ADDIS ABABA UNIVERSITY

COLLEGE OF HEALTH SCIENCES

DEPARTMENT OF PSYCHIATRY

POSTTRAUMATIC STRESS SYMPTOMS IN PREGNANT WOMAN WITH PRIOR PERINATAL COMPLICATIONS: A CROSS-SECTIONAL FACILITY-BASED STUDY

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Posttraumatic stress symptoms in pregnant woman with prior perinatal complications: A cross-sectional facility-based study

A Research Proposal Submitted to the Department of Psychiatry, School of Medicine, Addis Ababa University, in partial fulfillment of the requirements for the specialty certificate in Psychiatry

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Abbreviations

ANC	Antenatal Care
CMD	Common Mental Disorder
DSM	Diagnostic and Statistical Manual of Mental Disorders-5
IUFD	Intra- Uterine Fetal Death
LEC	Life Event Checklist
LMI	Low- and Middle-Income Countries
PCL-5	Post-Traumatic Stress Disorder checklist for DSM-V
PPTSD	Perinatal Post Traumatic Stress Disorder
PSS	Post-traumatic Stress Disorder Symptom Scale
PTSD	Post Traumatic Stress Disorder
SPSS	Statistical Package for the Social Sciences
UI	Upper Income
WHO	World Health Organization

Abstract

Introduction: Studies from high-income countries have shown that complications in a previous pregnancy or at childbirth are associated with common mental disorders (CMD) and post-traumatic stress disorder (PTSD) in the subsequent pregnancy. Even though pregnancy and obstetric complications are more common in low- and middle-income countries, only a small number of studies have assessed PTSD symptoms following childbirth in Africa and none have examined symptoms in the subsequent pregnancy.

Objective: to test the hypothesis that previous perinatal complications are a risk factor for PTSD in the subsequent pregnancy

Methods: Secondary data analysis was conducted using a dataset that is being collected as part of the ASSET (Health System Strengthening in sub-Saharan Africa) study. As part of ASSET, a cross-sectional facility-based study is being conducted among a sample of 2071 pregnant women as they present for antenatal care at eight selected health centers in Meskan and Sodo districts, Gurage Zone, Southern Nations, Nationalities and Peoples' region. Data on socio-demographic background, depressive symptoms, anxiety symptoms, substance use and intimate partner violence was collected in a direct interview using structured and standardized questionnaires. Trauma symptoms were assessed using the Life-Event Checklist (LEC) and Post-Traumatic Stress Disorder checklist for DSM-V (PCL-5), which have been adapted for the Ethiopian setting. Data on clinical characteristics and complications of current and past pregnancies was gathered from the clinical record using a structured form. For the analysis, the primary exposure was considered previous experience of perinatal complications and the primary outcome provisional diagnosis of PTSD using DSM-5 from PCL-5 (dependent variable).

Result: There were 844 participants in the study and around half of the women (50.6%; n=421) were in the third trimester of pregnancy. The mean age was 25.7 years (SD= 4.7) with minimum age at presentation 16 years and maximum 43 years. Nearly one-third of women (31%; n=258) were pregnant for the first time; the mean parity was 1.76 (SD= 1.7) with a range of 0 to 8. Slightly more than half of the participant (51%) had experienced one or more potentially traumatic events. From these 47.7% of women reported to have directly experienced physical assault. Women endorsed having negative feelings (such as fear, horror, anger, guilt or shame) more frequently than other PTSD symptoms on the PCL-5.The prevalence of PTSD using different criteria including the DSM-5 criteria vary between 2.9%-4.4% in this study. There was significant association between experienced number of potentially traumatic events and provisional diagnosis of PTSD using the DSM-5.

Limitation: Multivariable analysis of the association between previous obstetric complications and PTSD symptoms was not done because of the small proportion of obstetric complication. Data on other symptoms of mental health conditions including depression symptoms and care, anxiety symptoms and substance use were not included in the analysis and hence this factors was not controlled for.

Recommendation: Slightly over half of participant women reported having been exposed to one or more traumatic event. Further research is needed to explore the effect of these possibly traumatic experience on pregnancy and outcome Symptoms like having negative feeling, irritable behavior and sleep difficulties were relatively frequent. Integrating mental health screening with ANC follow up may help improve and the detection rate and care of mental health problems in pregnant women.

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1 Introduction

1.1 Background

According to reports from the World Health Organization (WHO), perinatal complications are common, and 800 women die from these complications daily. The risk of suffering from a perinatal complication is 36 times more likely for a pregnant woman from a low or middle-income country (LMIC)than for a woman from a high-income country (1). The UN estimate of the magnitude of obstetric complications is 15% for Ethiopia. A national cross-sectional census conducted in 2015 and included 3,804 public and private facilities reported that 4% of women had major direct obstetric complications (2).

Studies have shown that perinatal complications are associated with common mental disorders (CMD), including depression, anxiety and somatization symptoms (3). Posttraumatic stress disorder (PTSD) is also one of the mental disorders reported to occur as a result of traumatic experiences relating to pregnancy and childbirth, for example, miscarriage (4)

PTSD is a psychiatric disorder which is characterized by the development of the following core symptoms: intrusive images or memories of the event, persistent avoidance of stimuli associated with traumatic events, negative alterations of cognition, mood, arousal and hyperactivity following exposure to actual or threatened death, serious injury, or sexual violence (5).

Perinatal PTSD (PPTSD) is a moderately common mental health problemaffecting between 4% and 6% of women at different time points (6).It has distinctive attributes when compared to PTSD in relation to other contexts. A concept analysis done using Walker and Avant's method defined PPTSD as "a disorder occurring after a traumatic experience, diagnosed any time from conception to 6 month postpartum, lasting longer than 1 month leading to specific negative maternal symptoms and poor maternal, infant outcomes" (7) The same study identified antecedents to PPTSD which were trauma, particularly perinatal complications and abuse; and previous psychiatric history (7). Mode of delivery, of both neonate and placenta, and maternal experience of control during childbirth were also implicated as predictors of postpartum PTSD in a study (8).

A systematic review targeting works of literature about prevalence and risk factors of maternal mental health disorders in women living in Africa found that the most commonly assessed disorder is depression and that only a small number of studies assessed other disorders (9).

1.2 Literature Review

One of the first research studies to indicate that the incidence of Post-Traumatic Stress Disorder following childbirth is above zero, was a prospective study done at a large hospital in London between December 1996 and March 1998. Women between 16 and 36 weeks' gestation were recruited from antenatal care (ANC) settings and postpartum PTSD was measured using the Post- traumatic Stress Disorder Symptom Scale (PSS). The result showed that 2.8% of women fulfilled criteria for PTSD at 6 weeks and 1.5% at 6 months postpartum (10).

