THE EFFECT OF MATERNAL NEAR MISS ON THE PREVALENCE OF POST NATAL DEPRESSION COMPARED TO NORMAL PREGNANCY WITHIN ONE YEAR OF DELIVERY AT THE KENYATTA NATIONAL HOSPITAL.

A COMPARATIVE CROSS-SECTIONAL STUDY

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DEDICATION

I would like to dedicate this work to my family for their understanding and support through my studies and work on this project.

I also dedicate this work to all the women suffering post-natal depression in silence that they may get a voice and healing.

LIST OF ABBREVIATIONS

Abbreviation	Meaning
CEMD	Confidential Enquiry into Maternal Deaths
EPDS	Edinburgh Post- natal Depression Scale
GOK	Government Of Kenya
HIC	High Income Countries
KDHS	Kenya Demographic and Health Survey
LMIC	Low- and Middle- Income Countries
MD	Maternal Death
MDGs	Millennium Development Goals
MDR	Maternal Death Review
MDSR	Maternal Death Surveillance And Response
MI	Mortality Index
MNM	Maternal Near Miss
MOH	Ministry Of Health (Kenya)
MPDSR	Maternal and Perinatal Death Surveillance And Response
PND	Post- Natal Depression
PPD	Post- Partum Depression
QI	Quality Improvement
QOC	Quality of Care
SAMM	Severe Acute Maternal Morbidity
SDGs	Sustainable Development Goals
SMO	Severe Maternal Outcomes
UNFPA	United Nations Population Fund
WHO	World Health Organization
WHOMCS	World Health Organization Multi-Country Survey (on maternal and newborn health)

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ABSTRACT

BACKGROUND

Maternal morbidity is not as well studied and documented as maternal mortality. One of the new frontiers in quality of care assessment and improvement in maternal and new-born health is conducting Maternal Near Miss (MNM) reviews or audits. Maternal near miss refers to a woman who nearly died but survived a complication that occurred during pregnancy or within 42 days of delivery. Among the things that can be reviewed during MNM audits are the consequences of MNM on women's health including psychosocial well-being.

The landscape of maternal mortality and morbidity is changing with an increase in the incidence of non-communicable diseases including mental health disorders. The commonest psychiatric disorder of pregnancy is post-natal-depression (PND) but it is seldom screened for, diagnosed and managed (2). This is despite its far reaching effects on women, new-borns and their families.

AIM

To assess the effect of MNM on the prevalence of PND in women who survive MNM episodes compared to those with a normal pregnancy.

METHODOLOGY

Study design: This study used a comparative cross-sectional design.

Study setting: The study was conducted at the Kenyatta National Hospital (KNH).

Study population: The exposed were women who had suffered MNM after 28 weeks of gestation or within 42 days of delivery at KNH. The un-exposed group were women who had had a normal pregnancy without complications with delivery after 28 weeks of gestation at KNH. Both arms involved women who were within 1 year of delivery. Matching was done for gestation at delivery and time (date) of delivery.

Sample size: The study recruited 74 women with MNM and 140 women with uncomplicated pregnancies.

Data collection and analysis: Both arms were interviewed via telephone and screened for PND using the Edinburgh Post-Natal Depression scale (EPDS) after collection of sociodemographic and other medical information from medical records. The data was then analysed and a comparison made between women with MNM and those with a normal pregnancy in terms of the prevalence of PND. The characteristics of women in both groups suffering PND were also analysed and compared.

RESULTS: The main study findings were that there was a higher prevalence of PND after MNM (35.1%) compared to those with a normal pregnancy at 10.7%. The odds ratio for developing PND after MNM was 4.5 (2.07-8.74) with a p value <0.0001. A low level of education (adjusted OR 3.11 p value 0.048) and presence of an underlying medical

complication (Adjusted OR 2.89 p value 0.02) were also found to increase the risk of PND once MNM occurred.

CONCLUSION: This study showed that there was an increased risk of developing PND after MNM compared to after a normal pregnancy. An underlying medical condition and having a low level of education further elevated this risk.

KEY WORDS: **Maternal Near Miss; Post-Natal Depression; Edinburgh Post-Natal Depression Scale; Post-Natal care; Quality of Care**

1.0 INTRODUCTION

Maternal Near Miss (MNM) as defined by WHO refers to "*a woman who nearly died, but survived a complication that occurred during pregnancy, childbirth or within 42 days of termination of pregnancy*" (1).

Post-Natal Depression (PND) also known as Post-Partum Depression (PPD) is a mood disorder that is associated with child birth. It is characterized primarily by dysphoria and generalized feelings unhappiness and loss of interest in daily activities (2).

Maternal near miss has several consequences for the woman, new-born and her family including psychological disturbances. Among the mental health disorders affecting women during the peri-partum period, post-natal depression (PND) is the most common, yet it is seldom screened for and treated despite its far-reaching consequences.

Globally, the burden of maternal mortality remains high with 303,000 maternal deaths annually according to the World Health Organisation (WHO) in 2015. Unfortunately, 99% of these deaths occur in low and middle income countries(3). Kenya is one such country with an estimated 8000 maternal deaths annually with a high Maternal Mortality Ratio (MMR) of 362 per 100,000 live births according to the Kenya Demographic and Health survey (KDHS) 2014 (4).

To lower the maternal mortality (and morbidity), most strategies have in the past focused on increasing the amount (quantity) of care that women receive. In Kenya, the access to and utilization of formal health services has increased as shown by the comparison of indices e.g. for antenatal clinic attendance, hospital deliveries and skilled birth attendance from KDHS reports in a ten-year period (2004 to 2014). However, the fall in the maternal mortality ratio has not been in tandem with this increased access to and utilisation of maternal health services (4).

The reason behind this lack of decline of the MMR in relation to increased quantity of care has largely been shown to be due to the poor quality of care provided. Quality is often overlooked and indeed quality of care that women receive has been described as "the neglected agenda" by Van Den Broek and Graham in 2009 (5).

Attention has thus increased in recent years on the quality of care that pregnant women receive and to this end, Kenya has started several programmes to study and improve quality of care. These have largely focused on reviewing maternal deaths with maternal morbidity in general being not as well studied and documented as maternal mortality. A report in the United Kingdom (UK) parliament by The UK All Party Parliamentary Group on Population, Development and Reproductive Health described maternal morbidity as "a little known, little researched, and little understood topic" (6).

Review of maternal morbidity and especially the study of maternal near misses has been shown to be very important in quality improvement activities. It is estimated that for every maternal death, there are 20-30 women who face morbidity and that for every maternal death

there are about 6 near miss cases. It has also been found that 15% of all pregnancies will develop a severe complication that will require emergency obstetric care (EMONC) to prevent severe morbidity or mortality (7). In terms of numbers and burden, maternal death is really just “the tip of the iceberg”(8).

Also noteworthy is the change in patterns of maternal morbidity that have been seen in recent years. Indirect causes of maternal mortality and morbidity which include mental health issues have become increasingly important. Indirect causes in total now equal haemorrhage in terms of maternal deaths caused at 30%. This demonstrates the changing trends because haemorrhage has for long stood out as the most important cause of maternal deaths globally (3).

This study thus aimed at being part of quality improvement activities by conducting a maternal near miss review looking at two dimensions of maternal morbidity: It assessed the sequelae of the severest form of maternal morbidity: maternal near miss (MNM) with a focus on the mental health consequences. It involved screening survivors of MNM for post-natal depression (PND) and comparing the prevalence of PND to women who have had a normal pregnancy. An introduction into these two topics is covered in the literature review section.

2.0: LITERATURE REVIEW

2.1: Definition of maternal near miss

Maternal near miss is defined by the World Health Organisation (WHO) as "*a woman who nearly died, but survived a complication that occurred during pregnancy, childbirth or within 42 days of termination of pregnancy*" (1).

Maternal near miss is alternatively known as "Severe Acute Maternal Morbidity / Severe Adverse Maternal Morbidity" (SAMM) and also referred to in some literature as "obstetric near miss" (1).

The term "near miss" is borrowed from the aviation industry describing a situation whereby an accident involving two airplanes almost happens but is averted and lives saved. This is especially when referring to situations where two aircraft almost collide but narrowly miss hitting each other (9). Reviews of these critical incidents to learn lessons on how to avoid mishaps have been ongoing in the aviation industry for many years and have improved safety significantly.

In the field of maternal health, studies of these near miss cases, where a woman almost died but narrow missed death, started in the United Kingdom as an adjunct to ongoing quality improvement activities that had for a long time focused on reviewing maternal deaths. Due to improving quality of care, the maternal deaths declined in number leading to lack of cases for maternal death review. This necessitated the fronting of the studying of cases of maternal morbidity (near miss cases) as an alternative to auditing maternal deaths in countries and settings experiencing very few maternal deaths (10).

Although initially meant for settings that have very few maternal deaths, the review of maternal near miss has proven to be a valuable and viable addition to the study of maternal deaths even in Low and Middle Income Countries (LMIC) that record high numbers of maternal deaths (11).

Maternal near miss review is a form of criterion based audit (standards based audit) and is part of the international strategies to assess and improve quality of care in maternal health. These strategies summarised by Van den Broek and Graham (5) are Maternal Death Review

(MDR), Maternal Death Surveillance and Response (MDSR), Confidential Enquiry into Maternal Deaths (CEMD) and Standards (criterion) based audit.

2.2: Burden of maternal near miss

Maternal near miss, being a relatively new concept within the field of maternal morbidity is not very well studied and documented.

Globally the prevalence of maternal near miss varies with lower levels in more developed, high resource countries (12). In older studies (especially before 2009) the prevalence was found to vary significantly depending on the criteria used to define a near miss. It ranged from as low as 0.01% in management based criteria to 1.09% in organ-dysfunction based criteria to as high as 8.2% in disease specific criteria. These criteria are discussed further in the section on diagnosis of MNM. This lack of uniformity in diagnostic criteria made it difficult to compare different studies (12). More recent studies have employed the standard WHO MNM criteria and in these, the prevalence is seen to be lower in the more developed nations. The MNM ratio in the U.S.A was found to be 5.9 / 1000 live births giving a prevalence of 0.59% (13) while in Brazil it was found to be 21 / 1000 live births giving a prevalence of 2.1 % (14). In South-East Asia it was found to be 7.6 % at a referral facility in India (15). Regionally in Somaliland the prevalence is high at 8.8 % (16) while in Rwanda it was found by Kalisa and colleagues to be 2.1% (17).

In multi-ethnic settings the prevalence has been found to be higher among Hispanic women and women of African American origin when compared to white women. The same study again showed the correlation between wealth status and MNM with lower incidence being seen in wealthier populations. Once a complication occurred, the outcome was seen to be determined largely by the wealth status with worse outcomes among the poor (18). The same has been seen in Iran with increased MNM in poorer populations and worse outcomes seen in refugee populations (19).

In Kenya, there have been very few studies on maternal near miss and especially on its distribution. There however thankfully exists data from the World Health Organization Multi-Country Survey (WHOMCS) on maternal and new-born health that in 2011 did an assessment on maternal near miss and severe maternal outcomes (SMO) in 20 hospitals in three regions of Kenya, namely Nairobi, Central and Rift Valley regions. The study found 133 cases of SMO of which 78 were MNM and 55 were maternal deaths. There were 20,331 deliveries (20). The survey officially reported that the prevalence of severe maternal outcomes was 0.7% of live births.

In KNH, the survey found 1,938 deliveries with 22 being MNM and 20 maternal deaths.

The study also showed that with delivery after 28 weeks' gestation, the contribution of various morbidities to the occurrence of maternal near miss was as follows:

Haemorrhage 50%

Hypertensive disorders 30%

Others (Antepartum haemorrhage, sepsis, thromboembolism, etc.) 20%.

Other WHO near miss indicators were not officially given by the WHOMCS but have been secondarily calculated from the raw data in reports and presentations on the WHOMCS. This was done with the assumption that total births meant total live births. The WHO MNM indicators secondarily calculated are depicted below in table 1 below:

Table 1: Secondarily calculated MNM indicators from WHOMCS Kenya Source: Author

MNM Ratio	**SMO Ratio**	**MNM:1MD**	**Mortality Index (MI)**
3.8/1000 Live births	6.5/1000 Live births	1.4: 1MD	41.3%

The WHOMCS was a large study that used the standard WHO near miss criteria and was able to estimate some baseline data on MNM for Kenya that can be built upon.

A more recent quasi experimental study at KNH by Watau and colleagues in 2017 assessed the impact of the introduction of free maternity services (FMS) on occurrence of severe maternal and neonatal outcomes. The findings were that the incidence of maternal near miss reduced from a high of 4.5% in 1982 to a level of 3.8% in 2017 after introduction of FMS. This suggests better care for women, but calculation of MNM incidence was noted not to be based on total live births for the year. The same study also showed that the maternal near miss to mortality ratio rose from 2.3 to 4.4 in the same period. (21).

The other few studies on MNM in Kenya have been facility based studies that have described the causes of and contributing factors to MNM based on the three- delay model developed by Thaddeus and Maine in 1994 (22). In one study done at the Kenyan coast in Malindi, Echoka and colleagues found that the first delay (decision to seek care) and second delay (time taken travelling to and accessing healthcare) were responsible for most of the near miss cases. The third delay (timeliness and quality of care provided in the healthcare facility) was found to contribute only in a minority of the cases of MNM (23).

In Busia district hospital (now Busia County hospital), Skriver and Viuff (24) found that the third delay was the most important cause of maternal near misses and maternal deaths. Both studies were small facility based reviews that did not use the standard WHO near miss criteria opting for modified criteria. They are however novel in that they interviewed the women themselves and obtained their perspective on MNM.

2.3: Pathophysiology of maternal near miss

Maternal near miss can be thought of as a point in the continuum between life and death of a pregnant woman (25). Taking the example of hypertensive disorders in pregnancy, this continuum describes a transition from a healthy uneventful pregnancy with no medical complications and normal blood pressure (BP), progressing to a pregnancy with a mild non-life threatening complication e.g. transient gestational hypertension (pregnancy induced hypertension) with mild to moderate elevation of BP without further harm to the pregnant woman. This may then progress to a more serious medical complication that can potentially threaten the life of the mother (Potentially Life Threatening Complication - PLTC) e.g. severe pre-eclampsia, HELLP syndrome (Haemolysis, Elevated Liver enzymes, Low Platelets) etc. This may then progress to a life threatening condition like eclampsia. The mother may then unfortunately die from this life threatening condition, becoming a maternal death (MD) or may thankfully survive this and hence become a maternal near miss (MNM). Maternal deaths together with maternal near misses constitute what are known as Severe Maternal Outcomes (SMO) or Life Threatening Conditions (LTC).

