyo, umhle kangakanani umsebenzi othe wawenza ngokuthi uthathe amachiza akho entsholongwane kagawulayo ngendlela ebekumele uwathathe ngayo? <i>In the last 30 days, how good a job did you do at taking your HIV medication in the way you were supposed to?</i></p>	<input type="checkbox"/> Kakubi kakhulu <i>Very poor</i> <input type="checkbox"/> Kakubi <i>Poor</i> <input type="checkbox"/> Phakathi <i>Fair</i> <input type="checkbox"/> Kulungile <i>Good</i> <input type="checkbox"/> Kulunge kakhulu <i>Very good</i> <input type="checkbox"/> Kugqibelele <i>Excellent</i>
62.	<p>Kwintsuku ezingamashumi amathathu ezidlulileyo, zintsuku ezingaphi othe awalibala ukusela amachiza wakho? <i>In the last 30 days, how many days did you have with no missed doses?</i></p>	<p>_____ iintsuku <i>days</i></p>
63.	<p>Ulufumanaphi ukhathalelo lwezempilo mayelana nesimo sakho sentsholongwane kagawulayo (kugqirha, umongikazi) igama leziko lezempilo. <i>Where do you receive healthcare (i.e. doctor, nurse) for your HIV? (facility name)</i></p>	<input type="checkbox"/> Nzame Zabantu <input type="checkbox"/> Mzamomhle <input type="checkbox"/> Hannan <input type="checkbox"/> Nyanga <input type="checkbox"/> Vuyani <input type="checkbox"/> Masincedane <input type="checkbox"/> Okunye <i>Other</i> Cacisa <i>Specify</i> : _____
64.	<p>Bekunini ukugqibela kwakho ukubonana nogqirha okanye umongikazi mayelana nesimo sakho sentsholongwane kagawulayo? <i>When was the last time you saw a doctor or nurse for your HIV?</i></p>	<input type="checkbox"/> Ngaphantsi kwenyanga edlulileyo <i>Less than 1 months ago</i> <input type="checkbox"/> Phakathi kwenyanga neenyanga ezintathu ezidlulileyo <i>Between 1 and 3 months ago</i> <input type="checkbox"/> Phakathi kweenyanga neenyanga ezintandathu ezidlulileyo <i>Between 3 and 6 months ago</i> <input type="checkbox"/> Phakathi kweenyanga ezintandathu neenyanga ezilishumi elinesibini ezidlulileyo <i>Between 6 and 12 months ago</i>

		<input type="checkbox"/> Ngaphezu kweenyanga ezilishumi elinesibini <i>More than 12 months ago</i>
65.	Kokukukhulelwa kwakho kwangoku,ubukhe wabuvavanyelwa ubungakanani bentsholongwane yakho? <i>In your current pregnancy, have you had your viral load tested?</i>	<input type="checkbox"/> Ewe <i>Yes</i> <input type="checkbox"/> Hayi <i>No</i> <input type="checkbox"/> Andazi / Andikhumbuli <i>Don't know/don't remember</i>
66.	Bezisithini iziphumo zovavanyo lokugqibela? <i>What was the result of the last test?</i>	<input type="checkbox"/> Iyafumaneka <i>Detectable</i> <input type="checkbox"/> Ayifumaneki <i>Undetectable</i> <input type="checkbox"/> Andazi/Andisakhumbuli <i>Don't know/don't remember</i>
67.	Kokukhulelwa kwakho kwangoku,ingaba amajoni akho omzimba ebekhe avavanywa? <i>In your current pregnancy, have you had your CD4 count tested?</i>	<input type="checkbox"/> Ewe <i>Yes</i> <input type="checkbox"/> Hayi <i>No</i> <input type="checkbox"/> Andazi /Andikhumbuli <i>Don't know/don't remember</i>
		<p style="text-align: right;">→ Gqithela ku Q69 <i>SKIP to Q69</i></p> <p style="text-align: right;">→ Gqithela ku Q69 <i>SKIP to Q69</i></p>
68.	Bezisithini iziphumo zovavanyo lokugqibela? <i>What was the result of the last test?</i>	Inani _____ <i>Number</i> <input type="checkbox"/> Andazi /Andikhumbuli <i>Don't know/don't remember</i>

SECTION F: PHYSICAL ACTIVITY AND WEIGHT

69.	Uzibandakanya kangakanani ekuzilolongeni ngokomzimba? Umzekelo wokuzilolonga kuquka ukuhamba xa usiya venkileni,ukubaleka okanye ukudlala imidlalo nabantwana. <i>How often do you engage in physical activity? Examples of physical activity include walking to the shop, running, or playing a game with your children.</i>	<input type="checkbox"/> Andizibandakanyi rhoqo ekuzilolongeni ngokomzimba <i>I don't engage in physical activity regularly</i> → Gqithela ku Q71 <i>SKIP to Q71</i> <input type="checkbox"/> Kanye nakabini evekini <i>1-2 times per week</i> <input type="checkbox"/> Kathathu nakane evekini <i>3-4 times per week</i> <input type="checkbox"/> Ngaphezu kwesine vekini <i>More than 4 times per week</i>
70.	Ukuba uyazibandakanya ekuzilolongeni, unzima kangakanani umsebenzi/umdlalo? <i>If you engage in physical activity, how vigorous is the activity?</i>	<input type="checkbox"/> Ulula - nje ngokuhamba <i>Light - such as walking</i> <input type="checkbox"/> Uphakathi - njengokudlala igamzi nabantwana bam <i>Moderate - such as playing a game with your children</i> <input type="checkbox"/> Unzima - njengoku baleka okanye ngokuya uyozivocavoca <i>Vigorous- such as running or going to an exercise class</i>
71.	Ucinga ukuba ukuzilolonga xa ukhulelwe kukhuselekile? <i>Do you think exercising while pregnant is safe?</i>	<input type="checkbox"/> Ewe, ndicinga ukuba kukhuselekile ukuzilolonga loxa ukhulelwe <i>Yes, I think it is safe to exercise while pregnant</i> <input type="checkbox"/> Hayi, andiqondi ukuba kukhuselekile ukuzilolonga loxa ukhulelwe <i>No, I do not think it is not safe to exercise while pregnant</i> <input type="checkbox"/> Andazi <i>Don't know</i>
72.	Ingaba ukukhulelwa kwakho kuyichaphazela njani indlela otya ngayo?	<input type="checkbox"/> Nditya kakhulu kuba ndityela abantu ababini <i>I eat much more because I am eating for two</i>

	How does being pregnant influence how much you eat?	<input type="checkbox"/> Nditya kakhulwana, kodwa hayi kakhulu <i>I eat a little more, but not that much more</i> <input type="checkbox"/> Nditya ngokufanayo <i>I eat about the same as when I am not pregnant</i> <input type="checkbox"/> Nditya kancinci <i>I eat less</i> <input type="checkbox"/> Andazi <i>Don't know</i>
73.	Ingaba ugqirha wakho wakhe wathetha nawe ngokuba kumele unyuke kangakanani emzimbeni xa ukhulelwe? <i>Has your doctor ever talked with you about how much weight you should gain during pregnancy?</i>	<input type="checkbox"/> Ewe <i>Yes</i> <input type="checkbox"/> Hayi <i>No</i>
74.	Uceba ukuzijonga ukuba unyuka kangakanani ngokomzimba ngelixa ukhulelwe? <i>Do you plan to monitor how much weight you gain during this pregnancy?</i>	<input type="checkbox"/> Ewe <i>Yes</i> <input type="checkbox"/> Hayi <i>No</i> <input type="checkbox"/> Andazi <i>Don't know</i>
75.	Uceba ukunyuka kangakanani ngokomzimba wakho? <i>How much weight do you plan to gain?</i>	<input type="checkbox"/> Ndizimisele ukunyuka kakhuklu ngomzimba <i>I plan to gain as much weight as I can</i> <input type="checkbox"/> Ndizimisele ukunyuka ngomzimba hayi kakhulu <i>I plan to gain some weight, but not too much</i> <input type="checkbox"/> Andizimisela ukwenyuka ngomzimba konke-konke <i>I don't plan to gain much weight at all</i> <input type="checkbox"/> Andazi <i>Don't know</i>
76.	Uceba ukwehla emzimbeni emveni kokuba ubelekile? <i>Do you plan to lose the weight you gain during this pregnancy after delivery?</i>	<input type="checkbox"/> Ewe <i>Yes</i> <input type="checkbox"/> Hayi <i>No</i> → Gqithela ku SECTION G <i>SKIP to SECTION G</i> <input type="checkbox"/> Andazi <i>Don't know</i>
77.	Ukuba ewe, uceba ukwehla njani? <i>If yes, how do you plan to lose weight?</i>	<input type="checkbox"/> Ukutya kakuhle <i>Diet</i> <input type="checkbox"/> Ukuzivocavoca <i>Exercise</i> <input type="checkbox"/> Zombini ukutya kakuhle kunye nokuzivocavoca <i>Both diet and exercise</i> <input type="checkbox"/> Elinye, cacisa: _____ <i>Other, specify</i>

SECTION G: HOUSEHOLD FOOD INSECURITY

1.	Kwezinyanga ezintathu ezidlulileyo, ingaba benikhe nacutha ukutya kwabantwana (okanye amanye amalungu osapho okanye wena) endlini yakho kuba bekungekho mali yaneleyo yokutya? <i>In the last 3 months, were any meals made smaller for the children (or other family members or yourself) in your home because there wasn't enough money for food?</i>	<input type="checkbox"/> Ewe <i>Yes</i> <input type="checkbox"/> Hayi <i>No</i>
2.	Kwezinyanga zintathu zidlulileyo, ingaba abantwana (okanye amanye amalungu osapho okanye wena)	<input type="checkbox"/> Isidlo sakusasa <i>Breakfast</i>

	<p>endlini nikhe ningatyi kuba bekungekho mali yokuthenga ukutya? <i>In the last 3 months, did any children (or other family members or yourself) in the household ever skip the following meals because there wasn't enough money for food</i></p>	<input type="checkbox"/> Isidlo sasemini <i>Lunch</i> <input type="checkbox"/> Isidlo sangokuhlwa <i>Super</i> <input type="checkbox"/> Andikhe dingatyi <i>No meals skipped</i>	<p>→ Gqithela ku Q4 SKIP to Q4</p>
3.	<p>Ukuba ewe, kunkangaphi isenzeka kwinyanga ezintathu ezidlulileyo? <i>If yes, how often did this happen in the past three months?</i></p>	<input type="checkbox"/> Nqho ngenyanga <i>Every month</i> <input type="checkbox"/> Nge nyanga ezimbini <i>During two month</i> <input type="checkbox"/> Ngenyanga enye <i>During one month</i>	
4.	<p>Kwinyanga ezintathu ezidlulileyo, abantwana (okanye amanye amalungu osapho okanye wena) endlini nakhe nalamba kodwa anakwazi ukuthenga ukutya okuninzi? <i>In the last 3 months, were any children (or other family members or yourself) in the household ever hungry but you just couldn't afford more food?</i></p>	<input type="checkbox"/> Ewe <i>Yes</i> <input type="checkbox"/> Hayi <i>No</i>	
5.	<p>Kwezinyanga zintathu zidlulileyo, ingaba abanye abantwana (okanye amanye amalungu osapho okanye wena) endlini nakhe anaty imini yonke kuba kwakungekho mali yokuthenga ukutya? <i>In the last 3 months, did any children (or other family members or yourself) in the household ever not eat for a whole day because there wasn't enough money for food?</i></p>	<input type="checkbox"/> Ewe <i>Yes</i> <input type="checkbox"/> Hayi <i>No</i>	

SECTION H: FOOD FREQUENCY SCREENING

Ngoku sizokubuza imibuzo malunga noluhlu lwentlobo zokutya obukutyile kwiveki ephelileyo. Kukangakanani kuleveki iphelileyo (kwintsuku ezisixhenxe) usitya oku kutya kulandelayo? (PHAWULA KULUHLU LONKE) *We are now going to ask you some questions about the different food items you ate in past week. How often during the PAST WEEK (7 days) did you eat the following? (MARK EVERY ITEM)*

	Uluhlu lokutya <i>Food Item</i>	Zange <i>Never</i>	Hayi Rhoqo <i>Not everyday</i>		Rhoqo <i>Everyday</i>		
			Amaxesha ayi 1-3 ngeveki <i>1 - 3 times per week</i>	Amaxesha ayi 4-6 ngeveki <i>4 - 6 times per week</i>	Kanye ngosuku <i>1 time a day</i>	Kabini ngosuku <i>2 times a day</i>	Kathathu nangaph ezulu ngosuku <i>3+ times a day</i>
1.	Inyama ebomvu (nokuba yeyiphi) <i>Red meat (any)</i>						
2.	Inyama yenkukhu (nokuba yeyiphi) <i>Chicken (any)</i>						
3.	Ifishi enkonxiweyo/esetotini <i>Tinned fish</i>						
4.	Inyama yangaphakathi umzekelo isibindi <i>Organ meat e.g. liver</i>						
5.	Amaqanda (nokuba ngawaphi) <i>Eggs (any)</i>						
6.	Ubisi/iyogathi/amasi okusela/kwi papa <i>Milk/yoghurt/maas to drink/on cereals</i>						
7.	Ubisi etini/ekofini <i>Milk in tea/coffee</i>						
8.	Itshizi (ngaphandle kwe khotheji) <i>Cheese (except cottage)</i>						
9.	Izityalo umzekelo imbotyi ezinkonxiweyo/ezisetotini, ilentils						

	<i>Legumes e.g. baked beans, lentils</i>						
10.	Amantongomane <i>Peanut and nuts</i>						
11.	Isonka esibrawuni/isonka senengqolowa/irolls <i>Brown/whole wheat bread/rolls</i>						
12.	Ipapa yebrakfesi (engaphekwayo) <i>Breakfast cereal (instant)</i>						
13.	Isidudu se owutsi <i>Oats porridge</i>						
14.	Ibhotolo (ekwi khonteyina yeplastikhi) <i>Soft margarine (tub)</i>						
15.	Ibrokholi <i>Broccoli</i>						
16.	Isipinatshi (kuquka nemifuno) <i>Spinach (including morogo)</i>						
17.	Iminqatha/ikherotsi <i>Carrots</i>						
18.	Itumata (eluhlaza/ephekiweyo) <i>Tomato (raw/cooked)</i>						
19.	Iphizi eziluhlaza <i>Green peas</i>						
20.	Imbotyi eziluhlaza <i>Green beans</i>						
21.	Imifuno exutyiweyo <i>Mixed vegetables</i>						
22.	Ithanga/ibhathanathi <i>Pumpkin/butternut</i>						
23.	Ibhatata <i>Sweet potato</i>						
24.	Itapile (nokuba zilungiswe kanjani) <i>Potato (any preparation)</i>						
25.	Iziqhamo zesetrasi umzekelo iorenji <i>Citrus fruit e.g. orange</i>						
26.	Isiselo soqobo se orenji/gwava <i>Pure orange/guava juice</i>						
27.	Ibhanana <i>Banana</i>						
28.	Iimango <i>Mangoes</i>						
29.	Iiapile/amapere <i>Apples/pears</i>						
30.	iavokhado <i>Avocado</i>						

SECTION I: Edinburgh Postnatal Depression Scale (EPDS)

Singathanda ukwazi ukuba ubuziva njani kuleveki iphelileyo. Nceda ukhethe impendulo esondele ekubeni ubuziva njani kuleveki iphelileyo, hayi nje indlela oziva ngayo namhlanje. Nceda ufunde lonke uluhlu lwengxelo nganye.