Several other prospective studies have estimated the prevalence of postpartum PTSD since then; one prospective longitudinal study followed women over a 12 month period starting from their 3rd trimester of pregnancy then subsequently at 4 to 6 weeks postpartum, 12 weeks postpartum and 24 weeks postpartum. The study assessed the prevalence of PTSD at all-time points and showed that, after controlling for PTSD and partial PTSD due to previous traumatic events, as well as clinically significant anxiety and depression, the prevalence was 1.2% at 4 weeks, 3.1% at 12 and 3.1 % at 24 weeks postpartum (11).

A systematic review that included 59 studies published on the prevalence of prenatal and postpartum PTSD from 8 upper income and LMICs showed an overall mean prevalence of PTSD after birth of 5.4% (k=28, 95% CI, 3.6–8.1) and of PTSD due to birth as 5.9% (k=25, 95% CI, 3.84–8.95) ranging from 0% to 43.1%. From the 59 studies that were included in the review, 46 were community based while the rest, (n-13), were in high risk samples. Subjects in high-risk groups were at more risk of PTSD both during pregnancy and after birth, with a mean prevalence of 19.0% (95%, CI 10.6–31.4) and 18.5(95%, CI 10.6–30.4) respectively. (6)

Although many studies from UI countries showed that PTSD is prevalent in both perinatal and postnatal period, there are few studies done in LMI countries. One cross sectional survey from Nigeria that involved 876 women at 6 weeks postpartum showed that the prevalence of PTSD was 5.9% which is slightly higher than those found in high-income settings. The study also assessed for associated variables and found parity ($P < 0.001$), whether pregnancy was planned

or not (P < 0.001), any pregnancy-related hospital admissions (P < 0.001), place of delivery (P < 0.001), mode of delivery (P < 0.001), duration of delivery in hours (P < 0.001), analgesia use in labor (P = 0.004), mode of placental removal (P < 0.001) and maternal experience of control during childbirth

(P < 0.001) to be predictors of PTSD in the postpartum period (8). Few research studies have explored PTSD in the subsequent pregnancy following previous perinatal complications. (12; 13) One hospital-based study assessed presence of PTSD symptoms related to prior pregnancy loss or complication using the Clinician Administered PTSD Scale (CAPS-5). Out of the 56 women with a history of perinatal complications, 28.6% met criteria for partial PTSD on the CAPS questionnaire using rule-of-3 and 17.9 % on rule-of-4. Among the same population 12.5% of women met criteria for full PTSD using rule- of-3 and 8.9% using rule-of-4 (13).

1.3 Significance of the study

Most studies relating antenatal PTSD with previous perinatal complications have been done in UI countries. Identifying the prevalence of PTSD in relation to pregnancy in LMICs like Ethiopia, would contribute to recognizing possible differences in PTSD relating to sociocultural dissimilarities. Western studies not only have shown that PTSD can result from traumatic childbirth and perinatal complications but also that maternal PTSD is associated with subsequent perinatal complication, low birth weight and lower rates of breastfeeding. Perinatal complications and infant morbidity and mortality are still leading causes of burden of disease in Ethiopia. So far, no research has been done in Ethiopia to assess the prevalence of PTSD in association with pregnancy; knowing the prevalence would give opportunity for early intervention and possible prevention of further maternal and infant complications.

2 Objectives

2.1 General objective

- ✓ To the test the hypothesis that previous obstetric complications are a risk factor for PTSD in the subsequent pregnancy

2.2 Specific Objectives

- ✓ To identify and describe demographic factors and clinical characteristics of prior perinatal complications associated with PTSD in pregnant women with prior pregnancies
- ✓ To compare the relative contribution of previous perinatal complications and exposure to non-perinatal traumatic events to current antenatal PTSD symptoms.

3 Methodology

3.1 Study Design

Secondary data analysis of data collected from a facility based cross- sectional study.

3.2 Study Setting

The study was conducted in eight purposively selected health centers in Meskan and Sodo districts, in the Gurage Zone of the Southern Nations, Nationalities and Peoples' Region (SNNPR) of Ethiopia. According to the 2007 census, Meskan woreda has a total population of 155,782 of whom 76,396 are men and 79,386 women. Sodo woreda which is bordered by Meskane on the south, as to the 2007 census has a total population of 134,683 of whom 67,130 are men and 67,553 are women.

3.3 Study Population

The study population were all pregnant women who are on antenatal care follow up at the health centers. The reference population is all pregnant women with at least one prior perinatal complication living in Meskan or Sodo districts.

3.4 Operational Definitions

Perinatal complication: - One or more of the following complications during the time of a previous pregnancy or delivery

- Spontaneous/ induced abortion
- Ectopic pregnancy/ Ruptured ectopic pregnancy
- Hospital admission for Preeclampsia/ eclampsia
- Preterm labor
- Intra Uterine Fetal Death(IUFD)
- Obstructed labor
- Fistula
- Instrumental delivery
- Delivery by Cesarean section
- Postpartum Hemorrhage (PPH)

3.5 Inclusion Criteria

Pregnant women

- Attending the antenatal clinic during the study period
- Able to converse in Amharic

- Providing informed consent

3.6 Exclusion Criteria

- Acutely ill women who require emergency medical management

3.7 Sampling Strategy

Over the study period consecutive women presenting to the health centers for antenatal care follow-up were approached by data collectors and invited to participate in the study. Consenting women who fulfill the inclusion criteria were included within the time frame of the study period.

3.8 Sample size

The study is a part of a larger antenatal care study on the same study population with a sample size of 2071. The preliminary plan was to include the full sample of the principal study. A sample of 844 could be obtained within the time frame of the study period.

3.9 Data Collection Procedure

Socio-demographic data including age, marital status, place of residence, educational level, religion and ethnicity was gathered using structured measures in an interview format. Data on clinical characteristics of the current and past pregnancy was collected from clinical records using structured form. Trauma symptoms were assessed using the Life-Event Checklist (LEC) and Post-Traumatic Stress Disorder checklist for DSM-V (PCL-5) which have been translated into Amharic and adapted for a rural Ethiopia context.

3.10 Data processing and analysis

Data entry, cleaning was done with Microsoft Excel 2013 and descriptive analysis was done Statistical Package for the Social Sciences (SPSS) version 25.0. For the analysis, the primary exposure considered was previous experience of perinatal complications and the primary outcome (dependent variable) symptoms endorsed (an item with a score of 2 or higher on a scale) on PCL-5. Categorical data were presented as percentages and frequencies of occurrence and continuous variables as means and standard deviations.

4 Ethical Considerations

Ethical clearance was obtained from the Department of Psychiatry, School of Medicine, and Addis Ababa University.

The purpose the study explained to each participant and written informed consent was sought. It was made clear to participants that taking part in the study is on voluntary basis and that confidentiality will be upheld.

5 Dissemination of Results

The results of this study will be submitted to the Department of Psychiatry, School of Medicine, Addis Ababa University and written up for publication in a peer-reviewed journal.

