PERFORMANCE OF THE PATIENT HEALTH QUESTIONNAIRE AND EDINBURGH POSTNATAL DEPRESSION SCALE AS SCREENING TOOLS FOR ANTEPARTUM DEPRESSION

By

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LIST OF ABBREVIATIONS AND ACRONYMS

ACOG	American College of Obstetricians and Gynaecologists
ANC	Antenatal Clinic
APD	Antepartum Depression
AUC	Area under the Curve
BDI	Beck Depression Inventory
BDI-II	Beck Depression Inventory 2nd Edition
BLCM	Bayesian latent class model
CCC	Comprehensive Care Center
CES-D	Centre for Epidemiologic Studies Depression Scale
DIC	Deviance Information Criterion
DPR	Differential positive rate
DSM-V	Diagnostic and Statistical Manual of Mental Disorders, 5th Edition
ENT	Ear Nose and Throat

EPDS	Edinburgh Postnatal Depression Scale
ERC	Ethics and Research Committee
FNR	False negative rate
FPR	False positive rate
HICs	High income countries
HIV	Human immunodeficiency virus
IPT	Intermittent Preventive Treatment of Malaria
IUGR	Intrauterine Growth Retardation
KMC	Kangaroo Mother Care
KNH	Kenyatta National Hospital
KSCH	Karatina Sub-county Hospital
LCM	Latent Class Models
LMICs	Low and middle income countries
MCH	Maternal and Child Health
NPV	Negative predictive value
P	Prevalence

PCI	Posterior Credible Interval
PDSS	Postpartum Depression Screening Scale
PHQ	Patient Health Questionnaire
PI	Principal Investigator
PMTCT	Prevention of Mother to child transmission
PPD	Postpartum Depression
PPS	Probability proportional to size
PPV	Positive predictive value
RA	Research assistant
RDC	Research Diagnostic Criteria
SCID-5-RV	Structured Clinical Interview of DSM-V, Research Version
SD	Standard deviation
Se	Sensitivity
SES	Socioeconomic status
Sp	Specificity
SPI	Standardised Psychiatric Interview

STARD-BLCM	Standards for Reporting of Diagnostic accuracy studies that use BLCM
TB	Tuberculosis
TNR	True negative rate
TPR	True positive rate
UoN	University of Nairobi
UTI	Urinary Tract Infection

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DEFINITION OF OPERATIONAL TERMS

Antenatal care	Medical care women receive while pregnant
Antepartum Depression	Mildly to moderately severe depressive episode that begins in or extends into pregnancy
Antepartum/Antenatal	Period during pregnancy before childbirth
Early pregnancy	Pregnancy period before 24 weeks gestation
Late pregnancy	Pregnancy period at or after 24 weeks gestation
Negative predictive value	Probability of a patient not having a condition when they test negative
Perinatal depression	Major depressive disorder occurring during pregnancy or within 4 weeks after delivery
Positive predictive value	Probability of a patient having a condition when they test positive
Postpartum Depression	Mildly to moderately severe depressive episode that begins after pregnancy
Postpartum/Postnatal	Period of time from birth up to 6 weeks after delivery
Sensitivity	Proportion of patients who test positive when they actually have the disease

Specificity	Proportion of patients who test negative when they actually do not have the disease
Validity	The ability of a test to predict those who have a disease and those who don't or the sensitivity and specificity of a test.

ABSTRACT

Background:

Depression during pregnancy or antepartum depression (APD) is a condition of great public health concern with a high prevalence globally and locally. It has also been shown to lead to postpartum depression and other adverse sequelae such as preeclampsia and low birth weight and prematurity. The availability of APD screening tools whose accuracy has been tested in our population is key in informing APD surveillance and developing local guidelines for its clinical management. The Patient Health Questionnaire-9 (PHQ-9) and Edinburgh Postnatal Depression Scale (EPDS) are APD screening tools both of which are short and easy to use but whose performance in the Kenyan population has not been adequately studied.

Study objective:

The broad objective of the study was to assess the performance of the Patient Health Questionnaire-9 and the Edinburgh Postnatal Depression Scale as screening tools for antepartum depression in Nairobi county and Karatina sub-county.

Methodology:

A cross-sectional study was carried out where 263 and 220 pregnant women from Mutuini Hospital (MH) and Karatina Sub-county Hospital (KSCH) respectively who were 18 years and above of age, had no known medical history of mental illness, HIV, Diabetes or Hypertension and were not bereaved within a period of six months before the time of the interview were screened for APD using both the PHQ-9 and EPDS. A separate study questionnaire was also utilised to gather additional data on participants' sociodemographic factors. A Bayesian Latent Class Model (BLCM) was applied to the participants' cumulative scores gotten from the two APD screening tools.

Results:

The sensitivity (Se) and specificity (Sp) measures of both PHQ-9 and EPDS were optimized at cut-off values of ≥15 and ≥9 respectively. Both tests recorded very low Se (0.3%, 95% posterior credibility interval [PCI] [0.01, 1.2] for PHQ-9 and 5.2%, 95% PCI [0.4, 9.4] for EPDS) and Sp (63.2%, 95% PCI [7.5, 86.4] for PHQ-9 and 12.3%, 95% PCI [0.6, 42.1] for EPDS). The negative and positive predictive values for both tests were generally low across the two study populations. The posterior median APD prevalence in Karatina and Mutuini was 95.4 % (95% PCI 87.6, 99.1) and 93.1% (95% PCI 85.1, 97.1) respectively with no statistically significant difference between them.

Conclusion:

In low resource settings, the PHQ-9 and EPDS perform poorly in APD screening. Their use should be supplemented by mental state examinations from trained mental healthcare workers who thus should be availed at low level healthcare facilities. Based on the high true prevalence of APD, deliberate screening for the same is crucial and should be incorporated into the routine ANC package.

1 INTRODUCTION

1.1 Background

Depression during pregnancy, also referred to as antepartum depression (APD), is characterized by non-psychotic symptoms such as low mood, anhedonia, unintentional changes in weight and/or appetite, physical fatigue, having a slower thought process, presence of guilt feelings and recurrent suicidal thoughts, plans and/or attempts (APA, 2013, Mochache et al., 2018). It is a condition of great public health concern as it affects about 12% of women with a significantly higher burden among residents of low and middle income countries (Woody et al., 2017). In Kenya, the stated prevalence is roughly 18% (Ongeri et al., 2016).

Women with antepartum depression are likely to develop obstetric complications (Larsson et al., 2004) such as preeclampsia (Tapio Kurki et al., 2000). Antepartum depression has also been shown to lead to delivery of neonates with low birth weight and prematurity (Hoffman and Hatch, 2000, Mochache et al., 2018) and to progress into postpartum depression (PPD) (Josefsson et al., 2001, Ongeri et al., 2016).

Despite its high prevalence and adverse sequelae on the mother and child, antepartum depression can easily remain undetected and thus untreated (Marcus et al., 2003, Frank Peacock and Soto, 2010). This is because some of its associated symptoms such as erratic sleep patterns and changes in appetite could be mistaken for a normal occurrence in pregnancy. Locally, this situation is further compounded by a lack of routine screening for APD in routine antenatal care (ANC) clinics and a severe shortage or in certain parts of the country, total lack of qualified mental healthcare workers (Marangu et al., 2014, Ndetei et al., 2007).

Deliberate screening for APD is critical to accurate patient identification (Siu et al., 2016). Among the APD screening tools that have been used in research or clinical practice are the Edinburgh Postnatal Depression Scale (EPDS) and the Patient Health Questionnaire-9 (PHQ-9). These two tests have both reported good reliability and validity for identifying antenatal depression (Zhong et al., 2014, Sidebottom et al., 2012,

Woldetensay et al., 2018, Green et al., 2018). They are, in addition, rapid and easy to use in primary care settings. However, like other tests used for screening, the PHQ-9 and EPDS need to be validated before they can be applied in various settings owing to socio-demographic and cultural variations (Sackett et al., 1985). For instance, the comprehension and ability to relate to the questions in these two screening tools may vary based on one's educational or cultural background (Velloza et al., 2020, Kumar et al., 2020, Robinson et al., 2017) and therefore decrease the accuracy of the tests. Furthermore, the performance of these tools in screening for APD may be affected by the disease burden which can be influenced by factors such as poverty, intimate partner violence, fertility and degree of social support from one's partner (González-Mesaa et al., 2018) as well as perceptions of pregnancy and childbirth (Cosminsky, 1977).

The PHQ-9 is a self-administered questionnaire containing nine questions based on established criteria for diagnosis of depression that is used for depression screening among adults in the primary care setup (Egbi et al., 2014, Kurt Kroenke et al., 2001). The frequency of each of the depressive symptoms on this tool is given a score between zero and three, pointing towards the severity of the symptom (Zhong et al., 2014). This is advantageous because the total severity score obtained can be used to assess improvement or worsening of a patient's depressive symptoms during follow-up.

The PHQ-9 has demonstrated a high sensitivity (Se) and specificity (Sp) in identifying perinatal depression at a cut-off of ≥10 (Kurt Kroenke et al., 2001). Compared to the EPDS which assesses symptoms occurring in the seven days prior to evaluation (Zhong et al., 2014), PHQ-9 assesses symptoms occurring in the 14 days prior. The longer timeframe given in the PHQ-9 could increase the chances of omitting positive symptoms of depression due to recall bias (Robinson et al., 2017), therefore decreasing the tool's Se. On the other hand, the test may be associated with a high false positive rate (compromising Sp) because it screens for somatic symptoms like disrupted sleep patterns, changes in weight and/or appetite and feelings of fatigue which may be caused by the pregnancy itself (Marjorie H. Klein and Marilyn J. Essex, 1994).

The Edinburgh Postnatal Depression Scale (EPDS) is a self-reporting perinatal depression screening tool based on 10 cognitive and affective symptoms of depression (Murray and Cox, 1990, Lau et al., 2010). It was originally shown to have an optimal cut-off point of 14/15 for screening for APD (Murray and Cox, 1990). Unlike PHQ-9, EPDS omits questions that have a focus on somatic symptoms (Zhong et al., 2014, Moraes et al., 2017). As it is quick and easy to administer, the EPDS exhibits good acceptability to both the patients and health care providers and hence is recommended for assessing women in the perinatal period (Cox, 2017, Murray and Cox, 1990). In the antenatal period the test has displayed high Se and Sp across the various trimesters of pregnancy (Bergink et al., 2011, Felice et al., 2006). However, the Sp of this test could be compromised because the symptoms targeted by the scale are not exclusive to depression and could be suggestive of anxiety (Brouwersa et al., 2001, Navarro et al., 2007). The proportion of anxiety symptoms when patients are screened for depression using the EPDS has indeed been shown to be significantly higher during pregnancy than in the postpartum period (Ross et al., 2003).

Although the use of PHQ-9 and EPDS for APD screening has been validated in various settings, the accuracy estimates of a screening test evaluated on the basis of a reference standard are often plagued by information and selection bias (Enøe et al., 2000). Nonetheless, it is possible to examine two or more tests' Se and Sp without any prior knowledge of the underlying true disease status and without assuming that any of the tests is a gold standard by employing latent class models (Enøe et al., 2000, Branscum et al., 2005, Hui and Walter, 1980).

1.2 Statement of the Research Problem

The burden of APD in Sub-Saharan Africa ranges from 8.3% to 39% (Adewuya et al., 2007, Hartley et al., 2011) and in Kenya, the prevalence is as high as 18% (Ongeri et al., 2016).

Maternal mental health is inseparable from child health. Children born to women suffering from APD have been shown to have a higher risk of developing chronic malnutrition, more diarrheal episodes (McGee,

1997, Atif Rahman et al., 2004) and poorer mental development (Patel et al., 2003) compared to those born to mothers without depression. The presence of PPD which is likely to have been preceded by APD could also lead to a poor relationship between a mother and her infant, which in turn could affect the child's cognitive, social and emotional behaviour (Murray and Cooper, 1997). In addition, APD has been linked to poor outcomes such as low birth-weight and prematurity among neonates (Sundari et al., 2019, Mochache et al., 2018).