We would like to know how you have been feeling in the past week. Please choose the answer that comes closest to how you have felt in the past week, not just how you feel today. Please read all the options for each statement.

		0	1	2	3
1.	Bendiyihleka ndikwazi nokubona icala lezinto ezifani. <i>I have been able to laugh and see the funny side of thing.</i>	Njengoko bendihleli ndisenza. <i>As much as I always could.</i>	Hayi kangako okwangoku. <i>Not quite so much now.</i>	Ngokucacileyo hayi kangako okwangoku. <i>Definitely not so much now.</i>	Hayi kwaphela. <i>Not at all.</i>
2.	Bendijonge enkalweni ngokonwabela izinto. <i>I have looked forward with enjoyment to things.</i>	Njengoko ndandisenza. <i>As much as I ever did.</i>	Kancinci kunendlela endandisenza ngayo. <i>A little less than I used to.</i>	Ngaphantsi kunendlela endandisenza ngayo. <i>Much less than I used to.</i>	Kwakunzima nje kwaphela. <i>Hardly at all.</i>
3.	Ndasola isiqu sam ngokungeyomfuneko xa izinto zazihamba kakubi. <i>I have blamed myself unnecessarily when things went wrong.</i>	Ewe, ixesha elininzi. <i>Yes, most of the time.</i>	Ewe, ngenyelinye ixesha. <i>Yes, some of the time.</i>	Hayi kangako <i>Not very much.</i>	Hayi, zange <i>No, never.</i>
4.	Bendinexhala ngaphandle kwesizathu. <i>I have been anxious or worried for no good reason.</i>	Hayi, konke-konke. <i>No, not at all.</i>	Zange ifane yenzeke. <i>Hardly ever.</i>	Ewe, ngamanye amaxesha. <i>Yes, sometimes.</i>	Ewe, kakhulu. <i>Yes, very much.</i>
5.	Ndaziva ndisoyika okanye ndidyuduzela ngaphandle kwesizathu. <i>I have felt scared or panicky for no very good reason.</i>	Ewe, kaninzi. <i>Yes, quite a lot.</i>	Ewe, ngamanye amaxesha. <i>Yes, sometimes.</i>	Hayi kakhulu. <i>No, not much.</i>	Hayi, konke-konke. <i>No, not at all.</i>
6.	Izinto zindongamele. <i>Things have been getting on top of me.</i>	Ewe, amaxesha amaninzi bendinokwazi ukwenzanto kwaphela. <i>Yes, most of the times I haven't been managing at all.</i>	Ewe, ngamanye amaxesha bendinokwazi ukwenzanto njengesiqhelo. <i>Yes, sometimes I haven't been managing as well as usual.</i>	Hayi, ixesha elininzi bendinokwazi ukwenzanto kakuhle <i>No, most of the time I have managed quite well.</i>	Hayi, bendinokwazi ukwenza izinto kakuhle oko. <i>No, I have been managing as well as ever.</i>
7.	Bendingonwabanga kangangento yokuba bekubanzima nokulala. <i>I have been so unhappy that I have had difficulty sleeping.</i>	Ewe, ixesha elininzi. <i>Yes, most of the time.</i>	Ewe, ngamanye amaxesha. <i>Yes, sometimes.</i>	Hayi kakhulu. <i>Not very much.</i>	Hayi, kwaphela. <i>No, not at all.</i>
8.	Ndaye ndaziva ndilusizi okanye ndinxunguphele <i>I have felt sad or miserable.</i>	Ewe, ixesha elininzi. <i>Yes, most of the time.</i>	Ewe, ngamanye amaxesha. <i>Yes, sometimes.</i>	Hayi kakhulu. <i>Not very much.</i>	Hayi, kwaphela. <i>No, not at all.</i>
9.	Bendingonwabanga kangangento yokuba bendikhala <i>I have been so unhappy that I have been crying.</i>	Ewe, ixesha elininzi. <i>Yes, most of the time.</i>	Ewe, ngamanye amaxesha. <i>Yes, sometimes.</i>	Hayi kakhulu. <i>Not very much.</i>	Hayi, kwaphela. <i>No, not at all.</i>
10.	Into yokuzonzakalisa yaye yenzeka kum <i>The thought of harming myself has occurred to me.</i>	Ewe, kaninzi. <i>Yes, quite a lot</i>	Ngamanye amaxesha. <i>Sometimes</i>	Zange ifane yenzeke. <i>Hardly ever</i>	Zange <i>Never</i>

SECTION J: AUDIT (Alcohol Use Disorders Identification Test)

Ngoku sizokubuza eminye imibuzo malunga nokusebenzisa kwakho utywala njengoko uye wafumanisa ukuba ukhulelwe. Nceda ukhethhe impendulo echanekileyo ngokubiyela ibhokisi efanelekileyo. Nceda uqale umbuzo ngamnye ngo “Njengoko uye wafumanisa ukuba ukhulelwe”

Now we are going to ask you some questions about your use of alcohol beverages since you found out you were pregnant. Please choose the correct answer by circling in the appropriate box. Please start each question with “Since you found out you were pregnant”

		0	1	2	3	4
1.	Ubuseela kangakanani utywala? <i>How often do you have a drink containing alcohol?</i> Uba u'0' UGQIBILE If '0' END	Zange <i>Never</i>	Kanye ngenyanga nangaphantsi <i>Once a month or less often</i>	Kabini ukuya kwisine ngenyanga <i>2-4 times a month</i>	Kabini ukuya kwisithathu ngeveki <i>2-3 times a week</i>	Kane nangaphezulu evekini <i>4 times or more a week</i>
2.	Zingaphi iglasi zotywala oziselayo ngemini? <i>How many drinks containing alcohol do you have on a typical day when you are drinking?</i>	Kanye okanye kabini <i>1 or 2</i>	Kathathu okanye kane <i>3 or 4</i>	Kahlanu okanye kathandathu <i>5 or 6</i>	Kasixhenxe okanye kalithoba <i>7 or 9</i>	Kalishumi nangaphezulu <i>10 or more</i>
3.	Kukangakanani usela iglasi ezintandathu nangaphezulu ngexesha elinye? <i>How often do you have six or more drinks on one occasion?</i>	Zange <i>Never</i>	Ngaphantsi kwenyanga <i>Less than monthly</i>	Ngenyanga <i>Monthly</i>	Ngeveki <i>Weekly</i>	Ngosuku okanye phantse yonke imihla <i>Daily or almost daily</i>
4.	Kukangakanani kulonyaka uphelileyo ufumanisa ukuba awukwazi ukuyeka ukusela xa sele uqalile? <i>How often during the last year have you found that you were not able to stop drinking once you had started?</i>	Zange <i>Never</i>	Ngaphantsi kwenyanga <i>Less than monthly</i>	Ngenyanga <i>Monthly</i>	Ngeveki <i>Weekly</i>	Ngosuku okanye phantse yonke imihla <i>Daily or almost daily</i>
5.	Kukangakanani ungaphumeleli ukwenza into ebekumele ukuba uyayenza awakwazi ngenxa yokuba ubuseela? <i>How often have you failed to do what was normally expected of you because of drinking?</i>	Zange <i>Never</i>	Ngaphantsi kwenyanga <i>Less than monthly</i>	Ngenyanga <i>Monthly</i>	Ngeveki <i>Weekly</i>	Ngosuku okanye phantse yonke imihla <i>Daily or almost daily</i>
6.	Kukangaphi ufuna “ukuqabula” ekuseni kuba ufuna ukuqala usuku lwakho kakhuhle emva kokuba ubusele utywala kakhulu? <i>How many times have you needed a drink in the morning to get yourself going after a heavy drinking session?</i>	Zange <i>Never</i>	Ngaphantsi kwenyanga <i>Less than monthly</i>	Ngenyanga <i>Monthly</i>	Ngeveki <i>Weekly</i>	Ngosuku okanye phantse yonke imihla <i>Daily or almost daily</i>
7.	Kukangakanani uzifumanisa unesazela okanye uzisola emva kokuba usele? <i>How often have you had a feeling of guilt or remorse after drinking?</i>	Zange <i>Never</i>	Ngaphantsi kwenyanga <i>Less than monthly</i>	Ngenyanga <i>Monthly</i>	Ngeveki <i>Weekly</i>	Ngosuku okanye phantse yonke imihla <i>Daily or almost daily</i>
8.	Kukangakanani ungayikhumbuli into eyenzekileyo kubusuku obudlulileyo ngenxa yokuba ubuseela?	Zange <i>Never</i>	Ngaphantsi kwenyanga <i>Less than monthly</i>	Ngenyanga <i>Monthly</i>	Ngeveki <i>Weekly</i>	Ngosuku okanye phantse yonke imihla <i>Daily or almost daily</i>

	<i>How often have you been unable to remember what happened the night before because you had been drinking?</i>					
9.	Ukhe wonzakala okanye omnye umntu wonzakala ngenxa yokuba ubusele? <i>Have you or anyone else been injured as a result of your drinking?</i>	Hayi No	Ewe, kodwa hayi kulonyaka uphelileyo <i>Yes, but not in the past year</i>	Ewe, kulonyaka uphelileyo <i>Yes, during the past year</i>		
10.	Sikhona isizalwana okanye umhlobo wakho, ugqirha okanye omnye umsebenzi wezempilo othe waxhalaba ngendlela osela ngayo waza wakucebisa ukuba uthobe isantya? <i>Has a relative or friend, doctor or other health worker been concerned about your drinking or suggested you cut down?</i>	Hayi No	Ewe, kodwa hayi kulonyaka uphelileyo <i>Yes, but not in the past year</i>	Ewe, kulonyaka uphelileyo <i>Yes, during the past year</i>		
Record total of specific items here						

Name of QC officer: _____ Date: ____ / ____ / ____

GLUCOMETER CAPILLARY BLOOD READINGS

Baseline Glucose	<input type="text"/> <input type="text"/> . <input type="text"/> mmol/L	<input type="checkbox"/> Not Measured
60 min Glucose	<input type="text"/> <input type="text"/> . <input type="text"/> mmol/L	<input type="checkbox"/> Not Measured
120 min Glucose	<input type="text"/> <input type="text"/> . <input type="text"/> mmol/L	<input type="checkbox"/> Not Measured

LABORATORY VENOUS BLOOD RESULTS

Baseline Glucose	<input type="text"/> <input type="text"/> . <input type="text"/> mmol/L	<input type="checkbox"/> Not Measured
60 min Glucose	<input type="text"/> <input type="text"/> . <input type="text"/> mmol/L	<input type="checkbox"/> Not Measured
120 min Glucose	<input type="text"/> <input type="text"/> . <input type="text"/> mmol/L	<input type="checkbox"/> Not Measured
HDL	<input type="text"/> . <input type="text"/> <input type="text"/> mmol/L	<input type="checkbox"/> Not Measured
LDL	<input type="text"/> . <input type="text"/> <input type="text"/> mmol/L	<input type="checkbox"/> Not Measured
Triglycerides	<input type="text"/> . <input type="text"/> <input type="text"/> mmol/L	<input type="checkbox"/> Not Measured
Total Cholesterol	<input type="text"/> . <input type="text"/> <input type="text"/> mmol/L	<input type="checkbox"/> Not Measured

Signed Assessor of Measurements: _____ Date: ____ / ____ / ____
DD MMM YYYY

Signed QC Officer: _____ Date: ____ / ____ / ____
DD MMM YYYY

PWID: _____ - ____

MATERNAL PHYSICAL EXAMINATION FORM

**This CRF applies to ALL enrolled Group 2 Participants
Complete during Enrolment (≤20 weeks) Study Visit**

Visit Date								
D	D	M	M	M	Y	Y	Y	Y

Visit Code	
A	1

ANTHROPOMETRY

Height	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> cm	<input type="checkbox"/> Not Measured
Weight	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> kg	<input type="checkbox"/> Not Measured
MUAC	<input type="text"/> <input type="text"/> . <input type="text"/> cm	<input type="checkbox"/> Not Measured

BLOOD PRESSURE

Reading 1	Time of Measurement <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	Systolic: <input type="text"/> <input type="text"/> <input type="text"/> mmHg	Diastolic: <input type="text"/> <input type="text"/> <input type="text"/> mmHg
Reading 2	Time of Measurement <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	Systolic: <input type="text"/> <input type="text"/> <input type="text"/> mmHg	Diastolic: <input type="text"/> <input type="text"/> <input type="text"/> mmHg
Reading 3	Time of Measurement <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	Systolic: <input type="text"/> <input type="text"/> <input type="text"/> mmHg	Diastolic: <input type="text"/> <input type="text"/> <input type="text"/> mmHg

<input type="checkbox"/> Blood Pressure Not Measured → END			
Method: (tick one) <input type="checkbox"/> Manual <input type="checkbox"/> Automated			
Location: (tick one) <input type="checkbox"/> Left Arm <input type="checkbox"/> Right Arm			
Position: (tick one) <input type="checkbox"/> Sitting <input type="checkbox"/> Supine <input type="checkbox"/> Standing			

Additional Notes:

Signed Assessor measurements obtained by: _____

Date of QC: / /
 DD MMM YYYY

Signed Study Nurse: _____

PWID: _____ - ____

MATERNAL DEMOGRAPHICS, OBSTETRIC & MEDICAL HISTORY

**This CRF applies to ALL enrolled Group 2 Participants
(HIV-infected & ≤20 weeks GA as confirmed by USS)
Complete during Enrolment (≤20 weeks) Study Visit**

Visit Date							
D	D	M	M	M	Y	Y	Y

Visit Code	
A	1

SOCIODEMOGRAPHIC INFORMATION	
1. Mingaphi iminyaka yakho <i>What is your age?</i>	Age: _____ Iminyaka <i>years</i>
2. Uzelwe Nini <i>What is your date of birth</i>	____ / ____ / ____ DD MMM YYYY
3. Uthetha oluphi ulwimi ekhayai? <i>What language do you speak at home?</i>	<input type="checkbox"/> isiXhosa <input type="checkbox"/> isiZulu <input type="checkbox"/> isiBhulu <i>Afrikaans</i> <input type="checkbox"/> isiNgesi <i>English</i> <input type="checkbox"/> Olunye <i>Other</i> Cacisa <i>Specify:</i> _____
4. Leliphi elona banga liphezulu oliphumeleleyo? <i>What is the highest level of schooling/education that you have completed?</i>	<input type="checkbox"/> Umgangatho <i>Grade:</i> _____ Okanye <i>or</i> Ibanga <i>Standard:</i> _____ <input type="checkbox"/> Imfundo enomsila <i>Postsecondary :</i> _____ <input type="checkbox"/> None
5. Ngoku uyasebenza okanye uyafunda <i>Are you currently working and /or studying?</i>	<input type="checkbox"/> Ewe <i>Yes</i> <input type="checkbox"/> Hayi <i>No</i> → Gqithela ku Q7 SKIP to Q7
6. Ukuba nguEwe, yeyephi kwezi zilandelayo echaza, bhetele ukuba wenza ntoni? <i>If yes, which of one the following best describes what you do?</i> Khetha ibenye /Choose one only	<input type="checkbox"/> Ndiphangela isigxina <i>Employed full-time</i> <input type="checkbox"/> Ndiphangela mangqaphangqapha <i>Employed part-time</i> <input type="checkbox"/> Ndiphangela izingxungxo /ndingumatheng'ethengisa <i>Informal job/hawker</i> <input type="checkbox"/> Uhamba isikolo/ ungumfundi <i>Attending school/learner</i> <input type="checkbox"/> Uhamba isikolo semfundo enomsila <i>Attending tertiary education facility</i>