As noted earlier, maternal near miss lies at a critical point in the continuum between life and death. Going by this continuum, maternal death and maternal near miss have very similar pathways for occurrence and maternal near miss is a very critical point between life and death. Thence, the audit of maternal near misses can be used to come up with valuable solutions as to how maternal deaths can be averted and also on the complications that these women later face (26).

Maternal near miss reviews have been shown to possess several advantages over reviewing maternal deaths that include: (1)

- Near misses are much more common than maternal deaths.

- Their review is likely to yield useful information on the pathways that lead to severe morbidity and death being that they are similar.
- Investigating the quality of care received may be less threatening to providers because the woman survived as opposed to reviewing a maternal death.
- The survivors themselves can be interviewed and a lot can be learnt from them about their perception of the care they received after the severe illness.
- The impact of a near miss has far reaching consequences on the social, mental and physical wellbeing of survivors and indeed their families that can be reviewed.

Other advantages demonstrated in a study by Mantel in 1998 (27) showing that study of near misses yields up to five times the number of cases for review as does maternal death audits hence a greater wealth of information can be obtained. Hardee in 2012 also showed that for a greater impact in quality improvement, all strategies involving maternal death review should be expanded to include maternal morbidity (including maternal near miss) (8).

Despite the many advantages of near miss reviews, a few disadvantages of maternal near miss reviews do exist and include:(1)

- Difficulty in defining maternal near miss cases as there is still some debate globally as to the best criteria for use. The WHO MNM criteria of 2009 (1) has however sought to remedy this and make studies from different parts of the world comparable.
- Obtaining consent from the surviving women when they need to be interviewed as it may bring to light lapses in the quality of care they may have received and spark off medico-legal suits.
- Not identifying cases that occur in the community. As has been seen in Kenya, facility deliveries are only at 61% (4) meaning that a significant amount of morbidity and mortality occurs in the community and not it the hospitals. The WHO MNM approach is largely facility based and may miss out on these community cases.
- Even when women are followed into the community after a near miss, some studies found that there is often a discrepancy between the woman's recall of her childbirth or morbidity experience and the medically diagnosed and documented complication from medical records (28) .
- Drife in his early recommendation for adoption of MNM reviews in the UK in addition to maternal death reviews in 1993 (10) foresaw that extending the same reviews to developing countries would be a challenge and would represent "moving

the benchmark" for countries that were already struggling to catch up with and establish maternal death reviews.

Risk factors for occurrence of maternal near miss have been sought, especially the socio-demographic characteristics of women who suffer MNM. These include:

1. Low maternal education (less than secondary school education) was found as a risk factor in a WHO survey on MNM in Egypt done by Sultan and colleagues (29).
2. Living in remote areas that are far from healthcare facilities and being referred from other health facilities to the study facility (7 times odds) are risk factors for MNM according to the case control study in Ethiopia. This finding was also replicated in Nigeria (30).
3. Low socio-economic status was shown as a factor with higher occurrence of MNM among deprived populations that also had worse outcomes once a complication occurred (12).
4. Displaced and refugee populations were found to have a higher occurrence of MNM in Iran compared to un-displaced and native populations (19).
5. Racial and ethnic differences have also been shown with a higher prevalence of MNM among African-American and Hispanic women compared to white women in a study in the United states of America (18).

Other factors that have been associated with the occurrence of maternal near miss include:

1. Delay in seeking healthcare (more than four hours after onset of a complication) had 8 times increased odds of developing MNM according to a case control study done in Ethiopia (30). Similar findings were found in studies done in Nigeria and Morocco (30).
2. Prior history of caesarean section was found as a risk factor for MNM in subsequent pregnancies in Brazil. This was also shown in studies done in Ethiopia and South Africa (30).
3. Inadequate antenatal care was also found as a risk factor in the Egypt survey by Sultan and colleagues (29).
4. Finding a complication during the first antenatal visit was found as a predictor of MNM in Nigeria (31).
5. Bad perinatal (new-born) outcomes, in particular birth asphyxia and low birth weight, have also been shown to be a predictor of MNM in a prospective case control study in Nigeria (31).

2.4: Diagnosis of maternal near miss

The definition of a maternal near miss case has undergone evolution since the concept begun. A systematic review carried out by the World Health Organization (WHO) in 2004 found that there was a lot of heterogeneity in the definition of maternal near misses and thus comparing various studies was difficult (12).

This led to the establishment of a technical working group that in 2009 came up with the current uniform definition. Standardized criteria for diagnosis of maternal near miss were then created by merging and refining the various criteria that had been previously used. A classification similar to that used to classify maternal death was also adopted for ease of classification and use in quality improvement activities (32).

Criteria previously used to diagnose near miss were either: (12)

- Disease specific criteria: clinical diagnoses of certain clinical conditions were used to denote a near miss e.g. eclampsia, massive post-partum haemorrhage etc.
- Intervention specific criteria: certain medical interventions performed on patients were used as the basis for diagnosis of a maternal near miss e.g. Intensive Care Unit (ICU) admission, hysterectomy etc.
- Organ failure specific criteria: demonstration of certain organ failure states was used as a method of diagnosing maternal near miss e.g. renal failure with high creatinine etc.
- Mixed criteria have also been employed in the past using various combinations of the categories above.

Each of these criteria possesses several advantages but also disadvantages and this led to heterogeneity with both over and under reporting of near miss cases. This has now been solved by the WHO standard maternal near miss criteria. These criteria are shown below with occurrence of any one of the diagnostic criteria in a patient who survives the adverse morbidity meeting the threshold for diagnosis of a maternal near miss: (1)

A. Women who suffer a severe complication of pregnancy:

• *Severe postpartum haemorrhage*

• *Severe pre-eclampsia*

• *Eclampsia*

• *Sepsis or severe systemic infection*

• Ruptured uterus

• Severe complications of abortion

B. Critical interventions or intensive care unit use

• Admission to intensive care unit

• Interventional radiology

• Laparotomy (includes hysterectomy, excludes caesarean section)

• Use of blood products

C. Life-threatening conditions/organ failure (near-miss criteria)

• Cardiovascular dysfunction

Shock, cardiac arrest (absence of pulse/heart beat and loss of consciousness), use of continuous vasoactive drugs, cardiopulmonary resuscitation, severe hypoperfusion (lactate >5 mmol/l or >45 mg/dl), severe acidosis (pH<7.1)

• Respiratory dysfunction

Acute cyanosis, gasping, severe tachypnea (respiratory rate >40 breaths per minute), severe bradypnea (respiratory rate <6 breaths per minute), intubation and ventilation not related to anaesthesia, severe hypoxemia (O2 saturation <90% for ≥60 minutes or PAO2/FiO2 <200)

• Renal dysfunction

Oliguria non-responsive to fluids or diuretics, dialysis for acute renal failure, severe acute azotemia (creatinine ≥300 µmol/ml or ≥3.5 mg/dl)

• Coagulation/haematological dysfunction

Failure to form clots, massive transfusion of blood or red cells (≥5 units), severe acute thrombocytopenia (<50 000 platelets/ml)

• Hepatic dysfunction

Jaundice in the presence of pre-eclampsia, severe acute hyperbilirubinemia (bilirubin >100 µmol/l or >6.0 mg/dl)

• Neurological dysfunction

Prolonged unconsciousness (lasting ≥12 hours)/coma (including metabolic coma), stroke, uncontrollable fits/status epilepticus, total paralysis

• Uterine dysfunction

Uterine haemorrhage or infection leading to hysterectomy

2.5: Utility of studies on maternal near miss

Studies on maternal near miss have been found to have various applications by Ronsmans in 2009 (33). These include:

1. Evaluating the quality of obstetric care
2. Learning from women's accounts of their experiences of care
3. Identifying the prevalence of maternal morbidity
4. Documenting the long term consequences of MNM

As demonstrated, one of the advantages and utilities of maternal near miss reviews is that the consequences and complications of the near miss can be assessed by interviewing the women themselves. This study dwells on documenting the long term consequences of maternal near miss and will be looking at its influence on occurrence of PND.

An introduction to post-natal depression is thus warranted and is discussed in the following section.

2.6: Definition of post-natal depression

Post-Natal Depression (PND) also known as Post-Partum Depression (PPD) is a mood disorder that is associated with child birth. It is characterized primarily by dysphoria and generalized feelings unhappiness and loss of interest in daily activities. It affects how a man feels, thinks, acts, relates with others and her day to day functioning.

PND is classified among the depressive disorders in the Diagnostic and Statistical Manual for diagnosis of psychiatric disorders 5th edition (DSM V) published by the American Psychiatric Association (APA) in 2013 under the title depressive disorder with peri-partum onset (34).

Symptoms mimic a depressive episode that would otherwise occur outside of pregnancy or puerperium in the general population but gets the tag "peri-partum onset" when these symptoms first occur during pregnancy or within four weeks following delivery. It has been found that of what is traditionally referred to as "post-partum" depression, 50% has onset within pregnancy before delivery hence the collective term "peri-partum depression" has been adopted in the DSM V (34).

2.7: Burden of post-natal depression

Psychological disturbances and disorders are fairly common after delivery with the mild form known as postpartum blues or baby blues affecting up to 80% of mothers (2). This is however short lived (less than two weeks) and does not hamper normal functioning.

The more serious disorder that is postnatal depression is not as prevalent but affects a significant number of women. Globally it is estimated that 10-45 % of women will experience symptoms of depression in varying severities. PND on average affects 1 in 10 mothers with a higher occurrence in teenage mothers (4 in 10) (2).

In 2008 a report by the WHO estimated that PND affects 1 in 3 to 1 in 5 women in low and middle income countries. The prevalence was lower in high income countries with 1 in 10 being affected by the condition (35). In the Kenyan setting, studies done have demonstrated the prevalence of post-natal depression to be 10.6 % of mothers at six weeks post-delivery at the Kenyatta National Hospital according to a cross-sectional study done in 2013 by Musau and colleagues (36). At another hospital in Kenya, the Agha Khan Hospital, which is a large private and high resource referral hospital the prevalence was found to be 13.8% among mothers delivering there through an unpublished cross-sectional survey by Warfa in 2011. In the same institution (Agha Khan Hospital), it was found in a cross-sectional study by Mutiso and colleagues to be 34% among mothers who had suffered a miscarriage (37). The studies above used the Edinburgh Post-Natal Depression Scale (EPDS) for diagnosis of PND. Among pregnant adolescents in Kenya a high prevalence was found at 32.9% in a cross-sectional study by Osok in 2018. The study by Osok however did not use the EPDS tool and instead screened for depression using the Patient Health Questionnaire (PHQ-9) tool. This limits comparability with this and other studies that use the EPDS tool (38).

2.8: Pathophysiology of post-natal depression

The exact cause of PND has not yet been identified but various risk factors have been shown to be associated with occurrence of post-natal depression and include: (39)

1. Temperament and personality type especially cluster B personalities (negative affectivity).
2. Family history of depression.
3. Previous history of post-partum depression.
4. Environmental stressors including childhood experiences and adverse life events.

5. Other psychiatric disorders.
6. Mood and anxiety disorders during or after the pregnancy including baby blues.
7. Substance abuse.
8. Chronic or disabling medical conditions including a traumatic or complicated birth.
9. Gender based violence.
10. Lack of social support and poor relationships especially with the partner.
11. Low social economic status.

2.9: Diagnosis of post-natal depression

Diagnosis of post-natal depression is difficult and often missed out on because many of the symptoms of PND tend to mimic the normal and expected transient symptoms that a new mother gets as she transitions to motherhood and adjusts to her new roles as a mother. Also affecting this are the various physiological and endocrine changes that occur simultaneously in the mother's body. Gender stereotypes and culturally accepted or tolerated psychological symptoms further complicate the diagnosis and what women and their families would report as abnormal (2). Many symptoms such as feeling sad, fatigued or sleep disturbances are experienced by a majority of women after delivery and yet they form the core symptomatology for a depressive episode. Medical complications such as those that may occur during pregnancy and childbirth may further complicate the diagnosis as there is grief normally associated with severe morbidities and outcomes such as a hysterectomy or loss of the new-born which again can again mimic symptoms of depression (34).

However, failure to diagnose and offer treatment or referral for care in post-natal depression has been shown to be associated with adverse outcomes for both the mother, new-born and even her family, extending even to future pregnancies and it is thus important for a correct and timely diagnosis to be arrived at (2,34). To overcome this difficulty in diagnosis, the APA through the DSM V has developed diagnostic criteria for a depressive episode that must be met for a diagnosis to be clinched. These are listed below ad verbatim as depicted in the DSM V:

Major Depressive Episode (MDE) Diagnostic Criteria from the DSM V

A. Five (or more) of the following symptoms have been present during the same 2-week period and represent a change from previous functioning: at least one of the symptoms is either (1) depressed mood or (2) loss of interest or pleasure.

Note: Do not include symptoms that are clearly attributable to another medical condition.

