

**PREVALENCE OF POSTPARTUM PSYCHOLOGICAL
DISTRESS AMONG MOTHERS OF PRETERM NEONATES IN
KENYATTA NATIONAL HOSPITAL NEWBORN UNIT**

**DISSERTATION SUBMITTED IN PART FULFILLMENT OF THE
REQUIREMENTS OF THE UNIVERSITY OF NAIROBI FOR AWARD OF
THE DEGREE OF MASTER OF MEDICINE IN PAEDIATRICS AND
CHILD HEALTH**

INVESTIGATOR:

DR. ALICE NKIROTE NYARIBARI

MBChB (UON)

H58/61411/2013

DECLARATION

This dissertation is my original work and has not been presented for the award of a degree in any other university.

Dr. Alice Nkirote Nyarbari

MBChB (University Of Nairobi)

Signature:  Date: 29/09/2015

This dissertation has been submitted with our full approval as supervisors:

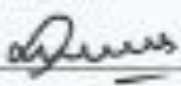
Professor Fred Were

MBChB, MMED (Paed), FNIC, PHD

Professor and Neonatologist, Department of Paediatrics and Child Health,

Dean School of Medicine,

University Of Nairobi.

Signature:  Date: 5-10-15

Dr. Josephine Omond

MBChB, MMED (Psych), Cert. Child/Adolescent Psychiatry

Consultant child and adolescent psychiatrist,

Kenyatta National Hospital.

Signature:  Date: 29/9/15

DEDICATION

I dedicate this book to my family for their patience, help and support during the M.Med programme. My husband Joshua and my children Michelle and Hope, thank you for being a constant motivation during my training.

ACKNOWLEDGEMENTS

I wish to thank:

- My supervisors Prof.Fred Were and Dr. Josephine Omondi for their support and guidance.
- The staffat Kenyatta National Hospital, newborn unit for their cooperation during the study period.
- The lecturers in the department of paediatrics and childhealth for their guidance during the proposal and results presentation which has greatly improved the dissertation.
- God, the reason I am.

TABLE OF CONTENTS

DECLARATION	Error! Bookmark not defined.
ACKNOWLEDGEMENTS	iv
TABLE OF CONTENTS	v
LIST OF TABLES AND FIGURES	vii
LIST OF ABBREVIATIONS	viii
DEFINITION OF TERMS	ix
ABSTRACT	x
1. INTRODUCTION, BACKGROUND AND LITERATURE REVIEW	1
1.1 BURDEN OF PREMATURETY	1
1.2 PSYCHOLOGICAL ASPECTS OF NORMAL PREGNANCY AND EARLY MOTHER-CHILD RELATIONSHIP	2
1.3 EFFECTS OF PRETERM BIRTH ON THE MOTHER	4
1.4 PSYCHOLOGICAL DISTRESS	6
1.5 PREMATURETY, MATERNAL PSYCHOLOGICAL DISTRESS AND CHILD DEVELOPMENT	7
1.6 POSTPARTUM PSYCHIATRIC DISORDERS	7
1.7 PREVALENCE OF POSTPARTUM PSYCHOLOGICAL DISTRESS AMONG MOTHERS OF PRETERM NEONATES	8
1.8 DEPRESSION, ANXIETY AND STRESS SCALES (DASS)	11
2. STUDY JUSTIFICATION AND UTILITY	13
3. STUDY OBJECTIVES	13
3.1 Primary objective	13
3.2 Secondary objective	13
4. STUDY METHODOLOGY	14
4.1 Study Design	14
4.2 Study period	14
4.3 Study site	14
4.4 Study Population	14
4.4.1 Inclusion Criteria	14
4.4.2 Exclusion Criteria	14
4.5 Sample size	15
4.6 Sampling Technique	15
4.7 Study personnel	15

4.8 Study procedure	15
4.9 Study tool	16
5.DATA STORAGE, ANALYSIS AND PRESENTATION	16
6. MINIMIZATION OF BIAS.....	17
7. ETHICAL CONSIDERATIONS	17
8 RESULTS	18
9 DISCUSSION, CONCLUSION AND RECOMMENDATIONS	28
9.1 DISCUSSION	28
9.2 CONCLUSION.....	31
9.3 RECOMMENDATIONS	32
10 STUDY LIMITATIONS	32
11 REFERENCES	33
12 APPENDICES	36
APPENDIX 1: QUESTIONNAIRE.....	36
APPENDIX 2: Depression Anxiety and Stress Scale (DASS-21).....	42
APPENDIX 3: DASS normative table.....	46
APPENDIX 4: CLIENT INFORMATION AND CONSENT FORM	47
APPENDIX 5: BUDGET	51
APPENDIX 6: ETHICAL APPROVAL.....	52

LIST OF TABLES AND FIGURES

Tables

Table 1: Survival of preterm babies by gestation

Table 2: Studies on prevalence and factors associated with psychological distress among mothers of preterm neonates

Table 3: Socio-demographic characteristics of the mothers of preterm neonates admitted at KNH newborn unit

Table 4: Characteristics of the preterm neonates born to the mothers in KNH newborn unit

Table 5: Prevalence of postpartum psychological distress among mothers of preterm neonates in KNH newborn unit

Table 6: Comorbidities

Table 7: Maternal socio-demographic factors and psychological distress

Table 8: Previous pregnancy factors and psychological distress

Table 9: Antenatal and delivery factors and psychological distress

Table 10: Neonatal factors and psychological distress

Table 11: Multivariate (logistic regression) output of associated maternal factors

Table 12: Logistic regression output of associated neonatal factors

Figures

Figure 1: Illustration of psychological distress

LIST OF ABBREVIATIONS

KNH.....	Kenyatta National Hospital
NBU.....	Newborn Unit
NICU.....	Neonatal Intensive Care Unit
WHO.....	World Health Organization
DASS-21.....	Depression Anxiety Stress Scale-21
SPSS.....	Statistical Package For Social Sciences
UON.....	University Of Nairobi
OR.....	Odds ratio
AOR.....	Adjusted odds ratio
CI.....	Confidence interval

DEFINITION OF TERMS

Neonate: Newborn infant less than one month old.

Preterm neonate: Any neonate born before 37 completed weeks of gestation.

Psychological distress: A general term used to describe unpleasant feelings or emotions that impact an individual's level of functioning.

Depression: A mental disorder characterized by sadness, loss of interest or pleasure, feelings of guilt or low self-worth, disturbed sleep or appetite, feelings of tiredness, and poor concentration.

Anxiety: A state of apprehension, uncertainty, and fear resulting from the anticipation of a realistic or fantasized threatening event or situation, often impairing physical and psychological functioning.

Stress: An adverse response to what an individual perceives as too much pressure.

Operational definition of psychological distress: One or more of depression, anxiety or stress. For purposes of this study, a mother who had any of the above psychological disturbances, or a combination of two, or all three of them together was considered to have psychological distress.

ABSTRACT

Background: Preterm birth rates are high both locally and globally. In Kenya 10-15% of all babies born are preterm. Prematurity is the leading cause of newborn death, and many of the babies who survive face a lifetime of disability. Preterm birth and the associated perinatal problems is experienced by the mother as an acute emotional crisis characterized by depression, anxiety, stress and for some self-blame. Having increased maternal psychological symptoms is a risk factor for emotional attachment difficulties and decreased maternal responsiveness towards the baby.

Objectives: To determine the prevalence of postpartum psychological distress i.e depression, anxiety and stress (according to DASS-21 scale) among mothers of preterm neonates in KNH newborn unit and the factors associated with psychological distress among these mothers.

Methods: A hospital based cross-sectional study was done. All mothers with preterm neonates admitted in the KNH newborn unit, that met eligibility criteria and gave consent were enrolled. A questionnaire capturing maternal and neonatal history and the diagnostic screening tool DASS-21 was administered. Data collected was analyzed using the SPSS computer software. Chi-square analysis was used to establish association between psychological distress and the various risk factors, while logistic regression analysis was used to determine the factors independently associated with psychological distress among mothers of preterm neonates.

Results: The mean age of the mothers who took part in the study was 27 ± 5.3 years. The mean gestational age at birth of the preterm neonates was 32 ± 2.5 weeks. The prevalence of postpartum psychological distress (one or more of depression, anxiety or stress) among mothers of preterm neonates was 27.4%. The prevalence of depression, anxiety and stress was 17%, 21.5% and 10.4% respectively. Younger maternal age less than 25 years, low level of maternal education, low monthly family income, being unmarried and having not planned to be pregnant were maternal factors significantly associated with postpartum psychological distress among mothers of preterm neonates ($P < 0.05$). Neonatal factors that were significantly associated with postpartum psychological distress among mothers of preterm neonates were oxygen therapy, a neonate with a low weight at the time of the interview or a neonate not on milk feeds ($P < 0.05$). However, at multivariate analysis the factors that remained significant were low family income (AOR=5.3, 95% CI 1.8-15.8, $P=0.003$), low level of maternal education ($P=0.04$), oxygen

therapy (AOR=1.6, 95% CI 1.2-2.2, P=0.01), or a neonate not on milk feeds (AOR=3.5, 95% CI 1.2-10.2, P=0.022).

Conclusion: Post partum psychological distress is a significant problem among the mothers of preterm neonates in the KNH newborn unit. Low maternal education, low family income, having a neonate on oxygen therapy or a neonate not on milk feeds are independent predictors of post partum psychological distress among mothers of preterm neonates. Health care workers in the newborn unit should have a high index of suspicion for psychological distress among mothers of preterm neonates, and support structures for these mothers need to be put in place.