<p>7. Uhlala kwikhaya elinjani? <i>What kind of home do you live in?</i></p>	<p><input type="checkbox"/> Ityotyombe/ uhlaliso olungahlelwanga <i>Shack/informal dwelling</i></p> <p><input type="checkbox"/> Indlu yesitena <i>Formal house</i></p> <p><input type="checkbox"/> Ifleti/ indlu kamaspala <i>Flat/council home</i></p> <p><input type="checkbox"/> Olunye <i>Other</i> Cacisa <i>Specify:</i> _____</p>	
<p>8. Ingaba indlu yakho inazo ezi zinto zilandelayo: <i>Does your house have the following:</i></p> <p>Phendula ZONKE <i>Respond to ALL</i></p>	<p>a. Indlu yangasese <input type="checkbox"/> Ewe <i>Yes</i> <i>A toilet inside</i> <input type="checkbox"/> Hayi <i>No</i></p> <p>c. Umbane <input type="checkbox"/> Ewe <i>Yes</i> <i>Electricity inside</i> <input type="checkbox"/> Hayi <i>No</i></p> <p>e. Umnxeba <input type="checkbox"/> Ewe <i>Yes</i> <i>A telephone</i> <input type="checkbox"/> Hayi <i>No</i></p>	<p>b. Amanzi abalekayo empompo <input type="checkbox"/> Ewe <i>Yes</i> <i>Running water inside</i> <input type="checkbox"/> Hayi <i>No</i></p> <p>d. Isikhenkcisi <input type="checkbox"/> Ewe <i>Yes</i> <i>A refrigerator</i> <input type="checkbox"/> Hayi <i>No</i></p> <p>f. Umabona kude <input type="checkbox"/> Ewe <i>Yes</i> <i>A television</i> <input type="checkbox"/> Hayi <i>No</i></p>
<p>9. Ukhulelwe kangaphi (kudibene nesi isisu)? <i>How many times have you been pregnant (incl. current pregnancy)?</i></p>	<p>Inani lokukhulelwa: _____ <i># of pregnancies:</i></p>	
<p>10. Bangaphi abantwana obazeleyo? <i>How many children have you given birth to?</i></p>	<p>Inani labantwana: <input type="checkbox"/> _____ <input type="checkbox"/> None <i># of children</i></p> <p>→ Ukuba awunabo abantwana, Gqithela ku Q12 <i>If NONE, SKIP to Q12</i></p>	
<p>11. Bangaphi kwaba bantwana abaphilayo? <i>How many of these children are living?</i></p>	<p>Inani labantwana: <input type="checkbox"/> _____ <input type="checkbox"/> None <i># of children</i></p>	
<p>12. Uya thandana ngoku? <i>Are you currently in a relationship?</i></p>	<p><input type="checkbox"/> Ewe <i>Yes</i></p> <p><input type="checkbox"/> Hayi <i>No</i> → Gqithela ku Q15</p>	
<p>13. Ungaluchaza njani uthando lwakho? <i>How would you describe your current relationship?</i></p>	<p><input type="checkbox"/> Utshatile <i>Married</i></p> <p><input type="checkbox"/> Anditshatanga ,ndiya hhlisana <i>Not married, living together</i></p> <p><input type="checkbox"/> Nditshatile, asihlali kunye <i>Married, not living together</i></p> <p><input type="checkbox"/> Anditshatanga, asihlali kunye <i>Not married, not living together</i></p> <p><input type="checkbox"/> Olunye <i>Other</i> Cacisa <i>Specify:</i> _____</p>	
<p>14. Lileshe ellingakanani unobudlelwana nalomntu? <i>How long have you been in a relationship with this person?</i></p>	<p>Ixesha <i>Duration in:</i> Inyanga <i>Months:</i> _____ Okanye <i>or</i> Iminyaka <i>Years:</i> _____</p>	

PWID: _____ - ____

CLINICAL & ART HISTORY

<p>15. Ubuqala ukufumanisa ukuba unentsholongwa kagawulayo kolumitho okanye phambi kokuba ukhulelwe? <i>Did you first test HIV positive <u>in this pregnancy</u> or <u>before this pregnancy</u>?</i></p>	<p><input type="checkbox"/> Koku ukukhulelwa → Gqithela ku Q41 <i>In this pregnancy</i></p> <p><input type="checkbox"/> Phambi koku ukukhulelwa <i>Before this pregnancy</i></p>
<p>16. Kwakunini ukuqala kwakho ukufumanisa ukuba unentsholongwane kagawulayo? <i>When did you 1st test HIV-positive?</i></p>	<p>____ / ____ / ____ DD MMM YYYY</p>
<p>17. Kwakutheni ukuze oluhlolo lwenziwe? <i>Why was this test conducted?</i></p>	<p><input type="checkbox"/> Ndivavanywe ngelishesha ndikhulelweyo <i>Tested during pregnancy</i></p> <p><input type="checkbox"/> VCT/Ndandifuna ukuvavanywe <i>VCT/Wanted to be tested</i></p> <p><input type="checkbox"/> Ndafunyaniswa ndinesifo sephepha (TB) <i>Diagnosed with TB</i></p> <p><input type="checkbox"/> Ndangeniswa esibhedlele <i>Admitted to the hospital</i></p> <p><input type="checkbox"/> Olunye <i>Other</i> Cacisa <i>Specify:</i> _____</p>
<p>18. Emva kokugqibela kwethu ukuthetha, ukhe watya iAZT? <i>Have you ever taken any AZT (while you were pregnant)?</i></p>	<p><input type="checkbox"/> Ewe <i>Yes</i></p> <p><input type="checkbox"/> Hayi <i>No</i> → Gqithela ku Q21</p>
<p>19. Kwizisu zakho ozi khulelweyo uyifumene kangaphi iAZT <i>For how many pregnancies have you taken AZT?</i></p>	<p># izisu: _____ <i># pregnancies</i></p>
<p>20. Ugqibele nini ukuyitya? <i>When did you last take AZT?</i></p>	<p>____ / ____ / ____ DD MMM YYYY</p>
<p>21. Emva kokugqibela kwethu ukuthetha, ukhe watya iNVP? <i>Have you ever taken any NVP (at delivery)?</i></p>	<p><input type="checkbox"/> Ewe <i>Yes</i></p> <p><input type="checkbox"/> Hayi <i>No</i> → Gqithela ku Q24</p>
<p>22. Kwizisu zakho ozi khulelweyo uyifumene kangaphi iNVP <i>For how many pregnancies have you taken NVP?</i></p>	<p># izisu: _____ <i># pregnancies</i></p>
<p>23. Ugqibele nini ukuyitya? <i>When did you last take NVP?</i></p>	<p>____ / ____ / ____ DD MMM YYYY</p>
<p>24. Wawuke wawathatha amachiza okuthomalalisa intsholongwane (awobomi bakho bonke) <i>Have you ever taken triple drug antiretroviral therapy (lifelong ART)?</i></p>	<p><input type="checkbox"/> Ewe <i>Yes</i></p> <p><input type="checkbox"/> Hayi <i>No</i> → Gqithela ku Q41</p>

<p>25. Ingaba wawafumana amachiza okuthomalalisa intsholongwane ukugqibela kakho? <i>Where did you receive ART the last time?</i></p>	<p>Igama lekliniki: _____ <i>Name of clinic:</i></p>
<p>26. Ukususela ukuqala kwakho ukutya amachiza, wawuke wawayeka na? <i>Since you first started taking ART, have you ever stopped?</i></p>	<p><input type="checkbox"/> Ewe <i>Yes</i> <input type="checkbox"/> Hayi <i>No</i> → Gqithela ku Q31</p>
<p>27. Mangaphi amaxesha uyeka uphinde uqalele ukutya amachiza? <i>How many times have you stopped and restarted ART?</i></p>	<p>Amaxesha: _____ <i># times</i></p>
<p>28. Bekunini ukugqibela kwakho ukuqalela amachiza? <i>When did you restart ART the last time?</i></p>	<p>_____ / _____ / _____ DD MMM YYYY</p>
<p>29. Usawatyama amachiza okuthomalalisa intsholongwane kagawulayo? <i>Are you still on ART?</i></p>	<p><input type="checkbox"/> Ewe <i>Yes</i> → Gqithela ku Q31 <input type="checkbox"/> Hayi <i>No</i></p>
<p>30. Ukuba nguHayi, uyeke nini ukuwatya amachiza okuthomalalisa intsholongwane kagawulayo? <i>When did you stop taking ART?</i></p>	<p>_____ / _____ / _____ DD MMM YYYY → Gqithela ku Q41</p>
<p>31. Yintoni igama lamachiza owatyayo ngoku? <i>What are the names of the ARVs you are currently taking?</i></p>	<p><input type="checkbox"/> TDF-3TC-EFV <input type="checkbox"/> TDF-3TC-NVP <input type="checkbox"/> TDF-FTC-EFV (Tribuss/Odimune/Atripla) <input type="checkbox"/> AZT-3TC-NVP <input type="checkbox"/> AZT-3TC-EFV <input type="checkbox"/> TDF-3TC-LPV/r <input type="checkbox"/> AZT-3TC-LPV/r <input type="checkbox"/> Other: _____</p>
<p>32. iART uzithatha kangaphi ngemini? <i>How many times a day do you take your ART pills?</i></p>	<p>Amaxesha: _____ <i># of times</i></p>
<p>33. Zingaphi ipilisi ozityayo ngexesha? <i>How many pills do you take each time?</i></p>	<p># lipilisi: _____ <i># of pills</i></p>
<p>34. Mangaphi amachiza entsholongwane ohlukeneyo owatyayo? <i>How many different HIV medicines do you take?</i></p>	<p># Amchiza: _____ <i># of medicines</i></p>

PWID: _____ - ____

ADHERENCE	
<p>35. Njengokuba uqalile ukutya iART, ungazibeka kweliphi inqanaba lokutya ngendlela owawuyibonisiwe yokutya amachiza akho? <i>Since you started taking HIV medicine, how would you rate how well you usually do taking your HIV medicines in the way you are supposed to?</i></p>	<p><input type="checkbox"/> Kakubi kakhulu <i>Very poor</i></p> <p><input type="checkbox"/> Kakubi <i>Poor</i></p> <p><input type="checkbox"/> Ndiphakathi <i>Fair</i></p> <p><input type="checkbox"/> Kakuhle <i>Good</i></p> <p><input type="checkbox"/> Kakuhle kakhulu <i>Very good</i></p> <p><input type="checkbox"/> Kakuhle okugqithisileyo <i>Excellent</i></p>
<p>36. Ngoku cinga ngentsuku ezi-30 ezidlulileyo.yeyiphi kwezi zilandelayo echaza eyona ndlela otya ngayo amachiza akho? <i>Now think about the last 30 days. How would you rate how well you did taking your HIV medicines?</i></p>	<p><input type="checkbox"/> Kakubi kunakuqala <i>Worse than usual</i></p> <p><input type="checkbox"/> Kakuhle kunakuqala <i>Better than usual</i></p> <p><input type="checkbox"/> Kuyafana njengesiqhelo <i>About the same as usual</i></p>
<p>37. Kwezi ntsuku eziyi-30 ezidlulileyo, zimini ezingaphi okhe walibala ukutya amchiza akho entsholongwana? <i>In the last 30 days, on how many days did you miss at least one dose of any of your HIV medicines?</i></p>	<p>Iintsuku: _____(0-30) # of days</p>
<p>38. Kwezi ntsuku eziyi-30 ezidlulileyo, kukangaphi usitya amachiza akho entsholongwane ngendlela omele kuwatya ngayo? <i>In the last 30 days how often did you take your HIV medicines in the way that you were supposed to?</i></p>	<p><input type="checkbox"/> Zange <i>Never</i></p> <p><input type="checkbox"/> Kumbalwa <i>Rarely</i></p> <p><input type="checkbox"/> Ngamanye amaxesha <i>Sometimes</i></p> <p><input type="checkbox"/> Ngesiqhelo <i>Usually</i></p> <p><input type="checkbox"/> Malunga lonke ixesha <i>Almost always</i></p> <p><input type="checkbox"/> Lonke ixesha <i>Always</i></p>
<p>39. Kwezi ntsuku zi-30 zidlulileyo uwatye kakuhle kanjani amachiza akho entsholongwane njengohlobo omele ukuwatya ngalo? <i>In the last 30 days, how good a job did you do at taking your HIV medicines in the way that you were supposed to?</i></p>	<p><input type="checkbox"/> Kakubi kakhulu <i>Very poor</i></p> <p><input type="checkbox"/> Kakubi <i>Poor</i></p> <p><input type="checkbox"/> Ndiphakathi <i>Fair</i></p> <p><input type="checkbox"/> Kakuhle <i>Good</i></p> <p><input type="checkbox"/> Kakuhle kakhulu <i>Very good</i></p> <p><input type="checkbox"/> Kakuhle okugqithisileyo <i>Excellent</i></p>
<p>40. Kunzima kangakanani ukutya amachiza akho entsholongwane ngendlela omele kukuwatya ngayo? <i>How hard is it for you to take your HIV medicines in a way you are supposed to?</i></p>	<p><input type="checkbox"/> Kunzima kakhulu kakhulu <i>Extremely hard</i></p> <p><input type="checkbox"/> Kunzima kakhulu <i>Very hard</i></p> <p><input type="checkbox"/> Kunzima nje <i>Somewhat hard</i></p> <p><input type="checkbox"/> Akunzimanga <i>Not very hard</i></p> <p><input type="checkbox"/> Akunzimanga kwaphela <i>Not hard at all</i></p>