1. *Depressed mood most of the day, nearly every day, as indicated by either subjective report (e.g., feels sad, empty, hopeless) or observation made by others (e.g. appears tearful). (Note: In children and adolescents, can be irritable mood.)*
2. *Markedly diminished interest or pleasure in all, or almost all, activities most of the day, nearly every day (as indicated by either subjective account or observation).*
3. *Significant weight loss when not dieting or weight gain (e.g., a change of more than 5% of body weight in a month), or decrease or increase in appetite nearly every day.*

   (Note: In children, consider failure to make expected weight gain.)
4. *Insomnia or hypersomnia nearly every day.*
5. *Psychomotor agitation or retardation nearly every day (observable by others, not merely subjective feelings of restlessness or being slowed down).*
6. *Fatigue or loss of energy nearly every day.*
7. *Feelings of worthlessness or excessive or inappropriate guilt (which may be delusional) nearly every day (not merely self-reproach or guilt about being sick).*
8. *Diminished ability to think or concentrate, or indecisiveness, nearly every day (either by subjective account or as observed by others).*
9. *Recurrent thoughts of death (not just fear of dying), recurrent suicidal ideation without a specific plan, or a suicide attempt or a specific plan for committing suicide.*

B. *The symptoms cause clinically significant distress or impairment in social, occupational, or other important areas of functioning.*

C. *The episode is not attributable to the physiological effects of a substance or to another medical condition.*

Note: *Criteria A-C represent a major depressive episode.*

Note: *Responses to a significant loss (e.g., bereavement, financial ruin, losses from a natural disaster, a serious medical illness or disability) may include the feelings of intense sadness, rumination about the loss, insomnia, poor appetite, and weight loss noted in Criterion A, which may resemble a depressive episode. Although such symptoms may be understandable*

or considered appropriate to the loss, the presence of a major depressive episode in addition to the normal response to a significant loss should also be carefully considered. This decision inevitably requires the exercise of clinical judgment based on the individual's history and the cultural norms for the expression of distress in the context of loss.

D. *The occurrence of the major depressive episode is not better explained by schizoaffective disorder, schizophrenia, schizophreniform disorder, delusional disorder, or other specified and unspecified schizophrenia spectrum and other psychotic disorders.*

E. *There has never been a manic episode or a hypomanic episode.*

Note: *This exclusion does not apply if all of the manic-like or hypomanic-like episodes are substance-induced or are attributable to the physiological effects of another medical condition.* (40)

The DSM criteria is used in more formal diagnosis especially when the patient has been referred to a psychiatrist. More commonly, screening tools are used especially by healthcare practitioners working in obstetrics and gynaecology or other reproductive health units where they will usually be the first to encounter the women who they suspect may be showing signs and symptoms of PND and yet are not per se mental health experts. The most commonly used tool is the Edinburgh Post-Natal Depression Scale (EPDS). This is a short questionnaire consisting of 10 questions and the responses are scored with a maximum score of 30. A score of more than 10 makes the diagnosis of PND likely, with a score of 13 or more making the diagnosis of PND and necessitating referral for psychiatric evaluation. A positive answer to question 10 (on thoughts of suicide and self-harm) also requires urgent referral or connection to help to avoid the risk of a completed suicide (41).

The EPDS has been validated in various studies and proven to be a versatile tool for use in screening women for post-natal depression. The EPDS has been found to have a sensitivity of 100% and specificity of 95% when a cut off of 13 is used. It has also been found to be the most frequently used tool in measuring post-natal depression and has "moderate psychometric soundness"(36). It has been adopted for use in this study mainly due to its validity and reliability but also due to its brevity and ease of administration. The WHO in 2008 recommended simple-to-use screening tools in diagnosis of PND and put forward the EPDS as the preferred tool. In the WHO guidelines for post-natal care it has also been

recommended that screening for post-natal psychological disturbances, including, PND should be done for all mothers (35).

2.10: Diagnosing and screening for PND using telephone interviews

Post-natal depression is usually screened for and diagnosed using one on one interviews and the tools used for this are designed for one to one interviews or even as self-assessed questionnaires. However, in instances where patients cannot be reached physically, the use of telephone call based interviews to administer the screening tools has been shown to work in diagnosis of depression.

A large cross-sectional study done in Brazil by Figueiredo and colleagues in 2014 assessed the reliability and validity of using telephone interviews to administer the EPDS tool in screening for PND. After screening 1083 women who were within one-year post-partum via telephone, they demonstrated that its efficacy and reliability was comparable to face to face interviews. The study showed a sensitivity of 72.2 %, a specificity of 71.6 %, and a positive predictive value of 67.7 % of phone-call based screening using the EPDS (42).

BenDavid and colleagues in 2016 conducted an evidence based practice project and demonstrated that in a setting with limitations in health access due to costs, distance and time, the use of telephone based screening for post-natal depression was as effective as in-person screening. It also showed that most women "appreciated the call" and were "grateful for the concern" in reaching out to them using telephone calls (43).

The use of telephone based interviews to diagnose depression has also been done in the Kenyan setting in a cross-sectional study screening for depression among patients with obstetric fistula by Khisa and colleagues in 2011. The rationale for this was that the patients were far from the interview site and it was logistically impractical to have one on one interviews. The study used the EPDS screening tool (44). This situation is similar to the one in this study and the use of telephone based interviews is feasible.

Another benefit of phone call based interviews in screening for depression is that they have been shown to provide anonymity over face to face interviews and thus remove the barriers that are shame or shyness, stigma and phobia that often restrict women from accessing mental health care. Use of this method could therefore increase patient access to care (43).

2.11: Consequences of post-natal depression

The ill-effects of post-natal depression have been shown to affect the woman, her new-born baby and even extend to her family. The WHO cites PND as contributing to maternal

morbidity and mortality (35). In the UK, peri-natal mental health problems were associated either directly or indirectly with 17% of maternal mortality between 2012 and 2014. Mortality may occur directly through suicides or indirectly through reduced self-care, reduced health seeking behaviour and decreased compliance to recommended treatments. It may lead to substance abuse, reckless behaviour, gender based and domestic violence with further consequences to the physical health of the woman with PND. Medical illnesses that may be superimposed may also cause death and disability through a phenomenon known as diagnostic overshadowing where-by physical symptoms are misattributed to mental illness by healthcare workers and end up being ignored or under-treated by healthcare workers leading to complications and death (2).

Consequences for the baby include reduced bonding, reduced breastfeeding with resultant malnutrition, stunting, delayed physical and mental milestones when the mother has PND. These effects on the child have been shown to be independent of poverty, crowded living conditions or even infectious diseases. Social consequences also occur that may include strained relationships, marital break-ups, inability to work productively with financial consequences. Of note is that a variant of PND has also been described that affects the new father, although this is beyond the scope of the current study (2,35).

2.12: Association between NMM and PND

The consequences of the occurrence of MNM have been studied albeit insufficiently. They range from physical to mental illnesses with accompanying social consequences. The link between MNM and mental disorders including post-natal depression has been studied with varying results. In the UK a report on consequences of MNM reported long-term psychological effects including PND (45). A cohort study by Waterstone in 2003 found the risk of post-natal depression after a near miss not to be statistically significant with 23 % of exposed patients with near miss versus 20.5% of non-exposed scoring 13 or higher on the EPDS. The median score was higher at 9 for the exposed (MNM) group than for the non-exposed (normal) group at 7. This study was however conducted before there was a uniform definition of a maternal near miss (46). Regionally, a cohort study conducted in Morocco in 2015 that found 34% of women with MNM consequently suffered PND compared to 10.7% of women who had uncomplicated pregnancies. The risk was highest in women with MNM plus a perinatal loss with an odds ratio (OR) of 4.7 compared to those with an uncomplicated pregnancy. For those with MNM and a live baby the OR was 4.08. This represented an

overall five-fold risk of developing PND after MNM**.** The results also showed that perinatal mortality did not increase the risk of PND significantly (47). The risk of post-natal depression was seen to be higher in women with MNM and a hysterectomy / tubal ligation. In 2007 Filippi and colleagues using a cohort study found that in Benin, women who had a severe obstetric complication were more like to have post-natal depression (OR 1.87) and also have higher risk (OR 2) of suicidal thoughts during the first year after delivery when they were assessed at 3 months, 6 months and at one year after delivery (45).

In all these studies the EPDS was the screening tool of choice in assessing for post-natal depression.

This study aimed at studying maternal near miss and its impact on PND in the Kenyan setting using the WHO near miss criteria and the EPDS.

3.0: CONCEPTUAL FRAMEWORK

3.1 Diagrammatic

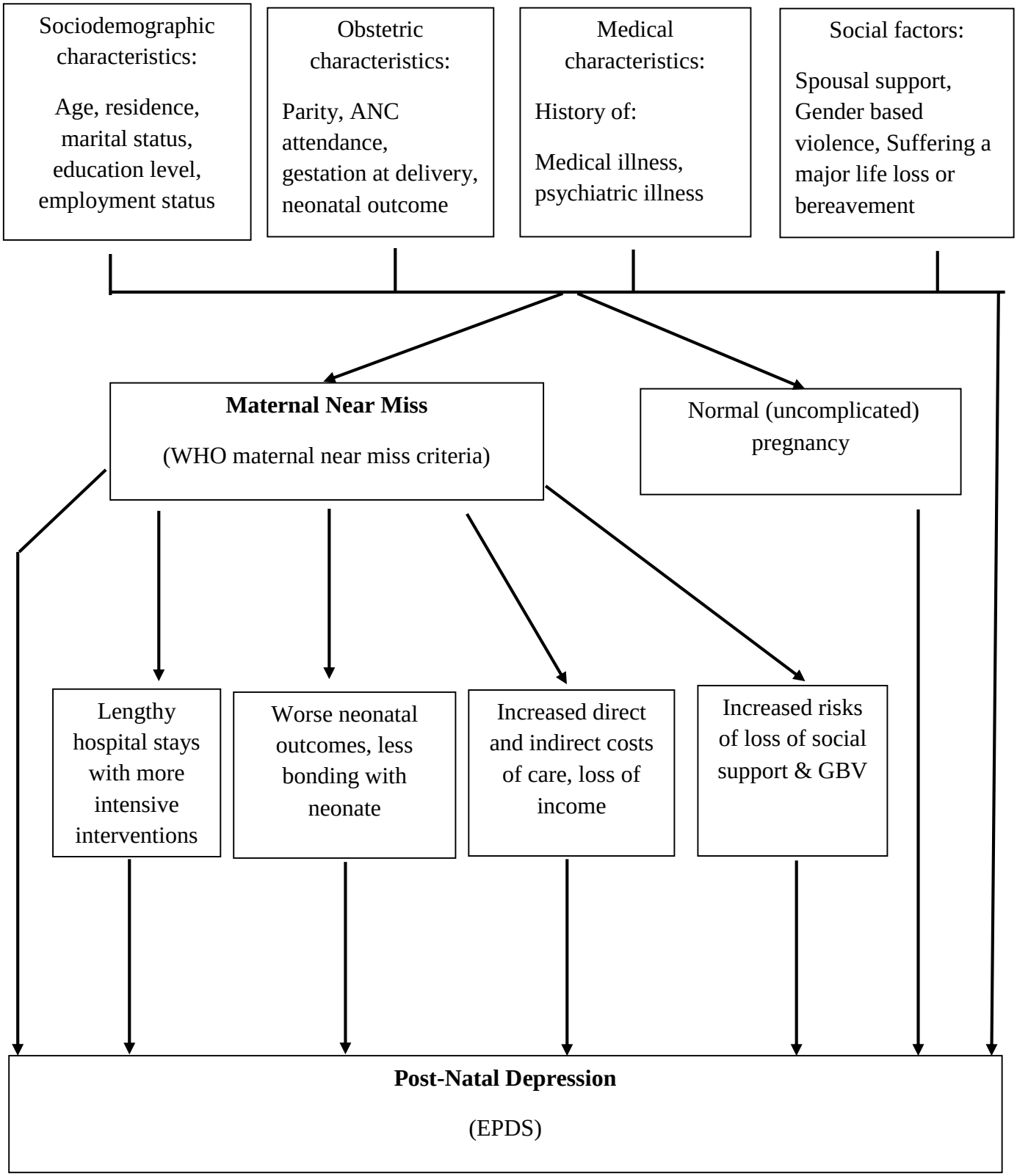

Figure 1: Conceptual framework Source: Author

3.2 Narrative

As shown in figure 1, it is the general expectation that a woman who becomes pregnant will transition through pregnancy without any complications and have a normal delivery and then go on to have a healthy post-natal period.

However, the reality is that a continuum exists where-by a woman progresses from one end of this spectrum with an uncomplicated pregnancy and post-natal period and transitions through non-life threatening complications to potentially life threatening complications. These potentially life threatening morbidities may then progress to a true life threatening event where-by the woman may die, or may luckily survive, becoming a maternal near miss.

During the post-natal period, again women are at risk of developing various morbidities including psychological disorders of which the most common is post-natal depression. This is preceded by either a normal pregnancy or by a complicated pregnancy in which the woman could have suffered a maternal near miss.

Various background factors including socio-demographic characteristics such as age, parity, marital status/ social support, educational level, employment status; obstetric characteristics such as Ante-natal clinic (ANC) attendance, unplanned pregnancy, complications of pregnancy and medical illnesses among other risk factors contribute to the development of complications during pregnancy and the post-natal period including maternal near miss and post-natal depression.

It is thus expected that a maternal near miss being a major illness will be a risk factor for post-natal depression. This occurs because MNM causes changes in the experience of pregnancy and puerperium in that it causes severe illness with multiple complications. These then necessitate lengthy hospital stays with admission to critical care units and with multiple interventions during which the woman will be psychologically stressed by the care itself and by seeing others possibly succumb to similar complications around her. MNM also causes worse new-born outcomes with possible neonatal deaths or stillbirths. The mother or the new-born or both may be too unwell for the normal bonding that occurs to take place between a mother and her new-born and this may in turn heighten her psychological stress. Further effects of MNM are seen in that the costs of care may be increased directly. Where free care exists, like in Kenya, indirect costs may occur due to loss of income while unwell, the need for family to travel to see her or the need to hire additional care-givers in her absence from the home. The severe complications of MNM may further strain the relationship between the woman and her partner and family with a loss of social support and even a higher risk of gender based violence. All these factors put the woman at increased risk of psychological disorders, especially post-natal depression.

It is thus necessary to study and document this potential association between maternal near miss and post-natal depression and test out the hypothesis in the Kenyan setting.

4.0: JUSTIFICATION

A study on the psychological consequences (PND) of severe maternal morbidity (MNM) would contribute to a greater understanding of maternal morbidity, namely maternal near miss and post-natal depression. This is because maternal morbidity has not been as extensively studied as maternal mortality.