1.INTRODUCTION, BACKGROUND AND LITERATURE REVIEW

1.1 BURDEN OF PREMATURITY

According to the World Health Organization, every year about 15 million babies are born prematurely, which is more than one in 10 of all babies born around the world. Africa is the second highest in preterm birth rates in the world, 12.3% of all babies born in Africa are preterm. The preterm birth rate in Kenya is between 10 and 15%. Prematurity is the world's single biggest cause of newborn death, and the second leading cause of death among children under five years. About 1.1 million babies die annually from preterm birth complications. Many of the preterm babies who survive face a lifetime of disability¹

Preterm birth is defined by the World Health Organization as delivery occurring before 37 completed weeks from the first day of the last menstrual period. Preterm infants are classified according to gestational age as extreme preterm delivered before 28 weeks of gestation, very preterm delivered between 28 to 31 weeks of gestation and the moderate to late preterm delivered between 32 and 36 weeks gestation. The late preterms make up to 84% of all preterm deliveries, the very preterm make up to 10%, while the remaining 6% are the extreme preterms. Low birth weight often co-occurs with prematurity and is also related to a number of serious health complications for babies.¹

Consequences of preterm birth

Prematurity is associated with significant morbidity and mortality, particularly for the youngest and smallest infants.²

According to the March of Dimes fact sheet Preterm births February 2007, the survival of preterm babies increases by gestation. A baby born at 23 weeks of gestation has a 17% likelihood of survival and this increases with gestation to 95% at 32-33 weeks. At 34 weeks and above the likelihood is almost the same as that of a full-term baby, as shown in table 1 below. However, advances in technology have resulted in increasing survival rates even for extremely premature infants, particularly in the developed world.³

Table 1: Survival of Premature Babies by Gestation

Length of Pregnancy	Likelihood of Survival
23 weeks	17%
24 weeks	39%
25 weeks	50%
26 weeks	80%
27 weeks	90%
28-31 weeks	90-95%
32-33 weeks	95%
34+ weeks	Almost as likely as a full-term baby
<i>Sources: March of Dimes, Quint Boenker Preemie Survival Foundation</i>	

Neonatal problems associated with prematurity include respiratory distress syndrome, bronchopulmonarydysplasia ,apnea, patent ductus arteriosus, anemia of prematurity, necrotizing enterocolitis, hyperbilirubinemia, hypocalcemia, hypoglycemia, intraventricularhaemorrhage and increased neonatal infections. Some of the negative longterm outcomes of prematurity include mental retardation, deafness, blindness, cerebral palsy, respiratory disorders and lower cognitive capabilities.²

1.2 PSYCHOLOGICAL ASPECTS OF NORMAL PREGNANCY AND EARLY MOTHER-CHILD RELATIONSHIP

Pregnancy and birth are integral to the process of becoming a parent.Considerable psychological preparation occurs during the pregnancy and is necessary for adjustment to parenthood,particularly if it is the first child.Pregnancy is a normal developmental crisis

involving profound psychological and physical changes. These crisis are meant for personal maturation and growth.⁴All women manifest remarkable psychological changes during pregnancy,and these changes profoundly affect the early mother-child relationship.

According to Bibring et al,a woman during pregnancy goes through 3 psychological stages.⁴ During the first stage,the woman accepts the fetus as part of herself.There is marked physiological and anatomical changes and increased concentration on herself.The increased concentration facilitates acceptance of the fetus as part of herself.The acceptance of pregnancy requires that a woman accepts changes in her role, familiar patterns of work and leisure.Many women find this acceptance difficult even for planned pregnancies.This is because the physiological changes at this stage cause tiredness, nausea and other symptoms which may decrease positive feelings.Ambivalence is very common at this stage,and the excitement of creating new life is mitigated by fear and realization of parenthood's great responsibility.⁵ Ambivalence persists until quickening occurs.

The second stage begins after quickening.The fetus is perceived as a separate individual. The perceived fetal movements lead to further acceptance of pregnancy and the mother realizes that this is a separate individual.In contrast to the first stage which involves focusing on the self,the second stage focuses on the fetus. The pregnant woman's nesting behavior is seen,which includes active preparations that allow her to express her feelings about the baby.For example she starts to buy clothes and other items for the baby.This marks the beginning of mother-child relationship and is a developmental achievement in becoming a mother.

The third stage occurs within a month to term.This is called letting go ,or the active wish that the baby gets born. The physical discomfort present at this stage is what makes most women wish that the baby is born,in contrast to the time before that,when women wish to retain the pregnancy.The first pregnancy is a more profound adjustment than subsequent pregnancies in which the developmental process is accelerated.⁶According to Brazelton⁷, this set of adjustment makes the mother ready for attachment to the new baby and prepares her for the many new roles she will have to play soon.If the adjustment is not adequate during pregnancy,there may be disturbances and tensions between the mother and the newborn.⁶

Pregnancy being a developmental crisis, it is characterized by intense emotion. The emotional changes that occur have been described by Colman and Colman as an orderly progression of themes that correspond to trimesters. In the first trimester there is significant anxiety and a feeling of loneliness with a strong wish to be protected. In the second trimester there is increased emotional stability and less anxiety, with increase in self confidence and drive. In the third trimester, anxiety increases again. There is anticipation of the unknown together with pride and fulfillment. Anxiety is often the consequence of the changes that occur during pregnancy. Though hormonal levels may be correlated with mood changes and depression in pregnancy,⁸ it is difficult to separate the effects of physiological changes from the many psychological factors. The changes in body image that occur during pregnancy are often a cause of concern, anxiety or depression.⁹

In his study, Grossman et al documented that adaptation to pregnancy is related to maternal postpartum adjustment (the degree to which the mother recognizes and responds to her infant's needs) and infant development and adjustment.¹⁰

Preterm delivery disrupts the normal psychological progression of Bibring's model. The mother therefore does not want to end the pregnancy and may not be ready for the baby.

1.3 EFFECTS OF PRETERM BIRTH ON THE MOTHER

For almost all families and especially the mothers, the birth of a premature infant and the associated perinatal problems are experienced as an acute emotional crisis which is characterized by anxiety, depression, stress, grief, and for some parents, anger and self blame.¹¹ The increased risk of psychological symptoms is due to factors such as increased infant risk of mortality and high morbidity, the enforced separation of the parent from the infant, anticipated extended hospital stay and costs and the crisis atmosphere in the newborn unit, or the neonatal intensive care unit.¹²

Premature delivery is a critical event in the life of a family and studies have shown that mothers of these infants are at increased risk of psychological distress.¹³ A large proportion of mothers show symptoms of traumatization even long after hospital discharge and describe painful memories of the postnatal period. These memories are mostly unpleasant and

intrusive, and recollections are often connected with attempt to avoid reminders of the experience that followed from premature birth. Intrusion and avoidance are 2 symptoms of posttraumatic stress disorder. Hyperarousal, the third symptom of posttraumatic stress disorder has also been seen in these mothers.¹⁴

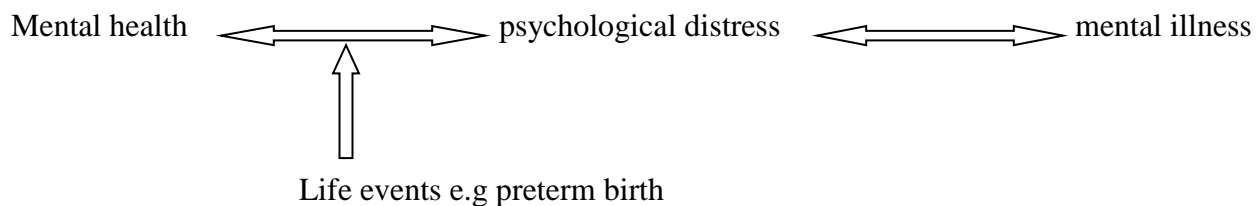
Unresolved psychological trauma may result in a posttraumatic stress disorder, which may have negative, long-term impact on parental well-being, attitude, and behavior. Emotional conditions determine parental self-confidence which has significant influence on those parent-child relationships that are crucial for a favourable outcome. Biological conditions are decisive in this respect, but psychosocial factors also can alter developmental deficits. In a follow-up study in 10 year-old children, those born at 24 to 31 weeks performed less well in school than term children, but environmental factors were stronger predictors of school performance than were perinatal complications. The environmental influence was more pronounced in children who were born preterm.¹⁵

This suggests that it may be beneficial to set up an early, secondary prevention program based on the principles of trauma prevention.

1.4 PSYCHOLOGICAL DISTRESS

Psychological distress is a general term used to describe unpleasant feelings or emotions that impact an individual's level of functioning. It occurs when external events or stressors place demands that the individual is unable to cope with. Psychological distress can be thought of as a continuum with mental health and mental illness at opposing ends, as shown in figure 1.

Figure 1: Illustration of Psychological Distress



Different life experiences make an individual move back and forth on the continuum

Life experiences that may trigger psychological distress include traumatic experiences such as the birth of a premature baby¹⁴, or death of a loved one. Major life transitions such as moving to a new state or having a new job can also cause psychological distress. Other causes of psychological distress include having a serious medical illness such as cancer, and so on.

Preterm delivery poses increased risk of psychological distress in mothers because they are worried about the increased risk of mortality and morbidity, being separated from their babies, the expected prolonged hospital stay and the associated costs and the tense atmosphere in the NICU for those admitted there.¹²

Patients with psychological distress manifest with symptoms such as sadness, anxiety, fatigue, memory problems, anger management problems, obsessive thoughts or compulsions, physical symptoms not explained by a medical condition, decreased pleasure in sexual activities, and may even experience delusions or hallucinations.

Effects of psychological distress include impaired level of functioning of the individual, impaired social life and relationships, and adverse health effects such as increased risk of cardiovascular disease.