Surveillance of APD is necessary for informing mental health care policies in maternal and child health clinics. Early detection and treatment of APD has been shown to lower maternal, child and overall family morbidity and mortality (Lusskin et al., 2007). Lack of deliberate APD screening in the primary health care settings both due to lack of government-recommended screening tools and a severe shortage of qualified mental healthcare workers as is the case in Kenya (Marangu et al., 2014), could lead to underestimation of the disease burden and predispose pregnant women with undetected depression to adverse sequelae.

The EPDS and PHQ-9 are freely available APD screening tools, both which have been previously translated into the local national language (Kiswahili) and used by researchers here in Kenya (Kumar et al., 2015, Omoro et al., 2006). Both have been found to be fairly accurate in identifying APD in a rural community in Western Kenya (Green et al., 2018) but have also reflected underperformance in the Kenyan context due to poor comprehension of and inability to relate to certain elements of the questionnaires by a number of pregnant women (Velloza et al., 2020, Kumar et al., 2020).

For depression screening, a tool with a high false negative rate (FNR) would present a tremendous limitation because a high number of true cases would remain unidentified and therefore at risk of the adverse complications related to the condition. A tool having a high false positive rate (FPR) would be less precarious since positive cases should ideally be subjected to existing diagnostic assessments for confirmation before being subjected to treatment (Eack et al., 2006).

1.3 Justification

Although both EPDS and PHQ-9 have been validated in various populations globally (Bergink et al., 2011, Felice et al., 2006, Levis B., 2019), studies on the performance of these two tools in APD screening have only been done in a small part of Western Kenya (Green et al., 2018). Furthermore, even where their performance in APD screening has been assessed, the evaluation was done against a reference test. This may have given biased estimates of the accuracy of the tests.

Establishing the performance of these tools is critical to supporting the development of guidelines for the clinical management of APD in Kenya. Moreover, knowledge of the accuracy of these tests is central to informing surveillance of APD with a view to quantifying its burden locally. This study is important since it will evaluate the performance of the EPDS and PHQ-9 in screening for APD in Kenya's urban and rural population.

1.4 Research Questions

1. How accurate are the Patient Health Questionnaire-9 and Edinburgh Postnatal Depression Scale for screening antepartum depression in Nairobi and Nyeri counties?
2. How accurately do the positive and negative test outcomes of the EPDS and PHQ-9 reflect a pregnant woman's true depression status in Nairobi and Nyeri counties?
3. What are the optimal cut-off points for screening for antepartum depression using the Patient Health Questionnaire-9 and Edinburgh Postnatal Depression Scale in Nairobi and Nyeri counties?
4. What is the estimated true prevalence of antepartum depression in Nairobi and Nyeri counties?

1.5 Aim and Objectives

1.5.1 Broad Objective

To assess the performance of the Patient Health Questionnaire-9 and the Edinburgh Postnatal Depression Scale as screening tools for antepartum depression in Nairobi county and Nyeri county.

1.5.2 Primary objectives

1. To estimate the sensitivity and specificity of the Patient Health Questionnaire-9 and the Edinburgh Postnatal Depression Scale in screening for antepartum depression in Nairobi county and Nyeri county
2. To estimate the positive and negative predictive values of the Patient Health Questionnaire-9 and the Edinburgh Postnatal Depression Scale in screening for antepartum depression in Nairobi county and Nyeri county
3. To identify the optimal cut-off points for screening for antepartum depression using the Patient Health Questionnaire-9 and the Edinburgh Postnatal Depression Scale in Kenya

1.5.3 Secondary objective

To estimate the true prevalence of antepartum depression in Nairobi county and Nyeri county

2 LITERATURE REVIEW

2.1 Introduction

This chapter outlines reviews of literature on the burden of APD and the associated screening tools that have been used for research or clinical practice.

2.2 Burden of APD

Pregnant women have been shown to have higher rates of depressive symptoms compared to their non-pregnant counterparts (Esimai et al., 2008). Additionally, it has been shown that the burden of perinatal depression is higher in the antepartum than postpartum period (Jonathan Evans et al., 2001, Josefsson et al., 2001) and that low and middle income countries (LMICs) have higher rates than high income countries (HICs) (Fisher et al., 2012). The latter could be attributed to a greater burden of poverty, violence and lack of social support in LMICs (Rahman et al., 2003, Lovisi et al., 2005, Hartley et al., 2011).

Prevalence studies in LMICs have shown rates of APD as high as 28% in Pakistan (Rahman et al., 2003), 27.5% in Turkey (Golbasi et al., 2010), 19.6% in Brazil (Faisal-Cury and Rossi Menezes, 2007) and 18% in Bangladesh (Hashima E Nasreen, 2011, Nasreen et al., 2010). In North-West Ethiopia, the estimated prevalence was 11.8% (Bisetegn et al., 2016) while the proportion of pregnant women in a South-African study population found to have depressed mood was 39% (Hartley et al., 2011). A study among women in Ghana and Cote d'Ivoire identified 26.6% and 32% respectively as having APD (Bindt et al., 2012). A study done in Mathari and Mbagathi hospitals in Kenya showed an APD prevalence of 18% (Ongeri et al., 2016) while another study done in Pumwani Maternity hospital identified 38.4% of the study population as having APD symptoms (Mochache et al., 2018).

Poor obstetric and neonatal outcomes and the development of PPD have been linked to APD. The presence of APD increases a pregnant woman's risk of developing preeclampsia (Hu et al., 2015, Tapio Kurki, 2000) and delivering low-birth weight and premature babies (Grote et al., 2010, Sundari et al., 2019, Mochache et al., 2018). In a study done in Sweden, patients with symptoms of depression in pregnancy had a higher likelihood of developing PPD (Josefsson et al., 2001). There were similar findings obtained from a study based in Kenya where APD was shown to contribute six-fold towards PPD (Ongeri et al., 2016).

2.3 APD Screening and Diagnosis

The screening of APD is important for early identification, referral, treatment and follow-up of symptomatic patients so as to prevent the associated obstetric and neonatal complications. In order to improve perinatal outcomes, health systems not only need to ensure that APD screening takes place but that appropriate screening tools are used (Kendig et al., 2017, ACOG, 2018). Without continuous and fairly accurate screening, APD symptoms could easily remain unrecognized and pass as normal physiologic pregnancy changes (Yonkers et al., 2009). According to Luskin et al. (2007), early identification and management of APD reduces the associated maternal and childhood morbidity and mortality.

Antepartum depression screening in low resource settings such as Kenya require use of rapid and reliable tools with good Se and Sp measures (Chorwe-Sungani and Chipps, 2017, Cox et al., 1987). The Edinburgh Postnatal Depression Scale (EPDS), Patient Health Questionnaire-9 (PHQ-9), Postpartum Depression Screening Scale (PDSS), Beck Depression Inventory (BDI), Beck Depression Inventory-II (BDI-II), Centre for Epidemiologic Studies Depression Scale (CES-D) and Zung Self-Rating Depression Scale are commonly available tools for screening of depression in the perinatal period. All these tests, apart from the EPDS and PHQ-9 have 20 questions or more and therefore need a longer time to fill in, a possible hindrance to their successful application in busy clinical setups. The inclusion of somatic symptoms such as changes in weight and appetite in most of these tests decreases their Sp.

2.3.1 The Edinburgh Postnatal Depression Scale (EPDS)

The EPDS, a self-reporting depression screening tool that contains 10 items, was originally validated among a sample of 84 postpartum women residing in Edinburgh or Livingston new town, UK. The EPDS scores obtained from these women were evaluated against a psychiatric evaluation for depression and found to have Se of 86% and Sp of 78% in identifying women with depression in this population (Cox et al., 1987). This study revealed good acceptability of this scale among women of child-bearing age who could complete it in less than five minutes. The method of scoring was also shown to be simple. Although originally developed for use in the postpartum period, questions contained in the EPDS tool are not specific for this period only. Based on this understanding, EPDS was subsequently used in a study conducted among 100 women who were 28 and 34 weeks pregnant and were seeking ANC care from North Staffordshire Maternity Hospital, England. In this study, the women who filled in the EPDS were also assessed for depression using two different reference tools, the Research Diagnostic Criteria (RDC) for depression (Robert L. Spitzer et al., 1978) and the Standardized Psychiatric Interview (SPI) (D. P. Goldberg et al., 1970). When evaluated against the RDC for major depression, the best EPDS cut-off was 14/15 which yielded a Se of 100% and Sp of 96%. In this same study, the EPDS threshold of 12/13 was identified as optimal for identifying APD when performance of EPDS was evaluated against the total weighted scores obtained from the SPI (Murray and Cox, 1990).

Locally, a study done in Bungoma, Western Kenya among 193 randomly selected women who were either pregnant or new mothers, assessed alongside the EPDS and PHQ-9 how accurate an APD screening tool that was locally developed was. The research version of the Structured Clinical Interview of DSM-V (SCID-5-RV) (Mohammadkhani et al., 2018) was used as the reference tool for diagnosis of depression. An EPDS cut-off point of ≥16, higher than in most other studies was identified as optimal for identifying patients with depression and this tool yielded a Se and Sp of 70% and 72% respectively (Green et al., 2018).

A review and meta-analysis of 25 studies conducted among women residing in North and sub-Saharan African countries showed that the most frequently used tool for perinatal depression screening was the EPDS. At a cut-off value of ≥ 9, it had a pooled Se of 0.94 (95% CI 0.68-0.99) and Sp of 0.77 (95% CI 0.59-0.88). There would be better Sp but compromised Se yielded at higher cut-off points (Tsai et al., 2013). According to another systematic review on APD screening tools done in low resource settings, EPDS was used in majority of the studies. Its Se ranged from 0.88 to 1.0 and Sp from 0.733 to 0.915. The pooled Se and Sp was 0.80 and 0.81 respectively (Chorwe-Sungani and Chipps, 2017).

In Nigeria, a study done among 182 women in their third trimester of pregnancy showed that EPDS was a valid APD screening tool (Adewuya et al., 2009). These women were screened for APD using either the English or Yoruba language versions of the EPDS and the performance of the EPDS in diagnosing depression evaluated against a psychiatric assessment. The best threshold for identifying major depression in this population was 12 with a Se of 100% and Sp of 96% while the best threshold for identifying both major and minor depression was 10 with a Se and Sp of 86.7 and 91.5% respectively. Among a population of Malawian pregnant women, EPDS assessed against psychiatric assessment as gold standard for diagnosis of depression in pregnancy had 81.1% (95% CI 73.4 – 88.9%) as the Area under the Curve (AUC) (Stewart et al., 2013).

In Brazil, a study done among 247 women attending ANC in a public facility found that EPDS had a Se of 0.81 and Sp of 0.73 (Castro et al., 2015). Approximately 75% of the women were correctly classified as either having depression or not using this scale at an optimal cut-off value of ≥11. In Mexico, the best cut-off point for identifying combined major and minor depression was 8/9 according to a study done among 120 pregnant women in their teenage years. At this threshold, EPDS was found to have a Se of 70.4%, Sp of 84.9%, positive predictive value (PPV) of 47.6% and negative predictive value (NPV) of 91.0% (Alvarado-Esquivel. et al., 2014). Another study done in the adult population in the same country identified the threshold 9/10 as the most ideal for screening combined major and minor depression with a Se and Sp

of 75.7% and 74.4% respectively and PPV and NPV of 50.8% and 94.7% respectively (Alvarado-Esquivel. et al., 2014). In both studies, EPDS performance was assessed against a diagnosis of depression made by clinical assessment. EPDS use was also studied among a group of 194 pregnant women in South India and shown to have Se of 100% and Sp of 84.9% at a cut-off≥13 (Fernandes et al., 2011).

Contrary to the evidence available of its validity in the antenatal period, some studies point out a few demerits of the EPDS. One study done in a city in Midwestern US showed that use of the EPDS might be limited to the postnatal period only. In this study, EPDS was shown to have poor Se for depression in the antepartum period (Mosack and Shore, 2006). Another longitudinal study done among 150 obstetric patients in Toronto, Canada suggested that EPDS does not directly measure depression. In this study, about 47% of the total EPDS score in late pregnancy could be accounted for by the three anxiety items of the scale (Ross et al., 2003).