There have been a few studies on the prevalence and causes of maternal near miss in Kenya but none was found during literature review that has looked at the sequelae of MNM. Further to this is the fact that there is low post-natal clinic attendance in Kenya (currently standing at 53% of mothers according to the KDHS 2014 (4).This means that for most women, including those who suffer a maternal near miss, their follow up and care ends soon after discharge from hospital after delivery. There is therefore a lack of information on the long term consequences of MNM including psychological disorders that affect women with near miss episodes.

This study thus served to increase knowledge on maternal morbidity, specifically maternal near miss and bridge gaps in documentation of the psychological consequences of maternal near miss specifically within Kenyatta National Hospital where a large proportion of women with MNM are managed.

This study also helped in identifying women who may not be on follow up for post-natal depression after a near miss and help link them to care. It has been shown that in the developing world, less than 5% of mothers with mental health issues receive any support and care (35). Treatment for post-natal depression is available in the form of psycho-therapy and / or antidepressant drugs and thus women with PND should be appropriately diagnosed and linked with care.

5.0 PROBLEM STATEMENT

Women who survive a maternal near miss suffer a variety of sequelae including psychological disorders. In the Kenyan setting, due to low overall post-natal clinic attendance (currently at 53%) (4) and lack of continued contact between the women and healthcare providers, most of them are lost to follow up at discharge from hospital after delivery with most of these complications remaining undiagnosed.

Post-natal depression is the most common psychological disturbance during and after pregnancy. It is however seldom screened for and diagnosed.

There therefore exists a population of women surviving severe morbidities especially maternal near miss that are near death experiences who are potentially at an increased risk of developing post-natal depression, yet are not routinely followed up and screened for the same. Other consequences of maternal near miss on their health also remain undiagnosed. In Kenya there is a lack of studies on the consequences of maternal near miss.

6.0 RESEARCH QUESTION

Does maternal near miss predispose patients to post-natal depression compared to uncomplicated pregnancies within one year of delivery at KNH?

7.0: HYPOTHESIS

H_o: Maternal near miss does not increase the prevalence of post-natal depression compared to women with a normal pregnancy.

8.0 OBJECTIVES

8.1 Broad Objective

To determine the effect of maternal near miss on the prevalence of post-natal depression and associated characteristics in patients delivering at Kenyatta National Hospital.

8.2 Specific Objectives

To determine:

1. The difference in prevalence of post-natal depression after maternal near miss compared to women with a normal pregnancy.
2. The effect of socio-demographic characteristics on suffering post-natal depression after a near miss compared to after a normal pregnancy.

3. The effect of obstetric characteristics on suffering post-natal depression after a near miss compared to after a normal pregnancy
4. The effect of medical characteristics on suffering post-natal depression after a near miss compared to after a normal pregnancy
5. The effect of social support factors/ characteristics on suffering post-natal depression after a near miss compared to after a normal pregnancy

9.0: METHODOLOGY

9.1: Study Design

This was a quantitative analytical study with a comparative cross-sectional study design. The study recruited women who had suffered a maternal near miss as one group and screened them for post-natal depression using the Edinburgh Post-Natal Depression Scale (EPDS). They were then compared with a comparative group of women who had not had a life threatening illness during pregnancy (had had a normal pregnancy) who were also screened for PND using the EPDS. The women were interviewed once at point in time during their first year post-partum making the study cross-sectional. The comparison with a normal group makes the study comparative (analytical).

9.2: Study site and setting

The study was conducted at the Kenyatta National Hospital which is the largest teaching and referral hospital in Kenya. It is situated in Nairobi the capital city of Kenya in the Upper Hill area. It has a bed capacity of 2063 with the maternity unit having a capacity of 115 beds. There are roughly 1000 deliveries in a month. In addition to this, the gynaecological unit has a capacity of 45 beds. It has a wide catchment area serving residents of Nairobi and multiple other neighbouring counties mainly Kiambu, Machakos and Kajiado. This is in addition to being the largest national referral facility and hence receives referrals from far and wide across the country (21). The study was mainly conducted in the maternity unit that consists of labour ward with an acute room for severely ill patients and a theatre unit. It also involved other sentinel units within the hospital that handle patients with life threatening morbidities such as the intensive care unit (ICU) / critical care unit (CCU), renal unit and blood transfusion unit.

9.2.1: Factors that made the site suitable:

1. Being the largest referral facility in the country and thus receives referrals of a large number of patients with severe obstetric complications from many hospitals in the country.
2. Existence of a pool of specialists in various fields capable of managing patients with severe obstetric complications.
3. An acute care section within the labour ward, dedicated to patients with severe complications during pregnancy and childbirth.
4. Presence of a maternity theatre for handling obstetric surgical emergencies.

5. Presence of an acute gynaecology ward that admits and takes care of women who suffer post-partum and early pregnancy complications.
6. Presence of a Critical Care Unit (CCU) / Intensive Care Unit (ICU) dedicated to management of patients with near miss events and other life threatening conditions
7. Presence of a renal unit for haemodialysis of patients with renal failure.
8. Presence of a blood transfusion unit for patients requiring blood transfusions
9. Presence of a records department that keeps records and disease codes of all patients managed in the facility.
10. The site was easily accessible.

9.2.2: Factors that limited the suitability of the site:

1. Though well ahead of most public hospitals in Kenya, KNH is still a relatively low resource setting and lacks some of the diagnostic tests and has a shortage of facilities needed to diagnose and manage critically ill patients and as such the study will rely on a combination of intervention based, laboratory based and clinical parameters for diagnosis of a near miss event.
2. Being a large referral hospital, the findings may not represent the picture in other smaller hospitals
3. Patients may have been referred from far off areas of the country and one on one interviews may not be possible for all the clients necessitating the use of phone call based interviews.
4. Records kept are mostly manual and prone to missing entries and lengthy searches through voluminous records.
5. A number of the patients may not be fluent in English therefore the data collection tools will have to be standardized and translated into Kiswahili, a widely used language.

9.3: Study Population

The study participants were women who delivered and / or had a maternal near miss at KNH between 31st January 2018 and 31st December 2018. This was to ensure that only women who were within one year post-delivery are included in the study. The study period also only captured those who have had at least three weeks from delivery. This is because a minimum two-week duration of symptoms is required for a diagnosis of PND to be made and to avoid overlap with the common entity known as maternal (post-partum) blues which occurs within the first two weeks after delivery. The EPDS questionnaire asks questions on how the women have been feeling in the preceding seven days hence the three-week period. The women were thus interviewed only after they had completed three weeks post-delivery.

Those who had suffered a maternal near miss as defined by the WHO maternal near miss criteria of 2009 after 28 weeks' gestation up to 42 days after delivery made up the exposed group.

The comparison group was composed of women with uncomplicated pregnancies who delivered in KNH after 28 weeks' gestation within the same time period and was used to make comparisons.

These two groups of women were recruited for the study at various points within their first post-natal year and screened for depression using the EPDS. They were grouped according to time in months elapsed since delivery for analysis.

9.4: Inclusion and exclusion criteria

9.4.1 Inclusion criteria

The study used a combination of disease specific, intervention specific and organ failure specific criteria to define a maternal near miss as proposed in the WHO maternal near miss criteria for identification of the MNM exposed group.

- The exposed arm was made up of women who suffered a maternal near miss as defined in the WHO MNM criteria who deliver / suffer the near miss after 28 weeks' gestation and were within one year of delivery / near miss.
- The comparative arm included women who had had an uncomplicated pregnancy with delivery after 28 weeks of gestation and were within one year of delivery. There were two unexposed women for every exposed woman.

Matching was done for gestation at delivery and the date of delivery.

9.4.2 Exclusion criteria:

- Women with pre-existing psychiatric conditions / substance abuse disorders.
- Women having a pre-term delivery (including miscarriages) before 28 weeks of gestation.
- Women who were more than one year after the date of delivery / near miss.
- Women who were less than three weeks from the date of delivery / near miss.
- Women with an ectopic pregnancy.
- Women with a molar pregnancy.
- Women with debilitating central nervous system damage or other severe complications unable or unfit to respond to the interview.
- Women who did not voluntarily consent for the study.

- Women whose files were found to have significant data missing were also excluded. The critical data included: phone numbers and other contact information, diagnosis, date of delivery and gestation at delivery.

9.5: Sample size calculation

According to the WHOMCS the MNM ratio for Kenya is estimated at 3.8/ 1000 live births representing a prevalence of 0.38 % of live births. Though a relatively rare event, MNM is clustered at KNH being a level 6 national referral facility and the prevalence of MNM at KNH was 1.1% of live births. The survey identified 22 MNM cases at KNH over a 2-month period in 2011. This translates to roughly 120 patients with MNM annually (20). In another study by Watau at KNH in 2017 the prevalence of MNM was found to be 3.8% of deliveries with 48 MNM cases being identified over a one-year period (June 2009-May 2010) (21).The prevalence of PND in KNH is 10.6 % from a study done within the institution by Musau in 2013 (36). A study in Morocco showed that mothers having MNM have increased chances of suffering PND with 34% of mothers with MNM screening positive for PND compared to 10.7 % of mothers with a normal pregnancy, translating to a 3 fold increase in the risk (47).

In this study, the sample size was calculated using the difference in proportions - Fleiss JL formula (Statcalc epi-info^{TM}). The findings from a similar study conducted in Morocco by Bouchra Assarag (47) were be applied as follows:

$$n = \left(\frac{r+1}{r}\right)\frac{(\bar{p})(1-\bar{p})(Z_{\beta}+Z_{\alpha/2})^2}{(p_1-p_2)^2}$$

n = sample size per arm

r = ratio of exposed to unexposed, 1:2 in this case

P_1= proportion of mothers with depression following a near miss delivery 38%

P_2=proportion of mothers with depression following uncomplicated delivery 10.6%

Ṕ =measure of variability, taken as 38+10.8/2

Z_{β}=Value corresponding to the power of the study, in this case 80% = 0.84

$Z\alpha$ = Value corresponding to the normal standard deviate at 95% C.I in this case = 1.96, with 0.05 level of significance

P_1- P_2 = effect size (difference in proportions)

Relative risk to be detected of 2.0

Applying this in the Statcalc epi info software gives a value of 204 as shown in figure 2 below:

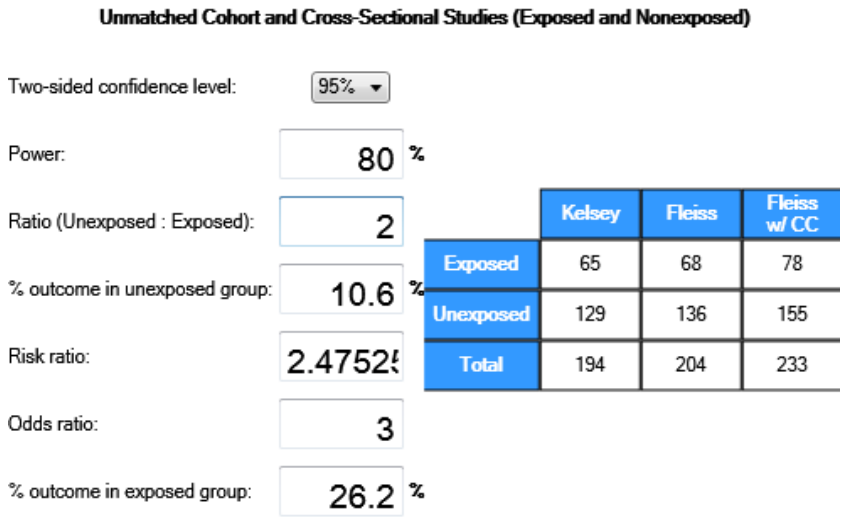

Figure 2: Sample size calculation Source: Statcalc epi info

The study thus aimed at recruiting 68 women with MNM and 136 women with uncomplicated deliveries with a 10% allowance for dropping out / incomplete records giving a final target of 78 exposed and 155 unexposed women.

9.6: Sampling Procedure

Consecutive sampling was used in identification of the exposed group where-by every patient file encountered fitting the maternal near miss criteria was sampled to identify all near miss cases during the study period. This is because maternal near miss is a relatively rare event and all the files would need to be captured consecutively to achieve the desired sample size.

There were two patients in the comparison group for every exposed patient who were selected through simple random sampling using computer generated random sampling tables. Matching was done for gestation at delivery and date of delivery. Regarding the date of delivery, for each exposed woman, one comparison woman who delivered one week before her and another one delivering one week after her were chosen. For the gestation at delivery for each exposed case two women who delivered within 2 weeks of her date of delivery were chosen.

The women were contacted via telephone after retrieving the patient files and assessing them for meeting the study inclusion criteria. The study was explained to them and then verbal consent sought. The questionnaire was then administered to the women via telephone. At the

end of each interview the questionnaire was reviewed and any missing data clarified. The use of telephone based interview was necessitated by a number of factors:

1. The diagnosis of post-natal depression requires a period with symptoms of 2 weeks or more after delivery, by which point most patients especially in the comparison normal pregnancy group would have been discharged.

2. The recovery from MNM takes a variable amount of time depending on severity and organ systems involved and as such patients are discharged at varying time periods of hospital stay.

(These two factors made it difficult to capture patients after a specific and uniform post-natal period.)

3. Being a referral facility, the patients may not reside in Nairobi and may not attend post-natal clinics at KNH.

4. Due to low post-natal clinic attendance currently at 53% for the first check-up (4) majority of the patients may have been lost to follow-up.

The use of mobile phones was supported by the finding in the KDHS 2014 that the use of mobile phones is widespread in Kenya with of 86% households owning a mobile phone (4). The patient files at KNH also have a section whereby mobile phone contacts of the patient and their next of kin are recorded.

9.7: Recruitment procedures

Participants/ patients were recruited from details found during the review of files in the records department of KNH and in the patient registers in the maternity unit, maternity theatre unit, acute gynaecological unit, renal unit, Intensive Care Unit and blood transfusion units.

9.8: Data Variables

The study variables that were assessed by the study were:

Independent variables:

1. **Maternal near miss** exposed patients based on WHO MNM criteria.
2. **Normal pregnancy** unexposed group without any complications as defined above.

Dependent variables:

1. **Post-natal depression** where-by a score of 13 or more on the EPDS was be used to diagnose PND. This was further analysed based on duration since delivery, severity of symptoms and a positive response to question no. 10 on the EPDS on risk of suicide or self-harm.