1.5 PREMATURITY, MATERNAL PSYCHOLOGICAL DISTRESS AND CHILD DEVELOPMENT

Having increased maternal psychological symptoms is a risk factor for attachment difficulties and decreased maternal responsiveness towards the baby.¹⁶ Maternal traumatic experience related to preterm birth and associated psychological distress may have long lasting influence on mother-child interactional behavior. The negative interactive patterns formed during the critical early bonding period may affect later child development.¹⁵

1.6 POSTPARTUM PSYCHIATRIC DISORDERS

Childbirth is supposed to be a joyous and exciting time, but some women experience postpartum disorders that can adversely affect a woman's mental health and consequently her newborn baby. Postpartum anxiety disorders and postpartum depressive disorders are the most frequent maternal psychiatric disorders following delivery.¹⁷

A serious mental health disorder that they may experience is postpartum depression. According to the World Health Organization the global prevalence of postpartum depression is 10 to 15%.¹⁸ Risk factors for postpartum depression include having been treated for postpartum depression before, history of depression before conception, a family history of depression particularly postpartum depression, poor social support, marital instability, young maternal age, adverse life events during postpartum period and a baby with health problems or difficult temperaments. Hormonal fluctuations that occur during or immediately after childbirth such as decreased serotonin levels may play a role in postpartum depression. Symptoms of postpartum depression are similar to those of a major depressive episode experienced at any time. Minor differences include that in postpartum depression there is in addition difficulty sleeping when the baby sleeps, lack of enjoyment in the maternal role and feelings of guilt related to parenting ability. Treatment of postpartum depression includes one or more of psychotherapy, antidepressant drugs, socialization through support groups, exercise and good nutrition. For the mother untreated depression can lead to the development of chronic depressive illness and poses a risk of suicide. Untreated maternal depression has many negative consequences for the baby. The negative interactive patterns formed during the critical early period may affect the later development of the child.^{15,16} These children may develop conduct disorders, inappropriate aggression, cognitive and attention deficits. These disorders have been

described in children exposed to maternal depression and persisted even after remission of the maternal depression.¹⁸

Postpartum anxiety disorders are as common as post partum depression, and sometimes the two conditions can occur together. Matthey et al found that 16.2% of mothers were diagnosed with a pure anxiety disorder six weeks postpartum. The prevalence of comorbid depression and anxiety was 4.2%. Anxiety disorders that mothers may present with during the postpartum period include panic, phobias, generalized anxiety disorder/acute adjustment disorder with anxiety, obsessive compulsive disorder, acute stress disorder or post traumatic stress disorder.¹⁷ Perinatal anxiety symptoms can include panic attacks, hyperventilation, excessive worry, restless sleep, chest pain, shaking, dizziness or repeated thoughts or images of frightening things happening to the baby. Anxiety disorders differ from anxiety in general in that the experience or feelings are more intense and last longer. Anxiety disorders also interfere with the normal functioning of people at work, at play and in relationships. Postpartum anxiety disorders in new mothers are often missed, therefore a high index of suspicion is required. Treatment of these disorders is psychotherapy in the form of cognitive behavioural therapy and/or pharmacotherapy.¹⁹

Postpartum psychosis is a rare condition. According to WHO the prevalence of postpartum psychosis is 1-2 per 1000 live births. It is a condition with a rapid and severe onset and is treated as a medical and obstetric emergency.¹⁸

1.7 PREVALENCE OF POSTPARTUM PSYCHOLOGICAL DISTRESS AMONG MOTHERS OF PRETERM NEONATES

Upkong et al, in 2003, did a cross-sectional study, looking at postpartum emotional distress in mothers of preterm infants. The study was done at the neonatal intensive care units and obstetric units of Obafemi Awololo University teaching hospital, Nigeria. They found increased emotional distress among mothers of preterm neonates at 27.3%, while 15.1% of them were depressed. The recommendation from this study was that a multidisciplinary approach is essential in the detection and management of these problems. The paediatrician and the obstetrician therefore have a role to detect and refer appropriately to the psychiatrist, and this has a number of implications for preventive psychiatry.²⁰

In another study, Bener in 2010 looked at psychological distress among postpartum mothers of preterm infants and associated factors. He found that 29.4% of the mothers were depressed, while 26.5% were anxious. Young mothers and those who had less than secondary education and lower monthly household income were more depressed and anxious after premature birth. Psychological distress was higher in mothers with history of preterm birth and delivery complications. The results of this study recommended that mothers of preterm infants be routinely screened for postpartum depression and anxiety²¹. This is as shown in table 2

Table 2: Prevalence and Factors associated with Psychological Distress among Mothers of Preterm Neonates

Country Year of study	Authors	Study design Sample size	Findings
Qatar 2013 ²¹	Bener.A	Hospital based cross-sectional study n=170	Prevalence of depression-29.4%, Anxiety -26.5% Stress-11.2% Psychological distress was higher in younger, less educated mothers and those with lower household income.
Nigeria 2003 ²⁰	Upkong et al	Hospital based cross-sectional study n=60	Prevalence of emotional distress was 27.3%,depression-15.1%
Nigeria 2009 ²²	Upkong	Cross-sectional study in NICU n=57	Prevalence of psychological distress-36.8%, depression-19.3%, and anxiety-12.3% .
U.S.A 1995 ²³	Meyer EC et al	Cross-sectional study n=142	Prevalence of psychological distress was 28%

1.8 DEPRESSION, ANXIETY AND STRESS SCALES (DASS)

The Depression Anxiety and Stress scales were developed by researchers at the University of New South Wales in Australia, using a sample of responses from the comparison of sets of results from a sample of first year university students.²⁴ The scores were then subsequently checked for validity against outpatient groups. The reliability scores of the scales in terms of Cronbach's alpha scores were 0.91 for the depression scale, 0.84 for anxiety scale and 0.90 for stress scale. The scale therefore meets the standard threshold of 0.9 required for research. In a study done to evaluate the psychometric properties and the ability of the DASS to detect cases with anxiety disorders and depression in a population of employees absent from work because of mental health problems, it was found to have high internal consistency for depression, anxiety and stress.²⁵ In another study to evaluate the psychometric properties of the DASS, in which the subjects were also administered the Beck Depression Inventory (BDI) and the Beck Anxiety Inventory (BAI), the DASS was shown to possess satisfactory psychometric properties, and the factor structure was substantiated both by exploratory and confirmatory factor analysis. In comparison to the Beck Depression Inventory and Beck Anxiety Inventory, the DASS scales showed greater separation in factor loadings.²⁶

DASS-21 is a quantitative measure of distress on the basis of 3 subscales of depression, anxiety and stress. It is a 21-item version of the full DASS which consisted of 42 items. Each of the 3 DASS-21 subscales contains 7 items each, representing the dimensions of depression, anxiety and stress. The scores for each of the DASS-21 scales are derived by totaling the scores for each subscale and multiplying by two, and then comparing the results to the DASS normative data. DASS-21 is preferred over the full DASS for research purposes because it takes a shorter time to administer, has the same factor structure and gives similar results. A score of 10 or more on the depression subscale is used to detect depression, a score of 8 or more on the anxiety subscale is used to identify anxiety, while a score of 15 or more on the stress subscale identifies stress.

The main purpose of the DASS-21 is to isolate and identify aspects of emotional disturbance and it is not designated as a comprehensive diagnostic tool. The results are intended as a guide to health. The assumption on which the DASS development was based (and which was confirmed by research data) is that the differences between the depression, anxiety and stress experienced by normal subjects and the clinically disturbed are essentially differences of degree.

The DASS therefore,has no direct implications for the allocation of patients to discrete diagnostic categories postulated in classifying systems such as the Diagnostic and Statistical Manual(DSM) or International Classification of Diseases(1CD).

The DASS-21 scale is in public domain and may be downloaded and copied without restriction.²⁷ A sample of the DASS-21 scale is shown as appendix 2.

2. STUDY JUSTIFICATION AND UTILITY

The KNH newborn unit admits between 1 and 3 preterm babies daily. It is known from previous studies that preterm birth is associated with psychological distress among mothers. The psychological well-being of the mothers affects how they interact with and take care of their babies. There are no local data on the prevalence of postpartum psychological distress among these mothers. This study has sought to determine the burden of postpartum psychological distress among mothers of preterm neonates, and this will set a way forward on detection and management of the same, and lay a base for more studies. Information on risk factors associated with postpartum psychological distress will allow for interventional measures to be formulated.

3. STUDY OBJECTIVES

3.1 Primary objective

To determine the prevalence of postpartum psychological distress (depression, anxiety and stress) according to DASS-21 scale, among mothers of preterm neonates in Kenyatta National Hospital Newborn Unit.

3.2 Secondary objective

To describe the factors associated with psychological distress among mothers of preterm neonates admitted in KNH newborn unit.

4. STUDY METHODOLOGY

4.1 Study Design

This was a hospital based cross-sectional study, involving interviewing of post partum mothers of preterm neonates admitted in the KNH newborn unit.

4.2 Study period

The study period ran for 4 months between August and November 2014

4.3 Study site

The study was conducted in Kenyatta National Hospital Newborn Unit. KNH is a tertiary hospital, the National Referral Hospital in Kenya. All neonates weighing less than 1800g are admitted to the newborn unit regardless of whether born in KNH or not. Sick neonates of any weight, born within KNH are also admitted in the unit. Neonates born at home or referred from other facilities and are less than 24 hours old are also admitted here. The mothers of the neonates arrive to the newborn unit between the first and the third day post-partum depending on whether they had a vaginal or caesarean delivery. They reside within the KNH hostels or postnatal wards and visit the unit every 3 hours when they feed their babies and do kangaroo mother care.