6 Results

6.1 Sociodemographic Characteristics of Study Participants

Out of the 844 participants, 38.2 % (n= 318) were attending the health center for their first ANC visit. The mean age was 25.7 years (Standard Deviation (SD) 4.7) with minimum age at presentation 16 years and maximum 43 years. Most 73.5% (n= 611) of the women had received some formal education, out of which only 3.2% (n=27) had attended post-secondary education. The majority of women (93%; n=774) were in a monogamous marriage; few 3.6% (n= 30) were single and only 14 were in a polygamous marriage. Two of the most represented religions in the study were Islam (52.4%, n= 436) and Orthodox Christianity (37% n= 308).

6.2 Current and Previous Pregnancy Characteristics

Around half of the women (50.6%; n=421) were in the third trimester of pregnancy. Nearly one-third of women (31%; n=258) were pregnant for the first time; the mean parity was 1.76 (SD= 1.7) with a range of 0 to 8.

From the chart review, the presence of comorbid medical problems was only recorded for two women. A history of previous pregnancy complications was documented for very few women: n=5 with a history of stillbirth; n=1 with a history of prolonged labor and n=1 with a history of fistula. A previous history of ≥3 consecutive miscarriages was documented for three women, and a past history of post-partum hemorrhage was only documented for three women. A history of previous admission for hypertension/ preeclampsia was documented for two women. Only one woman was documented as having undergone a Cesarean section previously and two had a history of reproductive tract surgery. None of the chart documentation showed a woman having previously delivered a neonate with birth weight ≤ 2500gm or ≥ 4500gm, a neonate with congenital abnormality or going through an assisted delivery.

6.3 Trauma exposure and PTSD symptoms

Physical assault was the most commonly experienced type of traumatic event for all levels of exposure, except for learning about trauma for which transportation accident was the commonest type. We considered a women as having direct exposure to the potentially traumatic event if she indicated that it happened to her. Direct exposure to trauma was reported more than witnessing a traumatic event happen (See Figure 1.) A total of 414 women (48.8%) reported that none of the

potentially traumatic events from the LEC happened to them. The rest of the women (51%) had experienced one or more potentially traumatic events with 9 being the maximum number of traumatic events a women has experienced. (See Figure 2.) From these 47.7% of women reported to have directly experienced physical assault. Gender based violence such as sexual assault and unwanted/uncomfortable sexual experience were relatively low in proportion with 5.1% of women and 3.5% of women reporting them respectively. Direct exposure to combat or war zone was the least reported type of trauma with 0.5% of women reporting it.