Control variables:

a) **Socio-demographic characteristics** of the women recruited into the study.

b) **Risk factors** for PND including major life disruptions: bereavement, loss of a job, separation from partner prior to the near miss.

c) **Obstetric characteristics** including ANC attendance, number of ANC visits and any complications found or interventions made during ANC. Characteristics of previous deliveries and occurrence of post-natal blues were also analysed against the occurrence of post-natal depression.

d) **Medical characteristics** including medical illnesses and any prior psychiatric illnesses were also analysed.

e) **Social and spousal support** presence or absence of social support from spouse and family was analysed.

f) **Occurrence of self-reported gender based violence** prior to the near miss or delivery was analysed in both groups and analysed.

Intervening variables

The following intervening variables that could influence how a maternal near miss can lead to post-natal depression were also assessed and analysed.

a) Length of hospital stay

b) Admission to critical care units

c) Complicated interventions such as undergoing renal replacement therapy (dialysis)

d) Self-reported increased spending on healthcare

e) Social and spousal support after the near miss

f) Self-reported gender based violence after the near miss

Confounders and risk factors were adjusted for during data analysis.

Dummy tables showing the proposed data analysis have been annexed at the end of the proposal (annex 1)

9.9: Data Collection and Management

Data was collected from the patients' files and case notes using the data extraction tool annexed at the end of this proposal (annex 2). The women recruited into the study were also interviewed using telephone interviews and data collected from them using the study questionnaire that also included the EPDS after obtaining informed consent (annex 2)

Cases were identified using the WHO MNM criteria while the controls were identified as those with uncomplicated pregnancies as per patient case notes.

The data collection tools were pre-tested and gaps identified were corrected prior to commencement of formal data collection.

Data was entered, cleaned and coded using Microsoft excel spreadsheets.

Cleaned data was then fed in IBM SPSS software version 22 for analysis. Descriptive statistics was used to analyse the raw data and calculate prevalence rates for PND and distribution of characteristics.

Matched analysis, linear regression and students T-test were applied to compare the prevalence of PND and associated risk factors and odds ratios between the two groups.

Continuous data was presented through measures of central tendency while categorical data was presented as frequency tables.

Associations and comparisons between the maternal near miss and comparison groups were calculated and presented as odds ratios.

Data quality was ensured by repeating every tenth questionnaire by a different data collector and calculation of a kappa score to ensure reproducibility of findings between the data collectors.

Data safety was ensured by only using the principal investigator and trained data collection assistants during the data collection phase of the study. During data entry and analysis, security of the data was ensured by using password protected computers with access restricted to the principal investigator, data collection assistants and the statistician. The study questionnaires were also anonymous and kept in a locked cabinet by the principal investigator with restricted access.

9.10: Study results Dissemination and Closure

The final results of the study were presented to the department of obstetrics and gynaecology and later published into a dissertation for filing in the University of Nairobi Library services.

The findings will then be summarized into papers and sent out to maternal health and mental health journals for publishing and wider dissemination. The findings will in future also be presented at conferences and continuous medical education (CME) events.

There was also individual communication of the results to the study participants. Participants found to be suffering from and/or at increased risk of post-natal depression and / or self-harm were linked with counselling and psychiatric care at KNH or at a location that was convenient and accessible for them.

9.11: Ethical considerations

The study proposal was submitted to the Kenyatta National Hospital/ University of Nairobi Ethics and Research Committee (KNH-UoN ERC) for ethical approval before commencing the study. Permission was also sought from the University of Nairobi Department of Obstetrics & Gynaecology and the KNH administration before the study commenced.

Particular ethical considerations included:

9.11.1 Benefits of the study:

1. Patients potentially benefitted from enhanced post-natal care with screening for post-natal depression.
2. Patients found to be having post-natal depression were counselled and linked to mental health services.
3. Patients found to be at risk of suicide / self-harm were linked on emergency basis to mental health services.
4. The use of telephone interviews potentially reduced the barriers to accessing mental health care by providing a forum with anonymity that has been shown to enhance diagnosis of depression (43).
5. The study potentially fostered a continuity of care model of care, providing an example of how patients, particularly with severe morbidities who are discharged from hospital can be followed up into the community.
6. The study also fostered the use of modern communication technologies in the follow-up of patients in addition to the traditional facility based face to face care model.

9.11.2 Risks of the study:

1. Mobile phone scams are prevalent in Kenya and use of phone interviews has loopholes and participants may have felt vulnerable. To counter this, the study was explained to the patient and consent to obtain information over the phone sought. There was also explicit explanation that they were not required to make any

payments and that the interviewer would bear the full costs of the phone call or any other communication that may be needed. There was also explicit explanation that the interview was not part of a reward or promotional scheme and that they were not required to divulge any details regarding mobile money transactions or passwords and neither would there be any form of monetary reward or expense from participating in the study.

Attempts were also made to try and use an official KNH phone at the principal investigator's own cost but a mobile phone device was unavailable for use during the study period.

2. The interviews were conducted at the participants' convenience and free time to avoid disrupting their daily activities.
3. Participants may potentially have been unwilling to re-live the memories of the near miss and the study could potentially trigger post traumatic depression symptoms. Such participants were excluded from the study and every effort made to link them to psychological care. One of the supervisors for this study was a consultant psychiatrist and assisted in follow-up of these women
4. Some of the questions asked were sensitive and may potentially have cause psychological distress as noted in no. 3 above. To further avoid this occurrence, a standardized questionnaire was administered and research assistants trained beforehand on how to build rapport, administer the questionnaire humanely and how to respond to patients found to be traumatised by the questioning. During consent seeking, the sensitive nature of the study was explained to the participants.
5. Participants who were too ill to participate in the study were excluded but efforts made to link them with the needed health services including physical and mental healthcare. For those in the environs of Nairobi, this was done at KNH while for those who resided far from Nairobi the nearest yet appropriate health facility was be used for referral of such patients. A follow-up phone call within one week was made to assess the patients access to the needed care.
6. The participants reserved the right of pulling out from the study at any stage and this was respected without any consequences to the participant including referral to needed psychiatric and/or medical care.
7. Confidentiality was preserved by omitting the patients' names or other identifying details from the study. Each participant was assigned a unique and random study number.

8. The study questionnaires, data collected and generated were stored in password protected computers and remain in the custody of the principle investigator unless otherwise permitted.
9. Participants who were found to be suffering from post-natal depression and especially those at risk of self-harm were urgently referred for psychiatric care. The steps to be taken in such cases (no. 9 above) are outlined below.

9.12: Steps taken when a diagnosis of post-natal depression is made

Once a diagnosis of PND was made in a study participant, whether in the near miss group or the normal pregnancy group, the following steps were to be taken to link them to care. This is because of the potentially grave consequences of untreated depression in any patient.

1. The patient was empathetically informed of the diagnosis and attempts made to confirm if the patient has insight into their condition.

2. The available treatment options were explained to, and discussed with the patient.

3. The patient was assisted to access care at a convenient location. For those in the environs of Nairobi, this was to be done at KNH while for those very far off it was to be done at the closest facility that can offer the appropriate level of care. There exists a referral system within the Kenyan healthcare set-up and psychiatric services are available in lower level facilities away from KNH (4). In the event the patients needed more specialized care then referral would be made along the appropriate referral channels and this will be followed up via phone calls as discussed below.

4. With the patient's consent, the next of kin or chosen close contact was informed and recruited to assist in ensuring the patient receives medical attention. Details of the patient's condition (PND) were discussed with the chosen close contact only to the extent permitted by the patient to safeguard their privacy and safeguard relationships

5. The patients were followed up via telephone / via their chosen close contact to monitor adherence and response to treatment one week after the diagnosis and referral to care. A second follow-up phone call was made 2 weeks after the first call.

6. One of the study supervisors (Dr Kigamwa) is a consultant psychiatrist and was instrumental in guiding this follow-up.

7. The patients found to have PND were linked to a support group. To this end, links have been fostered with the non-profit organization: Climb Out of The Darkness (COTD) – Kenya chapter, an organisation that supports mothers going through post-partum depression and who are willing to support the patients in their recovery. This organisation is supported by Postpartum Support International (PSI). More information on these organisations can be found at: http://www.postpartum.net/join-us/climbout/ and https://web.facebook.com/COTDKENYA/.

9.13: Study limitations

Some limitations were encountered during the conduct of this study. These are listed below with strategies used to overcome these limitations.

1. An agreement on a universally acceptable set of identification criteria for maternal near miss had not yet been reached globally: The study used the WHO (2011) composite criteria that have been validated in both high income and low income settings and has been used in Kenya during the WHOMCS. This makes the findings of the study comparable with those from other parts of the world.
2. Non-response from recruited women due to unwillingness to respond or re-live the events during the severe illness when answering questionnaire: explanation of the study and informed consent prior to starting interviews. Non response also occurred because some participants were not reachable or dropped out from the study. An allowance for this was made in sample size calculation.
3. Triggering acute psychiatric illness upon relieving the events: patients adversely affected by the questioning were followed up and referral for psychiatric services and excluded from the study. Overall there were attempts to gently and humanely administer the questionnaire. As outlined earlier, the sensitive nature of the study was also explained to the participants while obtaining consent for the study. The patients were allowed to defer further questioning until when they are comfortable to continue with the study (if still willing to continue). Focus would then shift to getting the patient the needed care and support.
4. Some patients with near miss were found not to have passed through the maternity unit. In addition to the maternity unit, records of patients with maternal near miss were also sought from and other sentinel units like the ICU, renal unit and acute gynaecology ward.
5. This being a hospital based study, the findings may not be generalizable to the community. In addition, being a study based in the national referral hospital (a level 6 facility), the findings may not be generalizable to smaller hospitals in the periphery.
6. The study was prone to several forms of bias:
    a) Selection bias during assignment of women into the exposed and unexposed groups was minimized by using the WHO MNM criteria to identify the exposed and unexposed group.
    b) Recall bias during the interviewing process was minimised because the EPDS tool asks how the patient has been feeling within the last 7 days to the date of interview, a relatively short period.

c) Bias also occurred due to loss to follow-up but this was mitigated by using a retrospective design.

7. The use of telephone based interviews meant that there was a lack of face to face contact and reading body language which means the information given by participants was taken at face value and may further introduce bias. This was minimized by using the standard EPDS screening tool.
8. The use of a retrospective design meant some of the required information was found to be missing.
9. The effect of confounders may not be fully have been controlled for especially because some information was not available in the medical records used in selecting patients. Matching of study participants in the two arms of the study for gestation at delivery and date of delivery to control for these confounders.

10. STUDY FLOW

10.1 Diagrammatic

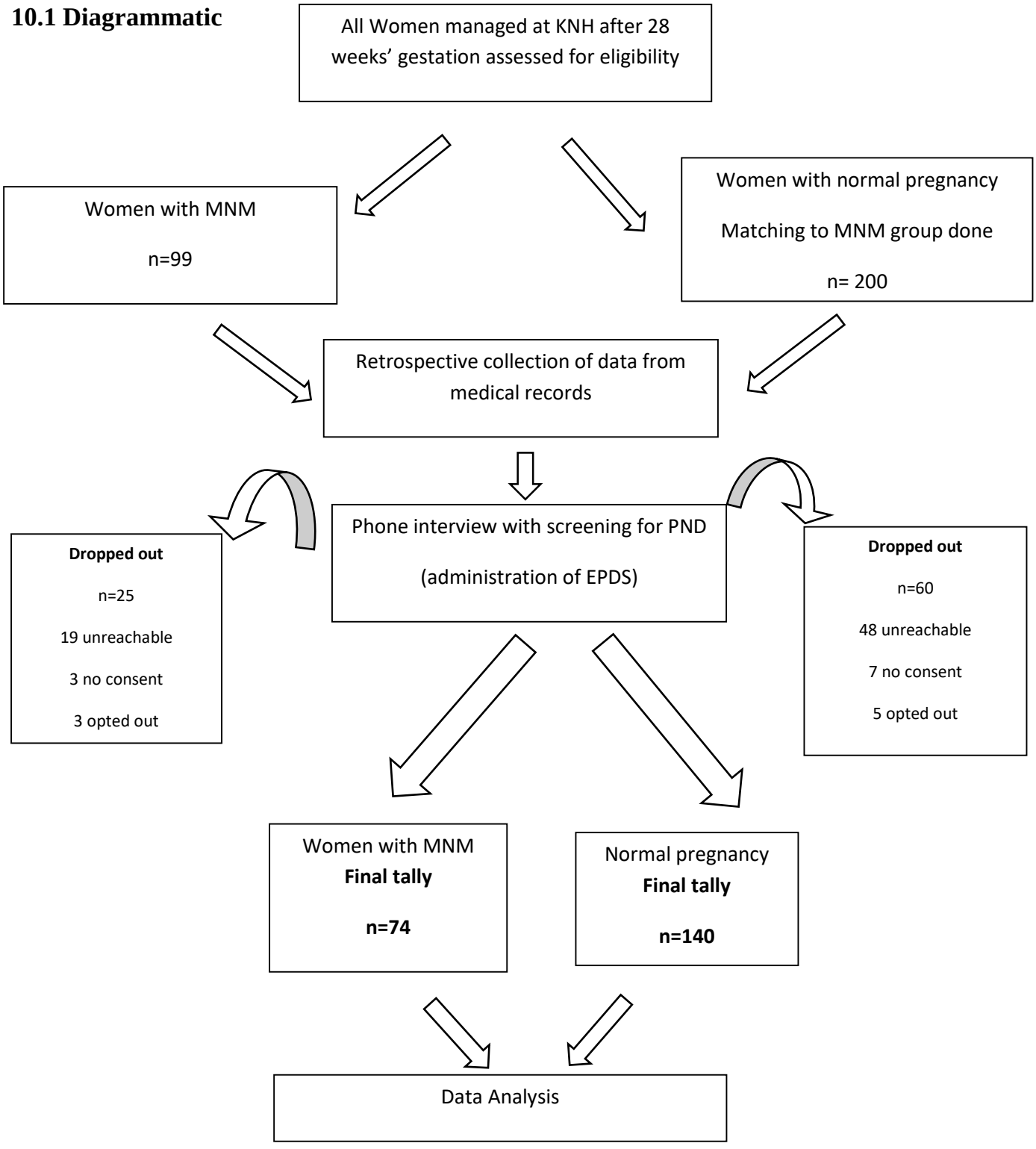

Figure 3: Study flow chart Source: Author

10.2 Study flow narrative

As depicted in figure 3 above, 99 cases of MNM were found at KNH. This was done by going through records of patients admitted to sentinel units within the hospital namely, the critical care unit (intensive care unit), renal unit, blood transfusion unit, maternity theatre, maternity ward acute room. This identified patients with life threatening conditions and they were then assessed for inclusion into the study using the WHO MNM criteria.