4.4 Study Population

All mothers with preterm neonates in the newborn unit one week after birth. Gestational age was determined using Naegele's formula which utilizes the first day of the last normal menstrual period.²⁸ If a mother was not sure of her dates, obstetric ultrasound done during pregnancy was to be used. If the above two were not available, Finnstrom maturity score done within the first 24 hours of delivery was used.

4.4.1 Inclusion Criteria

1. Mothers of preterm babies who were still in the newborn unit one week after delivery
2. Signed informed consent.

4.4.2 Exclusion Criteria

1. Mothers who were unable to come to the newborn unit because of ill health
2. History of past psychiatric illness
3. Mothers of preterm babies with congenital abnormalities

4.5 Sample size

The calculation was as follows using Fisher's formula:

$$n = \frac{Z^2 P (1-P)}{d^2}$$

Where: n is the minimum sample size.

Z is confidence level at 95 % (standard value of 1.96).

P is the expected proportion of mothers of preterm neonates with psychological distress-27.3 % (Upkong et al in Nigeria).

D is the precision- 7.5% (0.075).

$$n = \frac{(1.96)^2 0.273 (1-0.273)}{0.075^2}$$

= 135

4.6 Sampling Technique

Consecutive recruitment of mothers with preterm babies who met the selection criteria was done until the desired sample size was achieved. Recruitment was done one week after delivery. It was done 7 days a week to capture mothers of preterm babies who were 1 week post delivery.

4.7 Study personnel

This included the principal investigator, and one trained research assistant. This was a qualified clinician who had completed his diploma course in clinical medicine. He was trained on all the procedures regarding the study. Further, the principal investigator collected the initial part of the data with the assistant just to make sure he had understood all the procedures.

4.8 Study procedure

All mothers of preterm babies, that met selection criteria, and gave consent were enrolled. A questionnaire was administered to capture maternal and neonatal information, and the diagnostic screening tool DASS-21 was administered. The interviews were carried out by the principal investigator or a trained research assistant.

4.9 Study tool

The questionnaire had three parts. The first part obtained maternal socio-demographic data, obstetric history and family and social history. The second part obtained neonatal history and parameters. The third part was the diagnostic screening tool for psychological distress-DASS-21.

The DASS-21 scale is a tool that can either be self-administered or administered by another party. Mothers who could comfortably read, comprehend, and write, and opted to fill on their own, were allowed to do so, but felt free to seek clarification where necessary, as the interviewer sat with them throughout the interview. The principal investigator or the research assistant administered the tool for those having any of the above problems, and in this study only the 4 mothers without any formal education required that the scale be administered to them. For those who found English difficult, the tool had been translated to Kiswahili. In this study, a score of 10 or more on the depression subscale was used to identify depression, a score of 8 or more on the anxiety subscale was used to identify anxiety, while a score of 15 or more on the stress subscale was used to identify stress. The DASS-21 is a user friendly tool that can be administered within 3-5 minutes, therefore it can be used on a more or less daily setting in a busy unit for screening.

5. DATA STORAGE, ANALYSIS AND PRESENTATION

Data was coded, cleaned, verified and analyzed using SPSS computer software. The maternal characteristics assessed included age, level of education, marital status, family income, parity, history of previous abortions and preterm birth, whether pregnancy was planned, and history of illness or medication use during pregnancy. Neonatal characteristics assessed included birth weight, gestational age at birth, oxygen therapy and neonatal feeding. Mean, median and standard deviation were used to summarise the data. Prevalence of postpartum psychological distress was described by simple proportion. Descriptive statistics were reported to describe the variables and inferential statistics were used to establish association between psychological distress and the various risk factors using a chi-square analysis for categorical variables. Multivariate logistic regression analysis was used to determine the factors independently associated with postpartum psychological distress among mothers of preterm neonates. Presentation of data was done in form of tables.

6. MINIMIZATION OF BIAS

Measures to avoid the various types bias included:

i. Measurement bias

- There was careful planning of the data collection process and pre testing the data collection tool,including the diagnostic screening tool DASS-21.

ii. Sampling bias

- Only those who met the eligibility criteria were included.

iii. Information bias

- The familiarization of the principal investigator and the research assistants with the information to be collected prior to implementation of the study.Extensive training of the research assistant was done.
- The researchers were not asking leading questions.
- The method of asking questions was harmonized

7. ETHICAL CONSIDERATIONS

1. Approval to carry out the study was granted by the KNH/UON Ethics and Research committee.
2. Written informed consent was issued to the mothers.
3. For mothers detected to have psychological distress, arrangements were made for them to receive the appropriate professional assessment and treatment.
4. Confidentiality of information collected was observed.
5. No cost was incurred by the study participants.

8. RESULTS

During the study period between August and November 2014, a total of 140 mothers of preterm neonates in the KNH newborn unit were eligible for participation in the study. Of these 5 mothers refused to take part. Thus 135 mothers of preterm neonates were finally recruited and took part in the study.

Socio-demographic characteristics

Table 3 summarises the background socio-demographic characteristics of the study participants

Table 3: Characteristics of the mothers of preterm neonates

Characteristic	Frequency (n=135)	%
Age (years)		
<25	41	30.4
25-34	79	58.5
>35	15	11.1
Marital status		
Married	107	79.3
Unmarried	28	20.7
Education		
≤Primary	55	40.8
Secondary	38	28.1
Higher education	42	31.1
Monthly family income(Ksh)		
≤10 000	42	31.1
10001-20000	36	26.7
20001-30000	23	17
30001-50000	21	15.6
>50000	13	9.6

The mean(sd) maternal age was 27.0±5.3 years, with most of the mothers (58.5%) aged between 25-34 years. Majority of the mothers (79.3%) were married. 28% of the mothers had attained secondary education while 31% had attained higher education. The minimum and maximum household income reported by the respondents was Ksh. 2000 and Ksh. 270000 per month

respectively. The median (interquartile range (IQR)) family income was 20000 (KSh. 10000 to KSh. 32000) per month. Overall, 31.1% of the mothers had a monthly family income of KSh. 10000 or less, while 9.6% reported a family income of more than KSh. 50000 per month.

Characteristics of the preterm newborns

Table 4 summarises the characteristics of the preterm neonates born to the mothers who took part in the study

Table 4: Characteristics of the preterm neonates

Characteristic	Frequency (n=135)	%
Gestation age at birth (weeks)		
≤27	7	5.2
28-31	47	34.8
32-33	40	29.6
≥34	41	30.4
Birth weight		
Extremely low (<1000g)	12	8.9
Very low (1000-1499g)	46	34.1
Low (1500-1999g)	61	45.2
Borderline low (2000-2499g)	16	11.9
Weight at time of interview		
<1000g	16	11.9
1000-1499g	51	37.8
1500-1999g	55	40.7
2000-2499g	13	9.6

The mean(sd) gestational age of the preterm neonates at birth was 32.0 ± 2.5 weeks. 5.2% of the neonates had a gestation age of 27 weeks or less at birth, while 30.4% were 34 weeks and above. The mean(sd) birth weight was 1532 ± 399 grams with 8.9% of the neonates being extremely low birth weight, 34.1% were very low birth weight, 45.2% were low birth weight, while 11.9%

were borderline low birth weight. The weight of the neonates at the time of the interview is as shown in table 4

Prevalence of postpartum psychological distress among mothers of preterm neonates in KNH newborn unit

Table 5 shows the prevalence of postpartum psychological distress, depression, anxiety and stress among mothers of preterm neonates in the KNH newborn unit.

Table 5: Prevalence of postpartum psychological distress among mothers of preterm neonates

Condition	Number (n=135)	Prevalence (95% CI)
Psychological distress	37	27.4% (19.9%-34.9%)
Depression	23	17.0% (10.7%-23.4%)
Anxiety	29	21.5% (14.5%-28.4%)
Stress	14	10.4% (5.8%-16.4%)

Out the 135 mothers of preterm neonates who were interviewed, 37 were found to have psychological distress, thus an overall prevalence of postpartum psychological distress of 27.4% (95% Confidence Interval (CI) 19.9%-34.9%). Out of these mothers, 23 were depressed, 29 mothers were anxious, while 14 mothers were stressed. Some of the mothers had 2 or all 3 of these conditions co-existing. A mother with any of the psychological disturbances i.e depression, anxiety or stress (or a combination of 2 or all 3 of them) was considered to have psychological distress. The prevalence of depression was 17.0% (95% CI: 10.7%-23.4%). The prevalence of anxiety was 21.5% (95% CI:14.5%-28.4%), while the prevalence of stress was 10.4% (95% CI:5.8%-16.4%).

Co-morbidities

Table 6 shows how the psychological conditions co-existed with one another

Table 6: Co-morbidities

Characteristics	Frequency	%
No. of conditions (n=37)		
1	18	48.6
2	8	21.6
3	11	29.7
Comorbidities(n=19)		
Depression and anxiety	1	5.3
Depression and stress	7	36.8
Depression, anxiety and stress	11	57.9

Of the 37 respondents who were found to have postpartum psychological distress, eighteen (48.6%) had only one condition (either depression, anxiety or stress). Eight (21.6%) had two of the three conditions while the rest (11, 29.7%) had all the conditions occurring concomitantly (Table 6)

Correlates of postpartum psychological distress

The current study also sought to determine the factors associated with postpartum psychological distress among mothers of preterm neonates admitted in the KNH newborn unit.

Sociodemographic factors

Table 7 summarises the association between selected sociodemographic attributes and postpartum psychological distress.