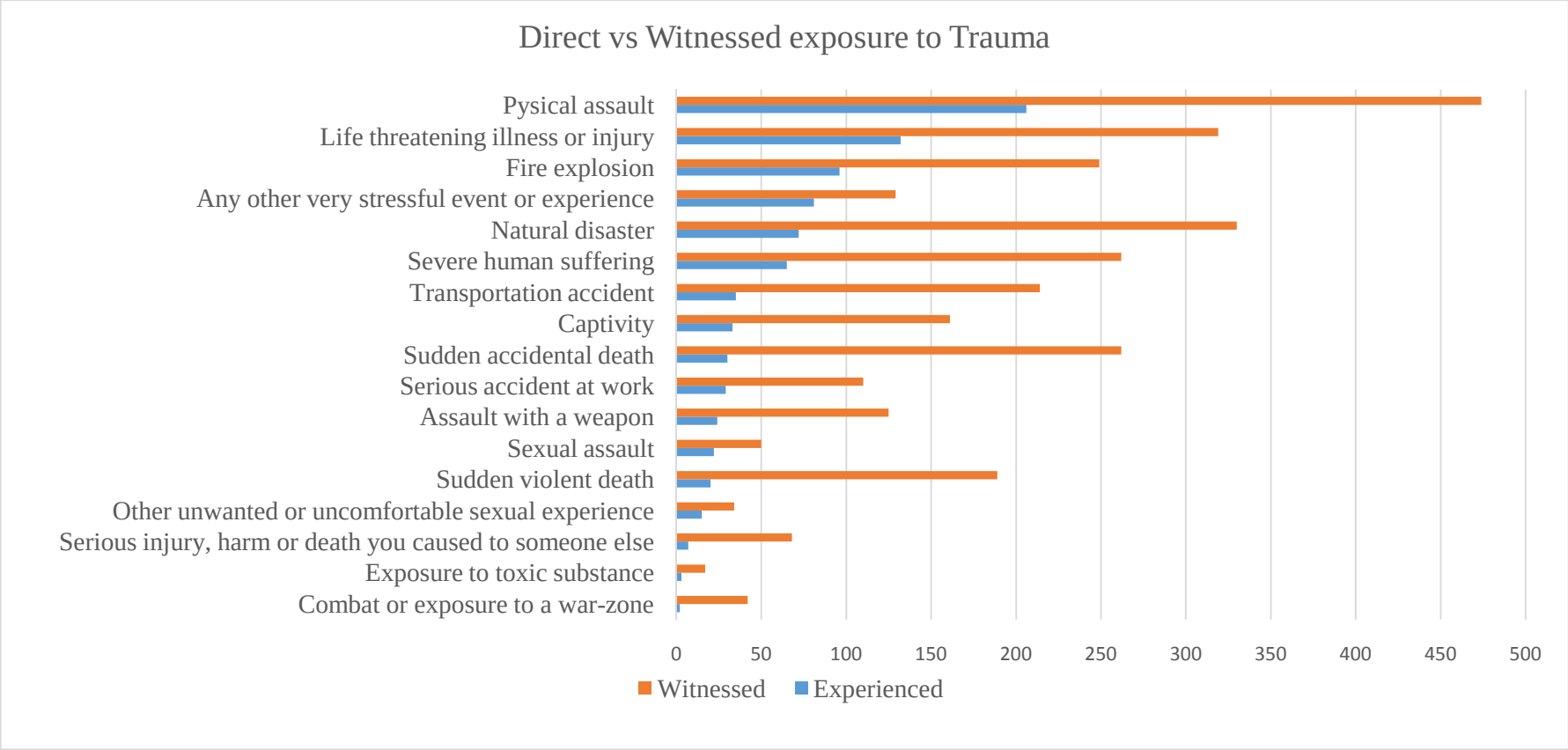

Figure 1Direct vs Witnessed exposure to Trauma

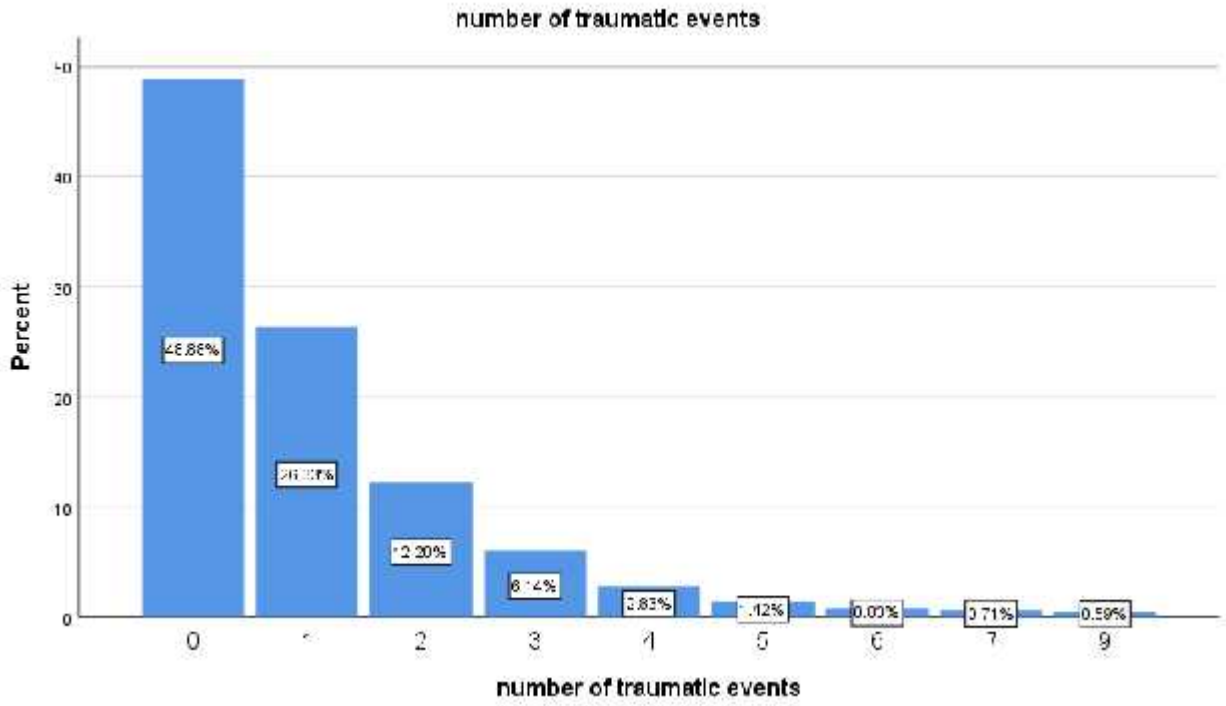

Figure 2 Number of traumatic events

An item on PCL-5 is considered symptom endorsed if it's rated '2' (moderately) or higher. Based on this, having negative feelings (such as fear, horror, anger, guilt or shame) was the commonest symptom endorsed on the scale as shown in Figure 3.Symptoms on the PCL-5 follow the DSM-5 diagnostic category and Questions 1-5 reflect criterion B symptoms; questions 6-7 reflect criterion C; questions 8-14 reflect criterion D; questions 15-20 reflect criterion E.Frequency of the symptoms arranged in clusters is presented below in Figure 3.