For the normal comparison arm, a ratio of 1:2 was used because the incidence of depression was expected to be much lower in this group compared to women who had suffered life threatening complications. Matching was done for date of delivery and gestation at delivery to control for confounders and a total of 200 participants were recruited.

In the MNM arm of the study, out of 99 potential participants, 25 were dropped from the study with the main reason being participants who were unreachable due to wrong phone numbers recorded or numbers out of service (19 participants). 3 dropped out after declining to consent for the study while a further three dropped out subsequently after initially consenting for the study.

In the normal pregnancy comparison arm of the study, 60 participants were excluded from the study (48 unreachable, 7 declined to consent and 5 requested to withdraw from the study).

Finally, a total of 74 women with MNM and 140 women with a normal pregnancy were included into the study, data collected from them and their patient files and data analysis done.

11.0 RESULTS

In this study a total of 214 participants were included. Of these, 74 participants had suffered MNM and 140 participants had a normal pregnancy. The results from analysis of the data collected from them are described below.

11.1 Socio demographic characteristics of study participants

Table 2: Sociodemographic characteristics compared between the two groups Source: Author

Characteristic		Near miss Exposed n = 74) n (%)	Normal pregnancy (Non exposed n = 140) n (%)	Odds Ratio (CI)	P value
Age (yrs.)	Less than 25	17 (22.7)	37 (26.4)	0.822	0.63
	More than 25	57 (77.3)	103 (73.6)	(0.37-1.84)	
Marital Status	Unmarried	5 (6.1)	3 (02.2)	2.84	0.16
	Married	69 (93.9)	137 (97.8)	(0.62-13.07)	
Level of Education	Primary and below	28 (38.5)	28 (20.1)	2.48	0.006
	Secondary and above	46 (61.5)	112 (79.9)	(1.29-4.76)	
Employment Status	Not employed	68 (92.1)	127 (90.5)	1.22	0.76
	Employed	6 (7.9)	13 (09.5)	(0.33-4.53)	
Residence	Rural	15 (20.7)	1 (0.9)	N/A	<0.0001
	Urban	59 (79.3)	139 (99.1)		
Parity	Primigravidae	44 (59.5)	90 (64.3)	0.815	0.49
	Multigravidae	30 (40.5)	50 (35.7)	(0.46-1.45)	
Mode of Delivery	C S	42 (59.7)	10 (7.2)	NA	<0.0001
	SVD	32 (40.3)	130 (92.8)		

As shown in table 2 above, the socio-demographic characteristics were similar between the two groups. The median age for the study participants was 29 years (Standard Deviation

±5.86). When analysed for the two groups it was found that majority were above 25 years of age (77% in the near miss group and 73% in the normal pregnancy group).

The median gestation for the study participants was term at 37weeks (Std. Dev. ±3.64). and was similar for both groups (37 weeks – early term in near miss group and 39 weeks- full term in normal group).

The median period in months since delivery was 10 months (Std. Dev. ±5.09) and the median number of ante-natal visits was 4 (Std. Dev. ±1.89). This was similar in both groups since matching had been done.

206 (96.5%) of the study participants were married, with rates being similar in both groups (93% of the near miss group were married with 98% of the normal pregnancy group being married).

In terms of education level, majority of study participants- 102 (47.7%) had secondary level of education as their highest level of education. (61% of the near miss group and 79.9 % of the normal pregnancy group had secondary education and above).

A majority of the study participants were not employed and these were 140 (65.7%). This represented 92.1% of women in the near miss group and 90.5% in the normal pregnancy group being unemployed.

204 (95.2%) reported to be living in an urban set up. this was 79.9% of the near miss group and 99.1 % of the normal pregnancy group.

For both groups most women were primigravidae in their first pregnancy. This was 59.5% of the near miss group and 64.3% of the normal pregnancy group.

In table 2 above, 170 (79.4%) of the study participants had delivered via spontaneous vertex delivery with 44 (20.6%) delivering via caesarean section. In the near miss group, majority delivered via caesarean section (59.7%) while in the normal pregnancy group majority delivered via normal vaginal delivery (92.8%).

Other findings were that Ante Natal Care (ANC) attendance was almost universal with 211 (99%) of participants attending ANC at least once. The average number of ANC visits was 4.

Out of all the deliveries, 190 (88.4%) had live births with 12 (5.8%) having fresh still births and another 12 (5.8%) having macerated still births.

11.2 The prevalence of post-natal depression after maternal near miss during pregnancy compared to women with a normal pregnancy.

The main outcome of interest was the difference in the prevalence of post-natal depression among the women with a near miss compared to those with a normal (uncomplicated) pregnancy as assessed using the EPDS. A diagnosis of PND was made when the EPDS score was ≥13. Overall 41 participants (19%) had PND.

Table 3: Prevalence of Post Natal Depression Source: Author

Characteristic	**Near Miss Exposed (n=74) n (%)**	**Normal pregnancy Non exposed (n=140) n (%)**	**Odds Ratio (CI)**	**P value**
Depression	26 (35.1)	15 (10.7)	4.5	
No Depression	48 (64.9)	125 (89.3)	(2.07-8.74)	<0.0001

The prevalence of PND among patients who had a near miss was 35.1% while the prevalence of depression among patients without a near miss was 10.7%. This is shown in table 3 above. Patients with near miss had 4.5 greater odds of developing post-natal depression compared to the patients with normal pregnancies and was statistically significant (OR 4.5, p <0.0001).

11.3 Classification of risk to develop depression

As per the EPDS scoring system, the assignment of a patient as having depression or being at high risk of depression or being at low risk of depression is done according to the total score as outlined below:

≥ 13 = Post-natal depression

10-12 =High risk of PND

≤ 9 = low risk of PND

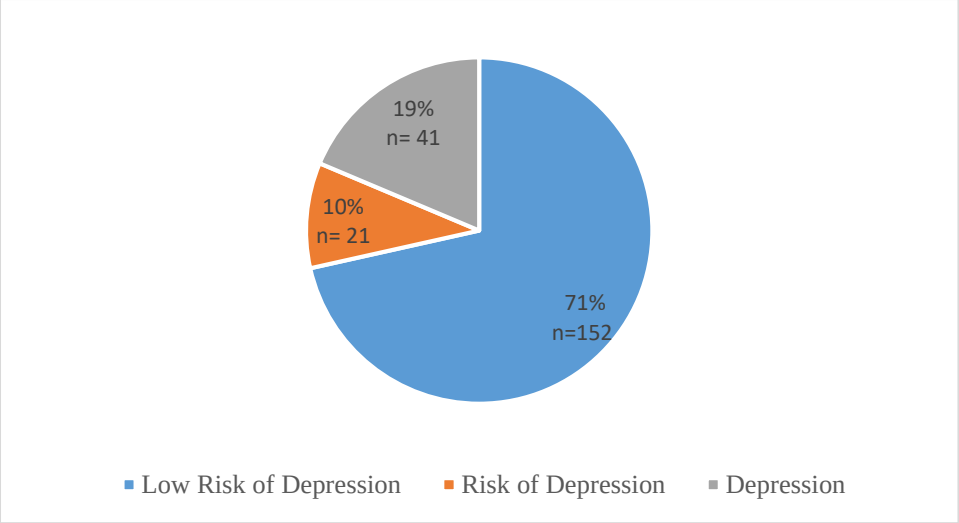

Figure 4:Classification of Post Natal Depression Source: Author

The predominant EPDS score was 0 (20.1%). Overall, 152 (71 %) of participants had a low risk for developing PND while 21 (10%) were found to have a high risk for developing PND while 41 (19 %) of participants were diagnosed as suffering from PND. This is summarized in figure 4 above.

Comparing the two groups of study participants, those with a high risk for developing PND, among the MNM group were 9 (12.8%) while among those without MNM, this was 9 (6.4%). Those with a low risk for depression were 38 (52%) in the MNM group against 113 (80.7%) in the normal pregnancy group.

The likelihood of suicide (as demonstrated by a positive answer to question no. 10 on the EPDS), among the women with near miss was 4 (5.4%), while among those who had a normal pregnancy this was 8 (5.7 %).

On analysis of the association between socio-demographic characteristics and the development of PND in both groups, there was no significant association with regards to age ($p=0.21$) and marital status($p=0.51$). However, an education level of primary and below ($p=0.02$) and an urban residence ($p=0.04$) were significantly associated with depression.

Table 4: Socio demographic characteristics and association with Depression Source: Author

Characteristic		Near Miss Exposed (N=74)		Normal pregnancy Non exposed (N=140)		Odds Ratio (C I)	P value
		With depression (n= 26) n (%)	**Without Depression (n=48) n (%)**	**With depression (n= 15) n (%)**	**Without Depression (n=125) n (%)**		
Age (yrs) (n=214)	Less than 25	7 (16.1)	8 (27)	4(26.66)	38 (30.4)	0.52 (0.87 – 1.46)	0.21
	More than 25	19 (83.9)	40 (73)	11 (73.4)	87 (69.6)		
Marital Status (n=214)	Unmarried	2 (7.7)	3 (6)	1 (6.67)	7 (5.6)	1.74 (0.33 – 9.35)	0.511
	Married	24 (92.3)	45 (94)	14 (93.3)	118 (94.4)		
Education Level (n=214)	Primary and below	13 (50)	10 (20.8)	8 (53.3)	25 (20)	3.24 (1.53 – 6.90)	0.002
	More than primary	13 (50)	38 (79.2)	7 (46.7)	100 (80)		
Residence (n=214)	Rural	5 (19.2)	1 (2)	3 (20)	2 (1.6)	7.43 (1.55 – 35.6)	0.004
	Urban	21 (80.8)	47 (98)	12 (80)	122 (98.4)		

Among those with MNM and post-natal depression, 13 (50%) had higher than primary education with 13 (50%) having primary level and below education. In the normal group with PND 8 (53.3%) had higher than primary education and 7 (46.7 %) had primary or less education.

Among those with MNM and PND 5 (19.2%) had an urban residence with 21 (80.8%) reporting a rural residence. Of those with normal pregnancy and PND, 3 (20 %) had an urban residence with 12 (80 %) having a rural residence. This is summarised in table 4 above.

11.5 The association between obstetric characteristics of women suffering post-natal depression after a near miss compared to a normal pregnancy

On analysis of the obstetric characteristics of the women suffering MNM and subsequently PND, 13 (50 %) had delivered more than 1 child (more para 1) with 13 (50%) being para 1 and below. This is compared to the group with normal pregnancy and PND whereby 7 (46.7%) were more than para 1 with 8 (53.3. %) being para 1 and below.

In the MNM plus PND group 14 (53.8 %) had a gestation less than 36 weeks while 12 (46.7%) were greater than 36 weeks' gestation. In the normal pregnancy group with PND, 8 (53. 33%) were below 36 weeks with 7 (46.67 %) being above 36 weeks' gestation.

The ANC attendance was found to be similar in both groups with 100% of the near miss group attending ANC and 98% in the normal pregnancy group attending ANC.

Table 5: The association between obstetric characteristics of women suffering post-natal depression after a near miss compared to a normal pregnancy. Source: Author

Characteristic		**Near Miss Exposed (N=74)**		**Normal pregnancy Non exposed (N=140)**			
		With depression (n= 26) n (%)	**Without Depression (n=48) n (%)**	**With depression (n= 15) n (%)**	**Without Depression (n=125) n (%)**	**Odds Ratio (C I)**	**P Value**
Parity	Para 1or less	13 (50)	32 (66.67)	7 (46.67)	83 (66.4)	0.46	0.027
(n=214)	More than para 1	13 (50)	16 (33.33)	8 (53.33)	42 (33.6)	(0.23–0.92)	
Gestation	Less than 36 weeks	14 (53.8)	19 (39.5)	8 (53.33)	50 (40)	1.63	0.171
(n=214)	More than 36 weeks	12 (46.2)	29 (60.5)	7 (46.67)	75 (60)	(0.81–3.32)	
Mode of	Caesarean section	9 (34.6)	9 (13)	5 (33.33)	21 (16.8)	4.93	0.026
Delivery (n=214)	Vaginal delivery	17 (65.4)	39 (87)	10 (66.67)	104 (83.2)	(2.38-4.1)	
Outcome of	Live birth	20 (46.1)	44 (92)	11 (73.3)	113 (90.4)	0.26	0.002
Delivery (214)	Still birth	6 (53.9)	4 (8)	4 (26.7)	12 (9.6)	(0.10-0.63)	

Statistically significant associations were found between having a still birth (p=0.002), delivery via caesarean section (p= 0.026) and being above para 1 (p= 0.027) for developing PND. These findings are summarised in in table 5 above.

When the various obstetric complications that cause maternal near miss were analysed it was found that of the patients who suffered MNM, 50% were due to PPH, 38 % due to eclampsia / pre-eclampsia with severe features and 9% being due to other conditions. Among those with MNM and PND, PPH contributed to 44% of cases, eclampsia 40% and other conditions 16%. There was no statistically significant difference in the underlying cause of the near miss and the occurrence of PND (Chi square statistic 0.77, p value of 0.68).

11.6 The medical characteristics of women suffering post-natal depression after a near miss compared to a normal pregnancy.