Table 7: Association between psychological distress and selected socio-demographic attributes

Characteristic	Total	Psychological Distress		OR (95% CI)	P-value
		Absent (n=98)	Present(n=37)		
Age (years)					
<25	41	21(51.2%)	20(48.8%)	4.314(1.925-9.665)	<0.001
≥25	94	77(81.9%)	17(18.1%)	Ref	
Marital status					
Unmarried	28	14(50.0%)	14(50.0%)	3.652(1.526-8.741)	0.003
Married	107	84(78.5%)	23(21.5%)	Ref	
Education					
≤Primary	55	34(61.8%)	21(38.2%)	2.471(1.142-5.347)	0.020
≥ Secondary	80	64(80.0%)	16(20.0%)	Ref	
Family income(KSh)					
<10000	31	11(35.5%)	20(64.5%)	9.305(3.780-22.904)	<0.001
≥10000	104	87(83.7%)	17(16.3%)	Ref	

On bivariate analysis, the age of the mother was significantly associated with psychological distress with a higher proportion of the younger mothers (< 25 years) reporting a higher prevalence of psychological distress as compared to their older counterparts aged 25 years or more (48.8% versus 18.1% respectively, OR = 4.314, 95% CI: 1.925-9.665, p<0.001). Marital status was also a significant determinant of psychological distress (p=0.003). Being unmarried was associated with about 3.7-fold increase in the likelihood of a mother of a preterm neonate being psychologically distressed (OR = 3.652 (95% CI: 1.526-8.741)). Having primary school or less as the highest level of education attained was found to increase the probability of being psychologically distressed by 2.5 times when evaluated against having secondary or higher education (OR=2.471(95%CI: 1.142-5.347), p=0.020). Low family income (less than Ksh. 10 000 per month) was found to increase the likelihood of postpartum psychological distress by about 9.3 times (OR=9.305(95% CI: 3.780-22.904), p<0.001).

Previous pregnancy factors

Table 8 presents the association between psychological distress among mothers with preterm neonates and their previous pregnancy characteristics.

Table 8: Association between psychological distress and previous pregnancy factors

Characteristic	Total	Psychological distress		OR (95% CI)	P-value
		Absent (n=98)	Present (n=37)		
Parity					
Primiparous	61	44(72.1%)	17(27.9%)	1.043(0.488-2.229)	0.913
Multiparous	74	54(73.0%)	20(27.0%)	Ref	
Previous abortions					
Yes	24	16(66.7%)	8(33.3%)	1.414(0.548-3.650)	0.473
No	111	82(73.9%)	29(26.1%)	Ref	
Previous preterm					
Yes	16	10(62.5%)	6(37.5%)	1.703(0.572-5.075)	0.335
No	119	88(73.9%)	31(27.3%)	Ref	

Parity was not a significant predictor of postpartum psychological distress among the mothers of preterm neonates ($p=0.913$). Although a higher proportion of mothers who reported having had an abortion in the past were found to be psychologically distressed when compared to their colleagues who reported on the contrary, this association did not reach statistical significance ($p=0.473$). Similarly, having a previous preterm delivery was not a significant factor for postpartum psychological distress among mothers with preterm neonates ($p=0.335$).

Antenatal and birth history

Table 9 summarises the association between antenatal and birth history and psychological distress

Table 9: Association between psychological distress and antenatal and birth history

Characteristic	Total	Psychological distress		OR (95% CI)	P-value
		Absent (n=98)	Present (n=37)		
Planned pregnancy					
No	47	29(61.7%)	18(38.3%)	2.254(1.036-4.903)	0.038
Yes	88	69(78.4%)	19(21.6%)	Ref	
History of illness during pregnancy					
Yes	44	30(68.2%)	14(31.8%)	1.380(0.625-3.044)	0.424
No	91	68(74.7%)	23(25.3%)	Ref	
Under medication during pregnancy					
Yes	55	36(65.5%)	19(34.5%)	1.818(0.846-3.904)	0.123
No	80	62(77.5%)	18(22.5%)	Ref	
Receive counseling regarding preterm delivery					
Yes	25	18(72.0%)	7(28.0%)	1.037(0.394-2.732)	0.941
No	110	80(72.7%)	30(27.3%)	Ref	

Mothers of preterm neonates who had not planned to be pregnant were about 2.3 times more likely to be in psychological distress (OR=2.254(95%CI: 1.036-4.903), p=0.038). Other factors including history of illness during pregnancy, medication use in pregnancy and counseling on preterm delivery were not significantly associated with prevalence of postpartum psychological distress among mothers with preterm neonates (Table 9).

Relationship between neonatal factors and psychological distress

Table 10 presents the association between psychological distress and characteristics of the newborns

Table 10: Relationship between neonatal factors and psychological distress

Characteristic	Total	Psychological distress		OR (95% CI)	P-value
		Absent	Present		
Birth weight (g)					
<1500	58	39(67.2%)	19(32.8%)	1.597(0.746-3.418)	0.226
≥1500	77	59(76.6%)	18(23.4%)	Ref	
Weight at the time of interview					
<1500	67	43(64.2%)	24(35.8%)	2.361(1.078-5.172)	0.030
≥1500	68	55(80.9%)	13(19.1%)	Ref	
Gestation age at birth (weeks)					
<32	54	38(70.4%)	16(29.6%)	1.203(0.559-2.590)	0.636
≥32	81	60(74.1%)	21(25.9%)	Ref	
Neonatal feeding					
Not on milk feeds	26	13(50.0%)	13(50.0%)	6.700(2.425-18.508)	<0.001
Partial milk feeds	32	18(56.3%)	14(43.8%)	5.211(1.987-13.664)	<0.001
Full milk feeds	77	67(87.0%)	10(13.0%)	Ref	
Oxygen therapy over the last week					
Yes	80	53(66.3%)	27(33.8%)	2.292(1.002-5.243)	0.046
No	55	45(81.8%)	10(18.2%)	Ref	

The weight of the neonates at the time of the interview was significantly associated with psychological distress among the study participants (p=0.030). Psychological distress was found to be 2.3 times more prevalent in mothers of neonates with lower weight at the time of the interview (less than 1500 grams) when evaluated against those who had a higher weight (≥1500 grams) (OR = 2.361(95% CI: 1.078-5.172), p = 0.030). Conversely, the weight of the neonate at the time of birth was not a significant determinant of postpartum psychological distress among mothers of preterm neonates (p=0.226). Neonatal feeding was a significant predictor of

psychological distress in the mothers. As compared to mothers of neonates who were on full milk feeds, mothers of neonates who were not on milk feeds at all, or mothers of neonates who were on partial milk feeds were, respectively, about 6.7 and 5.2 times more likely to be psychologically distressed. Mothers whose neonates had been on oxygen therapy for at least a day during the week prior to the survey were about 2.3 times more likely to be psychologically distressed (OR = 2.292(95% CI 1.002-5.243) p = 0.046). Gestational age at birth was not significantly associated with postpartum psychological distress.

Multivariate analysis

The maternal and neonatal variables that were significantly associated with postpartum psychological distress when bivariate analysis was carried out were subjected to multivariate analysis. The effect of each of the selected independent variables was modeled against psychological distress while controlling for the other independent factors. The outputs of the binary logistic regression are outlined in Tables 11 and 12.

Maternal Factors

Table 11: Logistic regression output: Maternal factors predictive of psychological distress

Variable	aOR [#]	95% CI		P-value
		Lower	Upper	
Age	0.988	0.412	2.369	0.978
Marital status	1.138	0.389	3.328	0.814
Level of education	0.439	0.203	0.952	0.037
Unplanned pregnancy	0.433	0.176	1.065	0.068
Monthly family income	5.294	1.778	15.759	0.003

[#]Adjusted odds ratio

Maternal factors that were found to be independent predictors of postpartum psychological distress among mothers of preterm neonates were, having the level of education achieved as below secondary and a low family income. Mothers who had achieved secondary and above education had a fifty six percent reduction in the likelihood of having psychological distress. A low family income (less than Sh. 10000 per month) was associated with a 5.9 times increased likelihood of having postpartum psychological distress in mothers of preterm neonates.

Neonatal Factors

Table 12: Logistic regression output: Neonatal factors predictive of psychological distress

Variable	aOR [#]	95% CI		P-value
		Lower	Upper	
Weight at the time of recruitment	0.569	0.255	1.272	0.169
Oxygen therapy over the last week	1.627	1.194	2.218	0.010
Neonatal feeding				
Not on milk feeds	3.483	1.193	10.174	0.022
Partial milk feeds	2.602	0.966	7.014	0.059

Neonatal factors that were found to be independent predictors of postpartum psychological distress among mothers of preterm neonates were oxygen therapy, and having a neonate not on milk feeds. Mothers of neonates who had received oxygen during the previous week were 1.6 times more likely to be psychologically distressed compared to their counterparts that had not received oxygen. Having a neonate who is not on any milk feeds at all increased the likelihood of having psychological distress by about 3.5 times.

9.DISCUSSION, CONCLUSION AND RECOMMENDATIONS

9.1DISCUSSION

Postpartum psychological disorders can complicate the postnatal period for a mother. This has negative consequences for both the mother and the baby. Mothers of preterm neonates are at a higher risk of psychological distress, due to factors such as increased infant risk of mortality and morbidity, the enforced separation of the parent from the neonate, anticipated extended hospital stay and costs and the crisis atmosphere in the newborn unit. This study is a valuable source of local data on the magnitude of this problem and has identified risk factors for postpartum psychological distress among mothers of preterm neonates, and this will guide in the formulation of interventions. The current study was a hospital based cross-sectional study whose objectives were to determine the prevalence and factors associated with postpartum psychological distress among mothers of preterm neonates in the KNH newborn unit.