2.3.2 The Patient Health Questionnaire (PHQ-9)

The PHQ-9 is a self-administered questionnaire containing nine items that has been validated in both obstetrics and gynaecology clinics and primary care (Spitzer et al., 2000, Robert L. Spitzer et al., 1999). As a depression screening tool, it has the advantages of being brief, easy to score, self-administered with good acceptability among patients and multipurpose because it also measures severity of depression (Robert L. Spitzer et al., 1999). It is also freely available to the public.

According to a validation study done in Western Kenya, this tool was found to be 70% sensitive and 73% specific for depression among pregnant women. However, in this Kenya-based study, the optimal cut-off point for PHQ-9 in pregnant women was 15, higher than in most other studies (Green et al., 2018). In Sub-Saharan Africa, its use in screening for APD was also validated against a psychiatric interview in a study conducted among 246 Afaan Oromo Ethiopian women in various trimesters of pregnancy. In this study, it was shown to have a Se of 80.8% and Sp of 79.5% at a cut-off point of 8 (Woldetensay et al., 2018).

In the United States, a total of 6000 participants attending different primary care and obstetrics and gynaecology clinics completed the PHQ-9 and were subsequently assessed for depression by a mental health practitioner. In this study, PHQ-9 established a Se of 88% and Sp of 88% for depression at a cut-off of 10. The tool had equally good Se and Sp in the primary care compared to the obstetrics and gynaecology setting hence showing good reliability (Kurt Kroenke et al., 2001). A study done in Minnesota among 745 pregnant women also showed high validity of the PHQ-9 when its performance was assessed against clinical interviews for diagnosis of depression. At a threshold of 10, the tool had Se and Sp values of 85% and 84% respectively for depression and a PPV and NPV of 17% and 99%, respectively (Sidebottom et al., 2012).

In Peru, pregnant women seeking ANC were also subjected to APD assessment using both the PHQ-9 and EPDS and the results from the two tools compared. The scores were categorised into two (≥ 10 or <10) to show presence or absence of depression respectively. With this, there was concordance in classification of depression in 74% of the study participants. These findings suggested that administering these two tests concurrently could lead to better identification of symptoms of depression in pregnancy because while the PHQ-9 includes questions on somatic symptoms, the EPDS includes questions on symptoms of anxiety, all which could be present in early pregnancy (Zhong et al., 2014).

2.3.3 Other screening tools

Other common screening tools for APD that have been used in clinical practice or research include the Postpartum Depression Screening Scale (PDSS), Beck Depression Inventory (BDI) and the Centre for Epidemiologic Studies Depression Scale (CES-D).

The PDSS is an instrument composed of 35 questions focusing on seven main elements of mental health: disturbances in sleeping or eating, feeling anxious or insecure, impaired cognition, self- loss, feelings of guilt or shame, emotional instability and thoughts of self-harm. The items in these seven elements aim to describe a mother's feelings in the immediate postpartum period (Beck and Gable, 2001). The lowest and

highest possible scores on this scale are 35 and 175 respectively. Limited studies have been done on the use of the PDSS in the antepartum period. One such study was done in China among 842 pregnant women with obstetric complications and assessed the combined use of the PDSS with EPDS for APD screening. According to this study, the total scores obtained from EPDS and PDSS were strongly correlated (r=0.652, p=0.000). A score of 79/80 was recommended as the ideal cut-off point for major depressive illness, with a Se and Sp of 86.4% and 100%, respectively (Zhao et al., 2015).

The Beck Depression Inventory (BDI) is a four-point self-reporting tool containing 21 items that is usually used for assessing the severity of symptoms of depression (A. T. Beck et al., 1961, Čuržik and Begić, 2012) and not for the purpose of screening or diagnosis (Chorwe-Sungani and Chipps, 2017). Originally developed by Aaron Beck in 1961, it was later revised (BDI-II) to assess depression severity among patients in line with the clinical criteria for diagnosis of depression (Hailu Gebrie, 2018). Like most other depression screening tools, some of its items may be physiological changes in pregnancy and not unique features of depression (Huffman et al., 1990). The inclusion of these items on the scale compromises its Se for APD screening (Čuržik and Begić, 2012). It should therefore be used cautiously among pregnant women (Huffman et al., 1990). It takes about five to ten minutes to complete but needs to be administered in an environment that allows enough concentration and provides adequate light for reading (Farinde, 2013). The various responses in the questionnaire can also be easily misinterpreted by patients with low literacy levels (Tetine L. Sentell and Brenda Ratcliff-Baird, 2003). It is also not freely available and may require the presence of a skilled mental health practitioner to administer and help in interpretation (Hailu Gebrie, 2018).

Despite these disadvantages, BDI has been used to assess depression in various perinatal populations where it has illustrated good reliability and validity as a screening tool (William L. Holcomb et al., 1996, Tandon et al., 2012, Castro et al., 2015, Siu et al., 2016). ,

The Centre for Epidemiologic Studies Depression Scale (CES-D) is a self-administered questionnaire containing 20 items primarily used in research to measure symptoms of depressive illness (Radloff, 1977). It focuses on symptoms that are cognitive, behavioural, affective and somatic in nature (Breedlove and Fryzelka, 2011). Depressive symptoms are indicated using this tool when scores ≥16 are obtained. The instrument takes five to ten minutes to complete and does not require trained professionals (Radloff, 1977). It is widely used as a screening instrument for research on depression during the prenatal period and is recommended as an initial assessment tool (Breedlove and Fryzelka, 2011).

A study in Baltimore comparing use of EPDS, CES-D and BDI-II for identification of depression in the perinatal period showed that all three were accurate detectors of major and major and/or minor depression in the perinatal period. The CES-D had a Se of 87.5% and Sp of 81.0% for depression, at a score of ≥20 as the optimal cut-off point. Of the three tests, CES-D was the most sensitive for major and/or minor depression (87.5% versus 84.4% for both EPDS and BDI-II) (Tandon et al., 2012). This is in agreement with another study done among 98 pregnant women and new mothers in the U.S where CES-D seemed to be more sensitive in measuring depression in comparison to EPDS. While none of the pregnant women in this study were depressed based on the EPDS score, six were identified as depressed on the CES-D (Mosack and Shore, 2006). However, CES-D has been shown to give more false positive results among pregnant women (Myers and Weissman, 1980).

3 METHODOLOGY

3.1 Introduction

This chapter describes the study area, study design and population, eligibility criteria of study participants, sample size calculation and sampling strategy, definition of the target condition, plan for data collection, processing and analysis, minimization of errors and biases and ethical considerations.

3.2 Study area

This study was conducted at Mutuini Hospital (MH) and Karatina Sub-county Hospital (KSCH), two health facilities serving an urban and rural population respectively. The regional diversity this provided is important because the prevalence of APD has been shown to vary according to people's socio-economic status (SES) and whether they live in an urban or rural area (Osok et al., 2018, Patrick, 2013). Conducting the study in these two facilities stratified the study population into two sub-populations, each assumed to have a different prevalence of APD therefore making it easier to generalize the results obtained to the overall Kenyan population.

Located in Nairobi County, MH is a level four facility that serves the population of Dagoretti South constituency. Having a limited inpatient capacity of only about 20 beds, it mainly operates as an outpatient facility that offers general outpatient medical, paediatric and surgical care, Human Immunodeficiency Virus (HIV) comprehensive care and counselling (CCC) and Maternal and Child Health (MCH) services. The MCH clinic includes the child immunization, antenatal care (ANC) and postnatal clinics. The ANC operates on a daily basis from 8am to 5pm with majority of the pregnant women seeking services between 8am and 2pm. It is run by a team of nurses who serve approximately 30 pregnant women daily. Approximately six to eight of the patients seen in a day are usually attending the clinic for their first visit. On average, each patient is seen about four times during their pregnancy. Other than the physical examination of pregnant

women, this clinic offers comprehensive antenatal care with intercalated services such as tetanus toxoid immunization, screening for HIV, tuberculosis (TB), anaemia and urinary tract infections (UTI), blood group and rhesus testing, Intermittent Preventive Treatment of Malaria (IPT) and supplementation with iron and folic acid. Notably, screening for APD is not one of the services offered routinely and the facility does not have a psychology clinic.

MH is a good study area because of the presence of a busy ANC clinic that serves a large population of the urban dwellers in Nairobi, a population that has been shown to have a high prevalence of APD (Ongeri et al., 2016, Osok et al., 2018).

Located in Nyeri County, KSCH is also a level four health facility that serves the population of Mathira constituency. The facility offers general and specialised medical, surgical, obstetrics and gynaecology and paediatric inpatient and outpatient services. It has one specialised maternity theatre and one surgical theatre that run for 24 hours. It also has special clinics such as eye, Ear Nose and Throat (ENT), occupational and physiotherapy, mental health, dental, nutrition, CCC, TB and MCH clinics. The MCH clinic offers services such as immunization, family planning, CCC, ANC and postnatal care. Specific services offered in the ANC include physical examination of pregnant women, anaemia, UTI, TB and HIV screening, blood group and rhesus testing, couple HIV testing and counselling where applicable, tetanus toxoid immunization, deworming, IPT and offering iron and folate supplements.

The ANC clinic operates from 8am to 5pm on Mondays to Fridays. Approximately 30 pregnant women are followed up in this clinic on a daily basis by a team of nurses. Majority of the women attend the clinic between 8am and midday. Of these, approximately seven to eight are usually new patients and each patient is seen in this clinic about four times during their pregnancy. KSCH is a good choice for our study because while MH provides a sample from an urban population, it provides a sample from a rural population. These

two study areas hence provide an overall sample that is more representative of the overall Kenyan population in terms of area of residence (urban versus rural).

3.3 Study design

A cross-sectional study was utilised to evaluate the performance of the PHQ-9 and the EPDS as screening tools for antepartum depression. This was an appropriate study design based on the ease of recruitment of expectant mothers presenting to the ANC clinic for care as well as its suitability for the descriptive nature of the proposed study.

3.4 Study population

3.4.1 Target population

The target population was all pregnant women seeking antenatal care services within Nairobi county and Nyeri county.

3.4.2 Source population

This population was composed of all pregnant women attending ANC in Mutuini Hospital and Karatina Sub-county Hospital who met the eligibility criteria for participation in this study.

3.5 Eligibility criteria of study participants

3.5.1 Inclusion criteria

All pregnant women above the age of 18 years attending ANC at Mutuini hospital and Karatina Sub-county hospital and who consented to participation were included in the study.

3.5.2 Exclusion criteria

Individuals with previous diagnosis of mental illness or any chronic illnesses such as HIV, diabetes and hypertension or those who had recently been bereaved were excluded from the study.

3.6 Target condition

The study targeted to detect the latent or unobserved depression status of pregnant woman (referred to as antepartum depression) as determined by scores obtained on the PHQ-9 and EPDS that were above preselected cut-off points.

3.7 Determination of sample size and sampling strategy

3.7.1 Sample size estimation

McNemar's sample size formula for paired proportions (Connor, 1987) was used to estimate the required sample size as shown below:

$$n_{per\ test} = \left(\frac{Z_{\propto/2}\sqrt{p_{disc}} + Z_{\beta}\sqrt{p_{disc} - p_{diff}^2}}{p_{diff}} \right)^2$$

$$p_{disc} = (1 - Se_1) + (1 - Se_2)$$

$$p_{diff} = (1 - Se_1) - (1 - Se_2)$$

Where: $n_{\textbf{per test}}$ is the sample size required for each test, $Z_{\alpha/2}$ (1.96) is the critical value specifying the two-tailed 95% confidence level, Z_{β} (- 0.84) is the critical value specifying the statistical power of 80% that is

desired and Se_1 and Se_2 are estimates of sensitivity of the PHQ-9 and EPDS respectively (from literature). Notably, Se_1 is 0.70 (Green et al., 2018) and Se_2 is 0.87 (Adewuya et al., 2009).

Based on the specified figures, coding for this formula was done and run on R software, generating a required total sample size of 483, after adjusting upwards by 5% to account for non-response.