PWID: _____ - ____

TB HISTORY	
<p>41. Kolu umitho ingaba, ugqira okanye unesi uthe une-TB? <i>During your <u>current</u> pregnancy, has a doctor or nurse told you that you have TB?</i></p>	<p><input type="checkbox"/> Ewe <i>Yes</i> <input type="checkbox"/> Hayi <i>No</i></p> <p style="text-align: right;">→ Gqithela ku Q46</p>
<p>42. Uxelelwe nini ngoku kugula? <i>When did you receive this diagnosis?</i></p>	<p>____ / ____ / ____ DD MMM YYYY</p>
<p>43. Uxelelwe phi ngoku kugula? <i>Where did you receive this diagnosis?</i></p>	<p>Igama lekliniki : _____ <i>Name of clinic</i></p>
<p>44. Iphi emzimbeni wakho le TB? <i>Where in your body was the TB (eg, lungs, other location)?</i></p>	<p>Indawo emzimbeni : _____ <i>Place in body</i></p>
<p>45. Uye wafumana unyango lwayo? <i>Did you receive treatment for TB?</i></p>	<p><input type="checkbox"/> Ewe <i>Yes</i> <input type="checkbox"/> Hayi <i>No</i></p>
<p>46. Ngaphandle koku kukhulelwa, ugqira okanye unesi bakhe bakuxelela ukuba une-TB? <i>Other than during this pregnancy has a doctor or nurse ever told you that you have TB?</i></p>	<p><input type="checkbox"/> Ewe <i>Yes</i> <input type="checkbox"/> Hayi <i>No</i></p> <p style="text-align: right;">→ Gqithela ku Q52</p>
<p>47. Waxelelwa nini ngoku kugula kuqala ingekuko ngoku ukhulelwe? <i>When did you receive this diagnosis the last time (not during this pregnancy)?</i></p>	<p>____ / ____ / ____ DD MMM YYYY</p>
<p>48. Waye walufumana unyango ngoko? <i>Did you receive treatment for TB the last time?</i></p>	<p><input type="checkbox"/> Ewe <i>Yes</i> <input type="checkbox"/> Hayi <i>No</i></p> <p style="text-align: right;">→ Gqithela ku Q52</p>
<p>49. Kungamaxesha amangaphi ewonke ufumana unyango lweTB? <i>How many times in total have you been treated for TB?</i></p>	<p>Amaxesha: _____ <i># of times</i></p>
<p>50. Walufumana phi unyango lwe TB? <i>Where did you receive your TB treatment?</i></p>	<p>Igama lekliniki : _____ <i>Name of clinic</i></p>
<p>51. Lixesha elingakanani ufumana unyango lweTB ukugqibela kwakho ukunyangelwa yona? <i>How long did you receive treatment for TB the last time you were treated for TB?</i></p>	<p><input type="checkbox"/> 6 nyanga <i>6 months</i></p> <p><input type="checkbox"/> 8 nyanga <i>8 months</i></p> <p><input type="checkbox"/> 9 nyanga <i>9 months</i></p> <p><input type="checkbox"/> Iyaqhubekeka <i>On-going</i></p> <p><input type="checkbox"/> Amanye, cacisa: _____ <i>Other, specify</i></p> <p><input type="checkbox"/> Andazi <i>Don't know</i></p>

MEDICAL HISTORY			
52. Wakhe whacitha ubusuku esibhedlele? <i>Have you ever spent the night in hospital?</i>		<input type="checkbox"/> Ewe <i>Yes</i> <input type="checkbox"/> Hayi <i>No</i>	→ Gqithela ku Q54
53. Ukuba nguEwe, cacisa ngezantsi ulaliso ngalunye <i>If yes, list details for each admission below:</i>			
a. Isizathu <i>Reason for admission</i>	b. Ulaliswe nini? <i>Date of Admission</i>	c. Isibhedlele/kliniki <i>Hospital/ Clinic</i>	d. Wawukhulelwe <i>Were you pregnant at the time of this admission?</i>
i.	____ / ____ / ____ <small>DD MMM YYYY</small>		<input type="checkbox"/> Ewe <i>Yes</i> <input type="checkbox"/> Hayi <i>No</i>
ii.	____ / ____ / ____ <small>DD MMM YYYY</small>		<input type="checkbox"/> Ewe <i>Yes</i> <input type="checkbox"/> Hayi <i>No</i>
iii.	____ / ____ / ____ <small>DD MMM YYYY</small>		<input type="checkbox"/> Ewe <i>Yes</i> <input type="checkbox"/> Hayi <i>No</i>
iv.	____ / ____ / ____ <small>DD MMM YYYY</small>		<input type="checkbox"/> Ewe <i>Yes</i> <input type="checkbox"/> Hayi <i>No</i>
v.	____ / ____ / ____ <small>DD MMM YYYY</small>		<input type="checkbox"/> Ewe <i>Yes</i> <input type="checkbox"/> Hayi <i>No</i>

SUBSTANCE USE	
54. Ngaphambili ukhe wasebenzisa oku kulandelayo <i>In the past, have you used any of the following :</i>	Alcohol: <input type="checkbox"/> Ewe/ <i>Yes</i> <input type="checkbox"/> Hayi/ <i>No</i> Cigarettes: <input type="checkbox"/> Ewe/ <i>Yes</i> <input type="checkbox"/> Hayi/ <i>No</i> Drugs: <input type="checkbox"/> Ewe/ <i>Yes</i> <input type="checkbox"/> Hayi/ <i>No</i>
55. Kwezi ntsuku ziyi 30 ukhe wasebenzisa oku kulandelayo <i>In the last 30 days, have you used any of the following</i>	Alcohol: <input type="checkbox"/> Ewe/ <i>Yes</i> <input type="checkbox"/> Hayi/ <i>No</i> Cigarettes: <input type="checkbox"/> Ewe/ <i>Yes</i> <input type="checkbox"/> Hayi/ <i>No</i> Drugs: <input type="checkbox"/> Ewe/ <i>Yes</i> <input type="checkbox"/> Hayi/ <i>No</i>

Signed Interviewer completing CRF: _____

Date of QC: ____ / ____ / ____
DD MMM YYYY

Signed Site Coordinator: _____

PWID: _____ - ____

MATERNAL PHYSICAL EXAMINATION

This CRF applies to ALL enrolled BPOS participants

To be completed at ALL Study visits

Visit Date							
D	D	M	M	M	Y	Y	Y

Visit Code	
A	1

ANTHROPOMETRY:

Height	_____. ____ cm	<input type="checkbox"/> Not measured
Weight	_____ kg	<input type="checkbox"/> Not measured
MUAC 1	_____ cm	<input type="checkbox"/> Not measured
MUAC 2	_____ cm	<input type="checkbox"/> Not measured

Additional Notes:

Nceda ubhale phantsi nantoni na oyikrokrelayo ngelixesha uthatha lemilinganiselo.

Please write down anything suspicious that you might take note off while taking these measurements.

Signed Assessor of Measurements: _____

Date: ____ / ____ / ____
DD MMM YYYY

Signed QC Officer: _____

Date: ____ / ____ / ____
DD MMM YYYY

Signed Study Coordinator: _____

Date: ____ / ____ / ____
DD MMM YYYY

PWID: _____ - ____

MATERNAL DEMOGRAPHICS & CLINICAL HISTORY
 This CRF applies to ALL enrolled BPOS participants

Visit Date							
D	D	M	M	M	Y	Y	Y

Visit Code	
A	1

A: SOCIODEMOGRAPHIC INFORMATION

<p>1. Uzelwe Nini? <i>What is your date of birth?</i></p>	<p align="center">____ / ____ / ____ <small>DD MMM YYYY</small></p>
<p>2. Uthetha oluphi ulwimi ekhaya? <i>What language do you speak at home?</i></p>	<p> <input type="checkbox"/> isiXhosa <input type="checkbox"/> isiZulu <input type="checkbox"/> isiBhulu <i>Afrikaans</i> <input type="checkbox"/> isiNgesi <i>English</i> <input type="checkbox"/> Olunye <i>Other</i> Cacisa <i>Specify</i>: _____ </p>
<p>3. Leliphi elona banga liphezulu oliphumeleleyo? <i>What is the highest level of schooling/education that you have completed?</i></p>	<p> <input type="checkbox"/> Inqanaba: _____ <small>Grade</small> Okanye or Ibanga: _____ <small>Standard</small> <input type="checkbox"/> Imfundo ephezulu: cacisa _____ <small>Postsecondary, specify</small> <input type="checkbox"/> Akukho nanye <small>None</small> </p>
<p>4. Ingaba uyasebenza na ngoku kwaye/okanye uyafunda? <i>Are you currently working and/or studying?</i></p>	<p> <input type="checkbox"/> Ewe <i>Yes</i> <input type="checkbox"/> Hayi <i>No</i> </p> <p align="right">→ Gqithela ku Q8 SKIP to Q8</p>
<p>5. Ukuba nguEwe, yeyiphi kwezi zilandelayo eyichaza ngcono into oyenzayo? <i>If yes, which one of the following best describes what you do?</i></p> <p>Khetha ibenye kuphela <i>Choose ONE only</i></p>	<p> <input type="checkbox"/> Uphangela isigxina <small>Employed full-time</small> <input type="checkbox"/> Uphangela manqapha-nqapha <small>Employed part-time</small> <input type="checkbox"/> Umsebenzi onjengokuthengisa endlini okanye esitalatweni. <small>Informal job/hawker</small> <input type="checkbox"/> Uhamba isikolo/ngumfundi <small>Attending school/learner</small> <input type="checkbox"/> Uhamba isikolo eYunivesithi/Kholeji <small>Attending tertiary education (University/College)</small> </p>
<p>6. Ingaba ukhona umvuzo owufumanayo? <i>Do you earn an income?</i></p>	<p> <input type="checkbox"/> Ewe <i>Yes</i> <input type="checkbox"/> Hayi <i>No</i> </p> <p align="right">→ Gqithela ku Q8 SKIP to Q8</p>

<p>7. Ingaba ungakanani umvuzo owufumanayo ngenyanga? <i>How much income do you earn per month?</i></p>	<p><input type="checkbox"/> Ngaphantsi kwe waka lerandi ngenyanga <i>Less than R1 000 per month</i></p> <p><input type="checkbox"/> Iwaka ukuya kumawaka amahlanu erandi ngenyanga <i>R1 000 to R5 000 per month</i></p> <p><input type="checkbox"/> Amawaka amahlanu ukuya kumawaka alishumi erandi ngenyanga <i>R5 000 to R10 000 per month</i></p> <p><input type="checkbox"/> Amawaka alishumi ukuya kumawaka alishumi elinesihlanu erandi ngenyanga <i>R10 000 to R15 000 per month</i></p> <p><input type="checkbox"/> Ngaphezu kwamawaka alishumi elinesihlanu erandi ngenyanga. <i>More than R15 000 per month</i></p>
<p>8. Ingaba lukhona naluphi na uhlobo lwesibonelelo sika rhulumente olufumanayo? <i>Do you currently receive any social assistance in the form of government grants?</i></p>	<p><input type="checkbox"/> Ewe <i>Yes</i></p> <p><input type="checkbox"/> Hayi <i>No</i></p> <p style="text-align: right;">→ Gqithela ku Q11 <i>SKIP to Q11</i></p>
<p>9. Loluphi uhlobo lwesibonelelo sika rhulumente olufumanayo ? <i>Which type of government grant do you receive?</i></p>	<p><input type="checkbox"/> Isibonelelo sabantwana <i>Children's grant</i></p> <p><input type="checkbox"/> Isibonelelo sokukhubazeka <i>Disability grant</i></p> <p><input type="checkbox"/> Isibonelelo sokukhathalela <i>Care Dependency grant</i></p> <p><input type="checkbox"/> Okunye , nceda cacisa: _____ <i>Other, please specify</i></p>
<p>10. Ufumana izibonelelo ezingaphi kwezi zikhankanywe ngasentla (Q9)? <i>Nceda ucacise inani</i> <i>How many of each of the grants mentioned above (Q9) do you receive?</i> Please specify number</p>	<p><input type="checkbox"/> Isibonelelo sabantwana inani lezibonelelo ____ <i>Children's grant</i> # of grants</p> <p><input type="checkbox"/> Isibonelelo sokukhubazeka inani lezibonelelo ____ <i>Disability grant</i> # of grants</p> <p><input type="checkbox"/> Isibonelelo sokukhathalela inani lezibonelelo ____ <i>Care Dependency grant</i> # of grants</p> <p><input type="checkbox"/> Ezinye, nceda cacisa inani lezibonelelo ____ <i>Other, please specify: _____</i> # of grants</p>
<p>11. Uhlala kwikhaya elinjani? <i>What kind of home do you live in?</i></p>	<p><input type="checkbox"/> Ityotyombe/ uhlaliso olungahlelwanga <i>Shack/informal dwelling</i></p> <p><input type="checkbox"/> Indlu yesitena <i>Formal house</i></p> <p><input type="checkbox"/> Ifleti/ indlu kamasipala <i>Flat/council home</i></p> <p><input type="checkbox"/> Elinye, Cacisa: _____ <i>Other Specify:</i></p>

PWID: _____ - ____

<p>12. Ingaba indlu yakho inazo ezi zinto zilandelayo: <i>Does your house have the following:</i></p> <p>Phendula kuzo ZONKE <i>Respond to ALL</i></p>	<p>a. Indlu yangasese engaphakathi <i>A toilet inside</i></p> <p><input type="checkbox"/> Ewe <i>Yes</i> <input type="checkbox"/> Hayi <i>No</i></p>	<p>b. Amanzi empompo ngaphakathi endlini <i>Running water inside</i></p> <p><input type="checkbox"/> Ewe <i>Yes</i> <input type="checkbox"/> Hayi <i>No</i></p>
	<p>c. Umbane ngaphakathi endlini <i>Electricity inside</i></p> <p><input type="checkbox"/> Ewe <i>Yes</i> <input type="checkbox"/> Hayi <i>No</i></p>	<p>d. Isikhenkcezisi <i>A refrigerator</i></p> <p><input type="checkbox"/> Ewe <i>Yes</i> <input type="checkbox"/> Hayi <i>No</i></p>
	<p>e. Umnxeba wasendlini <i>A landline telephone</i></p> <p><input type="checkbox"/> Ewe <i>Yes</i> <input type="checkbox"/> Hayi <i>No</i></p>	<p>f. Umabonakude <i>A television</i></p> <p><input type="checkbox"/> Ewe <i>Yes</i> <input type="checkbox"/> Hayi <i>No</i></p>

<p>13. Oku kuquka nawe, bangaphi abantu (abadala nabantwana) abahlala endlini yakho. <i>Including yourself, how many people (adults and children) live in your house?</i></p>	<p>Inani Labantu: _____ <i>Number of people</i></p>
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<p>14. Ukhulelwe kangaphi (kuquka noku kukhulelwa kwangoku)? <i>How many times have you been pregnant (including current pregnancy)?</i></p>	<p>Inani lokukhulelwa: _____ <i>Number of pregnancies</i></p>
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<p>15. Bangaphi abantwana obazeleyo? <i>How many children have you given birth to?</i></p>	<p>Inani labantwana: <input type="checkbox"/> _____ <input type="checkbox"/> Abekho <i>Number of children</i> <i>None</i></p> <p>→ Ukuba awunabo abantwana, Gqithela ku Q17 <i>If NONE, SKIP to Q17</i></p>
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<p>16. Bangaphi kwaba bantwana abaphilayo? <i>How many of these children are living?</i></p>	<p>Inani labantwana: <input type="checkbox"/> _____ <input type="checkbox"/> Abekho <i>Number of children</i> <i>None</i></p>
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B: MEDICAL HISTORY

Ngoku sizokubuza imibuzo embalwa malunga nembali yempilo yakho kuquka isifo sephepha kunye nentsholongwane kagawulayo.
We are now going to ask you a few questions about your previous medical history including TB and HIV.