Table 6: The association between medical characteristics of women suffering post-natal depression after a near miss compared to a normal pregnancy Source: Author

Characteristic	**Near Miss Exposed (N=74)**		**Normal pregnancy Non exposed (N=140))**		**Odds Ratio (C I)**	**P value**
	With depression (n= 26) n (%)	**Without Depression (n=48) n (%)**	**With depression (n= 15) n (%)**	**Without Depression (n=125) n (%)**		
With Complications	6 (23)	4 (26.6)	4 (27)	10 (8)	3.9	<0.0001
Without Complications	20 (77)	44 (73.4)	11 (73)	115 (92)	(1.66 – 09.50)	

Women with MNM and PND found to be having underlying medical complications had increased odds of suffering PND with an odds ratio of 3.9 (CI 1.6-9.50) and p-value <0.001. This is summarised in table 6 above.

11.7 The social support characteristics and factors of women suffering post-natal depression after a near miss compared to a normal pregnancy.

The association between social factors and characteristics of women suffering post-natal depression after a near miss compared to a normal pregnancy are summarised in table 7 below.

Table 7: The association between social factors and characteristics of women suffering post-natal depression after a near miss compared to a normal pregnancy. Source: Author

Characteristic		**Near Miss Exposed (N=74)**		**Normal pregnancy Non exposed (N=140))**		**Odds Ratio (C I)**	**P value**
		With depression (n= 26) n (%)	**Without Depression (n=48) n (%)**	**With depression (n= 15) n (%)**	**Without Depression (n=125) n (%)**		
Partner Support	No Yes	26 (100) 0 (0)	47 (98) 1 (2)	14 (93.3) 1 (6.7)	123 (98.4) 3 (1.6)	N/A	0.234
Family Support	No Yes	8 (30.7) 18 (69.3)	3 (6.25) 45 (93.75)	5 (33.33) 10 (66.67)	13 (10.4) 112 (89.6)	3.21 (1.37-7.52)	0.005
Intimate Partner violence	Yes No	6 (23) 20 (77)	5 (10.5) 43 (89.5)	5 (33.33) 10 (66.67)	10 (8) 115 (92)	07.05 (2.56-19.42)	<0.0001

Statistically significant associations were seen between lack of family support (p 0.005) and the presence of intimate partner violence (p >0.001) with suffering PND in both groups.

11.8 Logistic regression, controlling for near miss and other factors

Table 8: Logistic regression, controlling for near miss Source: Author

Characteristic		Crude Odds Ratio (C I)	Adjusted Odds Ratio (C I)	P value
Near miss	Yes No	4.5 (2.07-8.74)	9.16 (1.24-67.58)	0.03
Educational Level	Primary and below Secondary and above	3.24 (1.53 – 6.90)	3.11 (1.01-9.59)	0.048
Residence	Rural Urban	7.43 (1.58-35.6)	1.16 (0.26 – 4.90)	0.90
Family Support	No Yes	3.21 (1.37 – 7.52)	1.12 (0.05 – 3.42)	0.88
Mode of Delivery	Caesarean section Vaginal delivery	4.93 (1.1 – 2.38)	0.41 (0.05 – 3.42)	0.41
Medical Condition	With condition Without condition	3.9 (1.66 – 09.50)	2.89 (0.88-5.84)	0.02

For the factors discussed in sections 11.1 to 11.7 above (socio-demographic, obstetric, medical and social support factors), logistic regression was done to control for maternal near miss. This was to compare the groups who had MNM and those without MNM but had PND diagnosed using the EPDS.

When control was done for all other factors, it was found that women with a near miss and a low level of education (primary and below) had statistically significant chances of having PND (adjusted OR of 3.11, p value 0.048). A statistically significant association was also found in women who had an underlying medical complication and near miss when other factors were controlled for. An adjusted odds ratio of 2.89 and a p value 0.02 was found. There was no statistically significant association found for the other factors when a near miss occurred. This is summarised in table 8 above.

12.0 DISCUSSION

The sociodemographic characteristics of the study participants (Table 2, 4) were similar to findings from other studies. Notably when compared to a study by Watau and colleagues in 2013 on MNM at KNH, the study site for this study, the age, marital status, employment status of participants was found to be similar (21). These findings were also reflective of the findings in the Kenya Demographic and Health Survey 2014. Obstetric characteristics such as mode of delivery were also similar to this study, The ANC attendance was marginally higher with 99% of participants in this study having at least one visit compared to 93% in the Watau study. This higher ANC attendance reflects the trends in Kenya whereby ANC attendance has been steadily rising as shown in the KDHS 2014 when compared to earlier reports (4).

The main results from this study showed that the prevalence of post-natal depression was higher in women suffering a maternal near miss when compared to women with a normal pregnancy with a 4.5 times increased odds (Table 3). This was in keeping with findings from a cohort study in Morocco by Assarag et al. in 2015 that showed a 5-fold increase in PND after MNM (47). Both studies are similar in that they used the WHO MNM criteria to diagnose near miss cases and also used the EPDS to screen for depression. The setting was also similar with both studies being conducted in Africa.

This finding was further supported by a second cohort study done in Benin by Filippi and colleagues in 2010 whereby they found a 1.87 odds ratio of getting PND after MNM (45). This study also used WHO MNM criteria and the EPDS screening tool for depression. The study site is also similar to the Kenyan setting for this study. The risk is however lower than what has been found in this study. The study designs were different and this may account for the difference in the risks of PND.

The findings of increased PND after MNM (Table 3) were however contrary to findings from a cohort study done in 2003 by Waterstone et al. in the UK that found no difference in the occurrence of PND after MNM (46). This study however was done before the standard MNM criteria were developed hence the cases selected as MNM were different in that study compared to this current study and could account for the difference in results. The study setting was a high income country in contrast to Kenya that is a LMIC and could also account for the difference in results.

The other finding in the current study was that the risk of suicide was the same in the women with MNM and the group with a normal pregnancy (Table 3). This is contrary to the Benin study by Filippi that found a 2-fold increase in the risk of suicide (45). This difference can be attributed to the difference in study designs with this current study being cross-sectional in nature while the study by Filippi was a cohort study meaning that this study had the disadvantage of the investigators not having built rapport with the women prior to administering the EPDS. A study in the UK by Bromley et al. in 2017 reported that a continuity of care model is better for screening and follow-up of women for PND (2). This is because rapport created antenatally reduces barriers in women, their partners and families

opening up to healthcare workers in the post-natal period. It also helps healthcare workers to detect changes in behaviour and temperament in women they are familiar with.

Another significant finding was that certain socio-demographic factors appeared to influence the occurrence of PND. In this study a low level of education (primary level and below) was found to contribute to occurrence of PND in both groups of women with an odds ratio of 3.23 and p value 0.02 (Table 4). This is similar to a cross-sectional study done in Egypt by Sultan et al. in 2017 that found that low level of education influenced the occurrence of PND (29).

A higher incidence of both MNM and PND was seen in participants residing in urban settings compared to rural set ups (Table 4). This is in contrast to a study done by Kasahun and colleagues in 2018 in Ethiopia that found a 7- fold increased risk of depression in rural populations compared to urban populations. Another study done in Nigeria also found higher rates of PND in women who lived in rural areas compared to urban centres (30). This difference can be explained by the fact that in the current study, the setting was in KNH the Kenyan national referral hospital that is located in Nairobi, the Kenyan capital city and as such, a vast majority of the women in both the near miss and normal pregnancy groups (95.2%) were drawn from the surrounding urban catchment area. The other two studies quoted were based in regional facilities located in serving relatively rural populations.

Obstetric characteristics associated with occurrence of PND from this study included mothers who had a still birth when compared to those who had a live birth (OR 0.26 p-value 0.002) (Table 5). This is similar to a case control study done by Adeoye et al. in 2015 in Nigeria that also found an increased risk of depression after a bad perinatal outcome (31). Despite this similarity in findings, the Nigerian study however also included early neonatal deaths in its analysis. This finding was also shown by Stewart and colleagues in 2003 systematic review on factors predisposing women to PND (39). This shows that a bad neonatal outcome is associated with stresses that increase the risk of PND.

The association between medical characteristics and a near miss was also sought in this study and findings indicated that women with underlying medical conditions were more likely to suffer PND (OR 3.9) (Table 6). This is similar to findings on risk factors for PND done by Stewart et al in 2003 in the UK, despite the different study settings (39).

Social factors predisposing women to PND from this study are lack of family and partner support (OR 3.21) and also the experience of violence from the woman's intimate partner or family members (OR 7.05) (Table 7). These findings are similar to the study by Stewart and colleagues that also linked lack of social support and gender based violence to be predisposing factor for MNM (39).

After logistical regression to control for all other factors, a low level of education (primary and below) was found to correlate with PND once a near miss had occurred (Table 9). This is similar to the cross-sectional study done by Sultan et al., in Egypt (29) and probably denotes the fact that a woman's level of education influences her health (including mental health) in terms of preventive measures she would take, health seeking behaviour/ ability to recognize danger signs, compliance to treatment plans and overall empowerment.

Also found to be statistically significant after logistical regression was done was presence of an underlying medical complication (Table 8). Women with underlying medical disorders who then suffer a near miss were more likely to have post-natal depression. This is in agreement with the study done by Stewart and colleagues in 2003 (39). This denotes the probability that the effects of multiple illnesses are additive on the chances of suffering depression and the risk increases when there are comorbidities in addition to a near miss in the same woman.

13.0 CONCLUSION

In conclusion, maternal near miss is associated with an increased risk of the occurrence of post-natal depression. Women with a low level of education and underlying medical conditions who then suffer a near miss are also at an increased risk of PND compared to women with MNM but without these factors. These groups of women thus should have closer follow-up to screen and manage for the same. Telephone interviews are a viable option in the follow-up of women after discharge from hospital.

14.0 RECOMMENDATIONS

Based on findings from this study, the following recommendations are made:

In the short term:

1. Women who suffer a maternal near miss should be routinely followed up, screened and managed for post – natal depression based on their increased susceptibility.

2. Despite the lower risk of PND even women with a normal pregnancy should be screened due to the similar risk level for suicide and /or self-harm were found in both groups of women. This is because these findings are clinically significant even among the women with a normal pregnancy.

3. Thorough history should be taken at admission to screen women for underlying medical illnesses and proper family social history to elicit education level as these factors have been shown to increase the chances of PND especially once a near miss occurs.

4. Use of telephone interviews is a viable option for screening for PND and possibly this can extend to other areas of follow-up for women discharged form hospital. This is especially useful where they live far off areas. Even for those from near the hospital, it is still a convenient medium that does not disrupt the daily activities of the patients. It should be incorporated into the follow-up health system methods.

In the medium term

Larger studies should be designed especially prospective cohort and Randomised studies to further look into the associations between PND and MNM and possible treatments available for the same.

In the long term

In the long term and at policy level the following should be put under consideration:

1. Mental health services should be formally incorporated into post-natal care (PNC) programmes with screening for PND added to the routine PNC packages.

2. Hospital / maternity registers that include data on MNM and PND should be developed for ease of data collection.

15.1 Study Timelines

Source: Author

	Activity	Duration	Timeline
1	Proposal development	8 months	Jan – August 2018
2	Ethical approval	3 months	November 2018– January 2019
3	Data collection	1 months	January – February 2019
4	Data analysis	2 months	February – March 2019
5	Thesis write-up	2 months	February - March 2019
6	Manuscript development	3 months	March – April 2019

15.2 Budget

Source: Author

Items	**Unit Cost** **Ksh.**	**Units**	**Total** **Ksh.**
Research assistant allowances/ administration of questionnaires	100	200	20,000
Stationery & Flash drives	1,000	4	4,000
Printing / Photocopy	10	1000	10,000
Binding	500	4	2,000
Communication/ Airtime	5,000	4	20,000
Data analysis/ statistician	30,000	1	30,000
Miscellaneous	4,000	1	4,000
TOTAL			**90,000**

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17.0 ANNEXES

17.1 Annex 1: Questionnaire/ Data collection tool

SECTION 1: ELIGIBILITY & REGISTRATION (To be filled during interview and from the files in the records department)

The woman is within one year of delivery having delivered and /or been managed for a maternal near miss at Kenyatta national hospital (KNH) between 1st August 2017 to 31st July 2018 and:

1. The woman had a maternal near miss after 28 weeks of gestation or within 42 days of delivery. (near miss exposed group)
2. The woman had a normal pregnancy with delivery after 28 weeks' gestation (unexposed comparison group)

The woman / case file does not meet any exclusion criteria

INTERVIEW NUMBER. …… File number ……

NAME OF INTERVIEWER ….……...……...…….……

DATE OF INTERVIEW ……/…. /……...

CONSENT TAKEN Y/N……...

Maternal near miss group ☐ or Normal comparison group ☐ (tick as appropriate)

SECTION 2: STUDY PARTICIPANT DETAILS (to be filled from records in file)

Age (years) ……...

Marital status: Single ☐ Married ☐ Cohabiting ☐ Divorced/separated ☐ widowed ☐

Educational level: None ☐ Primary ☐ Secondary ☐ Tertiary ☐

Employment status:

formal employment ☐ self-employed ☐ unemployed ☐

Residence: county…… town ……. Estate/village……...

Rural or urban (choose one as appropriate) ……

Parity (For pregnancy in which near miss occurred) ……

Date of admission …/……/……. date of discharge …. /……./……..

Date of delivery …. /……./…….. outcome of delivery ……

Length of hospital stay (days) ……

History of previous caesarean section yes ☐ no ☐

If yes, specify number of previous caesarean sections ……

ANC attendance Yes ☐ No ☐ if yes number of visits…… blood group……

Any abnormalities noted during ANC: Low Hb ☐ high BP ☐ UTI ☐ bleeding ☐

HIV status positive ☐ negative ☐

Medical condition (specify)…….