3.7.2 Sampling strategy

Expectant mothers visiting the hospitals' ANC clinics were systematically randomly sampled based on their order of arrival and every second woman who met the eligibility criteria was selected for participation. Recruitment of participants was done upon their arrival into the clinic, after they had been triaged by the nurse, but before their antenatal assessment. The potential participants were each taken through a brief introduction to the study and what the screening process entailed before being asked if they consented to participation and if so being presented with the consent forms for signing. If a woman did not meet the eligibility criteria, they were excluded with non-replacement. This was done until the required sample size was reached. In KSCH, the screening was done at a corner of the ANC room while in MH, it was done in a tent right outside the clinic. In order to determine the number of women to be sampled from each facility, probability proportional to size (PPS) sampling (Skinner, 2016) was applied whereby the proportion of participants selected from each facility was weighted upon the number of patients seen in that facility's ANC every month. Based on this, 263 and 220 patients from MH and KSCH were included in the study respectively.

3.8 Study Flowchart

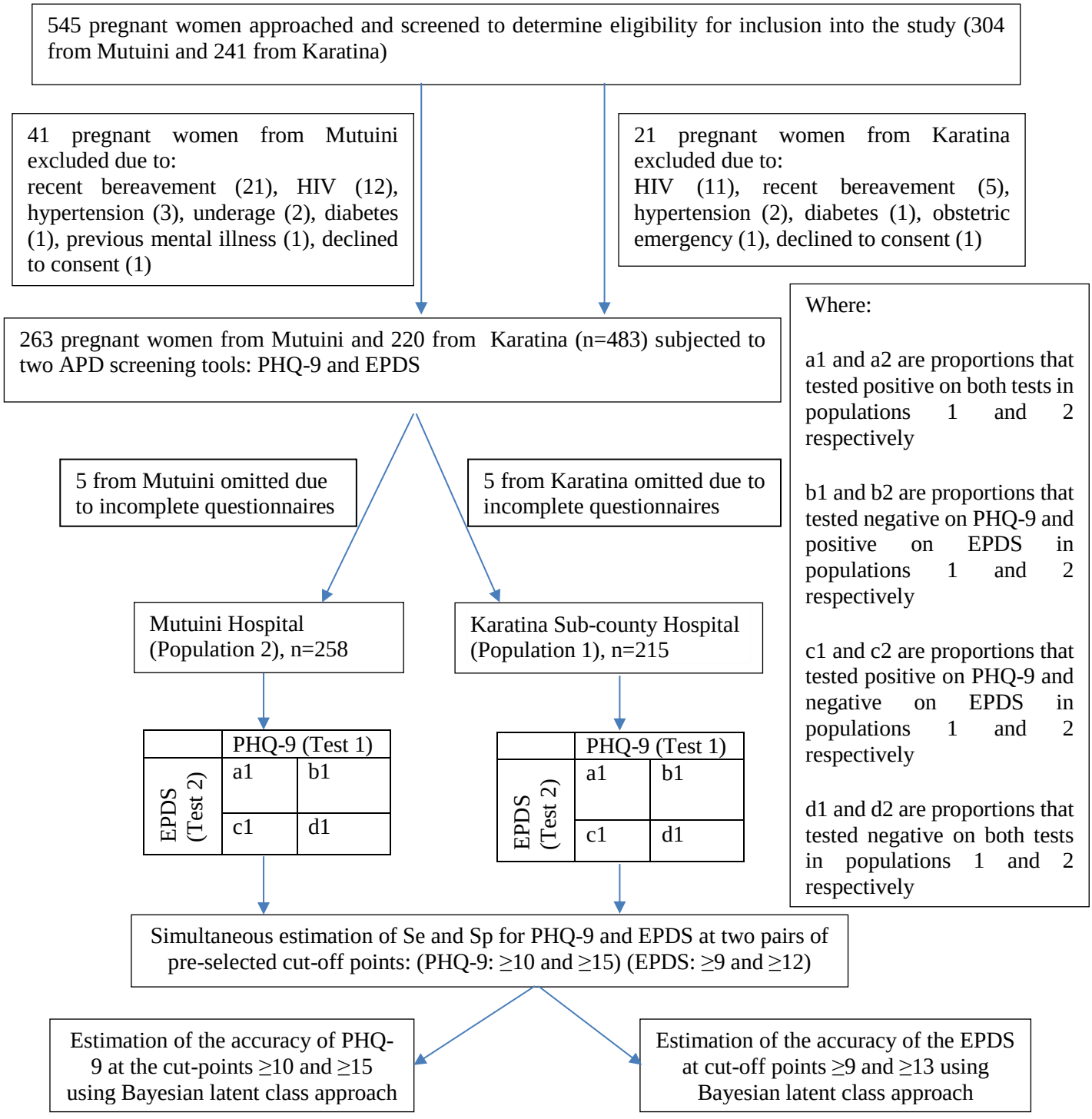

Figure 1: Flow chart displaying the process of evaluation of Se and Sp of PHQ-9 and EPDS at pre-selected cut-off points

3.9 Study Variables

Considering the descriptive nature of the study, the variables of interest related to the outcome, namely, the positive or negative test results from the PHQ-9 and EPDS tools. The PHQ-9 and EPDS are continuous scales used to assess a patient's likelihood of having depression. Moreover, the socio-demographic characteristics of the study participants (whose methods of measurement are outlined on table 1) were captured.

Table 1: Participants' socio-demographic characteristics and their method of measurement

Variable (type)	**Measurement**
Age (continuous)	This was captured in years
Gestational age (continuous)	This was specified as age of the foetus in weeks based on a woman's LNMP and/or obstetric ultrasound
Trimester of pregnancy (ordinal)	This was reported based on the gestational age as either First (0-12 weeks), Second (13-27 weeks) or Third (≥ 28 weeks)
Parity (nominal)	This was classified as either primiparous (not having given birth before) or multiparous (having given birth before)
Marital status (nominal)	This was categorised into the following groups: single, married, separated or divorced and widowed
Level of education (ordinal)	This was reported as either of the following: No formal education, Primary, Secondary and Tertiary
Employment status (binary)	This was outlined as either being employed or unemployed

3.10 Data Management

3.10.1 Data collection plan

Recruitment of two research assistants (RAs), one being a clinical officer and the other a medical student, was done to assist in data collection from KSCH and MH respectively. The RAs were trained by the principal investigator (PI) on how to administer the patient self-reporting APD screening tools (PHQ-9 and EPDS) to the participants and how to fill in the pre-coded questionnaire on participants' socio-demographic factors. They were also trained on how to subsequently check the tools for completeness. Kiswahili and English versions of the PHQ-9, EPDS and pre-coded questionnaires were availed according to a patient's language preference.

3.10.2 Data processing and analysis

Once filled in with the required data, the questionnaires, PHQ-9 and EPDS forms were checked for completeness. The data was then entered into a Microsoft excel spreadsheet by two independent data-entry personnel who then cross-checked the data between them in order to reduce data entry errors. The data collected from the two study sites were collapsed into one dataset. The cross-checked data was cleaned and then transferred to Stata version 11.2 and R software for analysis.

The frequency distribution of the patients' socio-demographic variables is displayed in table 2. The median values and their ranges have been computed for continuous variables and categorical variables summarized as proportions.

Based on the location from which the study participants were drawn from (either Mutuini or Karatina), a dichotomous variable termed 'location' was generated. A Bayesian Latent Class Model (BLCM) incorporated into OpenBugs version 3.2.2 (Lunn et al., 2009) and run through the package 'BRugs' (Thomas et al., 2006) on R software was applied in simultaneously predicting APD prevalence, Se and Sp

of the PHQ-9 and EPDS and their respective predictive values. The analysis plan followed the standards for reporting of diagnostic accuracy studies that use BLCM (STARD-BLCM) (Kostoulas et al., 2017).

As per (Hui and Walter, 1980), the model makes the following assumptions: 1.) There are two or more subpopulations, each with a different prevalence, that make up the target population. In this study, the target population consisted of two separate subpopulations: rural (Karatina Sub-county hospital) and urban (Mutuini hospital). Owing to their distinct settings, each of the two subpopulations was presumed to have a distinct true prevalence of APD. 2.) The tests' Se and Sp do not differ across the subpopulations. 3.) Given the disease status, there is conditional independence between the tests. This was a reasonable assumption considering the two tests have separate symptom targets; PHQ-9 assesses somatic symptoms whereas EPDS targets anxiety symptoms. Granted this, the probability of a patient testing either positive or negative on one tool was not affected by what they previously tested on the other tool.

It was assumed that the different combinations of test results, for each subpopulation, observed as counts (O_k) have a multinomial distribution as shown below:

$O_K | Se_{ik}\, Sp_{ik}\, P_k \sim$ multinomial ($prob_{k,}\, n_k$)

Where Se_{ik} and Sp_{ik} are the Se and Sp measures for the i^{th} test (i=1, 2) in the given subpopulation represented by k in the equation (k=1, 2) and P_k represents the k^{th} subpopulation's prevalence. $Prob_k$ represents a vector of probabilities of having observed the specific test results' combinations (e.g. +, +) while n_k is the sample size used in subpopulation k. The probabilities are defined using the specific test characteristics (Se and Sp) and prevalence (P) of each subpopulation. For example, $Prob_1$ for a person who tests positive on both tests in the first subpopulation is illustrated by:

$$Prob_1 = Pr\,(T_1^+ T_2^+ | D^+) + Pr\,(T_1^+ T_2^+ | D^-) = Se_{11}\, Se_{21}\, P_1 + [1\text{-}Sp_{11}]\,[1\text{-}Sp_{21}]\,[1\text{-}P]$$

Since there are two subpopulations, the latent class model contained six parameters i.e. each of the two tests' Se and Sp and each subpopulation's prevalence. These six parameters were estimated from the six degrees of freedom obtained from each of the two subpopulations. Since previous evaluations of the performance of PHQ-9 and EPDS had utilised imperfect reference standards, with the resultant test estimates potentially suffering information and selection bias, uninformative priors (beta (1, 1)) were used to specify the test parameters.

The PPV and NPV for test i and subpopulation k was calculated using the formula below:

$$PPV = P_k Se_{ik} / (P_k \ Se_{ik} + [1 - P_k][1 - Sp_{ik}\ ])$$

$$NPV = [1 - P_k\ ] Sp_{ik} / (P_k [1 - Se_{ik}] + [1 - P_k] Sp_{ik})$$

The model was initialized using three Markov Chain Monte Carlo chains each with a different value. Two sample chains with different iterations were initially used and the final number of iterations for each chain was based on an evaluation of their convergence by using Gelman-Rubin Diagnostic plots and density plots. The Deviance Information Criterion Statistic (DIC) was computed and used to compare the different models constructed from the various pairs of PHQ-9 and EPDS cut-off values. The model with the smallest DIC was interpreted as being the best and as having the optimal cut-off points. In addition, any two models were interpreted as statistically different only if their DIC values varied by three or more units (Spiegelhalter et al., 2002). The posterior distribution of each subpopulation's P and each test's Se and Sp and their predictive values were reported from the median values and the associated 95% posterior credible intervals (PCI). The Bayesian p-value for the difference between the Se and Sp measures was also computed.

3.11 Minimisation of errors and biases

Random sampling of the study participants was used to ensure generalisability of the findings to the study population and thus minimise selection bias. RAs were trained on how to administer the screening tools and fill in the questionnaire, in order to minimise information bias.

The data collected was double entered into an Excel sheet by two independent data entry personnel hence minimising data entry errors. The BLCM model used for analysis minimises biases in test estimates since the evaluation is conducted without assuming prior knowledge of the true disease status.

3.12 Ethical considerations

Approval to conduct this study was sought from Kenyatta National Hospital (KNH) - University of Nairobi (UoN) Ethics and Research Committee (ERC) and from the National Commission for Science, Technology and Innovation (NACOSTI). We also sought permission from the administration of both Mutuini and Karatina sub county hospitals for data collection from their facilities. Informed consent was sought and obtained from the participants before participation in the study. The questionnaires were de-identified to safeguard the participants' confidentiality.

No financial benefits were extended to the study participants. However, any patients suspected to have depression after the screening process were advised to visit a psychologist or psychiatrist.

4 RESULTS

4.1 Introduction

This chapter starts by outlining the sociodemographic characteristics of the sample population. It then displays the cross-classified counts of results obtained at the various cut-off points and also the sensitivity and specificity measures and predictive values of the PHQ-9 and EPDS scores in the screening of APD. The DIC values have also been displayed in order to show the optimal cut-off points for both tests.