B1: TB HISTORY

<p>17. Koku kukhulelwa kwakho kwangoku, ingaba ugqirha okanye unesi wakhe wakuxelele ukuba une-TB? <i>During your <u>current</u> pregnancy, has a doctor or nurse told you that you have TB?</i></p>	<p><input type="checkbox"/> Ewe <i>Yes</i> <input type="checkbox"/> Hayi <i>No</i></p> <p>→ Gqithela ku Q22 <i>SKIP to Q22</i></p>
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<p>18. Wafumanisa nini ukuba une TB? <i>When did you receive this TB diagnosis?</i></p>	<p>_____ / _____ / _____ <i>DD MMM YYYY</i></p>
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<p>19. Wafumanisa phi ukuba une TB? <i>Where did you receive this TB diagnosis?</i></p>	<p>Igama lekliniki : _____ <i>Name of clinic</i></p>
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<p>20. Yayiphi emzimbeni wakho le TB (e.g. kwimiphunga, kwenye indawo)? <i>Where in your body was the TB (e.g., lungs, other location)?</i></p>	<p>Indawo emzimbeni : _____ <i>Place in body</i></p>
<p>21. Waye walufumana unyango lwe TB? <i>Did you receive treatment for TB?</i></p>	<p><input type="checkbox"/> Ewe <i>Yes</i> <input type="checkbox"/> Hayi <i>No</i></p>
<p>22. Ngaphandle koku kukhulelwa, ingaba ugqirha okanye unesi wakhe wakuxelela ukuba une-TB? <i>Other than during this pregnancy has a doctor or nurse ever told you that you have TB?</i></p>	<p><input type="checkbox"/> Ewe <i>Yes</i> <input type="checkbox"/> Hayi <i>No</i></p> <p style="text-align: right;">→ Gqithela ku Q28 SKIP to Q28</p>
<p>23. Wafumanisa nini ukuba une TB eku Q22 (hayi koku ukukhulelwa)? <i>When did you receive this TB diagnosis from Q22 (not during this pregnancy)?</i></p>	<p>____ / ____ / ____ DD MMM YYYY</p>
<p>24. Waye walufumana unyango lwe TB ngelaxesha yayifunyaniswa (Ku Q22)? <i>Did you receive treatment for TB when last diagnosed (From Q22)?</i></p>	<p><input type="checkbox"/> Ewe <i>Yes</i> <input type="checkbox"/> Hayi <i>No</i></p>
<p>25. Ngamaxesha amangaphi ewonke owathi wafumana ngawo unyango lweTB? <i>How many times in total have you been treated for TB?</i></p>	<p>Inani lamaxesha: _____ <i>Number of times</i></p>
<p>26. Walufumana phi unyango lwe TB (Ku Q22)? <i>Where did you receive your TB treatment (From Q22)?</i></p>	<p>Igama lekliniki : _____ <i>Name of clinic</i></p>
<p>27. Yaba lixesha elingakanani ufumana unyango lweTB ngexesha lokugqibela eyathi yafunyaniswa ngalo? <i>How long was your TB treatment the last time you were diagnosed?</i></p>	<p><input type="checkbox"/> inyanga ezintandathu <i>6 months</i> <input type="checkbox"/> inyanga ezisibhozo <i>8 months</i> <input type="checkbox"/> inyanga ezilithoba <i>9 months</i> <input type="checkbox"/> Iyaqhubeleka <i>On-going</i> <input type="checkbox"/> Elinye, cacisa: _____ <i>Other, specify</i> <input type="checkbox"/> Andazi <i>Don't know</i></p>
<p>B2: HIV HISTORY</p>	
<p>28. Ingaba wakhe wayivavanyelwa intsholongwane kagawulayo? <i>Have you ever been tested for HIV?</i></p>	<p><input type="checkbox"/> Ewe <i>Yes</i> <input type="checkbox"/> Hayi <i>No</i></p>
<p>29. Ingaba uchaphazelekile na yintsholongwane ka gawulayo okanye hayi awuchaphazelekanga? <i>Are you HIV-negative or HIV-positive?</i></p>	<p><input type="checkbox"/> Andichaphazelekanga <i>Negative</i> <input type="checkbox"/> Ndichaphazelekile <i>Positive</i> <input type="checkbox"/> Andazi <i>Don't know</i></p>

PWID: _____ - ____

NB: Nceda gcwalisa yonke ifomu yentsholongwane ka gawulayo

Please complete HIV CRF for ALL PARTICIPANTS

Signed Interviewer completing CRF: _____

Date: _____ / _____ / _____
DD MMM YYYY

Signed QC Officer: _____

Date: _____ / _____ / _____
DD MMM YYYY

Signed Study Coordinator: _____

Date: _____ / _____ / _____
DD MMM YYYY

BMJ Guidance for Authors

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4.1 RESEARCH

4.1.1 What kind of research does The BMJ publish?

The BMJ gives priority to articles reporting original, robust research studies that can improve decision making in medical practice, policy, education, or future research and will be important to general medical readers internationally.

Competing interest forms at *The BMJ*

Section	Form information	Example statements
Editorials and Education articles (including State of the Art reviews and Therapeutics)	<p>Since 2014, <i>The BMJ</i> requires that such articles must be written by authors without relevant financial ties to industry. By “industry” we mean companies producing drugs, medical foods, nutraceuticals, devices, apps or tests; medical education companies; or other companies with a financial or reputational interest in the topic of the article. We consider the following relationships with industry to be relevant, making it unlikely that we would be able to publish your work: employment; ownership of stocks and shares (this excludes mutual funds or other situations in which the person is not in a position to control investment decisions); travel and accommodation expenses; paid consultancy or directorship; patent ownership; aid membership of speakers’ panels or bureaus and advisory board; acting as an expert witness; being in receipt of a fellowship, equipment, writing, or administrative support; writing or consulting for a medical education promotional or communications company. If you are in doubt about the relevance of any potential conflict of interest please discuss with the editor of the appropriate section before submission.</p> <p>All authors must review the updated COI policy and complete The BMJ’s Education Declaration of Interests form. If the article is accepted for publication these completed forms will be stored and made available on request. The corresponding author should insert within their manuscript a summary statement derived from the information provided in the COI forms (link below): “<i>/We have read and understood BMJ policy on declaration of interests and declare the following interests: [list them or state that you have none].</i>”</p>	<ul style="list-style-type: none"> No competing interests: “<i>We have read and understood BMJ policy on declaration of interests and declare that we have no competing interests.</i>” Competing interests disclosed: “<i>We have read and understood BMJ policy on declaration of interests and declare the following interests: AA is an unpaid member of XX group developing guidelines for ZZ.</i>”
Research and RMR articles	<p>We ask authors of research papers to use a revised version of the ICMJE’s unified disclosure form. The unified form can be used for several journals. Each journal, will, however, integrate the form into its processes in different ways.</p> <p>Authors must disclose three types of information:</p> <ul style="list-style-type: none"> Associations with commercial entities that provided support for the work reported in the submitted manuscript (the timeframe for disclosure in this section of the form is the lifespan of the work being reported). Associations with commercial entities that could be viewed as having an interest in the general area of the submitted manuscript (in the three years before submission of the manuscript). Non—financial associations that may be relevant or seen as relevant to the submitted manuscript. <p>All authors must complete the disclosure form and send it to the corresponding author who will use the information in the forms to craft the COI statement for the paper (examples provided below). The statement but not the forms must be included with the submission, and that must be included with the initial submission. If the paper is accepted, these forms will be required and will be published alongside the article.</p> <p>The statement in the manuscript should take the following format: <i>“Competing interests: All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf and declare: no support from any organisation for the submitted work [or describe if any]; no financial relationships with any organisations that might have an interest in the submitted work in the previous three years [or describe if any]; no other relationships or activities that could appear to have influenced the submitted work [or describe if any].”</i></p>	<ul style="list-style-type: none"> No competing interests: “<i>All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf and declare: no support from any organisation for the submitted work; no financial relationships with any organisations that might have an interest in the submitted work in the previous three years; no other relationships or activities that could appear to have influenced the submitted work.</i>” Grant funding for research but no other competing interest: “<i>All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf and declare: all authors had financial support from ABC Company for the submitted work; no financial relationships with any organisations that might have an interest in the submitted work in the previous three years; no other relationships or activities that could appear to have influenced the submitted work.</i>” Mixed competing interests: “<i>All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf and declare: no support from any organisation for the submitted work; AB has received research grants and honorariums from XYZ company, BF has been paid for developing and delivering educational presentations for BBB foundation, DF does consultancy for HHH and VVV companies; no other relationships or activities that could appear to have influenced the submitted work.</i>”
All other articles	<p>Complete <i>The BMJ’s</i> Disclosure form. We do not need to receive signed copies of the statements regarding competing interests or the licence to publication: these are for information only. When submitting your article (or a revised version of it) you will be prompted at our online editorial office to tick two boxes, confirming that you have read and complied with our policies on competing interests and licence to publication. Please also ensure that your manuscript, whether in original or revised form, also includes your written statements of competing interests and licence to publication.</p>	

The BMJ welcomes studies that will aid the translation of knowledge and implementation of evidence into practice and policy, and is particularly interested in evaluations of the comparative effectiveness of interventions. This knowledge may be most relevant to the day to day decisions doctors make with patients, to public health, or to policy decisions about healthcare.

To learn more about the kind of research articles we give priority to, and what services we offer to authors of research, please read the editorial “[Publishing your research study in the BMJ?](#)”. Please note that we welcome studies — even with “negative” results — as long as their research questions are important, new, and relevant to general readers and their designs are appropriate and robust.

Word count and style

To encourage full and transparent reporting of research we do not set fixed word count limits for research articles. Nonetheless, we ask you to make your article concise and make every word count. You will be prompted to provide the word

count for the main text (excluding the abstract, references, tables, boxes, or figures) when you submit your manuscript.

Original research articles should follow the IMRaD style (introduction, methods, results, and discussion) and should include a structured abstract (see below), a structured discussion, and a succinct introduction that focuses — in no more than three paragraphs — on the background to the research question.

For an intervention study, the manuscript should include enough information about the intervention(s) and comparator(s) (even if this was usual care) for reviewers and readers to understand fully what happened in the study. To enable readers to replicate your work or implement the interventions in their own practice, please also provide any relevant detailed descriptions and materials (uploaded as one or more supplemental files, including video and audio files where appropriate). Alternatively, please provide URLs to openly accessible websites where these materials can be found.

Please ensure that the discussion section of your article comprises no more than a page and a half and follows this overall structure, with subheadings:

- Statement of principal findings
- Strengths and weaknesses of the study
- Strengths and weaknesses in relation to other studies, discussing important differences in results
- Meaning of the study: possible explanations and implications for clinicians and policymakers
- Unanswered questions and future research

Structured abstract

Please ensure that the structured abstract is as complete, accurate, and clear as possible and has been approved by all authors. We may screen original research articles by reading only the abstract.

Abstracts should be 250–300 words long; you may need up to 400 words, however, for a CONSORT or PRISMA style abstract. MEDLINE can now handle up to 600 words. Abstracts should include the following headings, but they may be modified for abstracts of clinical trials or systematic reviews and meta-analyses according to the requirements on the [CONSORT extension for abstracts](#) and the [PRISMA extension for abstracts](#), respectively.

- **Objectives** — a clear statement of the main aim of the study and the major hypothesis tested or research question posed
- **Design** — including factors such as prospective, randomisation, blinding, placebo control, case control, crossover, criterion standards for diagnostic tests, etc.
- **Setting** — include the level of care, eg primary, secondary; number of participating centres. Be general rather than give the name of the specific centre, but give the geographical location if this is important
- **Participants** (instead of patients or subjects) — numbers entering and completing the study, sex, and ethnic group if appropriate. Give clear definitions of how selected, entry and exclusion criteria.
- **Interventions** — what, how, when and for how long. This heading can be deleted if there were no interventions but should normally be included for randomised controlled trials, crossover trials, and before and after studies.
- **Main outcome measures** — those planned in the protocol, those finally measured (if different, explain why).
- **Results** — main results with (for quantitative studies) 95% confidence intervals and, where appropriate, the exact level of statistical significance and the number need to treat/harm. Whenever possible, state absolute rather than relative risks.
- **Conclusions** — primary conclusions and their implications, suggesting areas for further research if appropriate. Do not go beyond the data in the article. Conclusions are important because this is often the only part that readers look at.
- **Trial registration** — registry and number (for clinical trials and, if available, for observational studies and systematic reviews).

When writing your abstract, use the active voice but

avoid “we did” or “we found”. Numbers over 10 do not need spelling out at the start of sentences. P values should always be accompanied by supporting data, and denominators should be given for percentages. Confidence intervals should be written in the format (15 to 27) within parentheses, using the word “to” rather than a hyphen. Abstracts do not need references.

Statistical issues

We want your piece to be easy to read but also as scientifically accurate as possible. We encourage authors to review the [“Statistical Analyses and Methods in the Published Literature or The SAMPL Guidelines”](#) while preparing their manuscript.

Whenever possible, state absolute rather than relative risks.

Please include in the results section of your structured abstract (and in the article’s results section) the following terms, as appropriate:

For a clinical trial:

- *Absolute event rates among experimental and control groups.*
- *RRR (relative risk reduction).*
- *NNT or NNH (number needed to treat or harm) and its 95% confidence interval (or, if the trial is of a public health intervention, number helped per 1000 or 100,000).*

For a cohort study:

- *Absolute event rates over time (eg 10 years) among exposed and non-exposed groups*
- *RRR (relative risk reduction)*

For a case control study:

- *OR (odds ratio) for strength of association between exposure and outcome*

For a study of a diagnostic test:

- *Sensitivity and specificity*
- *PPV and NPV (positive and negative predictive values)*

The box stating what is known and what this study adds (see below) should also reflect accurately the above information. Under what this study adds, please give the one most useful summary statistic eg NNT.

Please do not use the term ‘negative’ to describe studies that have not found statistically significant differences, perhaps because they were too small. There will always be some uncertainty, and we hope you will be as explicit as possible in reporting what you have found in your study. Using wording such as “our results are compatible with a decrease of this much or an increase of this much” or “this study found no effect” is more accurate and helpful to readers than “there was no effect/no difference.” Please use such wording throughout the article, including the structured abstract and the box stating what the paper adds.

Provide one or more references for the statistical package(s) used to analyse the data — for example, RevMan for a

Submitting a BMJ Research article

All BMJ Research articles should be submitted through our submission system at [submit.bmj.com](#)
Completed ICMJE forms are required for ALL Research authors

Research article checklist

[We have produced a checklist on bmj.com](#) to help you decide whether *The BMJ* is the right journal for your work.