The prevalence of postpartum psychological distress among mothers of preterm neonates in the KNH newborn unit was 27.4%. The prevalence found in this study is similar to the 27.3% reported by Upkong et al,²⁰ in Obafemi Awololo University Teaching Hospital in Nigeria, and the 29.4% reported by Bener in his study in Hamad General Hospital, Qatar²¹. In their study, Upkong and his colleagues had also compared the prevalence of psychological distress among mothers of preterm neonates and those of term neonates, and they found a higher prevalence among mothers of preterm neonates. The prevalence of postpartum psychological distress in the present study was however, lower than the 36.8% reported by Upkong in another study done at the Wesley Guild hospital, Ilesa Nigeria²². Though done in a teaching hospital similar to that of the current study, this Nigerian study was conducted on mothers whose babies were admitted in the neonatal intensive care unit, such neonates are considered high risk for morbidity and mortality and this could explain the higher prevalence of psychological distress.

Depression was found in 17% of the mothers of preterm neonates that took part in this study. This is comparable to what Upkong and his colleagues found in the Nigerian study (15.1%), but lower than Bener's findings in his Qatar study (29.4%). In his study in which he compared the prevalence of depression between mothers of preterm and those of term neonates within 6 months of postnatal period, Bener also found that mothers of preterm neonates were more likely to be depressed than mothers of term neonates.²¹ Anxiety was present in 21.5% of our study

participants. This is comparable to the 26.5% found in the Qatar study by Bener.²¹ The prevalence of stress in the current study was 10.4%. This is similar to what Bener found in the study described above (11.2%).

In the current study, it was demonstrated that younger maternal age was significantly associated with postpartum psychological distress among mothers of preterm neonates (OR =4.3; $P < 0.001$). This is comparable to what was found in the Qatar study by Bener,²¹ that determined that younger mothers were more likely to be psychologically distressed ($P = 0.031$). Young mothers may not have developed the emotional maturity, coping or financial capability to navigate the decisions thrust upon them by motherhood, and moreover the unexpected premature birth. In Qatar, for example early marriages are common with the minimum age at marriage being 16 years for girls.

The odds of psychological distress were 3.7 times higher among unmarried mothers of preterm neonates compared to married mothers. The unmarried mothers were either widowed or dropped out of school due to teenage pregnancy. The absence of a supportive partner to assist in making decisions regarding the fragile premature neonate could be what makes these mothers more prone to psychological problems. For some of these mothers, who are also the sole bread winners, having to stay in the hospital for a long time puts further strain on their finances and this increases their tendency to be psychologically disturbed.

It was demonstrated that mothers of preterm neonates who had achieved secondary or higher level of education had lower odds of being psychologically distressed (AOR=0.44, 95% CI 0.2-0.9). This is comparable with the findings of other studies^{21,29,30}. In the Qatar study, Bener also demonstrated decreasing odds of psychological distress among mothers who had secondary education or higher (AOR=0.7, $P = 0.02$). Illiterate or less educated mothers usually have less knowledge on child-rearing practices, and in this situation where the newborn is preterm, the challenge is greater. This group of mothers also may have less problem solving skills, leading to inability to make certain decisions regarding their preterm newborn.

This study showed a significant association between unplanned pregnancy and the odds of psychological distress among mothers of preterm neonates. This is in agreement with Bener's study in Qatar, that found out that mothers of preterm neonates who had not planned to be

pregnant were more likely to suffer psychological distress ($P=0.03$)²¹. This is likely because having a child that is not planned for is a big challenge and when such a child is born prematurely, the situation becomes more stressful for the parent.

The current study showed a strong association between low family income and increasing odds of psychological distress ($AOR=5.3$, $P=0.003$). This finding is in line with the findings of other studies^{21,30,31}. The Qatar study showed that mothers of preterm neonates who came from poorer families were more likely to have psychological distress ($P=0.03$). Preterm birth is marked by prolonged hospitalization for the baby, and often the mother who also has to remain within the hospital. This is associated with increased hospital costs which becomes a constant source of worry for the poor parent. The stress and worry is further aggravated by the fact that the mother has to be away from her day to day income generating activities, which worsens her financial situation.

Parity, history of previous preterm birth, and previous abortions were not significant factors for postpartum psychological distress among mothers of preterm neonates. This is contrary to what was found in the Qatar study²¹, which showed that primiparous women, those who had previous abortions and previous preterm birth had a significantly higher likelihood of psychological distress. Qatar is a country characterized by early marriages, therefore the increased tendency of these first time mothers to be psychologically distressed is probably because majority are very young and lack maturity and coping skills, compared to the Kenyan set up, where the age at marriage is higher. The lack of significant association between previous preterm birth and previous abortions and psychological distress in this study is probably due to methodological differences, the numbers that had these characteristics were smaller compared to the Qatar study which had a larger sample size. In this study, the sample size was limited by the relatively shorter study duration allocated, therefore further studies with a larger sample size are required to conclude satisfactorily on the risk associated with these two variables.

Birth weight and gestational age at birth were not associated with postpartum psychological distress among mothers of preterm neonates in this study. This is different from the findings of the NICU study by Upkong,²² in which he found that lower birth weight and gestational age at birth were associated with significantly increased likelihood of having psychological distress in the mother. The difference between this study and ours may be because Upkong's study was done

in a neonatal intensive care unit, where there is a high concentration of the most premature neonates and those with the lowest birth weights.

The neonatal weight at the time of the interview was however, found to increase the odds of psychological distress among mothers of preterm neonate (OR=2.4, P=0.03). Preterm neonates lose a significant proportion of their weight during the first week of life, and some lose more than others. Mothers of preterm neonates are often concerned about the little weight of their babies, and are likely to get more worried when they realize that their baby is even losing more weight. This may be because they tend to associate the little weight with increased vulnerability and likelihood of a poor outcome.

For mothers whose neonates were on oxygen therapy for at least a day during the previous week, the odds of psychological distress was 1.6 times higher (p=0.01). Similarly, mothers whose preterm neonates were not on milk feeds at all were significantly more likely to be psychologically distressed (AOR=3.5, 95% CI 1.2-10.2, P=0.02). This is in agreement with previous studies,^{30,32} which showed that mothers with sicker babies were significantly more likely to suffer psychological distress. Oxygen therapy and inability to be on milk feeds are considered to be indices of severe illness in a neonate. Mothers of such neonates are often aware of the degree of morbidity and the risk of mortality for their baby and this could explain why they are more likely to be psychologically distressed.

9.2 CONCLUSION

1. The prevalence of postpartum psychological distress among mothers of preterm neonates in the KNH newborn unit was 27.4%. Depression was present in 17%, anxiety was present in 21.5%, while stress was present in 10.4% of all the mothers.
2. Maternal risk factors for postpartum psychological distress among mothers of preterm neonates were younger age, low level of education, low family income, single motherhood, and having not planned to be pregnant.
3. Neonatal risk factors for postpartum psychological distress among mothers of preterm neonates were oxygen therapy, lower weight at the time of the interview, and nil milk feeds.

4. The independent predictors of postpartum psychological distress among mothers of preterm neonates in the KNH newborn unit were low level of maternal education, low household income, oxygen therapy, or a neonate not on milk feeds.

9.3 RECOMMENDATIONS

1. Health care workers in newborn units should have a high index of suspicion for psychological distress among mothers of preterm neonates, particularly those with the above risk factors.
2. Support structures for mothers with preterm neonates need to be put in place in the newborn unit, and this will help in prevention as well as management of those affected.

10. STUDY LIMITATIONS

1. The study relied on information given by mothers, and some mothers could have given inaccurate information. This was minimized by doing the interviews in private, making them feel at ease. Secondly they were promised confidentiality of the information collected.
2. As this was a cross-sectional study, it was not possible to establish the temporal sequence of the psychological status of the mothers. Therefore, at the point of interpretation of the study findings, it should be borne in mind that the study depicts the findings of psychological distress during the early postpartum period.
3. Interpretation or understanding of the questions created a few difficulties. This was addressed by having the principal investigator or research assistant clarify anything that the participant found unclear.

11. REFERENCES

1. JE Lawn, March of Dimes, PMNCH, Save the children, WHO. Born Too Soon: The Global Action Report on Preterm Birth. Geneva: World Health Organization; 2012.
2. Robert M, Richard E, Nina F. Nelson Textbook of Pediatrics. 19th ed. Philadelphia (USA): Saunders; 2011.
3. Leigh D, Heather M, Helen E. Mothers involvement in caring for their preterm infants: an historical overview. *Journal of Advanced Nursing* 2003;42:578-586.
4. Birbring G, Dwyer T, Huntington D, et al. The study of psychological process in pregnancy and the earliest mother-child relationship. *Psychoanal Study Child* 1961;16:9-24.
5. Kitzinger S. Education and counseling in childbirth. London: Macmillan publishing Ltd; 1997.
6. Taylor P, Hall B. Parent-infant bonding: Problems and opportunities in a perinatal center. *Semin Perinatol* 1979;3:73-84.
7. Brazelton T. Effect of maternal expectations on early infant behavior. *Early Child Dev care* 1973;2:259-273.
8. Williams J. Psychology of women. New York: Norton and company Inc; 1977.
9. Fawcett J. The relationship between identification and patterns of change in spouses' body images during and after pregnancy. *Int J Nurs Stud* 1977;14:199-213.
10. Grossman F, Eichler L, Winickoff S. Pregnancy, Birth and parenthood. San Francisco (USA): Jossey-Bass Publishers; 1980.
11. Leigh D. Factors influencing interaction between a mother and her premature infant. Brisbane (Australia): Queensland University of Technology; 2003.
12. Sophie S, Brett J, Maggie R, et al. Family centred care in neonatal units: A summary of research results and recommendations from the Poppy project. London: NCT; 2009.
13. Leigh D, Hellen E, Heather M, et al. The impact of very premature birth on the psychological health of mothers. *Early Human Development* 2003;73:61-70.
14. Jotzo M, Poets C. Helping parents cope with the trauma of premature birth: an evaluation of trauma-preventive psychological intervention. *Pediatrics* 2005;115:915-9.
15. Gross S, Mettelman B, Dye T, et al. Impact of family structure and stability on academic outcome in preterm children at 10 years of age. *J Pediatr* 2001;138:169-75.