4.2 Sociodemographic characteristics of the study participants

Approximately 45.5% (n=220) and 54.5% (n=263) of the pregnant women seeking antenatal care services from Karatina Sub-county Hospital (KSCH) and Mutuini Hospital (MH) respectively, in the months of June, July and August 2020, were enrolled into the study after giving their consent. Ten of these participants (five from Karatina and five from Mutuini) did not answer all the questions in either the PHQ-9 or EPDS forms therefore rendering their total depression scores unreliable. Based on this, these ten entries were omitted from the analysis. Table 2 outlines the sociodemographic characteristics of the remaining study participants.

The participants' ages ranged between 17 and 46 years with a median age of 26 years. The overall median gestational age was 29 weeks (range: 3-41 weeks). The ranges of maternal and gestational age in the two groups were statistically similar. More than 95% of the study participants from both KSCH and MH were in their second and third trimester of pregnancy. Karatina had a slightly higher proportion of participants who were in their first trimester of pregnancy (3.70%) compared to Mutuini (1.89%). Overall, roughly two-fifths (37.79%) of the study participants were primiparous with the distribution being quite similar in the two study populations.

Majority of the respondents (80.97%) were married and less than 2% were separated or divorced. None of the respondents were widowed. Compared to Mutuini (16.28%), a slightly higher proportion of the participants from Karatina (19.07%) reported that they were single. More than three-quarters of the respondents from both populations (77.38%) had attained secondary school education and above. Respondents who had a tertiary education were slightly more in Mutuini (27.52%) compared to Karatina (24.65%). Despite the high literacy levels, more than 75% of the respondents reported that they were not in any form of employment with some attributing their current state of unemployment to the COVID-19 pandemic that was ongoing at the time of the study. The proportion of those who were unemployed was slightly higher in Mutuini (79.46%) compared to Karatina (73.49%).

Table 2: Summary statistics of participants' sociodemographic characteristics, Kenya, 2020, (n=473)

Variable	Values	Median	Range	Frequency n (%)
Age (in completed years)				
Overall	-	26	17-46	-
Karatina	-	26	17-46	-
Mutuini	-	25	18-43	-
Gestation of pregnancy (in weeks)				
Overall	-	29	3-41	-
Karatina	-	29	3-41	-
Mutuini	-	30	5-40	-
Trimester of pregnancy				
Overall	First	-	-	11 (2.74)
	Second	-	-	158 (39.40)
	Third	-	-	232 (57.86)
Karatina	First	-	-	7 (3.70)
	Second	-	-	79 (41.80)
	Third	-	-	103 (54.50)
		-	-	
Mutuini	First	-	-	4 (1.89)
	Second	-	-	79 (37.26)
	Third			129 (60.85)
Parity				
Overall	Primiparous	-	-	178 (37.79)
	Multiparous	-	-	293 (62.21)

Karatina	Primiparous	-	-	82 (38.32)
	Multiparous	-	-	132 (61.68)
Mutuini	Primiparous	-	-	96 (37.35)
	Multiparous	-	-	161 (62.65)
Marital status				
Overall	Single	-	-	83 (17.55)
	Married	-	-	383 (80.97)
	Separated/divorced	-	-	7 (1.48)
Karatina	Single	-	-	41 (19.07)
	Married	-	-	172 (80.00)
	Separated/divorced	-	-	2 (0.93)
Mutuini	Single	-	-	42 (16.28)
	Married	-	-	211 (81.78)
	Separated/Divorced	-	-	5 (1.94)
Level of education				
Overall	No formal education	-	-	3 (0.63)
	Primary	-	-	104 (21.99)
	Secondary	-	-	242 (51.16)
	Tertiary	-	-	124 (26.22)
Karatina	No formal education	-	-	1 (0.47)
	Primary	-	-	46 (21.40)
	Secondary	-	-	115 (53.49)
	Tertiary	-	-	53 (24.65)
Mutuini	No formal education	-	-	2 (0.78)
	Primary	-	-	58 (22.48)
	Secondary	-	-	127 (49.22)
	Tertiary	-	-	71 (27.52)
Employment status				
Overall	Employed	-	-	110 (23.26)
	Unemployed	-	-	363 (76.74)
Karatina	Employed	-	-	57 (26.51)
	Unemployed	-	-	158 (73.49)
Mutuini	Employed	-	-	53 (20.54)
	Unemployed	-	-	205 (79.46)

4.3 Test outcomes

The cut-off points of ≥ 10 and ≥ 15 for the PHQ-9 (Kurt Kroenke et al., 2001, Green et al., 2018) and ≥ 9 and ≥ 13 for the EPDS (Chorwe-Sungani and Chipps, 2017, Osok et al., 2018) were used to classify the respondents as either being positive or negative for depression. The cross-classified counts of these dichotomous test results at the various cut-off point combinations of PHQ-9 and EPDS have been displayed in table 3 below.

Table 3: Cross-tabulated outcomes for the PHQ-9 and EPDS by population (n=473)

Population	Cut point	Test outcome (PHQ-9/EPDS)				
	(PHQ-9,EPDS)	(+[a]/+)	(+/-[b])	(-/+)	(-/-)	Total (%)
Karatina	≥10, ≥9	9	10	10	186	215 (45.5%)
Mutuini		16	19	11	212	258 (54.5%)
Karatina	≥10, ≥13	5	14	1	195	215 (45.5%)
Mutuini		12	23	0	223	258 (54.5%)
Karatina	≥15, ≥9	3	0	16	196	215 (45.5%)
Mutuini		6	1	21	230	258 (54.5%)
Karatina	≥15, ≥13	3	0	3	209	215 (45.5%)
Mutuini		5	2	7	244	258 (54.5%)

[a] Positive

[b] Negative

4.4 Sensitivity, specificity and optimal cut-off points

The models with the respective PHQ-9 and EPDS cut-points of (≥15 and ≥ 9) and (≥15 and ≥13) were the best fitting as they had the lowest and statistically similar DIC values of 26.9 and 26.4 respectively (Table 4). However, between these two models, Se and Sp values of both PHQ-9 and EPDS were optimized where the PHQ-9 cut-off was ≥15 (Se 0.3%; Sp 63.2%) and EPDS cut-off was ≥9 (Se 5.2%; Sp 12.3%). These cut-points (≥ 15 for PHQ-9 and ≥ 9 for EPDS) have therefore been used to display subsequent data.

In this study population, both PHQ-9 and EPDS performed very poorly as screening tools for APD as evidenced by their exceedingly low Se and Sp values (table 4). The EPDS recorded a higher Se (5.2 [95% PCI 0.4, 9.4]) compared to the PHQ-9 (0.3 [95% PCI 0.0, 1.2]), (Bayesian p-value = 0.023). The Sp of the PHQ-9 and EPDS were not statistically different (Bayesian p-value = 0.95). Increasing the PHQ-9 and EPDS cut-off points from 10 to 15 and 9 to 13 respectively compromised their Se (table 4).

Table 4: DIC and pooled estimates of sensitivity and specificity of PHQ-9 and EPDS at various cut-off points

Cut-off values		Test Parameter	Estimate (95% PCI)	DIC
PHQ-9	EPDS			
≥ 10	≥ 9	Se_{PHQ-9}	4.3 (0.2, 7.8)	
		Sp_{PHQ-9}	27.6 (1.8, 53.6)	34.7
		Se_{EPDS}	3.2 (0.2, 6.4)	
		Sp_{EPDS}	40.5 (4.3, 62.1)	
≥ 10	≥ 13	Se_{PHQ-9}	4.5 (0.3, 9.2)	
		Sp_{PHQ-9}	6.0 (0.2, 24.2)	29.5
		Se_{EPDS}	0.3 (0.0, 1.2)	
		Sp_{EPDS}	52.3 (6.6, 75.0)	
≥ 15	≥ 9	Se_{PHQ-9}	0.3 (0.0, 1.2)	
		Sp_{PHQ-9}	63.2 (7.5, 86.4)	26.9
		Se_{EPDS}	5.2 (0.4, 9.4)	
		Sp_{EPDS}	12.3 (0.6, 42.1)	
≥ 15	≥ 13	Se_{PHQ-9}	0.3 (0.0, 1.3)	
		Sp_{PHQ-9}	42.4 (4.0, 72.8)	26.4
		Se_{EPDS}	1.2 (0.1, 3.1)	
		Sp_{EPDS}	18.7 (1.1, 51.5)	

4.5 Negative and positive predictive values

Table 5 below displays the negative and positive predictive values of the PHQ-9 and EPDS in the two study populations. Although both tests generally yielded better PPV than NPV, the overall predictive values across the populations (apart from the PPV for EPDS in Karatina) were very low. In Karatina, EPDS had a NPV of 0.5% and a PPV of 56.2% while PHQ-9 had a NPV of 2.8% and PPV of 13.2%. In Mutuini, EPDS had a NPV of 0.8% and PPV of 45.1% while PHQ-9 had a NPV of 4.4% and PPV of 9.1%. There was no statistically significant difference between the predictive values of the two tests.

Table 5: Predictive values of PHQ-9 and EPDS by location at cut-points ≥15 and ≥9 respectively

Location	Predictive values		
	Test parameter	Estimate (95% PCI)	
		PHQ-9	EPDS
Karatina	NPV	2.8 (0.1, 10.3)	0.5 (0.0, 4.0)
	PPV	13.2 (0.6, 51.8)	56.2 (3.9, 90.5)
Mutuini	NPV	4.4 (0.2, 12.5)	0.8 (0.0, 5.4)
	PPV	9.1 (0.4, 37.6)	45.1 (3.2, 81.5)

4.6 True prevalence of antepartum depression

At the PHQ-9 and EPDS cut-off values of ≥15 and ≥9, the posterior median prevalence of APD was 95.4% (95% PCI 87.6, 99.1) and 93.1% (95% PCI 85.1, 97.1) for Karatina and Mutuini respectively. There was no statistically significant difference between the two prevalences (difference= 0.023, 95% CI [-0.019, 0.065]).

5 DISCUSSION

5.1 Introduction

Guided by the objectives of this study, the sensitivity and specificity measures, predictive values and optimal cut-off points for the PHQ-9 and EPDS in screening for APD in Nairobi and Nyeri County were estimated using a Bayesian latent class model. This chapter elaborates on the results obtained.

5.2 Sensitivity and specificity of the PHQ-9 and EPDS for APD screening

The PHQ-9 and EPDS depicted very poor Sp and even poorer Se for screening of APD in our study population. This could possibly be explained by difficulty faced by patients in comprehending certain questions in these tools as supported by the findings from various local studies. One study conducted among pregnant and postpartum women in Thika revealed challenges in understanding certain elements of and choosing between some of the response options in the PHQ-9. Participants in this study expressed challenges in distinguishing between the response options "several days" and "more than half the days" and in responding to questions that were not relevant to their lives such as "watching television". They were also reluctant to associate themselves with the questions surrounding suicide (Velloza et al., 2020). Another study also outlined major issues in the semantic clarity of both PHQ-9 and EPDS but reported that the response options in the EPDS were less difficult compared to those in the PHQ-9 (Kumar et al., 2020). The poor accuracy of EPDS yielded is also corroborated by findings from two other studies that suggest its undermined Se and Sp in the prenatal period (Mosack and Shore, 2006, Ross et al., 2003).

However, our results differ from those of other studies done in similar low resource settings where various reference standard tests were used in evaluating performance of the PHQ-9 and EPDS for APD screening and found them to have high Se and Sp (Woldetensay et al., 2018, Green et al., 2018, Adewuya et al., 2009, Tsai et al., 2013). In Kenya for example, a study evaluating the accuracy of both the PHQ-9 and EPDS

among pregnant women and new mothers against the SCID-5-RV as the reference standard test, found both tools to have Se and Sp values that were slightly above 70% (Green et al., 2018). However, it is possible to yield false Se and Sp values when evaluating a test against an imperfect reference. Notably, our study differed from the rest in that it utilized a Bayesian model for the evaluation. Enøe et al. (2000) contend that using a Bayesian model that does not assume knowledge of the underlying true disease status allows a test's accuracy to be established without misclassification errors that would otherwise be unavoidable when tests are evaluated based on an imperfect reference standard. Evaluations of diagnostic tests without using a gold standard have been recognized as useful paradigms in psychiatry nosology (Hoijtink et al., 2013, Laliberté et al., 2015, Faraone and Tsuang, 1994). The estimates obtained in this study are therefore generalizable to pregnant women in low resource settings.