Another resource, the [Authors' Submission Toolkit: A practical guide to getting your research published](#), summarises general tips and best practices to increase awareness of journals’ editorial requirements, how to choose the right journal, submission processes, publication ethics, peer review, and effective communication with editors.

If your work does not seem to fit in *The BMJ* you may prefer to try another journal with a more specialist or local readership, or a higher acceptance rate.

systematic review. There is no need to provide a formal reference for a very widely used package that will be familiar to general readers — for example, Stata — but please say in the text which version you used.

Reporting checklists and guidelines

Reporting guidelines promote clear reporting of methods and results to allow critical appraisal of the manuscript. We ask that all manuscripts be written in accordance with the appropriate reporting guideline. Please submit as supplemental material the appropriate reporting guideline checklist showing on which page of your manuscript each checklist item appears. A complete list of guidelines can be found in the website of the Equator Network. Below is the list of most often used checklists but others may apply.

RECOMMENDED REPORTING GUIDELINES

Clinical trials: For a clinical trials, use the [CONSORT checklist](#) and also include a structured abstract that follows the CONSORT extension for abstract checklist, the CONSORT flowchart and, where applicable, the appropriate CONSORT extension statements (for example, for cluster RCTs, pragmatic trials, etc.). A completed [TIDieR checklist](#) is also helpful as this helps to ensure that trial interventions are fully described in ways that are reproducible, usable by other clinicians, and clear enough for systematic reviewers and guideline writers.

Systematic reviews and meta-analysis: For systematic reviews or meta-analysis of randomised trials and other evaluation studies, use the [PRISMA checklist](#) and flowchart and use the PRISMA structured abstract checklist when writing the structured abstract.

Diagnostic accuracy: [STARD checklist](#) and flowchart

Observational studies: For observational studies, use the [STROBE checklist](#) and any appropriate extension STROBE extensions.

Genetic risk prediction: [GRIPS guidelines](#).

Economic evaluation studies: [CHEERS guidelines](#).

Prediction models: For studies developing, validating or updating a prediction model, [use TRIPOD](#).

For articles that include explicit statements of the quality of evidence and strength of recommendations, we prefer reporting using the [GRADE system](#).

Cover letter

A cover letter is your opportunity to introduce your study to the editor, highlighting the most important findings and novelty. Please include the following information:

- Details of previous publications from the same study — including in scientific abstracts or partial reports by the media at scientific meetings and in foreign language journals.
- Details of any previous publication of the same study in electronic form, including on any preprint server. *The BMJ* does not [consider posting of protocols and results in clinical trials registries to be prior publication](#), but

we would like to know if results have been posted, and where (please provide URLs or trial registration details). We require protocols for clinical trials that have now been published. We are pleased to consider articles based on longer systematic reviews and meta-analyses published at the Cochrane Library or HTA database.

- In most cases, we will follow suggestions for preferred and non-preferred reviewers. If you have suggestions for preferred reviewers, please provide us with their names and contact details; we may invite some of them to review the paper. Please also let us know if you would not like us to invite specific reviewers to look at your work but provide an explanation for your request.
- Assurance that a study funded or sponsored by industry follows the [guidelines on good publication practice](#). These GPP2 guidelines aim to ensure that such studies are published in a responsible and ethical manner. The guidelines cover companies' responsibility to endeavour to publish results of all studies, companies' relations with investigators, measures to prevent redundant or premature publication, the roles of authors and contributors, and the role of professional medical writers.
- Assurance that any article written by a professional medical writer follows the [guidelines by the European Medical Writers' Association](#) on the role of professional medical writers. The guidelines emphasise the importance of respecting widely recognised authorship criteria, and in particular of ensuring that all people listed as named authors have full control of the content of articles. The role of professional medical writers must be transparent. Please name any professional medical writer among the list of contributors to any article for *The BMJ* (not only original research articles), and specify in the formal funding statement for the article who paid the writer. Writers and authors must have access to relevant data while writing articles. Medical writers have professional responsibilities to ensure that the articles they write are scientifically valid and are written in accordance with generally accepted ethical standards.

Additional information that must be included with reports of Clinical Trials

Trial Registration

In accordance with the International Committee of Medical Journal Editors' [Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals](#), *The BMJ* will not consider reports of clinical trials unless they were registered prospectively before recruitment of any participants. For trials that started before 1 July 2005 retrospective registration will be acceptable, but only if completed before submission of the manuscript to the journal. The trial registration number and name of register should be included at the end of the structured abstract. *The BMJ* accepts registration in any registry that is a primary register of the [WHO International Clinical Trials Registry Platform \(ICTRP\)](#) or in ClinicalTrials.gov, which is a data provider to the WHO ICTRP.

Download recommended reporting guidelines directly
 All reporting guidelines recommended here are available for full download from our [Instructions for Authors](#) page.

Find out more about reporting trial registration
 All recommended trial registration reporting guidance is available to view on our [Instructions for Authors](#) page.

STATEMENTS THAT MUST BE INCLUDED IN RESEARCH SUBMISSIONS

Public and Patient Involvement statement:

The BMJ is encouraging active patient and public involvement in clinical research as part of its [patient partnership strategy](#). This is research which is “co produced” with patients, carers, or members of the public. To support coproduction of research we request that authors provide a Patient and Public Involvement statement in the methods section of their papers. We request this to both encourage the movement and ensure that BMJ readers can easily see whether, and if so how, patients and the public were involved in the research. If they were not involved in any way this information should be formally documented in the Patient and Public Involvement statement. As co production of research with patients and the public is relatively new we appreciate that not all authors will have involved them in their studies. We also appreciate that patient/public involvement may not be feasible or appropriate for all papers. We therefore continue to consider papers where they were not involved.

The Patient and Public Involvement statement should provide a brief response to the following questions, tailored as appropriate for the study design reported:

- *At what stage in the research process were patients/public first involved in the research and how?*
- *How were the research question(s) and outcome measures developed and informed by their priorities, experience, and preferences?*
- *How were patients/public involved in the design of this study?*
- *How were they involved in the recruitment to and conduct of the study?*
- *Were they asked to assess the burden of the intervention and time required to participate in the research?*

In addition to considering the points above we advise authors to look at guidance for best reporting of patient and public involvement as set out in the [GRIPP2 reporting checklist](#). Even if patients were not involved in the study described, we suggest that you consider enlisting their help in disseminating the research findings.

If information detailing whether there was patient and public involvement, or not, is missing in the submitted manuscript we will request authors to provide it. Where they have been involved we consider it good practice for authors to name and thank them in the contributorship statement after seeking their permission to do so; and to clearly identify them as patient/public contributors. When they have contributed substantially and meet authorship criteria they should be invited to coauthor the manuscript. Please note also note that it’s [The BMJ policy to send relevant research papers for review by patient reviewers alongside academic peer reviewers](#).

Ethics approval:

[All research studies published in *The BMJ* should be morally acceptable](#), and must follow the World Medical Association’s [Declaration of Helsinki](#). To ensure this, we aim to [appraise the ethical aspects](#) of any submitted work that involves human participants, whatever descriptive label is given to that work including research, audit, and sometimes debate. This policy also applies on the very rare occasions that we publish work done with animal participants. The manuscript must include a statement that the study obtained [ethics approval](#) (or a statement that it was not required), including the name of the ethics committee(s) or institutional review board(s), the number/ID of the approval(s), and a statement that participants gave informed consent before taking part.

Transparency statement:

Please include in your manuscript a [transparency declaration](#): a statement that the lead author (the manuscript’s guarantor) affirms that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as originally planned (and, if relevant, registered) have been explained. *The BMJ* is committed to making the editorial process transparent and ethical. *The BMJ*’s transparency policies are [accessible from this link](#).

Role of the funding source:

Please include in the funding statement a statement giving the details of all sources of funding for the study. As appropriate, the statement must include a description of the role of the study sponsor(s) or funder(s), if any, in the study design; in the collection, analysis, and interpretation of data; in the writing of the report; and in the decision to submit the article for publication. In addition, the statement must confirm the independence of researchers from funders and that all authors, external and internal, had full access to all of the data (including statistical reports and tables) in the study and can take responsibility for the integrity of the data and the accuracy of the data analysis is also required.

If you are submitting an original article reporting an industry sponsored clinical trial, postmarketing study, or other observational study please follow the [guidelines on good publication practice \(GPP2\)](#) and on properly reporting the role of [professional medical writers](#). Another resource, the [“Authors’ Submission Toolkit: A practical guide to getting your research published”](#) summarises general tips and best practices to increase awareness of journals’ editorial requirements, how to choose the right journal, submission processes, publication ethics, peer review, and effective communication with editors — much of which has traditionally been seen as mysterious to authors.

The BMJ will not consider for publication any study that is partly or wholly funded by the tobacco industry, as explained in [this editorial](#).

SUMMARY BOXES

Please produce a box offering a thumbnail sketch of what your article adds to the literature. The box should be divided into two short sections, each with 1–3 short sentences.

Section 1: What is already known on this topic

In two or three single sentence bullet points, please summarise the state of scientific knowledge on this topic before you did your study, and why this study needed to be done. Be clear and specific, not vague.

Section 2: What this study adds

In one or two single sentence bullet points, give a simple answer to the question “What do we now know as a result of this study that we did not know before?” Be brief, succinct, specific, and accurate. For example: “Our study suggests that tea drinking has no overall benefit in depression.” You might use the last sentence to summarise any implications for practice, research, policy, or public health. DO NOT make statements that are not directly supported by your data.

Data sharing with Dryad

The BMJ has partnered with the Dryad digital repository datadryad.org to make open deposition easy and to allow direct linkage by doi from the dataset to *The BMJ*'s article and back (for *The BMJ*'s articles' datasets see here)

Data sharing

We require a data sharing statement for all research papers. For papers that do not report a trial, we do not require that authors agree to share the data, just that they will say whether they will.

For reports of clinical trials, we ask that the authors commit to making the relevant anonymised patient level data available on reasonable request ([see editorial](#)). This policy applies to any research article that reports the main endpoints of a randomised controlled trial of one or more drugs or medical devices in current use, whether or not the trial was funded by industry.

"Relevant data" encompasses all anonymised data on individual patients on which the analysis, results, and conclusions reported in the paper are based. As for "reasonable request," *The BMJ* is not in a position to adjudicate, but we will expect requesters to submit a protocol for their re-analysis to the authors and to commit to making their results public. We will encourage those

requesting data to send a rapid response to thebmj.com, describing what they are looking for. If the request is refused we will ask the authors of the paper to explain why.

In addition, we will follow the [new ICMJE data sharing policy](#) that goes into place on July 1, 2018 (see editorial): manuscripts submitted to ICMJE journals that report the results of clinical trials must contain a data sharing statement that indicates whether individual de-identified participant data (including data dictionaries) will be shared; what data in particular will be shared; whether additional, related documents will be available (study protocol, statistical analysis plan, etc); when the data will become available and for how long; by what access criteria data will be shared (including with whom, for what types of analyses, and by what mechanism). Clinical trials that begin enrolling participants on or after January 1, 2019 must also include a data sharing plan in the trial's registration. If the data sharing plan changes after registration this should be reflected in the statement submitted and published with the manuscript, and updated in the registry record.

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For additional information, please see the section of instructions to authors on [copyright, open access, and permission to reuse](#) your article. For further information, contact openaccess.bmj@bmj.com.

OPEN ACCESS FOR RESEARCH

All research papers in *The BMJ* are published with Open Access. Open access articles may be reused according to the relevant Creative Commons licence. *The BMJ*'s default licence for open access publication of research is the [Creative Commons Attribution Non Commercial licence \(CC BY–NC 4.0\)](#). But where the funder requires it the author can select the [Creative Commons Attribution \(CC BY 4.0\)](#) licence during the submission process (funders who mandate CC BY include the Wellcome Trust, RCUK, and MRC).

To support this, we ask authors to pay an open access article publishing charge/fee of £3000/\$4800 (excluding VAT) on acceptance of their paper. We can offer discounts and waivers for authors who cannot pay. Consideration of the paper is not related to whether authors can or cannot pay the fee. We will ask for the fee only once we have accepted a paper, and we will send an invoice only once authors tell us. Please do not contact editors about open access fees: neither editors nor reviewers will know whether a fee is payable, and administrative staff will handle payments and all associated correspondence.

A number of institutions have open access institutional memberships with BMJ (the publishing group), which either cover the whole cost of open access publishing for authors at participating institutions or allow authors to receive a discount on the article processing charge.

We encourage authors of all research articles in *The BMJ* to link their articles to the raw data from their studies. For clinical trials, we require data sharing on request as a minimum and- if authors of such trials are willing to go further and share the data openly, so much the better.

SUPPLEMENTAL MATERIAL, VIDEO

- **Original raw data:** If you think they will help our reviewers (and maybe readers), or if we specifically request them. Please note our policy on data sharing, explained above.
- **Video , image , table, and audio files:** If these add educational value to your article. We may be able to publish additional files on bmj.com.
- **Video abstract:** These can summarise your findings and will be posted on bmj.com alongside your paper. You can find additional information about video abstracts [in this editorial](#), and [here](#).
- **Public and patient involvement materials used in your research**
- **Copies of any non—standard questionnaires and assessment schedules used in your research**
- **Copies of patient information sheets used to obtain informed consent for the study, or to comprise or deliver the intervention in a clinical trial**
- **Copies of closely related articles you've published (particularly important when details of the study are published elsewhere)**
- **Copies of any previous reviewers' reports on this article**

4.2 RESEARCH METHODS AND REPORTING

The BMJ is also interested in original studies on research methodology, research reporting, peer review, and evidence based medicine. The same criteria apply to these as to all the other types of research we consider. We will give priority to studies that will be relevant and interesting to enough of our readers (not only to editors, statisticians, and other experts on methodology) and will help them make better decisions when conducting research; searching for evidence; or using research evidence in their practice, their teaching, or their learning. We also publish essays about designing, conducting, and reporting research, in our [research methods and reporting section](#).

We are willing to consider papers that present new or updated research reporting guidelines, but only if the guideline pertains to a study type that we publish in *The BMJ*. The checklist itself must be included as part of the paper. We prefer to be the only journal publishing the guideline, but under some circumstances we will consider copublication with up to two other journals.

For an example of how to format a reporting guideline to appear in our research methods and reporting section, [see here](#).

Research Methods and Reporting articles should have the elements below.

Word count and style

We do not set fixed word count limits for RMR articles. Nonetheless, we ask you to make your article concise and make every word count. For some submissions this might be published in full on [bmj.com](#) with a shorter version or abstract in the print *BMJ*.

Title and abstract

A short title is followed by an 100–150 word italicised summary (the standfirst) which encapsulates the article's central message.

Introduction

Articles should begin with a brief paragraph that captures readers' attention and explains the aim of the piece.

Text

The body of the text should be broken up under subheadings that provide a logical narrative structure. Avoid acronyms and abbreviations unless they are universally recognised e.g. DNA. The evidence on which key statements are based should be explicit and referenced, and the strength of the evidence (published trials, systematic reviews, observational studies, expert opinion etc.) addressed.