When was an abnormality first detected: 1st visit ☐ subsequent visit ☐

Preventive measures given: TT ☐ Deworming ☐ IFAS ☐

malaria prophylaxis: IPT ☐ Nets ☐

Did participant suffer a maternal near miss? Yes ☐ No ☐

a) Cause of near miss
b) Underlying cause of near miss
c) Diagnostic criteria fulfilled (tick all applicable criteria for near miss fulfilled)

Clinical criteria	**Laboratory criteria**	**Management based proxies**
Shock ☐ Cardiac arrest ☐	pH< 7.1 ☐ Lactate>5mEq/mL ☐	Use of continuous vasoactive drugs ☐ Cardio-pulmonary Resuscitation (CPR) ☐
Acute cyanosis/Gasping ☐	Oxygen saturation <90% for ≥60 minutes. ☐	Intubation and ventilation not related to anaesthesia ☐

Respiratory rate >40 or <6 bpm ☐	PaO2<200mmHg ☐	
Oliguria no responsive to fluids or diuretics. ☐	Creatinine ≥300 µmol/l or 3.5 mg/dl ☐	Dialysis for acute renal failure ☐
Failure to form clots ☐	Acute severe thrombocytopenia (<50,000 platelets/ml) ☐	Transfusion of ≥ 5 units of blood/red cells. ☐
Jaundice in the presence of preeclampsia ☐	Bilirubin > 100 µmol/l or > 6.0mg/dl. ☐	
Any loss of consciousness lasting > 12h ☐ Stroke ☐ Uncontrollable fit/status epilepticus ☐ Total paralysis ☐		Hysterectomy following infection or haemorrhage. ☐

SECTION 3: PARTICIPANT INTERVIEW (details to be filled as at date of interview)

INTERVIEW NUMBER……

1. Current parity ……

2. current Marital status:

Single ☐ Married ☐ Co-habiting ☐ Divorced/separated ☐ widowed ☐

3. Current residence: county…… town …….. Estate/village……...

4. Current employment status:
   formal employment ☐ self-employed ☐ unemployed ☐

5. What is the current health status of the baby?

   Alive and well ☐ Alive with complication ☐ Diseased ☐

6. What is the current health status of the mother?
   No complications ☐ with complications ☐ (If with complications, specify)
   …….

7. Are you on any long term follow up for chronic medical illness prior to the near miss?
   Yes ☐ No ☐ If yes kindly specify…….

8. Do you have any permanent disabilities / long term condition as a result if the near miss?

   Yes ☐ No ☐ If yes kindly specify…….

9. Do you feel that your partner supports you enough?
   Yes ☐ No ☐ If yes kindly specify…….

10. Do you feel that your family supports you enough?
    Yes ☐ No ☐ If yes kindly specify…….

11. Has your partner been abusive or have you experienced any abuse from a member of your family?
    Yes ☐ No ☐ If yes kindly specify…….

12. Have you had any major life loss or bereavement?

Yes No If yes kindly specify and state if before or after the near miss / delivery …….

13. Have you suffered from any mental health disorder in the past (prior to the pregnancy in which the near miss occurred)?
    Yes ☐ No ☐ If yes kindly specify…….

    EXCLUDE IF DISORDER PRE-DATES THE NEAR MISS/ DELIVERY

14. Have you had or currently have any substance use disorder?
    Yes ☐ No ☐ If yes kindly specify…….

    EXCLUDE IF DISORDER PRE-DATES THE NEAR MISS/ DELIVERY

15. By your own assessment how has the near miss / delivery affected your financial status?
    Adversely ☐ slightly ☐ no change ☐ improvement ☐

Next, administer the Edinburgh post-natal depression scale tool for those still in the study

(score of 13 or more is the cur- off for post-natal depression)

SECTION 4: EDINBURGH POSTNATAL DEPRESSION SCALE (EPDS) (To be filled during participant interview)

INTERVIEW NUMBER……

Near miss Yes ☐ No ☐

Your Date of Birth: (dd/mm/yy) _____ Baby's Date of Birth: _____ Phone number: _____

As you are pregnant or have recently had a baby, we would like to know how you are feeling. Please check the answer that comes closest to how you have felt IN THE PAST 7 DAYS, not just how you feel today.

Here is an example, already completed.

I have felt happy:

☐ Yes, all the time

☒ Yes, most of the time

☐ No, not very often

☐ No, not at all

This would mean: “I have felt happy most of the time” during the past week.

Please complete the other questions in the same way.

In the past 7 days:

1. I have been able to laugh and see the funny side of things

☐ As much as I always could

☐ Not quite so much now

☐ Definitely not so much now

☐ Not at all

2. I have looked forward with enjoyment to things

☐ As much as I ever did

☐ Rather less than I used to

☐ Definitely less than I used to

☐ Hardly at all

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

☐ Yes, most of the time

☐ Yes, some of the time

☐ Not very often

☐ No, never

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

☐ No, not at all

☐ Hardly ever

☐ Yes, sometimes

☐ Yes, very often

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

☐ Yes, quite a lot

☐ Yes, sometimes

☐ No, not much

☐ No, not at all

*6. Things have been getting on top of me

☐ Yes, most of the time I haven't been able to cope at all

☐ Yes, sometimes I haven't been coping as well as usual

☐ No, most of the time I have coped quite well

☐ No, have been coping as well as ever

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

☐ Yes, most of the time

☐ Yes, sometimes

☐ Not very often

☐ No, not at all

*8. I have felt sad or miserable

☐ Yes, most of the time

☐ Yes, quite often

☐ Not very often

☐ No, not at all

*9 I have been so unhappy that I have been crying

☐ Yes, most of the time

☐ Yes, quite often

☐ Only Occasionally

☐ No, never

*10 The thought of harming myself has occurred to me

☐ Yes, quite often

☐ Sometimes

☐ Hardly ever

☐ Never

SCORING

QUESTIONS 1, 2, & 4 (without an *)

Are scored 0, 1, 2 or 3 with top box scored as 0 and the bottom box scored as 3.

QUESTIONS 3, 5-10 (marked with an *)

Are reverse scored, with the top box scored as a 3 and the bottom box scored as 0.

Maximum score: 30

Total score ☐☐

Administered/ interviewed by _____ Date _____

1. Source: Cox, J.L., Holden, J.M., and Sagovsky, R. 1987. Detection of postnatal depression: Development of the 10-item Edinburgh Postnatal Depression Scale. British Journal of Psychiatry 150:782-786.
2. Source: K. L. Wisner, B. L. Parry, C. M. Piontek, Postpartum Depression N Engl J Med vol. 347, No 3, July 18, 2002, 194-199

The EPDS has been translated into multiple languages including Kiswahili for ease of administration using the translation and back translation method by Kumar and colleagues in 2015 and has been applied in the study by Watau in KNH as summarized below (21):

IN THE PAST 7 DAYS	**KATIKA SIKU SABA ZILIZOPITA**
1. I have been able to laugh and see the funny side of things a) As much as I always could b) Not quite so much now c) Definitely not so much now d) Not at all	1. Nimekuwa na uwezo wa kucheka na kuona upande wa furaha wa vitu a) Kama vile nilivyokuwa awali b) Sio vile kwa sasa c) Kwa hakika sivyo vile kwa sasa d) Hata kamwe
2. I have looked forward with enjoyment to things a) As much as I ever did b) Rather less than I used to c) Definitely less than I used to d) Hardly at all	2. Nimetarajia kufurahia vitu a) Kama vile nilifanya daima b) Afadhali kidogo kuliko nilivyokuakwa hakika c) kidogo kuliko nilivyokuwa d) Hata kabisa
3. I have blamed myself unnecessarily when things went wrong a) Yes, most of the time b) Yes, some of the time c) Not very often d) No, never	3. nimejilaumu mwenyewe pasipo sababu vitu vikivurugika a) Ndio, wakati mwingi b) Ndio, wakati mwingine c) Sio mara nyingi d) La, kamwe
4. I have been anxious or worried for no good reason a) No, not at all b) Hardly ever c) Yes, sometimes d) Yes, very often	4. Nimekuwa na wasiwasi au sumbukopasipo na sababu nzuri 1. La, Hata kamwe 2. Kigogo sana 3. Ndio, wakati mwingine 4. Ndio, mara nyingi
5. I have felt scared or panicky for no good reason a) Yes, quite a lot b) Yes, sometimes c) No, not much d) No, not at all	5. Nimeshikwa na hofu ama kuhangaika pasipo sababu nzuri a) Ndio, hakika mara nyingi b) Ndio, wakati mwingine c) La, sio sana d) La, kamwe
6. Things have been getting on top of me a) Yes, most of the time I haven't been able to cope at all b) Yes, sometimes I haven't been coping as well as usual c) No, most of the time I have coped quite well d) No, have been coping as well as ever	6. Vitu vimekuwa vikinilemea a) Ndio, wakati mwingine sijaweza kuvumilia kabisa b) Ndio, wakati mwingine sijaweza kuvumilia kama kawaida c) La, wakati mwingi nimevumilia hakika vizuri d) La nimevumilia vizuri kama kila wakati
7. I have been so unhappy that I have had difficulty	7. Nimekuwa sina furaha hadi nimepata tatiza la

sleeping 1. Yes, most of the time 2. Yes, sometimes 3. Not very often 4. No, not at all	kulala a) Ndio, wakati mwingi b) Ndio, wakati mwingine c) Sio kila mara d) La, kamwe
8. I have felt sad or miserable 1. Yes, most of the time 2. Yes, quite often 3. Not very often 4. No, not at all	8. Nimejiskia sina furaha na kukosa matumaini a) Ndio, wakati mwingi b) Ndio, wakati mwingine c) Sio kila mara d) La, kamwe
9. I have been so unhappy that I have been crying a) Yes, most of the time b) Yes, quite often c) Only Occasionally d) No, never	9. Nimekuwa sina furaha hadi nimekuwa nikilia a) Ndio, wakati mwingi b) Ndio, mara kwa mara c) Mara chache tu d) La, hasha
10. The thought of harming myself has occurred to me a) Yes, quite often b) Sometimes c) Hardly ever d) Never	10. Wazo la kujudhuru mwenyewe limenijia a) Ndio, mara kwa mara b) Wakati mwingine c) Kwa nadra sana d) Hata, kamwe

Scoring for the Kiswahili version follows the same system as for the English version as described above.

17.2 consent form

This is to be read out to the potential participants at first contact prior to starting the telephone interview (A Kiswahili version is also available)

Hello, how are you doing? My name is _____ and I am calling from Kenyatta National hospital (KNH). I am working with Dr Stephen Karangau a masters student (registrar) at the University of Nairobi (UON /KNH) in the obstetrics and gynaecology department who is doing a study on psychological well-being after delivery or discharge from hospital KNH

Brief summary

I am calling you to seek your consent for participation in the study mentioned above. The study is aimed at following up women after a normal pregnancy / delivery (only for the normal pregnancy patients) or discharge after a complication in pregnancy (only for the near miss patients) from KNH.

Participation is completely voluntary and there are no consequences for choosing to participate or not to participate.

Study procedures

After you accept to participate in the study, you will be asked questions over the telephone regarding your progress since the birth of your baby (only for the normal pregnancy patients)/ discharge after the complication during pregnancy (only for the near miss patients)

Benefits and risks of the study

The study does not anticipate to cause any harm to you the participant as it is telephone based. There will be no physical contact, examination or blood tests related to the study. The study will be conducted at no cost to you and the interview can be rescheduled to a time convenient to you.

The results of this study will be confidential and will be available to you at the end of the study. The study seeks to provide evidence for the improvement of postnatal psychological health care and where shared with the public or authorities, there will be no personal details disclosed.

In case you are found to be having any psychological health issues during this study you will be helped to seek the care needed. A family member or any other person you nominate may be involved in helping you seek care but only with your approval

Some of the questions are personal in nature and do not hesitate to let the interviewer know of any questions you are not comfortable answering at any time.

In case you feel you need any further support or medical care, feel free to notify the interviewer who is ready to assist you to the extent possible and permitted by the study

Consent

Does the participant voluntarily and expressly give verbal consent to participate in the study?

Kiswahili version: Fomu ya idhini

Habari yako?Natumai unaendelea vyema. Mimi naitawa _____ na ninakupigia simu kutoka hospitali kuuu ya Kenyatta (KNH). Nafanya kazi na Dkt. Stephen Karangau ambaye ni mwanafunzi na daktari katika chuo kikuu cha Nairobi (UON/KNH) katika idara ya aya ya wanawake. Anafanya utafiti kuhusu afya ya akili katika kina mama waliojifungua ama kutibiwa KNH.

Mukhtasari

Ninakupigia simu kwa sababu ya kukuomba idhini ya kukuhusisha katika huu utafiti ambao unanuia kuwaangalia kina mama baada ya kujifungua mimba isiyo na matatizo am iliyo na matatizo ili kuwaangalia vile ilivyoadhiri afya yao ya akili.

Kujihusisha kwa huu utafiti ni kwa hiari yako na hakutakuwa na adhabu yoyote iwapo utakataa kujihusisha katika utafiti.

Jinsi utafiti utakavyofanywa

Iwapo utapeana idhini ya kujihusisha na huu utafiti, utaulizwa maswali kwa njia ya simu ili kujua vile afya yako inaendelea.

Manufaa na madhara ya huu utafiti

Kwa sababu utafiti utafanywa kwa njia ya simu, hatutarajii ya kwamba kutakuwa na madhara yoyote kwako. Hakutakuwa na kupimwa mwili au kutolewa damu ya kupimwa. Hautahitajika kwa wakati wowote kulipa pesa zozote kwa huu utafiti. Pia simu inaweza ikaahrishwa ifanyike kwa wakati uupendao (ukiwa na wakati) ili isikuzuie kufanya kazi zako za kawaida.

Matokeo ya huu utafiti yatalindwa kwa siri ili kutopeana majina ama mambo mengine ya kibinafsi ya watakaojihusish na utafiti. Matokea yatatolewa kwa kila aliyehusika na utafiti.

Iwapo utapatina na ugonjwa ama madhara yoyote ya akili tunapofanya utafiti, tutakusaidia kuyapata matibabu unayohitaji. Ukipenda, mtu mmoja wa familia yako utakayemchagua na kuidhinisha atahusishwa kwa kuhakikisha uyapate haya matibabu.

Maswali mengine yanaweza kuibua hisia na kumbukumbu za huzuni na ikiwa utajiskia unazidiwa na maswali tafadhali mjulishe anayekuuliza maswali, na kama ilivyosemekana awali hakutakuwa na adhabu yoyote ukijitoa kwa utafiti.

Kwa wakati wowote, kama ukijihisi unahitaji usaidizi Zaidi, tafadhali mjulishe anyekuuliza maswali ili aweze kukusaidia iwezekanavyo.

Idhini ya kuhusika kwa utafiti

Je, mwanamke huyo amepeana idhini yake kuhusishwa na utafiti?