At the optimal PHQ-9 and EPDS cut-off points, the EPDS recorded a higher Se compared to the PHQ-9. Since PHQ-9 assess symptoms present over a longer time-frame compared to EPDS, it is possible that some patients might find it more difficult to properly recall their symptoms hence the lower Se. A study by Robinson et al. (2017) reflected a propensity by patients to underscore themselves on the PHQ-9 due to recall bias, volatility of symptoms over time and also as a way of self-motivation. A few patients reported that not all relevant depression symptoms such as lack of libido and social withdrawal were covered in the PHQ-9.

Although it was expected that EPDS should have a lower Sp compared to PHQ-9 because the former not only screens for depressive but also anxiety symptoms (Brouwersa et al., 2001, Navarro et al., 2007, Ross et al., 2003), our findings show no statistically significant difference between the Sp values of PHQ-9 and EPDS (Bayesian p-value=0.95). It is possible that the Sp of PHQ-9 is equally compromised by the inclusion of questions on somatic symptoms such as fatigue and appetite changes that could be as a result of the pregnancy itself.

5.3 Predictive values of the PHQ-9 and EPDS in screening for APD

The PHQ-9 and EPDS both yielded poor PPV and NPV values. The low confidence in negative and positive test outcomes by these two tools shows that if used singly to screen for APD, they are not reliable hence cannot inform treatment. It is important that these tests are always supplemented by a mental state examination done by a qualified mental health practitioner if they have to be used for APD screening. This therefore underscores the need for mental health care workers in low level health facilities in order to be able to properly screen for and diagnose APD.

5.4 Optimal cut-off points

The optimal cut-off points for the PHQ-9 and EPDS were ≥ 15 and ≥ 9 respectively (table 4). A previous study done in Bungoma, Western Kenya also recorded a cut -point of ≥ 15 as optimal for the PHQ-9 but recorded a much higher cut-off point of ≥ 16 for the EPDS (Green et al., 2018). However, the optimal cut-off point of ≥ 9 for the EPDS is similar to that reported in a meta-analysis of various studies done in North and Sub-Saharan Africa (Tsai et al., 2013). Using the lower cut-off point of 10 would increase the Se of PHQ-9 while using the higher cut-off of 13 would compromise Se of EPDS. A similar pattern is seen in other studies done in Africa (Gelaye et al., 2013, Tsai et al., 2013).

5.5 True prevalence of antepartum depression

The true prevalence of APD in Karatina and Mutuini was 95.4% and 93.1% respectively, with no statistically significant difference between the two prevalences. These prevalences are higher than what has been reported in previous studies done in Kenya (Osok et al., 2018, Ongeri et al., 2016). It is possible that this could be due to the fact that our data collection period coincided with the COVID-19 pandemic, a situation that could have negatively impacted most of the respondents economically, socially and consequently psychologically. Notably, approximately 77% of the respondents in this study reported that

at the time, they were not in any formal employment with some stating that they had lost their jobs during the COVID-19 pandemic due to the government imposed movement restrictions, curfew measures, closure of academic institutions and call for people to work from their homes. All these are socioeconomic factors that could possible impact on people's mental health. Arguably, a number of studies have shown a rise in rates of depression among pregnant women during the COVID-19 pandemic (Berthelot et al., 2020, Wu et al., 2020, Bueno-Notivol et al., 2020). In particular, according to Berthelot et al. (2020), women who were pregnant during the COVID-19 pandemic had twice the odds of developing APD compared to those who were pregnant before this period. In addition, Bueno-Notivol et al. (2020) in a systematic review of 12 community-based studies on depression during the initial months of the COVID-19 pandemic (January-May) found a pooled prevalence of 25%, approximately seven times higher than the estimated 2017 global prevalence of 3.44%. This picture reflects an important effect of the COVID-19 pandemic on people's mental health status.

5.6 Study limitations

Since the APD screening tools used in the study were in the form of questionnaires targeting symptoms occurring within one to two weeks of the time of the interview, the study participants may have failed to properly recall their circumstances hence leading to either underreporting or over-reporting of their symptoms. This may have biased the tests' Se and Sp. In addition to this, both the PHQ-9 and EPDS are subjective tests, based on feelings that are generally volatile and easily influenced by the existing circumstances.

6 CONCLUSION AND RECOMMENDATIONS

6.1 Conclusion

At the established optimal cut-off points for the PHQ-9 and EPDS of ≥ 15 and ≥ 9 respectively, both tools yield poor performance and do not lend themselves readily to APD screening in low resource settings. They could grossly underestimate the true burden of APD and undermine control efforts aimed at mitigating the condition. There is need to supplement their use with a mental state examination conducted by a trained mental healthcare worker if a decision is to be made on whether or not to manage a patient for APD. The availability of qualified mental health care workers in low resource settings is therefore crucial in APD surveillance.

6.2 Recommendations

- Considering the high true prevalence observed in the two study populations, APD screening should be included in the routine ANC package.
- Based on the low Se and Sp values yielded by the PHQ-9 and EPDS in our setting, efforts to develop more accurate APD screening tools for use in similar populations should be put in place.
- Future studies should aim at validating these findings in other low resource settings.

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8 APPENDICES

8.1 Statement of information and written informed consent form

Study title: Performance of the Patient Health Questionnaire and the Edinburgh Postnatal Depression Scale as screening tools for Antepartum Depression

Principal Investigator and institutional affiliation: Dr Sally Wambui Ndung'u, University of Nairobi, School of Public Health

Supervisors:

Dr Marshall Mweu,

University of Nairobi, School of Public Health

Mr Lambert Nyabola,

University of Nairobi, School of Public Health

INTRODUCTION

I am Sally Wambui Ndung'u. I am currently pursuing a master's degree in Public Health. One of the requirements needed for the award of degree of Master of Public Health from the University of Nairobi is to conduct research. I am doing a study on the assessment of the performance of the Patient Health Questionnaire-9 (PHQ-9) and Edinburgh Postnatal Depression Scale (EPDS) as screening tools for antepartum depression.

PURPOSE

I intend to conduct a study on pregnant women seeking care at the antenatal clinic facilities in Mutuini and Karatina Sub-county hospitals. Participants who agree to participate in the study will be subjected to a brief questionnaire which seeks to describe their general socio-demographic characteristics and later subjected to two self-administered questionnaires used for screening for depression in pregnancy. These two screening tools are the Patient Health Questionnaire-9 (PHQ-9) and the Edinburgh Postnatal Depression Scale (EPDS). At pre-selected cut-off points, the performance of these two tools will be compared. This study will include all pregnant women who are over 18 years of age and have no known history of mental illness, HIV, diabetes or hypertension.

PROCEDURE

Two self-administered questionnaires, namely the PHQ-9 and EPDS will be given to the study participants for them to fill in. It will take approximately five minutes to complete each questionnaire, therefore a total of 10 minutes for both questionnaires. The investigator will ask you a few questions before giving you the screening forms to fill in.

SAFEGUARDING PRIVACY

The information you give will be kept secure and only used for the purpose of this research. Your name will not be on any questionnaire or record and will not be used during reporting. The information collected will only be available to the principal investigator and her assistants. You will be provided with a private and quiet space where you can fill in the study questionnaires.

BENEFITS

If you are suspected to have antepartum depression based on the scores you achieve, you will be referred to a psychologist or psychiatrist for proper follow up in terms of diagnosis and treatment.

Your participation in this study will help generate knowledge on how the PHQ-9 and EPDS perform in screening for antepartum depression in our population. This information will help inform policy on their inclusion into the basic antenatal care package in Kenya.

RISKS

Even as we try to protect your confidentiality by maintaining your anonymity and securing the questionnaires, your privacy might still be interfered with without our control.

COST

There are no direct financial costs for participating in this study. However, it may cost you a little if you have a follow-up question or concern regarding your participation that needs you to communicate with the principal investigator via phone.

UNDERSTANDING YOUR CHOICES

Your decision to participate in this study is voluntary. You are free to decline to participate or withdraw from the study at any point in time. Choosing to decline to participate or withdraw from the study will not affect the quality of care you receive as a patient.

OPPORTUNITY FOR FURTHER ENQUIRIES

Any further questions about this research can be directed to Dr Sally Ndung'u on 0720853536.

Any questions or concerns regarding your rights as a participant in this study can be directed to Professor Chindia M.L, secretary KNH/UoN ERC by calling 2726300 extension 44102 Nairobi or emailing uonknherc@uonbi.ac.ke

CONSENT FORM

Participant's statement

Following the explanation given to me and the answers to the questions I had, I have understood what this study is about. I understand that it is voluntary to participate in this study and that I will not be subjected to any penalty by declining to participate or withdraw from the study. I also understand that should I choose not to participate or withdraw my participation in the course of the study, I will continue to receive the same quality of care I am currently receiving.

I freely agree to participate in this study. I have been informed and understand that I am free to contact Dr Sally Ndung'u on 0720853536 if I have any questions or concerns about this study including my rights as a study participant.

I give informed consent to participate in this study YES ☐ NO ☐

Participant's signature_____

Date_____

Phone number_____

Researcher's statement

I have explained all details pertaining this study to the participant and I am positive that the participant has understood and freely given his/her consent to participate in this study.

Researcher's name_____

Researcher's signature_____

Date _____

Role in the study_____(Principal investigator (PI) or Research assistant (RA))

8.2 Taarifa ya habari na fomu ya idhini

Kichwa cha utafiti: Performance of the Patient Health Questionnaire and the Edinburgh Postnatal Depression Scale as screening tools for Antepartum Depression

Mchunguzi mkuu na ushirika wa kitaasisi: Dr Sally Wambui Ndung'u, University of Nairobi, School of Public Health

Wasimamizi wa mchunguzi:

Dr Marshall Mweu,

University of Nairobi, School of Public Health

Mr Lambert Nyabola,

University of Nairobi, School of Public Health

UTANGULIZI

Mimi ni Sally Wambui Ndung'u. Kwa sasa ninafuata digrii ya master's katika Afya ya Umma. Moja ya mahitaji yanayohitajika kwa tuzo ya digrii hii kutoka Chuo Kikuu cha Nairobi ni kufanya utafiti. Ninafanya utafiti juu ya tathmini ya utendaji wa Patient Health Questionnaire-9 (PHQ-9) na Edinburgh Postnatal Depression Scale (EPDS) kama zana za uchunguzi wa unyogovu katika ujauzito.

MALENGO

Ninakusudia kufanya uchunguzi juu ya wanawake wajawazito wanaotafuta huduma katika vituo vya kliniki vya wajawazito katika hospitali ya Mutuini na hospitali za kaunti ndogo ya Karatina. Washiriki ambao wanakubali kushiriki katika utafiti huu wataulizwa maswali kupitia dodoso fupi ambalo linatafuta kuelezea

sifa zao za jumla za kijamii na baadaye watazijaza dodoso mbili za uchunguzi wa unyogovu katika ujauzito. Zana hizi mbili za uchunguzi ni Patient Health Questionnaire-9 (PHQ-9) na Edinburgh Postnatal Depression Scale (EPDS). Kulingana na vizingiti ambavyo vitakuwa vimechaguliwa, utendaji wa zana hizi mbili utalinganishwa. Utafiti huu utajumuisha wanawake wote wajawazito ambao wana zaidi ya miaka 18 na wasio na historia inayojulikana ya magonjwa ya akili, ukimwi, ugonjwa wa sukari au shinikizo la damu.

TARATIBU ZITAKAZOHUSISHWA

Washiriki watapewa fomu za PHQ-9 na EPDS ili wazijaze. Itachukua takriban dakika tano kumaliza kujaza kila fomu. Hivyo basi, itamchukua mshiriki takriban dakika 10 kumaliza kuzijaza fomu zote mbili. Mshiriki atakuuliza maswali machache kabla ya kukupa fomu za uchunguzi za kujaza.