Boxes, tables and figures

Include tables, boxes, or illustrations (clinical photographs, imaging, line drawings, and figures) to enhance the text and add to or substantiate key points made in the body of the article. Figures may be in color. Worked out examples that

use specific methods under discussion can be included as additional boxes. If appropriate, include a box of linked information such as website urls for those who want to pursue the subject in more depth.

Web extras

We may be able to publish on [bmj.com](#) some additional boxes, figures, and references. Please include these as a web reference list in the main article file. You may also include suggestions for linked podcasts or video clips, as appropriate.

Contributors and sources

We ask for a 100–150 word supplementary paragraph (excluded from word count) to explain the article's provenance. It should include the relevant experience and expertise of each author, his or her contribution to the paper, and the sources of information used to prepare it. One author must be nominated as the guarantor of the article. Include a statement of sources and selection criteria.

Key messages box

Include up to four sentences, in the form of short bullet points, highlighting the article's main points.

References

Must be in Vancouver style and should be kept to a minimum; ideally no more than 20.

RESEARCH METHODS AND REPORTING — OPEN ACCESS

Research Methods and Reporting articles are not published as Open Access by default.

If you would like your article to be published with an Open Access licence, we recommend requesting this directly on submission. Standard *BMJ* Open Access fees apply to all Research Methods and Reporting articles published with an Open Access licence. Find out more about our Open Access policy [here](#).

Presubmission enquiries for a BMJ Analysis article

If you are unsure if your work is suitable for *The BMJ's* Analysis section we are willing to consider succinct pre-submission inquiries, [please complete this form and await a response](#) from one of the analysis editors.

4.3 ANALYSIS

The Analysis section of the journal is a forum for scholarly debate articles which discuss topical clinical, scientific, ethical, and policy issues that matter to doctors and patients. We look for our analysis articles to be interesting and thought-provoking to a broad range of readers based all over the world, including policy makers, doctors of all specialties, and other healthcare professionals. They should present a clearly reasoned argument, backed by an even-handed look at the evidence, with a clear key message. Articles that set out hypotheses are not suitable unless they contain a convincing attempt to test them.

Analysis articles should have the following elements:

Word count and style

The BMJ has an international readership that includes policy makers, health professionals, and doctors of all disciplines. Authors are advised to keep this readership in mind and to write their article for the non-expert. It's important to avoid jargon. Specialised terminology and references to organisations or practices that are specific to one country need to be explained. Clear writing and an attractive presentation are essential. Analysis papers should be 1800–2000 words long.

Title, standfirst and introduction

A short title is followed by an italicised single sentence (the standfirst) which encapsulates the article's central message. Articles should begin with a brief paragraph that captures readers' attention and explains the aim of the piece.

Text

The body of the text should be broken up under sub-headings that provide a logical narrative structure. Avoid acronyms and abbreviations unless they are universally recognised eg. DNA. The evidence on which key statements are based should be explicit and referenced, and the strength of the evidence (published trials, systematic reviews, observational studies, expert opinion, etc.) made clear. Articles should present a balanced, even-handed look at the evidence rather than selectively citing evidence that supports a particular view.

Boxes, tables and figures

These should extend and substantiate points made in the body of the paper. Any additional material should be concise.

Key messages box

This should be at the end of the article and include 2 to 4 points summing up the main conclusions. When submitting your article at [submit.bmj.com](#), please enter your key messages when prompted to enter the abstract.

References

Must be in Vancouver style and should be kept to a minimum; ideally no more than 20.

Contributors and sources

We ask for a 100–150 word supplementary paragraph (excluded from word count) to explain the article's provenance. It should include the relevant experience and expertise of each author, his or her contribution to the paper, and the sources of information used to prepare it. One author must be nominated as the guarantor of the article. You are welcome to invite co-authors to work with you on the article. We suggest including 2–3 co-authors with different locations and perspectives to help ensure articles are international in scope and accessible to our broad readership online and in print.

Report of patient involvement

As *The BMJ* is seeking to advance [partnership with patients](#), we also ask authors to seek their input into articles wherever relevant, and document their involvement as patient contributors or coauthors.

Conflicts of Interest

All authors should read our competing interests policy and include the appropriate declaration in their manuscript. Where a competing interest exists that might disqualify an author from contributing, it is wise to discuss it with a BMJ editor before writing the article.

Licence

We require the manuscript to include the following statement:

"The Corresponding Author has the right to grant on behalf of all authors and does grant on behalf of all authors, an exclusive licence (or non exclusive for government employees) on a worldwide basis to the BMJ Publishing Group Ltd ("BMJ"), and its Licensees to permit this article (if accepted) to be published in The BMJ's editions and any other BMJ products and to exploit all subsidiary rights, as set out in [our licence](#)."

Peer review

The BMJ has fully open peer review for analysis articles. This means that every accepted analysis article submitted will have its prepublication history posted alongside it on [thebmj.com](#). This prepublication history comprises all previous versions of the manuscript, the report from the manuscript committee meeting, the reviewers' signed comments, and the authors' responses to all the comments from reviewers and editors. Authors are welcome to suggest names of suitable reviewers, including patient reviewers.

Post-submission

- All submissions are read in full by one or more members of the editorial team.
- Articles that pass the initial editorial screen are sent for external peer review.
- Articles are then discussed at a regular analysis committee meeting where editors make one of three decisions: reject; reject with offer to resubmit; or provisionally accept.

Accepted analysis articles are published online at [bmj.com](#), the canonical version of *The BMJ*. A proportion of accepted analysis articles will also be published in the print journal.

Analysis prepublication history

In most cases we will publish the prepublication history alongside an accepted analysis article. This prepublication history comprises all previous versions of the manuscript, the report from the manuscript committee meeting, the reviewers' comments, and the authors' responses to all the comments from reviewers and editors. In rare instances we may determine after careful consideration that we should not make certain portions of the prepublication record publicly available.

4.4 EDUCATION

The *BMJ* publishes [different types of educational articles](#) to engage and challenge a range of postgraduate doctors and clinical researchers internationally. We strive to publish articles that are original in their content and/or presentation, and cannot be found elsewhere or in textbooks. We prioritise topics and situations that are common or have serious consequences, have international appeal, and that interest a variety of doctors, including GPs and specialists.

We encourage authors to write in teams, including those from other specialties, professions, and countries. We ask that one author is routed in the clinical environment of the intended reader. We encourage authors to write in plain English, to be clear about where there is uncertainty, and to include numbers and phrases where possible that will help doctors in conversation with their patients.

Our educational articles are shaped by two initiatives:

- *We believe that financial interests can distort education articles and we minimise or exclude authors who we judge have such a conflict.*
- *We encourage authors to seek input from patients either to inform the scope, develop the content, contribute to, or co-author articles.*

Submission process and presubmission enquiries

We receive more articles and suggestions than we can publish. We require all authors to submit proposals using the forms to the left, which pose the following questions:

- *What is your idea?*
- *Can you sum up the aim of your article in a sentence?*
- *Why is the topic important to The BMJ's readers?*
- *What is the prevalence of the symptom/condition/situation you wish to write about?*
- *Why cover it now? Has something new happened?*
- *What has The BMJ's Education section covered on this topic in the last five years? What will your contribution add?*
- *Can you provide the key evidence/references you might use?*
- *Why are your writing team well placed to cover the topic?*
- *Have you thought about what a patient would say about your idea?*

POLICIES FOR EDUCATION ARTICLES

Authorship

Education articles can have up to four authors. One author should be from the relevant specialty or setting, unless agreed otherwise. For example, if the article discusses presentation to the emergency department one author should be an emergency care doctor. [All authors should meet authorship criteria](#). We welcome authors or contributions from allied health professions and patient authors, and actively encourage authors from a primary care background.

Competing interests

The *BMJ* will not consider authors with financial interests when writing Education articles. It is important that we understand the financial interests of every author, and can judge to what extent we believe that they may be relevant to the article that you propose. We do not publish content from authors who [we judge have relevant financial ties to the industry](#) (excluding State of the Art reviews, Therapeutics articles, and Summaries of NICE Guidelines). The relevance of declared interests are judged by the *BMJ* team. This applies to every author. Any additional authors and their financial interests [must be discussed and agreed with the commissioning editor](#) before the article is submitted.

Patient involvement

As part of our drive to co-produce our content with patients we ask that you [seek patient input](#) into articles at the planning stage.

We ask all authors to what extent patients have been involved in and how involvement has changed an article. We ask that all writing encourages honesty and partnership with patients. Where uncertainty exists, share it. Where data exists present the numbers in a way that can be shared with the patient (absolute numbers, natural frequencies, and graphics). Use language that empowers patients to make the right choices for them in their situation (write that a doctor should/could offer a test, rather than should do a test).

When patients are involved in the manuscript, we ask for their consent. We have two types of consent forms for *BMJ* education articles:

- [A patient consent form](#) is required if any anonymised patient information is included in the review. Consent is needed for images even if the patients are not identifiable for example, in X-rays and histology slides, and for patients' stories/vignettes even if details are anonymised.
- [A patient contributor form](#) is required for any patients who are named within the review, for example, patient co-authors, patient contributors or named authors of patient stories.

Preparing your manuscript

We want our readers to have the ability to share decisions with their patients and make clear for them the degree of certainty (or lack of it) about a potential course of action. We therefore ask that you follow these recommendations:

- *Consider including in your manuscript a box explaining your strategy to search for evidence. It should include a search date, the sources searched, and brief inclusion criteria.*
- *Clearly distinguish suggestions made based on your experience, standard practice, guidelines, and evidence.*
- *Provide specifics about the evidence you discuss. For example, for key statements, please say: "A large, well conducted, randomised controlled trial showed INSERT number [CI] and or p value". "The findings of a small case series suggest..." "A subgroup analysis found..." etc.*
- *Use absolute numbers or explain why you have not used them.*
- *Consider how these numbers can be communicated by the clinician read to their patient in a clear way.*

What do we mean by patient involvement and co-production in Education?

We believe that patient involvement strengthens content. [Read our full guidance on what we mean by patient involvement and co-production.](#)

[Patient consent forms](#)

[Patient contributor forms](#)

Presubmission enquiries for BMJ Education articles

[Education article proposal forms](#)

[Endgames proposal forms](#)

[BMJ declaration of competing interest forms \(required for ALL Education authors\)](#)

BMJ policies

Find out more about [The BMJ's editorial and ethical policies](#)

Education article types			
Article Type	Focus/Audience	Content	Word Limit
Clinical Updates	These articles provide an up to date overview of a clinical condition. The content should be evidence based, aimed at non—specialists and have international appeal. It should include a broad update of recent developments (from the past 1—2 years) and their likely clinical applications in primary/community and secondary/hospital care.		1800 words, maximum of 40 references
Practice Pointer	These are practical, often problem based articles. They should help clinicians who are not specialists in a particular field know “how to” to approach a problem, diagnosis or management better.	There is no strict format to this article type. Consider the use of questions to draw the reader through such as: what are the risk factors? How do patients present? How is it diagnosed? When should we refer patients? How is it managed?	1,000 words and 15 references
Easily Missed	This series highlights conditions that are often missed at first presentation in general practice or the emergency department. For the condition in question provide evidence that the condition may be misdiagnosed or that diagnosis may be delayed and that timely recognition will benefit the patient. The condition should be reasonably common (likely to present at least once a year to a full—time primary care practitioner) or is serious and delayed diagnosis is likely to worsen prognosis. The condition should have easily defined diagnostic features and/or tests with known predictive characteristics.	<p>Include the following subheadings:</p> <p>Case history: Brief fictitious case illustrating how a patient might present and be diagnosed.</p> <p>Introduction: Description of the condition. Outline recent data on incidence, preferably from primary and/or emergency care.</p> <p>Why is it missed? Provide recent evidence of delayed diagnosis or misdiagnosis, which may include audit or medicolegal data if no other evidence is available. Describe factors which contribute to missing this diagnosis.</p> <p>Why does this matter? Describe the consequences of missed diagnosis.</p> <p>How is it diagnosed? Subdivide this into “Clinical features” and “Investigations” that are readily available. Comment on presence, absence and quality of predictive values or sensitivities/specificities (or frequencies for key clinical findings) of the clinical features and investigations mentioned.</p> <p>How is it managed? This should be discussed in 3—4 sentences, as it is not the focus of the series.</p>	1,000 words and 15 references
Rational Testing	These articles update clinicians on the best initial use of imaging methods or diagnostic tests for common or important problems. The aim of these articles is to equip frontline clinicians to exclude and diagnose important conditions, and to know when to refer to a specialist. Imaging articles will require relevant high—resolution images .	<p>Include the following subheadings:</p> <p>The patient: Describe the presentation of a common or important condition whose management will be influenced by ordering the right test.</p> <p>What is the next investigation? List the most important initial tests. Discuss the rationale, limitations and benefits of each, based on the evidence. Include sensitivities/specificities or positive/negative predictive values.</p> <p>Please avoid long lists of differential diagnoses and tests, as these are generally not helpful.</p>	1,000 words and 15 references
10 Minute Consultation	These articles describe how clinicians might use a (one) consultation to tackle a common scenario, in primary or secondary care. Articles must address a tightly framed issue for example how to explore a new symptom (eg tingling fingers), explain a diagnosis of a condition (eg Parkinson’s disease, or an aspect of its management) or act in an urgent situation, such as on receipt of a high INR reading.	<p>Include the following subheadings:</p> <p>What to cover.</p> <p>What to do.</p>	700 words and 10 references
Uncertainties	This series highlights areas of practice that lack convincing evidence.	<p>Include the following subheadings:</p> <p>Introduction: Succinctly describe the uncertainty phrased as a question.</p> <p>What is the evidence of uncertainty? Discuss the type and quality of the evidence confirming uncertainty or showing variation in clinical practice. If a relevant systematic review does not exist on this topic, please mention this. Is ongoing research likely to provide relevant evidence? Identify the key research questions that would address the evidence gap (and formulate them in PICO format — population, intervention, comparison, and outcome). Indicate if studies are underway that may address the gap.</p> <p>What should we do in the light of the uncertainty? Provide practical guidance to clinicians on what to do.</p> <p>Include a box of your search strategy for the body text and a second box of the registries you searched to identify forthcoming studies to address the uncertainty</p>	1,000 words and 15 references
Essentials	These articles provide a basic comprehensive summary of a topic that the reader should already know something about. They are aimed at non specialists. Essentials articles are not meant to give readers a full update, and may not be telling readers anything new. Ideally, we prefer an international author team and focus.	The articles follow a broad structure that outlines the evidence and best practice followed by some practical guidance on ‘How to do it’ perhaps with the use of short fictitious tasters. Authors should present the challenges and include links to other resources.	1,000 words and 15 references.
Therapeutics	<i>The BMJ’s Therapeutics series covers new drugs in clinical use or old drugs with important new indications or controversy. Articles are about 1000 words long, and aimed at doctors who aren’t specialists in the therapeutic field. They focus on what frontline clinicians need to know before prescribing the drugs, or treating patients already taking them. The editorial that launched the series is here: http://www.bmj.com/content/342/bmj.d37</i>	Detailed structures for this article type will be discussed during the commissioning process between author/editor.	1,000 words and 15 references
Change Page	This series highlights where practice may need to change.	<p>Include the following subheadings:</p> <p>The clinical problem: outline the current diagnostic/treatment approach and its limitations, giving evidence of current practice. End with your actual proposal for change.</p> <p>The evidence for change: include a box of methods (i.e. how you selected the evidence underpinning your proposal.) Indicate the type and quality of the evidence when citing each study. Consider adding a Box describing the pivotal studies.</p> <p>Barriers to change: Describe them (e.g. pragmatic difficulties, risks, contraindications.)</p> <p>How should we change our practice: give a practical description of what changes should be made, based on the evidence.</p>	1,000 words and 15 references