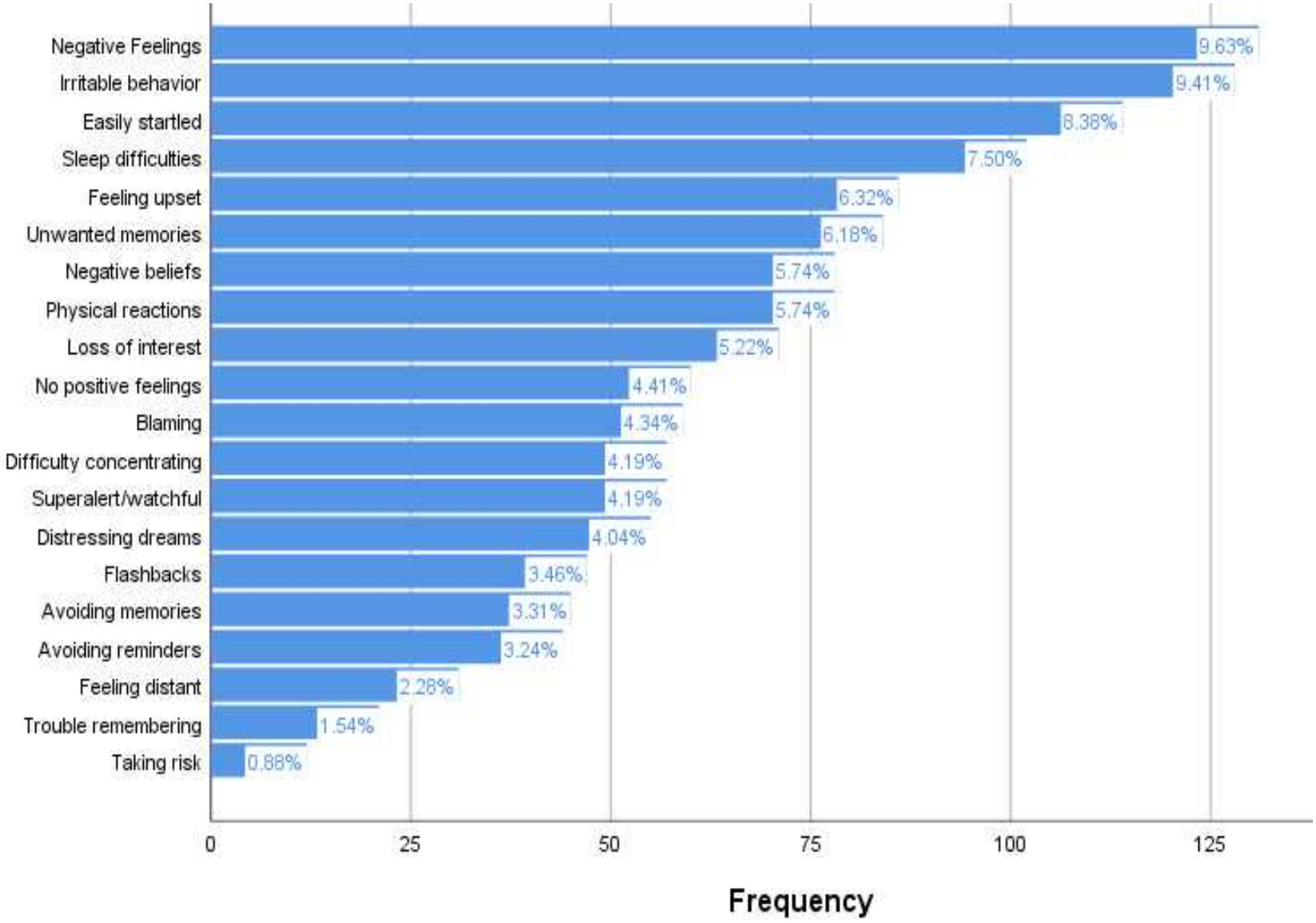

Figure 3 PTSD symptoms

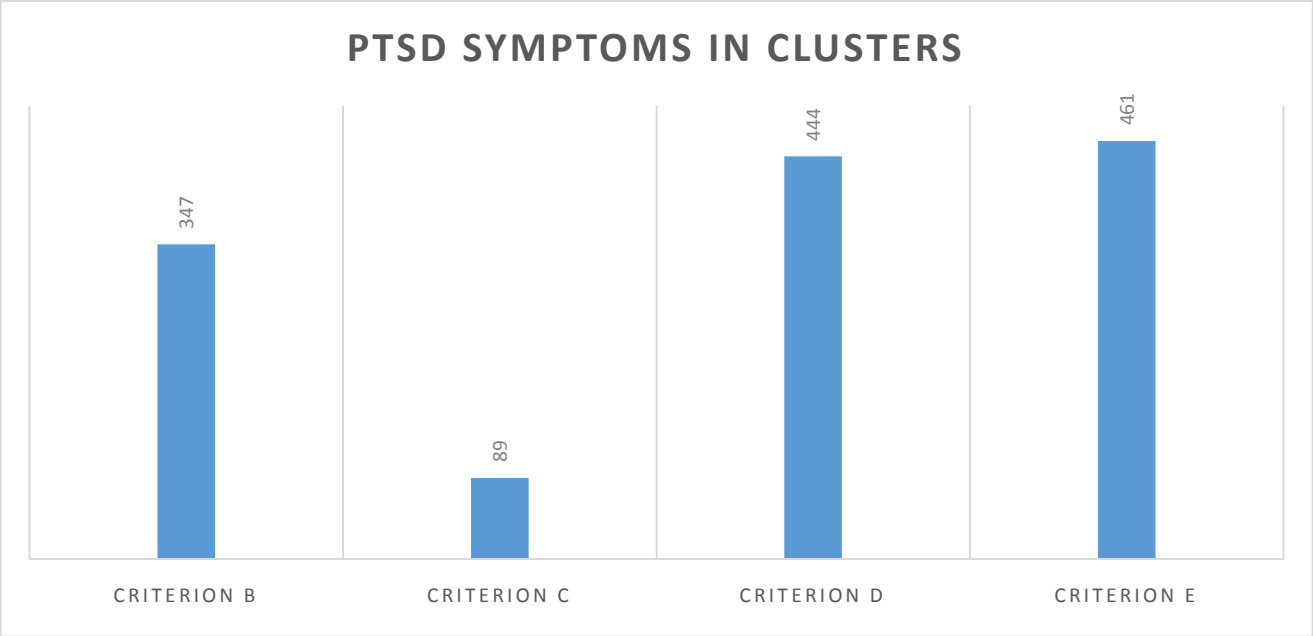

Figure 4 PTSD symptoms in clusters

There were 38 women (4.4%) who met DSM-5 criteria for PTSD. Of these women, 42% ere between the age of 27 and 30 but there was no significant relationship between age and provisional cases of PTSD (x^2 (df=3) 4.4, P=0.219) Other socio-demographic factors like level of education and marital status did not show any association with provisional cases of PTSD. Across the PCL-5 cutoff score between 31-33, there were 34 women (4%) who had a total score of PCL-5 ≥ 31; 29 women (3.4%) with a total score ≥ 32 and 25 women (2.9%) with a total score ≥ 33.

One half of the provisional cases of PTSD were at their third trimester of pregnancy with only 7.8% (n= 3) and 42.1 %(n=16) of women at first and second trimester respectively. This difference however was not significant (x2= 1.139, df= 2 p= 0.566). None of the provisional cases of PTSD had comorbid medical problem or previous obstetric complication and did not show association with provisional cases of PTSD. On average provisional cases of PTSD had higher number of previous number of pregnancies compared to women with no PTSD but this difference was not statistically significant (U= 13604, p= 0.237).

Table 1Sociodemographic characteristics of women versus provisional cases of PTSD

Sociodemographic characteristics	Provisional PTSD		X^2	df	P-value
	Yes	No			
Age (years)					
≤21	3	137	4.428	3	0.219
22-26	13	334			
27-30	16	244			
31+	6	95			
Education					
No formal	12	212	4.626	3	0.201
Primary	23	418			
Secondary	3	151			
Post-secondary	0	29			
Marital status					
Married	36	768	.000	1	0.983
Single, divorced/ widowed	2	42			

From a total of 433 (50.5%) of women who had experienced one or more potentially traumatic event 15.34 of them endorsed having repeated, disturbing and unwanted memories of the stressful experience; while only 4.4% of women endorsed the symptom without having experienced a potentially traumatic event in the past. This difference is significantly associated (x^2= 28.1 p<0.001). Other symptoms of PTSD were also significantly associated whether the women have experienced none or one or more traumatic event.

Table 2 PTSD Symptoms versus number of traumatic experiences

PTSD Symptoms	Number of traumatic experiences		X^2	P-value
	None	≥1		
Repeated, disturbing and unwanted memories				
Yes	18	66	28.118	**p< 0.001**
No	396	367		
Repeated, disturbing dreams				
Yes	10	45	22.18	**p<0.001**
No	404	388		
Flashbacks				
Yes	8	39	20.21	**p<0.001**
No	406	394		
Feeling very upset				
Yes	19	67	27.48	**p<0.001**
No	395	366		
Strong physical reactions				
Yes	19	59	20.67	**p<0.001**
No	395	374		
Avoiding memories, thoughts, or feelings				
Yes	9	36	15.86	**p<0.001**
No	405	397		
Avoiding external reminders				
Yes	10	34	12.70	**p<0.001**
No	404	399		
Trouble remembering important parts				
Yes	8	13	1.00	p=0.317
No	406	420		
Having strong negative beliefs				
Yes	19	59	20.67	**p<0.001**
No	395	374		
Blaming yourself or someone else				
Yes	15	44	13.96	**p<0.001**
No	399	389		
Strong negative feelings				
Yes	34	97	32.59	**p<0.001**
No	380	336		
Loss of interest				
Yes	18	53	17.16	**p<0.001**
No	396	380		

Feeling distant or cut off				
Yes	5	26	13.81	**p<0.001**
No	409	407		
Trouble experiencing positive feelings				
Yes	11	49	24.11	**p<0.001**
No	403	384		
Irritable behavior angry outbursts aggressiveness	32	96	34.40	
Yes	382	337		**p<0.001**
No				
Taking too many risks				
Yes	2	10	5.05	
No	412	423		p=0.025
Being "super-alert" or watchful				
Yes	12	45	18.93	**p<0.001**
No	402	388		
Easily startled				
Yes	38	76	12.73	**p<0.001**
No	376	357		
Difficulty concentrating				
Yes	13	44	16.62	**p<0.001**
No	401	389		
Sleep difficulty				
Yes	28	74	21.30	**p<0.001**
No	386	359		