USALAMA WA HABARI

Habari unayopewa itahifadhiwa salama na inatumika tu kwa madhumuni ya utafiti huu. Jina lako halitakuwa kwenye dodoso au rekodi yoyote na haitatumika wakati wa kuripoti. Habari iliyokusanywa itapatikana tu kwa mpelelezi mkuu na wasaidizi wake. Utapewa nafasi ya kibinafsi na ya utulivu ambapo unaweza kujaza dodoso za maswali.

FAIDA

Ikiwa unashukiwa kuwa na unyogovu wa ujauzito kulingana na alama unazofikia, utatumwa kwa mwanasaikolojia au mtaalamu wa magonjwa ya akili ili akuchunguze Zaidi na kukutibu iwapo inatakikana.

Kwa kushiriki katika utafiti huu, utatusaidia kujua kama fomu za PHQ-9 na EPDS ni zana nzuri za uchunguzi wa unyogovu wa ujauzito katika kwa idadi yetu na jinsi utendaji wa zana hizi unalingana. Habari hii itasaidia kufahamisha sera juu ya kuingizwa kwa zana hizi kwenye kifurushi cha utunzaji wa ujauzito nchini Kenya.

ATHARI

Hata tunapojaribu kulinda usiri wako kwa kulinda dodoso na kutoliandika jina lako, faragha yako inaweza bado kuingiliwa bila kupenda kwetu.

GHARAMA

Hakuna gharama za moja kwa moja za kifedha kwa kushiriki katika utafiti huu. Walakini, inaweza kukugharimu kidogo ikiwa una swali la kufuata au wasiwasi kuhusu ushiriki wako ambao unakuhitaji kuwasiliana na mpelelezi mkuu kupitia simu.

CHAGUZI ZAKO

Uamuzi wako wa kushiriki katika utafiti huu ni wa hiari. Uko huru kukataa kushiriki au kujiondoa kutoka kwa utafiti huu wakati wowote ule. Kuamua kukataa kushiriki au kujiondoa kwenye masomo haitaathiri ubora wa huduma unayopokea kama mgonjwa.

MFUMO WA MAHUSIANO ZAIDI

Maswali yoyote zaidi juu ya utafiti huu yanaweza kuelekezwa kwa Dr Sally Ndung'u kwa 0720853536.

Maswali au wasiwasi wowote kuhusu haki zako kama mshiriki katika utafiti huu unaweza kuelekezwa kwa Profesa Chindia M.L, katibu wa KNH / UoN ERC kwa kupiga 2726300 ugani 44102 Nairobi au kwa barua pepe uonknherc@uonbi.ac.ke

FOMU YA ITHINI

Taarifa ya Mshiriki

Kufuatia maelezo niliyopewa na majibu ya maswali niliyokuwa nayo, nimeelewa utafiti huu unahusu nini. Ninaelewa kuwa ni hiari kushiriki katika utafiti huu na kwamba sitaadhibiwa adhabu yoyote kwa kukataa kushiriki au kujiondoa kutoka kwa utafiti. Ninaelewa pia kuwa ikiwa nitaamua kutoshiriki au kuondoa ushiriki wangu katika uchunguzi huu, nitaendelea kupata huduma ile ninayopokea.

Nakubali kwa hiari yangu kushiriki katika utafiti huu. Nimeshafahamishwa na nimeelewa kuwa niko huru kuwasiliana na Dr Sally Ndung'u kwa 0720853536 ikiwa nina maswali yoyote au wasiwasi juu ya utafiti huu pamoja na haki zangu kama mshiriki wa utafiti huu.

Ninapeana idhini ya kushiriki katika utafiti huu NDIYO ☐ HAPANA ☐

Saini ya Mshiriki_____

Tarehe_____

Nambari ya simu_____

Taarifa ya mtafiti

Nimeelezea maelezo yote yanayohusu utafiti huu kwa mhusika na nina hakika kwamba mshiriki ameelewa na amepeana kwa hiari yake ruhusa ya kushiriki katika utafiti huu.

Jina la mtafiti_____

Saini ya mtafiti_____

Tarehe_____

Jukumu katika utafiti (Upelelezi mkuu (PI) au msaidizi wa Utafiti (RA))_____

8.3 Questionnaire

PERFORMANCE OF THE PATIENT HEALTH QUESTIONNAIRE AND THE EDINBURGH POSTNATAL DEPRESSION SCALE AS SCREENING TOOLS FOR ANTEPARTUM DEPRESSION

SERIAL NO:_____DATE:_____(day)_____(month)_____(year)

This questionnaire should only be filled in by the PI or RAs by interviewing a participant who has already given her written and signed consent to participate in this study. You are not required to put the participant's name on the questionnaire. Information collected from this questionnaire will be for purposes of research only.

INSTRUCTIONS

Please answer the following questions either by writing on the space provided or by putting a tick (√) in the appropriate box.

PART I

Q1: How old are you? (To the nearest completed years)_____(Insert figures only)

Q2 A): Do you recall the date of your Last Normal Menstrual Period (LNMP)?

Yes ☐ No ☐

(If you have selected 'YES', kindly answer Q2B), if 'No', proceed to Q3

Q2 B): When was the date of your LNMP?_____(Day)/_____(Month)/_____(Year)

Q3: What is the gestational age of your pregnancy in completed weeks? _____ (To be filled in by the PI or RA by referring to the participants' LNMP and/or obstetric ultrasound)

Q4: How many children have you given birth to? _____ (Insert figures only)

PART II

Q5: What is your marital status?

Single ☐ Married ☐ Separated/ divorced ☐ Widowed ☐

Q6: What is your level of education?

No formal education ☐ Primary ☐ Secondary ☐ Tertiary ☐

Q7: What is your employment status?

Employed ☐ Unemployed ☐

PART III

Q8: If you have any of the following medical conditions, please tick (√) the appropriate box.

HIV/AIDS ☐

Diabetes ☐

Hypertension ☐

Any mental illness ☐

None of the above ☐

Q9: Are you currently mourning the loss of a close friend or family member?

Yes ☐

No ☐

(Please exclude from this study if the participant suffers from any of the chronic illnesses in Q8 and if they are currently mourning the loss of a loved one according to their response to Q9)

PART IV: PHQ-9 FORM (To be filled in by the study participant)

PART V: EPDS FORM (To be filled in by the study participant)

PART VI (To be filled in by the PI or RA by referring to the participant's PHQ-9 and EPDS forms filled)

TOTAL PHQ-9 SCORE:_____

TOTAL EPDS SCORE:_____

8.4 Orodha ya maswali ya uchunguzi

PERFORMANCE OF THE PATIENT HEALTH QUESTIONNAIRE AND THE EDINBURGH POSTNATAL DEPRESSION SCALE AS SCREENING TOOLS FOR ANTEPARTUM DEPRESSION

NAMBARI:_____TAREHE:____(siku)/_____ (mwezi)/____(mwaka)

Orodha hii ya maswali ya uchunguzi itajazwa na mtafiti mkuu ama wasaidizi wake kwa kuwauliza maswali washiriki wa uchunguzi huu ambao wameelewa kuhusu uchunguzi huu na kupeana kibali cha kushiriki. Jina la mshiriki wa uchunguzi huu halipaswi kuandikwa hapa. Majibu yatakayokusanywa hapa yatatumika kwa uchunguzi huu tu.

MAELEKEZO

Tafadhali yajibu maswali yafuatayo kwa kuliandika jibu lifaalo kwenye nafasi uliyopewa au kuweka sahihi (√) kwenye sanduku ( ) linalofaa.

SEHEMU I

S1: Una miaka mingapi? _____(kwa nambari)

S2 A): Je, unakumbuka tarehe ya mwisho ulipopata damu yako ya mwezi?

Ndiyo ☐ La ☐

(Kama jibu lako ni 'Ndiyo', tafadhali jibu swali 2B, kama sivyo, endelea na swali S3

S2 B): Tarehe ya mwisho kupata damu ya mwezi ilikuwa lini? _____(siku)/_____(mwezi)/_____ _____(mwaka)

S3: Mimba yako imemaliza wiki ngapi? _____(Ijazwe na mtafiti mkuu ama wasaidizi wake kulingana na tarehe ya mwisho kupata damu ya mwezi au 'ultrasound')

S4: Je, umewahi kuwazaa watoto wangapi?_____

SEHEMU II

S5: Tafadhali tueleze hali yako ya ndoa?

Sijaolewa ☐ Nimeolewa ☐ Tumewachana/talaka ☐ Mjane ☐

S6: Je, umesoma hadi kiwango gani?

Sijaenda shuleni ☐ Shule ya msingi ☐ Shule ya upili ☐ Elimu ya juu ☐

S7: Je, umeajiriwa kazi?

Ndiyo, nimeajiriwa ☐ La, sijaajiriwa ☐

SEHEMU III

S8: Tafadhali tia sahihi (√) kwenye sanduku inayofaa kama unaugua ugonjwa wowote katika orodha ifuatayo.

Ukimwi ☐

Ugonjwa wa sukari ☐

Shinikizo la damu ☐

Magonjwa ya akili ☐

Siugui mojawapo ya magonjwa haya ☐

S9: Je, huenda ikawa unaomboleza kifo cha rafiki au familia mpendwa?

Ndiyo ☐

La ☐

(Mshiriki ambaye anaugua ugonjwa wowote katika S8 na ambaye anomboleza kifo cha rafiki au familia kulingana na jibu lake kwenye S9 anapaswa kuondolewa kutoka utafiti huu)

SEHEMU IV: FOMU YA PHQ-9 (Fomu hii inapaswa kujazwa na mshiriki wa uchunguzi)

SEHEMU V: FOMU YA EPDS (Fomu hii inapaswa kujazwa na mshiriki wa uchunguzi)

SEHEMU VI: (Sehemu hii inapaswa kujazwa na mtafiti mkuu au msaidizi wake kwa kuangalia fomu za PHQ-9 na EPDS zilivyojazwa na mshiriki wa utafiti)

JUMLA YA ALAMA YA PHQ-9:_____

JUMLA YA ALAMA YA EPDS:_____

8.5 Patient Health Questionnaire-9 (PHQ-9)

SERIAL NUMBER**:** _____ DATE**:**_____

Over the last two weeks, how often have you been bothered by any of the following problems? (use "√) to indicate your answer)

		Not at all	**Several days**	**More than half the days**	**Nearly everyday**
		0	1	2	3
1.	Little interest or pleasure in doing things				
2.	Feeling down, depressed or hopeless				
3.	Trouble falling or staying asleep, or sleeping too much				
4.	Feeling tired or having little energy				
5.	Poor appetite or overeating				
6.	Feeling bad about yourself- or that you are a failure or have let				

	yourself or your family down				
7.	Trouble concentrating on things such as reading the newspaper or watching television				
8.	Moving or speaking so slowly that other people could have noticed. Or the opposite-being so fidgety or restless that you have been moving around a lot more than usual				
9.	Thoughts that you would be better off dead, or of hurting yourself				
		ADD COLUMS			
		TOTAL			

8.6 Dodoso la Afya ya Wagonjwa-9

NAMBARI:_____ TAREHE: _____

Kwa jumaa mbili zilizopita, ni mara ngapi umesumbuliwa na matatizo haya? (weka alama "√" kuonyesha jibu lako)

	Maswali ya afya ya Mgonjwa				
		Hapana kabisa	**siku kadhaa**	**Zaidi ya nusu ya siku hizi**	**karibu kila siku**
		0	**1**	**2**	**3**
1.	Mwelekeo mdogo au kukosa raha wa kufanya vitu				
2.	Kujisikia kama huwezi kuchangamka, kusikia, huzuni au kukosa tumaini.				
3.	Tatizo kupata usingizi au tatizo kuendelea kulala baada ya usingizi, ama kulala kupita kiasi				
4.	Kujisikia kuchoka au kuwa na nguvu kidogo				
5.	Hamu ya kula ni mbaya, au kula kupita kiasi				

6.	Kusikia vibaya kuhusu binafsi, au kuskia kama umeshindwa, au umejishusha, ama umeshusha chini familia yako				
7.	Tatizo kutuliza akili kwenye vitu kama kusoma gazeti au kusilikiliza radio				
8.	Kusogea au kuzungumza pole sana hata ingeweza kuonekana kwa watu wengine. Ama kinyume-kuwa na mashaka/wasiwasi au kutotulia kiasi hata umekuwa ukitembea tembea sana kuliko kawaida				
9.	Fikira kwamba ni heri ukifa, au fikira za kujiumiza kawa njia fulani				

8.7 Edinburgh Postnatal Depression Scale (EPDS)

SERIAL NUMBER: _____DATE: _____

Since you are either pregnant or have recently had a baby, we want to know how you feel. Please place a **CHECK MARK** (✓) on the blank by the answer that comes closest to how you have felt **IN THE PAST 7 DAYS** — *not just how you feel today.* Complete all 10 items.