BMJ GUIDANCE FOR AUTHORS — EDUCATION

Article Type	Focus/Audience	Content	Word Limit
What Your Patient Is Thinking (WYPIT)	<p>This is a series led, and edited and written by patients and their carers and contain messages that are thought provoking, and challenging for readers of <i>The BMJ</i>, along the lines of “What I wish you [<i>The BMJ</i>’s audience] knew, and why.”</p> <p>Who can write one? Anyone who is using the healthcare system, either on their own behalf or for someone else. To avoid getting overwhelmed by ‘doctor as patient’ stories, we prioritise pieces from those who are not health professionals. Authors should bear in mind that our readership is international and avoid detailed comments about specific national policies. Some people find it difficult to turn a personal story into something doctors can learn from but if the story is still powerful we are happy to consider publication of articles in another form, for example as a BMJ blogs/opinion piece. If you have an idea for a WYPIT article and want to discuss it before submission please get in touch with BMJ patient editor Sally Carter (scarter@bmj.com) and include an outline of what you would like to say.</p> <p>What these articles are not Complaints about or praise of a named healthcare professional or clinic/hospital; Legal cases which are not resolved; A personal anecdote or journey through the healthcare system with no learning points; Written on behalf of someone else (for example, a carer must write about being a carer, not what they suspect it is like to be the patient) Promotion of a particular treatment or style that other healthcare professionals cannot</p>	<p>Summary Box: “What you need to know” This should include three short bullet points encapsulating the practical things that health professionals might consider doing as a result of reading the article. The editor will work with you to edit the text and may ask doctors working in <i>The BMJ</i> what elements they think are the most powerful to help the article.</p> <p>Other boxes: We are happy to consider a second box containing, for example, useful websites or other learning resources for health professionals. We may also suggest you add some extra explanatory information in a short box if we think the context of your care needs a bit more elaboration.</p> <p>What may be added: Illustrations: Articles are usually published with an accompanying illustration. This is commissioned after the article has been accepted. Questions for Doctors: To encourage ongoing professional learning and development we host a series of reflective questions for doctors based on the content of many of our education article, including WYPITs. These are written by one of the editors and ask the reader what they might do differently having read your article. (The authors of the education articles are not routinely asked to be involved in this process).</p> <p>Content style In the education section of the journal where WYPITs are published we aim to provide up to date and original content to engage and challenge postgraduate doctors and clinical researchers internationally. We ask authors to write in plain English, rather than academic sounding language, and we avoid an over-prescriptive tone. For example, we encourage authors to use words such as ‘suggest’, ‘might’, or ‘offer’ when describing how readers might change their practice (rather than use rigid statements such as ‘always’, ‘never’, ‘must’, ‘should’). Other considerations We encourage all authors to sign their articles but are happy to discuss anonymity if this is preferred. We also need authors to sign a competing interest form. If you need help in any way with this please let us know.</p>	<p>Around 650 words, including the summary box at the end of each piece, called “What You Need To Know.”</p>
Summary of NICE Guidelines	<p>These article types are solely commissioned by our editors.</p>		
State of the Art Reviews			
Minerva Pictures	<p>These are pictures which offer an educational message and which will publish clearly and depict the abnormality obviously. Pictures we are more likely to accept are those which offer an educational message and which will publish clearly and depict the abnormality obviously. Minerva pictures with the following characteristics are not usually accepted because they lack educational value for general readers:</p> <ul style="list-style-type: none"> • <i>Showing foreign bodies</i> • <i>Showing the results of gross trauma</i> • <i>With poor image quality, even if the story is sound and interesting</i> • <i>With pictures and stories which are simply “textbook” presentations</i> • <i>Reporting cases of very rare clinical presentations</i> • <i>Submissions which simply criticise other clinicians, or the patient.</i> <p>Please provide two or three sentences (no more than 100 words) explaining the picture, and please send us the signed consent to publication from the patient. Please make sure that the text includes all authors’ names together with their job titles and addresses (including departments’ and hospitals’ names) at the time the patient was seen, and the email address of the corresponding author. We also need to receive statements of competing interests and copyright/licence.</p> <p>NB: Minerva pictures/articles are not indexed in PubMed.</p>	<p>Less than 100 words</p>	
Endgames	<p><i>The BMJ</i> does not publish standard case reports. We do, however, publish articles about real cases if they are suitable for presentation in specific educational formats. These include Endgames case reviews and picture quizzes.</p> <p>Endgames is designed to help doctors across all levels and specialities test their knowledge and reflect on their practice for continuing medical education. Endgames articles are based on genuine clinical scenarios. We only consider common topics rather than clinical rarities (or very rare complications of common diseases, which may be more suitable for BMJ Case Reports journal.) We consider hospital and community based scenarios providing the content is generalisable. We do not publish articles if the patient management is controversial.</p> <p>At least one author must be a specialist (consultant, post CCT, or equivalent) in a field relevant to the topic and all authors must satisfy our strict competing interest criteria. The online competing interests form must be completed by all authors prior to submission. To avoid duplication of large paragraphs of text from textbooks or journals, we ask authors to provide a signed originality of work attestation form.</p> <p>Which cases are suitable? Please check our archive as we do not repeat topics within 3 years. We only consider common topics rather than clinical rarities and are unlikely to accept an article if the prevalence of the condition is less than 1/100 000 in the population. This includes very rare complications of common diseases, which may be more suitable for BMJ’s Case Reports journal. We consider hospital and community based scenarios providing the content is generalisable. We do not publish articles if the patient management is controversial. If you wish to inquire about the suitability of a particular case for Endgames please complete this form.</p>	<p>Writing up a Case Review: Case Review articles must include a short vignette and 3 questions with short answers for <i>The BMJ</i>’s print edition and three longer discussions/answers for bmj.com. Please ensure all information required to answer the questions is contained in the vignette. We encourage accompanying clinical illustrations. Please cover important points for generalists including red flags and advice for patients. The discussions/long answers must be evidence based with relevant citations. A maximum of four authors is allowed for each Case Review article, and each author should have no more than 2 articles under consideration at any one time.</p> <p>Writing up a Spot Diagnosis: Spot Diagnosis articles must be based on a clinical image that is distinctive of a particular condition. A short vignette should accompany the image and there should be one question relevant to the image and diagnosis. The article should include no more than two learning points as a take home message for readers. A maximum of two authors is allowed for each Spot Diagnosis article, and each author should have no more than 2 articles under consideration at any one time.</p>	<p>Varies — authors will be contacted by our editors prior after forms have been considered</p>

Pitching Minerva and Endgames

All Minerva articles should be submitted directly through our online editorial office at [submit.bmj.com](#). [Written consent is required from every patient](#), regardless of whether the patient can be identified or not in the picture.

All Endgame articles should be proposed via our online form, [available at this link](#). [Written consent is required from every patient](#).

ALL EDUCATION ARTICLES REQUIRE

“What you need to know” box

No more than three bullet points for practice articles and five for clinical updates encapsulating the specific take home messages from this article.

“How patients were involved in the creation of this article” box

Please include: Which patients were asked (e.g. patient advocates, networked patient communities and organisations, patients in your clinic etc). What they said (e.g. include more practical advice on how to inject insulin.) How you changed your article as a result (e.g. we included a box to address this.)

“Education into practice” box.

Include two to three bullet points about how a reader might at an individual or organisational level improve their practice (e.g. do you offer lifestyle advice to all patients with newly diagnosed hypertension?)

At least one other box or table and at least one figure or image that complement the text of the article.

4.5 EDITORIALS

These are usually commissioned but we are happy to consider and peer review unsolicited editorials. Please make clear the evidence base of each key statement:

- Expert opinion;
- Personal clinical experience;
- Observational studies;
- Trials; or
- Systematic reviews.

Please include a title page giving all authors’ names and corresponding details, as well as statements of competing interests and copyright/licence to publish.

Word count

Up to 800 words long. No more than 12 references

4.6 PERSONAL VIEWS/BMJ OPINION

These original, opinion based essays have a single author. The best personal view pieces make a strong, novel, and well argued point. They are also often topical, insightful, and attention grabbing. We publish anonymous personal view articles only by special arrangement when it would be impossible for the article to appear with the author’s name. Accepted articles are all published online initially on [BMJ Opinion](#), but may not be published in print. Please submit online at <http://submit.bmj.com>. We cannot promise publication before the piece is submitted.

We welcome all submissions for consideration for our [BMJ Opinion blog site](#). Writing should be clear, compelling, and appeal to our international readership. The best pieces make a single topical point. All opinion articles appear online. Those selected to appear in print receive a DOI and PubMed indexed.

Word count

600 words and 10 references (800 words for blogs)

4.8 BMJ CAREERS

If you have an idea for an article about doctors’ careers, please pitch it to us by emailing Tom Moberly (tmoberly@bmj.com). Send a few sentences explaining what you’d like to write about, how you’d like to cover the topic, and what you think readers would gain from the article you are proposing. If we like your idea we will contact you to discuss how we would like to proceed.

4.9 FILLERS AND ENDPICES

These are short articles that aim to entertain readers and make them think. Originally evolving to fill a gap in the print version of *The BMJ*, accepted submissions are now published online, and some are chosen to appear in print.

We welcome submissions on topics such as:

- A patient who changed my practice;
- A memorable patient;
- A paper that changed my practice;
- The person who has most influenced me;
- My most informative mistake;
- A story conveying instruction, pathos, or humour.

Word count

To be suitable for print, Fillers must be less than 300 words. Endpieces are quotations of no more than 80 words (often fewer) from any source.

4.10 OBITUARIES

We welcome obituaries for doctors with a connection to the UK within a year of their death. Please send your copy as a Word file to obituaries@bmj.com. We assume that material is sent exclusively to us, and we publish the full versions we receive on [bmj.com](#). We produce the short obituaries in the print issue from these full versions; these usually appear with a time lag of several weeks.

Obituaries include mandatory biographical details: the last position held, date of birth, place and year of qualification, postgraduate qualifications if applicable, and date and cause of death. Pictures should be sent as high-resolution images electronically or as photographs. We do not accept obituaries sent by post or handwritten obituaries. Please include a postal address if you want us to send one a copy of the relevant print issue to the families of the deceased (additional copies will have to be purchased from support@bmj.com).

We generally commission the full page obituaries for the print issue of *The BMJ* from professional writers: these are usually about doctors and are published no more than three months after death. We regret that we cannot provide individual progress updates. NB: Obituaries are not indexed in PubMed.

Word count

Around 150 words

Examples of other articles

The best way to get a feel for the different article types we publish is to look at a selection of our recently published content. Below you can find links to all content described on this page

[Editorials](#)

[Personal views](#)

[BMJ Opinion](#)

[BMJ Careers](#)

[Fillers and endpieces](#)

The BMJ submission system

You can submit articles using our system by visiting submit.bmj.com

5.1 SUBMITTING AN ARTICLE

Once you have read all of the above advice for your article type, and prepared your article, it's time to submit. Not all articles require submission through our submission system (some use a pitch form system), so please ensure you have taken note of this above before proceeding.

At *The BMJ*, we use a system called ScholarOne to manage our submission processes. Essentially, ScholarOne will convert your manuscript to a PDF for the review process. Most common word processing formats are accepted for text and tables, although the system prefers Microsoft Word, and images should be submitted as GIF, TIFF, EPS, or JPEG files.

The system can also accept supplementary files (for example: videos, datasets, research protocols, and checklists or statements), related articles published or available elsewhere, articles in press elsewhere, permission letters, etc. These are files that normally do not appear with the print article, although they might accompany the final version of the paper online. Supplementary files are not converted to PDF but will be available to reviewers or editors exactly as you upload them.

Registration

To access the system for the first time you will need to register [here](#). Please follow the "Register here," link in the right hand grey column. You will be asked to complete three steps:

- Name and email information;
- Address information;
- User ID and password;
- Your job description, specialty and marketing preferences should also be filled in on this page.

If you would like to be considered as a reviewer for *The BMJ* please also fill in your expertise terms. Anyone can respond without a subscription to any article published on *The BMJ* by sending a rapid response.

The submission process

We offer a step by step guide to submission on our website, available on our [Author Submission pages](#).

Detailed help files are available throughout our online editorial office and can be used without stopping the submission process. If you experience serious problems please email *The BMJ*'s editorial office at papersadmin@bmj.com

6.1 RAPID RESPONSES

What are rapid responses?

Anyone can respond without a subscription to any article published on *The BMJ* by sending a rapid response.

Rapid responses are electronic letters to the editor. Our weekly letters are edited selections of posted rapid responses and are indexed in PubMed. Rapid responses are not indexed in PubMed but they have their own URL and are retrievable in an advanced search of thebmj.com in perpetuity. Thus a rapid response is published with its first appearance online.

As an author, what should I know about rapid responses?

The corresponding author of every article in *The BMJ* receives an automated email when the paper is published online, and an automated reminder whenever a rapid response is posted to the article on thebmj.com. Given that authors have an academic duty to respond to substantive criticism of their work, *The BMJ* [expects authors to post their own rapid responses on bmj.com in reply to any such substantive comments](#), and editors may send reminders about this.

How to send rapid responses?

When you have found the article on thebmj.com that you would like to respond to, click on "Respond to this article" in the "Article Tools" section.

Fill in the form, typing or cutting and pasting your rapid response into the larger box under "Compose your response"; using the smaller box for the response title.

Accept the terms and conditions, and type the jumble of letters and numbers that you can see into the final box; these characters have been generated automatically as a spam filter to determine whether you are human or machine.

Click on 'Submit rapid response.' You should then get a message on the screen thanking you for sending your response, as well as an automatic acknowledgement to your email address. These two measures confirm that your rapid response has arrived at thebmj.com to be considered for posting.

Terms and conditions for rapid responses

We have a wide list of terms and conditions for rapid responses, applicable for both authors and readers. Read our full list of T&Cs online at our Resources for Readers pages.

FURTHER INFORMATION FOR AUTHORS

Although this document covers a large swathe of the article production and submission process at *The BMJ*, we offer a fully comprehensive guide for authors at our website, available at bmj.com/about-bmj/resources-authors

Read about our publishing model in detail at bmj.com/about-bmj/publishing-model

Read about our [ethics and policies](#) and our [complaints procedure](#)

For any further queries, please contact papersadmin@bmj.com

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