Similarly, 86.8% of the cases of provisional PTSD had experienced one or more potentially traumatic event while only 13.2% of the cases of provisional PTSD had reported not experiencing a potentially traumatic event. This difference was statistically significant (x^2=20.3, $p< 0.001$)

7 Discussion

In this cross- sectional survey of pregnant women attending antenatal care in rural health centers there were a total of 831 women included. The study found prevalence of PTSD using DSM-5 criteria to be 4.4% (n= 38).Common pregnancy complications such as previous history of postpartum hemorrhage (n=1), still birth (n=5), prolonged labor (n= 1), fistula (n=1) and consecutive miscarriages (n=3) were only reported by a very small number of women in this study. This finding is not in par with the national figures of obstetric complications (that shows 4% of major direct obstetric complications) or with UN estimates (15%) (2). This difference may have resulted because information about past obstetric history was collected from a chart review and the apparent scantiness of obstetric complications in the population may in fact indicate lack of documentation of the problem. In addition to this, because there is no integrated health information system, previous history of first time visitors could only be accessed from clinical history which may be underreported.

Among this study population, the most frequently reported potentially traumatic event was physical assault. High prevalence of violence against women in the country has been shown in previous publications (16, 17)studies also show that IPV increases particularly during pregnancy and can result in serious both to the mother and fetus. (17) One meta-analysis that assessed a total of 36 published articles from Ethiopia indicated this with lifetime prevalence of physical violence against women being 38.15% (16). This could explain why physical assault is the most frequently reported traumatic event.

From the PTSD symptoms listed on the PCL-5, having negative feelings (such as fear, horror, anger, guilt or shame) were the most commonly endorsed symptoms. Trauma specific symptoms like trouble remembering important parts of the stressful experience and avoiding reminders were reported in lower proportion. A possible explanation for the relative frequency is that the symptomatology is one that is shared by other CMDs and not specific to PTSD. **

The prevalence of PTSD using different criteria including the DSM-5 criteria vary between 2.9%-4.4% in this study. This finding differs from previously reported prevalence from the country. De Jong et al (2001) reported the prevalence of PTSD in Ethiopia to be 15.8% but this survey was conducted in randomly selected post- conflict survivors. Hence, the difference may

be because of differences in the characteristics of the sample population. This finding is slightly different from international figures of prevalence of PTSD which ranged from 0%-40% (k=35). The mean prevalence for all studies in the review was 4.6% (95% CI, 2.44-4.54) which is comparable with the finding of this study.

The study found significant association between experienced number of potentially traumatic events and provisional diagnosis of PTSD using the DSM-5. This finding is in line with literatures that indicated multiple exposure to the same type or to different type of traumatic events is associated with higher levels of symptoms of PTSD.

8 Limitation

The study is a cross-sectional facility-based study and any significant association found in the study does not help determine cause and effect. Figures indicated in the study may not reflect that of the reference population as it is a facility based study, although coverage of antenatal care is reported to be over 90% in the study districts. Multivariable analysis of the association between previous obstetric complications and PTSD symptoms was not done because of the small proportion of obstetric complications. Data on other symptoms of mental health conditions including depression symptoms and care, anxiety symptoms and substance use were not included in the analysis and hence these factors were not controlled for.

9 Recommendations

A little over half of the women (51%) reported having experienced one or more potentially traumatic event in their life time.Further research is needed to explore the effect of these possibly traumatic experience.

Symptoms like having negative feeling, irritable behavior and sleep difficulties were relatively frequent. Integrating mental health screening with ANC follow up may help improve and the detection rate and care of mental health problems in pregnant women.

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11 Annex

11.1 PCL-5

Instructions: Below is a list of problems that people sometimes have in response to a very stressful experience. Please read each problem carefully and then circle one of the numbers to the right to indicate how much you have been bothered by that problem in the past month.

In the past month, how much were you bothered by:	**Not at all**	**A little bit**	**Moderately**	**Quite a bit**	**Extremely**
1. Repeated, disturbing, and unwanted memories of the stressful experience?	0	1	2	3	4
2. Repeated, disturbing dreams of the stressful experience?	0	1	2	3	4
3. Suddenly feeling or acting as if the stressful experience were actually happening again (as if you were actually back there reliving it)?	0	1	2	3	4
4. Feeling very upset when something reminded you of the stressful experience?	0	1	2	3	4
5. Having strong physical reactions when something reminded you of the stressful experience (for example, heart pounding, trouble breathing, sweating)?	0	1	2	3	4
6. Avoiding memories, thoughts, or feelings related to the stressful experience?	0	1	2	3	4
7. Avoiding external reminders of the stressful experience (forexample, people, places, conversations, activities, objects, or situations)?	0	1	2	3	4
8. Trouble remembering important parts of the stressful experience?	0	1	2	3	4
9. Having strong negative beliefs about yourself, other people, or the world (for example, having thoughts such as: I am bad, there is something seriously wrong with me, no one can be trusted, the world is completely dangerous)?	0	1	2	3	4
10. Blaming yourself or someone else for the stressful experience or what happened after it?	0	1	2	3	4
11. Having strong negative feelings such as fear, horror, anger, guilt, or shame?	0	1	2	3	4
12. Loss of interest in activities that you used to enjoy?	0	1	2	3	4
13. Feeling distant or cut off from other people?	0	1	2	3	4

14. Trouble experiencing positive feelings (for example, being unable to feel happiness or have loving feelings for people close to you)?	0	1	2	3	4
15. Irritable behavior, angry outbursts, or acting aggressively?	0	1	2	3	4
16. Taking too many risks or doing things that could cause you harm?	0	1	2	3	4
17. Being “superalert” or watchful or on guard?	0	1	2	3	4
18. Feeling jumpy or easily startled?	0	1	2	3	4
19. Having difficulty concentrating?	0	1	2	3	4
20. Trouble falling or staying asleep?	0	1	2	3	4

11.2 LEC-5 Standard

Instructions: Listed below are a number of difficult or stressful things that sometimes happen to people. For each event check one or more of the boxes to the right to indicate that: (a) it happened to you personally; (b) you witnessedit happen to someone else; (c) you learned about it happening to a close family member or close friend; (d) you were exposed to it as part of your job (for example, paramedic, police, military, or other first responder); (e) you're not sure if it fits; or (f) it doesn't apply to you.