Below is an example already completed:

I have felt happy:

Yes, all of the time _____ (0)

Yes, most of the time √_____ (1)

No, not very often _____ (2)

No, not at all _____ (3)

This would mean: "I have felt happy most of the time" in the past week. Please complete the other questions in the same way.

1. I have managed to laugh and see the funny side of things:

   As much as I always could _____(0)

   Not quite so much now _____ (1)

Definitely not so much now _____ (2)

Not at all _____ (3)

2. I have looked forward with enjoyment to things:

As much as I ever did _____ (0)

Rather less than I used to _____ (1)

Definitely less than I used to _____ (2)

Hardly at all _____ (3)

3. I have blamed myself unnecessarily when things went wrong:

Yes, most of the time _____(3)

Yes, some of the time _____ (2)

Not very often _____ (1)

No, never _____ (0)

4. I have been anxious or worried for no good reason:

No, not at all _____ (0)

Hardly ever _____ (1)

Yes, sometimes _____ (2)

Yes, very often _____ (3)

5. I have felt scared or panicky for no good reason:

Yes, quite a lot _____ (3)

Yes, sometimes _____ (2)

No, not much _____(1)

No, not at all _____ 0)

6. Things have been getting to me:

Yes, most of the time I haven't been able to cope at all _____ (3)

Yes, sometimes I haven't been coping as well as usual _____ (2)

No, most of the time I have coped quite well _____(1)

No, I have been coping as well as ever _____(0)

7. I have been so unhappy that I have had difficulty sleeping:

Yes, most of the time _____ (3)

Yes, sometimes _____ (2)

No, not very often _____ (1)

No, not at all _____ (0)

8. I have felt sad or miserable:

Yes, most of the time _____ (3)

Yes, quite often _____ (2)

Not very often _____ (1)

No, not at all _____ (0)

9. I have been so unhappy that I have been crying:

Yes, most of the time _____ (3)

Yes, quite often _____ (2)

Only occasionally _____ (1)

No, never _____ (0)

10. The thought of harming myself has occurred to me:

Yes, quite often _____ (3)

Sometimes _____ (2)

Hardly ever _____ (1)

Never _____ (0)

8.8 Fomu ya mizani ya Edinburgh

NAMBARI: _____TAREHE: _____

Tungependa kujua jinsi unavyohisi ukiwa mjamzito. Tafadhali tia alama "√" katika jibu linalokaribia kabisa kueleza hisia zakokatika kipindi cha siku saba zilizopita.

Mfano:

Nimetarajia mambo kwa furaha

Kama tu hapo mbeleni _____ (0)

Imepunguka kidogo _____ (1)

Imepunguka kabisa _____ (2)

Mara chache sana ___√___ (3)

Hii inamaanisha kwamba katika kipindi cha siku saba zilizopita, nimetarajia mambo kwa furaha mara chache sana.

1. Nimeweza kucheka na kuona jambo la kuchekesha katika mambo

   Ndio, kama kawaida _____(0)

   Sio kama hapo mbeleni (awali) _____(1)

   Kwa hakika, sio kama hapo mbeleni _____ (2)

   La, hasha _____ (3)

2. Nimetarajia mambo kwa furaha

Kama tu hapo mbeleni _____ (0)

Imepunguka kidogo _____ (1)

Imepunguka kabisa _____ (2)

Mara chache sana _____ (3)

3. Nimejilaumu bila sababu wakati mambo yalipoenda vibaya

Ndio, mara nyingi _____ (3)

Ndio, mara kadhaa _____ (2)

Sio kawaida _____ (1)

La, sijawahi _____ (0)

4. Nimekuwa na wasiwasi bila sababu nzuri

La, sijawahi _____ (0)

Sio, kwa kawaida _____(1)

Ndio, mara kwa mara _____ (2)

Ndio, mara nyingi _____ (3)

5. Nimeshikwa na woga au hofu bila sababu njema

Ndio, mara nyingi _____ (3)

Ndio, mara kwa mara _____ (2)

La, si sana _____ (1)

La, sijawahi _____ (0)

6. Mambo yamekuwa yakinilemea

Ndio, mara nyingi nimeshindwa kukabiliana nayo _____ (3)

Ndio, mara kwa mara sijaweza kukabiliana nayo _____ (2)

La, mara nyingi nimeweza kukabiliana vyema _____ (1)

La, mara nyingi nimeweza kukabiliana vyema kama hapo mbeleni/awali _____ (0)

7. Nimekuwa na huzuni sana hadi nimekuwa na ugumu kupata usingizi

Ndio, mara nyingi _____ (3)

Ndio, mara kwa mara _____ (2)

Sio kila wakati _____ (1)

La, hapana _____ (0)

8. Nimesikia huzuni sana na kutokua na furaha

Ndio, mara nyingi _____ (3)

Ndio, mara kwa mara _____ (2)

Sio, kila wakati _____ (1)

La, hapana _____ (0)

9. Sijakuwa na furaha kabisa hadi nimetokwa na machozi

Ndio, mara nyingi _____ (3)

Ndio, mara kwa mara _____ (2)

Mara moja _____ (1)

La, sijawahi _____ (0)

10. Nimekuwa na mawazo ya kujitendea mabaya

Ndio, mara nyingi _____ (3)

Ndio, mara kwa mara _____ (2)

Sio, kwa kawaida _____ (1)

La, sijawahi _____ (0)

8.9 KNH/UoN Ethics Approval Letter

UNIVERSITY OF NAIROBI
COLLEGE OF HEALTH SCIENCES
P O BOX 19676 Code 00202
Telegrams: varsity
Tel:(254-020) 2726300 Ext 44355

KNH-UON ERC
Email: uonknh_erc@uonbi.ac.ke
Website: http://www.erc.uonbi.ac.ke
Facebook: https://www.facebook.com/uonknh.erc
Twitter: @UONKNH_ERC https://twitter.com/UONKNH_ERC

KENYATTA NATIONAL HOSPITAL
P O BOX 20723 Code 00202
Tel: 726300-9
Fax: 725272
Telegrams: MEDSUP, Nairobi

Ref: KNH-ERC/A/175

10th June 2020

Sally Wambui Ndung'u
Reg.No.U57/11994/2018
School of Public Health
College of Health Sciences
University of Nairobi

Dear Sally

RESEARCH PROPOSAL – PERFORMANCE OF THE PATIENT HEALTH QUESTIONNAIRE AND EDINBURGH POSTNATAL DEPRESSION SCALE AS SCREENING TOOLS FOR ANTEPARTUM DEPRESSION (P226/04/2020)

This is to inform you that the KNH- UoN Ethics & Research Committee (KNH- UoN ERC) has reviewed and **approved** your above research proposal. The approval period is 10th June 2020 – 9th June 2021.

This approval is subject to compliance with the following requirements:

a. Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
b. All changes (amendments, deviations, violations etc.) are submitted for review and approval by KNH-UoN ERC before implementation.
c. Death and life threatening problems and serious adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the KNH-UoN ERC within 72 hours of notification.
d. Any changes, anticipated or otherwise that may increase the risks or affect safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH- UoN ERC within 72 hours.
e. Clearance for export of biological specimens must be obtained from KNH- UoN ERC for each batch of shipment.
f. Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. (*Attach a comprehensive progress report to support the renewal*).
g. Submission of an *executive summary* report within 90 days upon completion of the study. This information will form part of the data base that will be consulted in future when processing related research studies so as to minimize chances of study duplication and/ or plagiarism.

For more details consult the KNH- UoN ERC website **http://www.erc.uonbi.ac.ke**

Yours sincerely,

PROF. M. L. CHINDIA
SECRETARY, KNH-UoN ERC

c.c. The Principal, College of Health Sciences, UoN
The Director, CS, KNH
The Chairperson, KNH- UoN ERC
The Assistant Director, Health Information, KNH
The Director, School of Public Health, UoN
Supervisors: Dr. Marshal M. Mweu, School of Public Health, UoN
Mr. Lambert Nyabola, School of Public Health, UoN

8.10 Authorization to collect data in Nyeri County

REPUBLIC OF KENYA

COUNTY GOVERNMENT OF NYERI
DEPARTMENT OF HEALTH SERVICES
OFFICE OF THE DIRECTOR

Email: nyericountyhealth@yahoo.com

COUNTY COMMISSIONER'S HQ
BLOCK 'A'
P.O. Box 110 - 10100

REF: CGN/HEALTH/HRM/5/VOL.II **Date: 23rd June 2020**

TO WHOM IT MAY CONCERN

RE: AUTHORIZATION TO COLLECT RESEARCH DATA

The bearer of this letter **Sally Wambui Ndung'u** is a student at university of Nairobi, pursuing a masters degree in Public Health.

She is hence introduced to collect data on the topic ***"Performance of the Patient Health Questionnaire and Edinburg Postnatal Depression scale as screening tools for antepartum depression".***

Kindly accord her the necessary assistance.

The student **must** deposit a copy of the final report with the department following completion of the study.

Dr. Oscar Agoro
For: County Director of Health Services
NYERI

8.11 Permission to carry out research at Mutuini sub county hospital

THE PRESIDENCY
EXECUTIVE OFFICE OF THE PRESIDENT
NAIROBI METROPOLITAN SERVICES

Telephone 2217131/3313481
Web: pmonairobi@yahoo.com
When replying please quote

NAIROBI HEALTH OFFICE
NYAYO HOUSE
P.O. BOX 34349-00100
NAIROBI

MUTUINI HOSPITAL

24/08/2020

Sally Wambui Ndung'u,

School of Public Health, College of Health Sciences,

University of Nairobi.

RE: PERMISSION TO CARRY OUT RESEARCH AT MUTUINI SUB COUNTY HOSPITAL

TITLE: PERFORMANCE OF THE PATIENT HEALTH QUESTIONNIARE AND EDINBURGH POSTNATAL SCALE AS SCREENING TOOLS FOR ANTIPARTUM DEPRESSION

Your request for permission to carry out the above named study has been approved. Permission granted is subject to compliance with the following requirements:-

- Only approved documents will be used
- All changes are submitted for approval by a Research Review Board before implementation and permission for this sought from the Hospital Administration
- Death and life threatening problems and severe adverse events are reported to the hospital within 24 hours
- Submit an executive summary report within 30 days upon completion of the study
- Provide reports on the study progress every 3 months
- Indemnify the hospital against any claim that may arise from the research

On completion submit a soft copy of the study findings to the hospital records department c/o Office of the Medical Superintendent

MEDICAL SUPRITENDENT
KIAMBETTI SUB - DISTRICT HOSP.

DR JOSEPHINE WAMBUI NGURI

MEDICAL SUPERINTENDENT

8.12 NACOSTI Research License

REPUBLIC OF KENYA

NATIONAL COMMISSION FOR SCIENCE, TECHNOLOGY & INNOVATION

Ref No: **637673**

Date of Issue: **/June/ 2020**

RESEARCH LICENSE

This is to Certify that Dr. Sally Wambui Ndung'u of University of Nairobi, has been licensed to conduct research in Nairobi,
Nyeri on the topic: Performance of the Patient Health Questionnaire and Edinburgh Postnatal Depression Scale as screening tools
for antepartum depression for the period ending:

License No: **NACOSTI/P/20/5457**

637673
Applicant Identification Number

Director
NATIONAL
SCIENCE, TECHNOLOGY
INNOVATION

Verification
QR Code

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8.13 Turn-it-in Originality Report

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