16. Muller-Nix C, Forcada-Guex M, Pierrehumbert B, et al. Prematurity,maternal stress and mother-child interactions.Early Hum Dev 2004;72:145-58.
17. Reck C, Struben K, Backenstrass M, et al. Prevalence, onset and comorbidity of postpartum anxiety and depressive disorders. ActaPsychitricaScandinavica2008 ;118:459-468.
18. Deirdre R, Xanthoula K. Psychiatric disorders in the postpartum period.BCMJ 2005;47:100-103.
19. Misri S, Reebye P.The use of paroxetine and cognitive behavioural therapy in postpartum depression and anxiety:A randomized controlled trial.Journal of clinical psychiatry 2004 ;65:1236-1241.
20. Upkong D, Fatoye F, Oseni S, et al. Post partum emotional distress among mothers of preterm infants: a controlled study.EastAfr Medical J 2003;80:289-92.
21. Bener A. Psychological distress among post partum mothers of preterm infants and associated factors: a neglected public health problem.Rev Bras Psiquiatr 2013;35:231-6.
22. Upkong D. Factors associated with psychological morbidity in mothers of preterm infants:a study from Wesley Guild Hospital,Nigeria.JObstetGynaecol 2011;31:146-8 .
23. Meyer E, Garcia C, Seifer R, et al. Psychological distress in mothers of preterm infants. J Dev BehavPediatr 1995;16:412-7.
24. Lovibond S, Lovibond P. Manual for the Depression Anxiety Stress Scales.2nd edition. Sydney: psychology foundation;1995.
25. Nieuwenhuijsen K, Boer A, Verbeek J, et al. The Depression Anxiety Stress Scales (DASS):detecting anxiety disorders and depression in employees absent from work because of mental health problems. Occup Environ Med 2008;60:77-82.
26. Lovibond P, Lovibond S. The structure of negative emotional states: comparison of the Depression Anxiety Stress Scales(DASS) with the Beck Depression and Anxiety Inventories. Behaviour Research And Therapy 1995;33:335-343.
27. University of New South Wales. Depression Anxiety Stress Scales (internet). c1995 (updated 2013 Jan 29: cited 2014 Feb18). Availablefrom:<http://www2.psy.unsw.edu.au/groups/dass/>.
28. Thomas F, Fritz N. Naegele's rule: a reappraisal. Br J ObstetGynaecol 2000;107:1433-1435.

29. Miles M, Burchinal P, Holditch-Davis D, et al. Perceptions of stress, worry, and support in black and white mothers of hospitalized, medically fragile infants. *J PediatrNurs* 2002;17:82-8.
30. Holditch-Davis D, Miles M, Weaver M, et al. Patterns of distress in African-American mothers of preterm infants. *J Dev BehavPediatr* 2009;30:193-205.
31. Halpern L, Brand K, Malone A. Parenting stress in mothers of very-low-birth-weight (VLBW) and full-term infants: a function of infant behavioral characteristics and child-rearing attitudes. *J PediatrPsychol* 2001;26:93-104.
32. Blumberg N. Effects of neonatal risk, maternal attitude, and cognitive style on early post-partum adjustment. *Journal ofAbnormal Child Psychology* 2006;89:139–150.

12 APPENDICES

APPENDIX 1:QUESTIONNAIRE

**Study Title: PREVALENCE OF POSTPARTUM PSYCHOLOGICAL DISTRESS
AMONG MOTHERS OF PRETERM NEONATES IN KNH NEWBORN UNIT**

Socio-Demographic data

Date _____

Study no _____

1.Age _____

2.Marital status	Single	(1)	<input type="checkbox"/>
------------------	--------	-----	--------------------------

Married	(2)
---------	-----

Divorced/Separated	(3)
--------------------	-----

Widowed	(4)
---------	-----

2b. For those married,type of marriage	Monogamous	(1)	<input type="checkbox"/>
--	------------	-----	--------------------------

Polygamous	(2)
------------	-----

2c. For those widowed,duration of the loss _____

3.Level of education	None	(1)	<input type="checkbox"/>
----------------------	------	-----	--------------------------

Primary	(2)
---------	-----

Secondary	(3)
-----------	-----

College/University	(4)
--------------------	-----

4.Occupation _____

Past obstetric history

5.ParityPrimiparous (1)

Multiparous (2)

6.If multiparous, number of children _____

7.Previous abortions yes No

7b.If yes how many times?_____

8.Previous children lost(died) yes No

8b.If yes how many times? _____

9.Previous preterm delivery Yes No

9b.If yes how many times?_____

Recent obstetric history

10.Was this pregnancy planned ? Yes No

11.History of illness during pregnancy Yes No

11b.If yes specify diagnosis _____

12.Alcohol intake during pregnancy Yes No

13.Cigarette smoking during pregnancy Yes No

14.Medication use during pregnancy Yes No

14b. If yes, specify the drugs used _____

14c.Currently on medication Yes No

14d. If yes, specify current medications _____

15. Gestation in weeks at delivery _____

15b. Method used to determine gestation Naegele's formula (1)

Obstetric ultrasound scan(2)

Finnstrom score of the baby (3)

15c. If Naegele's formula, last menstrual period _____

15d. If obstetric ultrasound, date of scanning _____

15e. Gestation at the time of scanning _____

15f. If Finnstrom maturity assessment, Finnstrom score _____

16. Was preterm delivery spontaneous or induced? _____

16b. If induced what was the indication? _____

17. Mode of delivery Vaginal (1)

Caesarean section (2)

17b. If caesarean section what was the indication? _____

18. Were there birth complications? Yes No

18b. If yes specify _____

19. Did you receive counseling regarding preterm delivery? Yes No

19b. If yes when was counseling done? Before delivery (1)

After delivery (2)

Family and social history

20. Family income per month (ksh) _____

21. For those single, has the father of the baby acknowledged the pregnancy yes No

21b. Is the father of the baby supportive Yes No

22. For those married, Spouse's occupation _____

22b. Does your spouse live with you? Yes No

22c. If no why? _____

22d. Does your spouse take alcohol? Yes No

22e. If yes, to what extent? Minimal (1)

Moderate (2)

Heavy (3)

22f. Is your spouse abusive towards you? Yes No

22g. If yes, specify _____

22 h. Does your spouse cater for your family expenses? Yes No

22i. Has he come to the hospital to see you and the baby? Yes No

23. Number of people in the household _____

24. Specify people in the household and whether they are supportive or not. (Options include spouse, mother, mother in law, sister, sister in law, brother, brother in law, cousin, friend etc).

Supportive (Yes or No)

1 _____

2 _____

3 _____

Neonatal characteristics

25. Birth weight in grams _____

26. Current weight in grams _____

27. Gestational age at birth in weeks _____

28. Sex _____

29. Where admitted over the last week	NICU	(1)	
General NBU	(2)		<input type="checkbox"/>
Both	(3)		
29b. If admitted in NICU, no of days there	_____		
29c. Currently in NICU	Yes	No	<input type="checkbox"/>
30. Oxygen therapy over the last week	Yes	No	<input type="checkbox"/>
30b. If yes no of days	_____		
30c. Currently on oxygen	Yes	No	<input type="checkbox"/>
31. Presence of neonatal illness	Yes	No	<input type="checkbox"/>

31b.If yes specify diagnosis and Management

DiagnosisManagement

_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____

32.Current type of feed Oral feeds (1)

Parenteral feeds (2)

Both (3)

32b.For those on oral feeds,mode of feeding NG tube feeding (1)

Cup feeding (2)

Breastfeeding (3)

32c.Type of oral feed Breast milk (1)

Formula milk (2)

32d.Type of parenteral feeds Intravenous fluids (1)

Total Parenteral nutrition (2)

32e. If on oral feeds, is the baby retaining? Yes No

32f.Total amount of milk in mls/kg Yes No

APPENDIX 2: Depression Anxiety and Stress Scale (DASS-21)

DASS 21	<i>Name:</i>	<i>Date:</i>
<p>Please read each statement and circle a number 0, 1, 2 or 3 which indicates how much the statement applied to you <i>over the past week</i>. There are no right or wrong answers. Do not spend too much time on any statement.</p> <p><i>The rating scale is as follows:</i></p> <p>0 Did not apply to me at all</p> <p>1 Applied to me to some degree, or some of the time</p> <p>2 Applied to me to a considerable degree, or a good part of the time</p> <p>3 Applied to me very much, or most of the time</p>		
1	I found it hard to wind down	0 1 2 3
2	I was aware of dryness of my mouth	0 1 2 3
3	I couldn't seem to experience any positive feeling at all	0 1 2 3
4	I experienced breathing difficulty (eg, excessively rapid breathing, breathlessness in the absence of physical exertion)	0 1 2 3
5	I found it difficult to work up the initiative to do things	0 1 2 3
6	I tended to over-react to situations	0 1 2 3
7	I experienced trembling (eg, in the hands)	0 1 2 3
8	I felt that I was using a lot of nervous energy	0 1 2 3
9	I was worried about situations in which I might panic and make a fool of myself	0 1 2 3
10	I felt that I had nothing to look forward to	0 1 2 3
11	I found myself getting agitated	0 1 2 3