Be sure to consider your *entire life* (growing up as well as adulthood) as you go through the list of

Event	Happened to me	Witnessed it	Learned about it	Part of my job	Not sure	Doesn't apply
1. Natural disaster (for example, flood, hurricane, tornado, earthquake)						
2. Fire or explosion						
3. Transportation accident (for example, car accident, boat accident, train wreck, plane crash)						
4. Serious accident at work, home, or during recreational activity						
5. Exposure to toxic substance (for example, dangerous chemicals, radiation)						
6. Physical assault (for example, being attacked, hit, slapped, kicked, beaten up)						
7. Assault with a weapon (for example, being shot, stabbed, threatened with a knife gun, bomb)						
8. Sexual assault (rape, attempted rape, made to perform any type of sexual act through force or threat of harm)						
9. Other unwanted or uncomfortable sexual experience						
10. Combat or exposure to a war-zone (in the military or as a civilian)						
11. Captivity (for example, being kidnapped, abducted, held hostage, prisoner of war)						
12. Life-threatening illness or injury						
13. Severe human suffering						
14. Sudden violent death (for example, homicide, suicide)						
15. Sudden accidental death						
16. Serious injury, harm, or death you caused to someone else						
17. Any other very stressful event or experience						

11.3 Information extracted from woman's clinical record

001	Card ID Number			
1.	Timing of first attendance for antenatal care	____ ____ weeks gestation		
2.	Number of current ANC visit	1st visit	1	
		2nd visit	2	
		3rd visit	3	
		4th visit	4	
		5th or more visit	5	
3.	Gravida	____ ____		
4.	Parity	____ ____		
5.	Gestation	____ ____ weeks		
6.	Any current problem documented? (if answer to Q #6 is no go to Q #8)	Yes		1
		No		0
7.	If any current problems are documented, please list here	1. 2. 3.		
8.	Are any of the following problems documented in the woman's notes			
8A	Medical problem (diabetes, heart/kidney disease, asthma, epilepsy, on TB treatment, hypertension, HIV stage 3 or 4)	Yes	1	
		No	0	
8B	Substance use/abuse	Yes	1	
		No	0	
8C	Current pregnancy problems (rhesus negative with antibodies, multiple pregnancy, < 18 years old, vaginal bleeding or pelvic mass)	Yes	1	
		No	0	

8D	Previous stillbirth or neonatal loss	Yes	1	
		No	0	
8E	Previous history of prolonged/obstructred labour	Yes	1	
		No	0	
8F	Previous history of fistula	Yes	1	
		No	0	
8G	≥ 3 consecutive miscarriages	Yes	1	
		No	0	
8H	Previous admission for hypertension or pre-eclampsia	Yes	1	
		No	0	
8I	birth weight < 2500g	Yes	1	
		No	0	
8J	birth weight > 4500g	Yes	1	
		No	0	
8K	Previous history of assisted delivery (instrumental delivery)	Yes	1	
		No	0	
8L	Previous caesarean section?	Yes	1	
		No	0	
8M	Previous congenital abnormality	Yes	1	
		No	0	
8N	Previous presence of postpartum haemorrhage (PPH)	Yes	1	
		No	0	
8O	Previous reproductive tract surgery? (if answer to Q #8O is no go to Q #9)	Yes	1	
		No	0	
8P	If the answer is yes, what type of surgery was it?	Elective		
		Emergency		
9.	Is it documented that the woman is classified as high risk and needs follow-up at the hospital or seen more frequently?	High risk, referred		
		High risk, increased follow-up frequency		
		High risk, no action documented		
		Not high risk		
10	Documentation of past history of mental health or substance use problems	Yes, documented history of mental disorder	1	
		Yes, documented that no history of mental disorder	2	
		Yes, documented history of substance use disorder	3	
		Yes, documented that no history	4	

		of substance use disorder			
		No documentation		5	
11	Documentation of current mental health problems	Yes		1	
		No		0	
12	Documentation of current substance use	Yes		1	
		No		0	
13	Documentation of current violence exposure	Yes		1	
		No		0	
14	What was the woman's blood pressure at this visit?	Systolic BP	____ ____ ____ mmHg		
		Diastolic BP	____ ____ ____ mmHg		
		Not recorded			
15	Was urinalysis requested?	Request documented		1	
		No request documented		2	
16	What was the urinalysis result	Not available		1	
		Abnormally high protein		2	
		Other abnormality		3	
		Normal		4	

11.4 Socio-demographic

1	How old are you?	____ ____ years		
2	Have you received any education?	No formal education	1	
		Primary education only	2	
		Secondary education only	3	
		Post-secondary education	4	
3	What is the highest educational grade that you have reached?	____ ____ grade		
4	Which sub-district (kebele) do you live in?			
5	What is your marital status?	Single (never married)	1	
		Separated	2	
		Divorced	3	
		Widowed	4	
		Monogamous marriage	5	
		Polygamous marriage	6	
6	What is your religious affiliation?	Orthodox Christian	1	
		Muslim	2	
		Protestant	3	
		Catholic	4	
		None	5	
		Other (specify)	6	
7	What is your ethnicity?	Gurage	1	
		Silti	2	
		Oromo	3	
		Amhara	4	
		Tigray	5	
		Other (specify)	6	

11.5 Information sheet for antenatal care study

Participant initials: [__] __] __]

IRB Reference Number:

YOU WILL BE GIVEN A COPY OF THIS INFORMATION SHEET

Health system strengthening in sub-Saharan Africa (ASSET): antenatal care study

We would like to invite you to participate in our research project. This study is a collaboration between researchers from Addis Ababa University, King's College London in the United Kingdom, University of Cape Town and University of KwaZulu-Natal in South Africa, the University of Zimbabwe and the College of Medicine and Allied Health Sciences in Sierra Leone.

You should only participate if you want to; choosing not to take part will not disadvantage you in any way. Before you decide whether you want to take part, it is important for you to understand why the research is being done and what your participation will involve. Please take time to read the following information carefully or have the information read out to you, and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information.

What is the purpose of the research project?

The purpose of this study is to improve the quality of care for women during pregnancy, childbirth and the postnatal period. We would like to find out about the health and social problems experienced by women who come for antenatal care. We also want to know about how well the antenatal care meets your expectations and identify any gaps in the service.

Why have I been invited to take part in this study?

We are inviting all pregnant women who have come to the health centre for antenatal care to participate in this study.

Do I have to take part?

Participation is voluntary. You do not have to take part. You should read this information sheet (you should listen to the information we will read out about the study) and if you have any questions you can ask the research team.

What will happen if I agree to take part?

If you agree to take part, we will ask you some questions about your health and social problems. We will ask you some questions about the service you have received today and your understanding about health problems in pregnant and postnatal women. We will also do some tests of your physical health. This includes checking your blood pressure and testing your blood for sugar. For the blood test, we will take a very small amount of blood (a drop) from your finger tip. This involves a small pin prick with a sterile needle.

We expect that the questions and the tests will take about one hour to complete.

With your permission, we will also use relevant information from your clinical records to understand more about the quality of the care that you have received.

Will other people be able to identify me from the information I give you?