12	I found it difficult to relax	0	1	2	3
13	I felt down-hearted and blue	0	1	2	3
14	I was intolerant of anything that kept me from getting on with what I was doing	0	1	2	3
15	I felt I was close to panic	0	1	2	3
16	I was unable to become enthusiastic about anything	0	1	2	3
17	I felt I wasn't worth much as a person	0	1	2	3
18	I felt that I was rather touchy	0	1	2	3
19	I was aware of the action of my heart in the absence of physical exertion (eg, sense of heart rate increase, heart missing a beat)	0	1	2	3
20	I felt scared without any good reason	0	1	2	3
21	I felt that life was meaningless	0	1	2	3

DASS- SWAHILI

DASS 21	<i>Jina:</i>	<i>Tarehe:</i>
Tafadhali soma kilataarifanauwekemviringokwanambari ambayoinaashiriakiwangoambachotaarifailihusiananawekwamudawa Hakunamajibusahihi au yasiosahihi. Usitumiemudamwingizaidikwataarifayoyote.	0,1,2 wiki	au 3 mojailiyopita.
Ridhaayakuratibunikamaifuatayo:		
0 Haikunitendekeahatakidogo		
1 Iinitendekeakwakiwango, au kwawakatimwingine		
2 Iinitendekeakwakiwangokiasi, au kwawakatimwingi		
3 Iinitendekeazaidi au maranyingi		
1	Niliona ugumu wa kupumzika/kustarehe	0 1 2 3
2	Nilikuwanafahamukukaukakwamdomowangu	0 1 2 3
3	Sikuwezakuhisihisiazozotenzurikamwe	0 1 2 3
4	Nilikuwanashidayakupumua (kwamfanokupumuakwakasisana, kukosahewayakutoshahatawakatihautumiinguvu)	0 1 2 3
5	Nilionaugumuwakupatamotishayakufanya mambo	0 1 2 3
6	Nilionaikiwarahisikwangukulipukakwahali	0 1 2 3
7	Nilikuwa natetemeka (kwa mfano mikono)	0 1 2 3
8	Nilihisikuwanilikuanatumianguvunyikingwasababuyauwoga/hofu	0 1 2 3
9	Nilikuwanawasiwasikuhusuhaliambazoningetetemekanakufanyanione kanemji nga	0 1 2 3

10	Nilihisikuwasikuwanachochote cha kutarajia	0	1	2	3
11	Nilijionanikiwasinautulivu	0	1	2	3
12	Nilionaikiwavigumukustarehe	0	1	2	3
13	Nilihisikuvunjikamoyonakuhuzunika	0	1	2	3
14	Sikuwanauvumilivukwachochotekilichonizuianisiendeleenachenyenilikuwanaf anya	0	1	2	3
15	Nilihisinikiwakaribukutetemeka	0	1	2	3
16	Nilishindwakuchangamkiajambololote	0	1	2	3
17	Nilihisisikuwawathamani	0	1	2	3
18	Nilihisikuwaningekasirishwaharaka	0	1	2	3
19	Nilikuwanafahamuujinsimoyowanguulikuwaukifanyakaziwakatisitumii Nguvu (kwamfano,kuhisimpigowamoyoukiongezeka, moyoukikosakupigakidogo)	0	1	2	3
20	Nilihisikuogopa bila sababunzuri	0	1	2	3
21	Nilihisimaishahainamaana	0	1	2	3

APPENDIX 3: DASS normative table

(if using the DASS 21 item version, multiply the score obtained by 2)

	Depression	Anxiety	Stress
Normal	0—9	0—7	0—14
Condition present	10 or more	8 or more	15 or more

In this study a score of 10 or more on the depression subscale was used to detect depression, a score of 8 or more on the anxiety subscale identified anxiety, while a score of 15 or more on the stress subscale was used to identify stress.

APPENDIX 4: CLIENT INFORMATION AND CONSENT FORM

Patient's study identification number _____

Date _____

Study Title: PREVALENCE OF POSTPARTUM PSYCHOLOGICAL DISTRESS AMONG
MOTHERS OF PRETERM NEONATES IN KNH NEWBORN UNIT

Investigator: Dr.AliceNkiroteNyaribari (MBChB)

Paediatrics Resident, University Of Nairobi

Tel Number: 0721557138

Supervisors: Prof Fred Were

Professor (Neonatologist), Department Of PaediatricsandChildhealth,

University Of Nairobi

Dr.JosephineOmondi

Consultant Psychiatrist (Subspeciality in Child Psychiatry),

Kenyatta National Hospital

Investigator's statement

We are requesting you and your baby to kindly participate in this research study. The purpose of this consent form is to provide you with the information you will need to help you decide whether to participate in the study. The process is called informed consent. Please read this consent information carefully and ask any questions or seek clarification on any matter concerning the study with which you are uncertain.

Introduction

Preterm birth is a critical event in the life of a mother and is often associated with psychological problems. Some mothers may develop problems such as depression, anxiety and stress. Occurrence of psychological distress may be related to some risk factors. By conducting some screening tests, it is possible to detect a mother with psychological distress. This study seeks to establish if you are experiencing significant psychological symptoms and to identify factors leading to your experience.

Study Procedure

A questionnaire will be administered to mothers of preterm babies. For the first part of the questionnaire, the researcher will ask the questions and fill the answers appropriately. For the diagnostic screening tool (DASS-21), the participants who are literate and opt to, will fill on their own, while the illiterate participants or those who opt for assistance, will be assisted by the researcher to read the questions and fill in the answers.

Benefits

The results of the study will be shared with you. If the results indicate that you are experiencing significant psychological symptoms, arrangements will be made for you to receive professional assessment and management, and this will enable you take better care of your baby. The results of the research will be used by the caregivers in this unit and other units to take better care of other mothers and their preterm babies.

Risks

There will be no risks to you or your baby during the study. There will be no invasive procedures carried out during the study that may harm your baby.

Refusal to participate will not jeopardize the treatment of your baby in any way.

Voluntariness

The study will be fully voluntary. There will be no financial rewards to you for participating in the study. One is free to participate or withdraw from the study at any point. Refusal to participate will not compromise your baby's care in any way.

Confidentiality

The information obtained about you, your baby and your family will be kept in strict confidentiality. No specific information will be released to any person without your permission. We will however, discuss general overall findings regarding all mothers assessed but nothing specific will be discussed regarding your psychological status. We will also not reveal your identity or that of your baby in these discussions.

Problems or Questions

If you ever have any questions about the study or about the use of the results you can contact the principle investigator, Dr. Alice Nyaribari by calling 0721-557138.

If you have any questions on your rights as a research participant you can contact the Kenyatta National Hospital Ethics and Research Committee (KNH-ESRC) by calling 2726300 Ext 44355.

Consent Form: Participant's statement

I _____ having received adequate information regarding the research, risks and benefits hereby AGREE/DISAGREE (cross out as appropriate) to participate in the study with my baby. I understand our participation is fully voluntary and that I am free to withdraw at any time. I have been given adequate opportunity to ask questions and seek clarification on the study and these have been addressed satisfactorily.

Mother's signature _____ Date _____

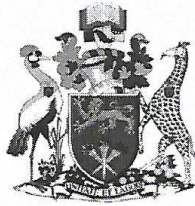
I _____ declare that I have adequately explained to the above participant, the study procedure, risks, benefits and given her time to ask questions and seek clarification regarding the study. I have answered all the questions raised to the best of my ability.

Interviewer's signature _____ Date _____

APPENDIX 5: BUDGET

ITEM	QUANTITY	UNIT PRICE	TOTAL
Biro pens	10	20	200
Pencils	10	10	100
Box file	2	100	200
Printing and photocopying	1	15,000	15,000
Final proposal booklet	1	10,000	10,000
Poster	1	5,000	5,000
Data statistician	1	20,000	20,000
Research assistant	2	10,000	20,000
Miscellaneous			20,000
TOTAL			90,500

APPENDIX 6: ETHICAL APPROVAL



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



KNH/UON-ERC
Email: uonknh_erc@uonbi.ac.ke
Website: www.uonbi.ac.ke



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

Ref: KNH-ERC/A/136

Link: www.uonbi.ac.ke/activities/KNHUoN

9th May 2014

Dr. Alice Nkirote Nyaribari
Dept. of Paediatrics & Child Health
School of Medicine
University of Nairobi

Dear Dr. Nyaribari

RESEARCH PROPOSAL: PREVALENCE OF POSTPARTUM PSYCHOLOGICAL DISTRESS AMONG MOTHERS OF PRETERM NEONATES IN KENYATA NATIONAL HOSPITAL NEWBORN UNIT (P105/02/2014)

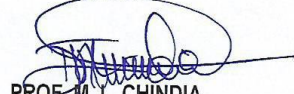
This is to inform you that the KNH/UoN-Ethics & Research Committee (KNH/UoN-ERC) has reviewed and **approved** your above proposal. The approval periods are 9th May 2014 to 8th May 2015.

This approval is subject to compliance with the following requirements:

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

For more details consult the KNH/UoN ERC website www.uonbi.ac.ke/activities/KNHUoN.

Yours sincerely



PROF. M. L. CHINDIA
SECRETARY, KNH/UON-ERC

- c.c. The Principal, College of Health Sciences, UoN
 The Deputy Director CS, KNH
 The Chairperson, KNH/UoN-ERC
 The Assistant Director, Health Information, KNH
 The Dean, School of Medicine, UoN
 The Chairman, Dept. of Paediatrics & Child Health, UoN
 Supervisors: Prof. Fred Were, Dr. Josephine Omondi