To safeguard your rights, we will use the minimum personally-identifiable information possible. Our research coordinator at Addis Ababa University will use your name and contact details to contact you about the research study, and make sure that relevant information about the study is recorded to oversee the quality of the study. Individuals from King's College London and Addis Ababa University and regulatory organisations may look at your research records to check the accuracy of the research study. The only people in King's College London and Addis Ababa University who will have access to information that identifies you will be people who need to contact you to for this research study or audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name or contact details.

We will use an identification number instead of your name on the questionnaires and test forms so that people cannot identify your personal details. We will keep a separate paper with your name and identification number on it. This will be kept in a locked cupboard and only members of the research team will be able to access this form.

Any information from this study will be stored securely in Addis Ababa University. Electronic data will be stored securely in Ethiopia (Addis Ababa University) with a copy at King's College London. We may share this anonymised electronic data with other researchers in our research team (based in Ethiopia, the United Kingdom, South Africa, Sierra Leone and Zimbabwe) but it will not be possible to identify you from the data.

What will you do with the information I give you?

King's College London in the United Kingdom and Addis Ababa University in Ethiopia are the sponsors for this study. We will be using information from you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. King's College London and Addis Ababa University will keep identifiable information about you for 7 years after the study has finished. We will keep the consent form for longer so that we can show you agreed to participate.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. You can withdraw from the study until 30th September 2018. After this date, if you withdraw from the study, we will keep the information about you that we have already obtained. You can find out more about how we use your information by contacting the study investigators (details below).

Your information could be used for research in any aspect of health or care. Where this information could identify you, the information will be held securely with strict arrangements about who can access the information. The information will only be used for the purpose of health and care research, or to contact you about future opportunities to participate in research. It will not be used to make decisions about future services available to you. Your personal information will not be shared with anyone outside the research team.

What are the possible benefits and risks of taking part?

A benefit of this study is that we will be doing some tests of your health, so that you will know more about your health during pregnancy. The test results will be given to your health worker so that they can make sure you receive the right care. We will compensate you for your time by paying 100 Birr.

We do not foresee risks in participating in the study. The blood test for the sugar involves a small pinprick which can cause a little discomfort which lasts for just a few seconds. Some of the questions we ask you about your health could be sensitive. If you are uncomfortable answering questions you can refuse or ask to stop the interview at any time.

What happens if I decide not to take part in this study?

Your participation in this study is entirely voluntary. Choosing not to take part in this study will not disadvantage you in any way. Whether or not you choose to participate will have no effect on the care that you receive in this health centre.

If you wish to withdraw from the study, please contact the researchers as described below.

What will happen to the results of the study?

Based on the information that you and other women give us, we will identify areas where the service can be improved and possible ways of achieving this.

We will share the study findings with health administrators, planners and researchers so that they can learn from the feedback that the women in the study have given. All results will be presented without giving any personal details about you, so other people will not be able to identify you.

Who has reviewed the study?

The ethics protocol of this study has been reviewed and approved by the Institutional Review Board of the College of Health Sciences of Addis Ababa University and by the Psychiatry, Nursing and Midwifery (PNM) Research Ethics Subcommittee (RESC) at King's College London.

How is the study being funded?

This research is funded by the National Institute of Health Research in the UK.

If I have some more questions about the research. Who can I speak to?

Please contact Charlotte Hanlon on 0912 803374 or email charlotte.hanlon@kcl.ac.uk or contact Dr Abebe Bekele on 0911241139 or Dr Solomon Shiferaw on 0911 406845 or Dr Ahmed Abdella on 9011238527.

If you would like to talk to someone else about this project, or if the study has harmed you in any way or if you wish to make a complaint about the conduct of the study, you can contact the Institutional Review Board of the College of Health Sciences of Addis Ababa University 0115-5538734.

If this study has harmed you in any way or if you wish to make a complaint about the conduct of the study you can contact King's College London using the details below for further advice and information:

> The Chair, Psychiatry, Nursing and Midwifery (PNM) Research Ethics Subcommittee (RESC) at King's College London. Email: rec@kcl.ac.uk.

11.6 Consent form for antenatal care cross-sectional study

CONSENT FORM FOR PARTICIPANTS IN RESEARCH STUDIES

Please complete this form after you have read the Information Sheet and/or listened to an explanation about the research.

Title of Study: Health system strengthening in sub-Saharan Africa (ASSET)

Addis Ababa University IRB Ref: _____

King's College Research Ethics Committee Ref:_____

Thank you for considering taking part in this research. The person organising the research must explain the project to you before you agree to take part. If you have any questions arising from the Information Sheet or explanation already given to you, please ask the researcher before you decide whether to join in. You will be given a copy of this Consent Form to keep and refer to at any time.

I confirm that I understand that by ticking/initialling each box I am consenting to this element of the study. I understand that it will be assumed that unticked/initialled boxes mean that I DO NOT conser to that part of the study. I understand that by not giving consent for any one element I may be deemed ineligible for the study.

		Please tick or initial
1.	I confirm that I have read and understood the information sheet dated [INSERT DATE AND VERSION NUMBER] for the above study. I have had the opportunity to consider the information and asked questions which have been answered satisfactorily.	
2.	I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason. Furthermore, I understand that I will be able to withdraw my data up to 30 September 2018.	
3.	I consent to the processing of my personal information for the purposes explained to me. I understand that such information will be handled in accordance with the terms of the General Data Protection Regulations	

	(2018) and Ethiopian data protection rules.	
4.	I agree that the research team can access relevant parts of my clinical record for the purposes of this project.	
5.	I understand that my information may be subject to review by responsible individuals from Addis Ababa University or King's College London for monitoring and audit purposes.	
6.	I understand that confidentiality and anonymity will be maintained and it will not be possible to identify me in any publications.	
7.	I agree to be contacted in the future by Addis Ababa University or King's College London researchers who would like to invite me to participate in follow up studies to this project, or in future studies of a similar nature.	
8.	I agree that the research team and future researchers may use my de-identified data for future research.	
9.	I agree that the information that I provide can be used for educational or research purposes, including publication. In these publications, my confidentiality and anonymity will be maintained and it will not be possible to identify me.	
10.	I understand that if I have any questions I can contact the study researchers.	

Statement of Consent

I have read the participant information sheet or had it read for me. All my questions have been answered. I have read or been told about the purpose and safety of the study, what will be done and the risks and benefits of the study. I agree to be in the study.

_____ _____

Name of participant Signature (thumbprint)* Date

*in case the participant is not able to read this form or sign their name, this attests that the consent form has been read and explained accurately by a member of the research staff in the presence of an witness, and that the participant has affixed their thumbprint as a consent.

Statement of a witness

I _____agree that the research project named above has been explained to _____ (participant) to his/her satisfaction and that he/she agrees to take part in the study. Both the notes written above and the Information Sheet about the project have been read to him/her.

_____

Signature Date

_____ _____

Name of research staff Signature Date