

**THE PSYCHOSOCIAL BURDEN AND QUALITY OF LIFE OF MOTHERS WITH
PRETERM BIRTH VERSUS TERM BIRTH AT KENYATTA NATIONAL HOSPITAL
(A MIXED METHODS STUDY)**

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DECLARATION

I hereby declare that this dissertation is my original work with the guidance of my supervisors and to the best of my knowledge has not been presented elsewhere for the award of a degree.

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DEDICATION

I dedicate this work to my son Bedan Mwaniki and daughter Jasmine Kamunya, may you find happiness in knowledge and in the Lord.

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LIST OF ABBREVIATIONS

ART	Assisted Reproductive Technology
CRH	Corticotrophin Releasing Hormone
DES	Di Ethyl Stilbesterol
ERC	Ethics Review Committee
FIRS	Fetal Inflammatory Response Syndrome
IBM	International Business Machines
IVH	Intraventricular hemorrhage
KNH	Kenyatta National Hospital
MHC	Major Histocompatibility Complex
MIAC	Microbial Invasion of Amniotic Cavity
NEC	Necrotizing Enterocolitis
NBU	New Born Unit
NICU	Neonatal Intensive Care Unit
PMN	PolyMorph Nuclear cells (Granulocytes)
PPROM	Preterm Premature Rupture of Membranes
PRR	Pattern Recognition Receptors
QoL	Quality of life
RDS	Respiratory Distress Syndrome
SPSS	Statistical Package for Social Sciences
TNF α	Tumor Necrosis Factor alpha

UON	University of Nairobi
UTI	Urinary Tract Infection
WHO	World Health Organization
WHOQOL-BREF	World Health Organization's Quality of Life assessment tool
ZBI	Zarit Burden Interview

DEFINITION OF KEY TERMS

Preterm birth: Delivery at gestation of less than 37wks + 0 days (<259 days). It is further sub-classified as:

- ✓ Extremely preterm: < 28 weeks gestational age
- ✓ Very preterm: 28 - 32 weeks gestational age
- ✓ Moderate to late preterm: 32 - <37 weeks gestational age

Term birth: Delivery at a gestation of above 37 weeks + 0 days (≥259 days) i.e.

Early Term: 37 wks 0 days – 38 wks 6 days

Full Term: 39 wks 0 days – 40 wks 6 days

Late Term: 41 wks 0 days – 41 wks 6 days

Post Term: ≥42 wks 0 days

Quality of Life: An individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns.

Domains	Facets incorporated within domains
1. Physical health	Activities of daily living; Dependence on medicinal substances and medical aids; Energy and fatigue; Mobility Pain and discomfort; Sleep and rest Work Capacity
2. Psychological	Bodily image and appearance; Negative feelings; Positive feelings; Self-esteem; Spirituality / Religion / Personal beliefs Thinking, learning, memory and concentration
3. Social relationships	Personal relationships; Social support; Sexual activity
4. Environment	Financial resources; Freedom, physical safety and security; Health and social care: accessibility and quality; Home environment Opportunities for acquiring new information and skills Participation in and opportunities for recreation / leisure activities;

	Physical environment (pollution / noise / traffic / climate); Transport
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ABSTRACT

Background: Globally there are 13 million premature babies born annually. Prematurity comes with an increased demand in care, neonatal morbidity and mortality as well as attendant long term sequelae. These pose a burden to the baby, the mother, the community and the health system. Locally there is paucity of data on the psychosocial burden experienced by women who have had preterm delivery compared to their counterparts with term deliveries and how that may consequently affect their quality of life.

Objective: This study evaluated the psychosocial burden and quality of life of women with preterm birth compared to those with term birth in Kenyatta National Hospital (KNH).

Methodology: The study adopted a mixed method design: Descriptive cross-sectional study and Qualitative methods using Focused Group Discussions for aspects not captured in the quantitative assessment tools. The study recruited 267 mothers with preterm birth and 814 mothers with term birth from the labour and post natal wards of KNH. The Zarit Burden Interview and WHOQOL-BREF tools were administered to assess the psychosocial burden and Quality of life respectively. The participants were then subjected to focused group discussions in groups of 5-10 where their reported subjective burden was assessed. The data was cleaned and analyzed into frequencies, odds ratios, percentages, tables, charts and bar graphs. Linear regression using proportional odds and multivariate analysis was used for adjusting and analyzing confounders and associated factors. The level of significance was set at $P < 0.05$ for comparisons of the two groups.

Results: Mothers with preterm birth had lower education levels (primary/no education in 30.7% vs. 18.8% and tertiary education 27.7% vs. 39.4%) in preterm vs. term birth mothers respectively ($p < 0.0001$). Mothers with preterm birth were more likely to be unemployed with a smaller proportion on formal employment compared to the term mothers (14.2% vs. 24.7%, $p < 0.0002$). They had a 12% chance of suffering greater burden (OR 1.12; C.I. 0.81, 1.53) compared to term mothers. The preterm birth mothers' quality of life was lower in the physical (52.30% vs. 50.12%, $P = 0.0187$) and environmental domains (65.03% vs. 62.30%, $P = 0.0014$) the preterm birth mothers who were breastfeeding their neonates also had a better quality of life. The Focused Group Discussions revealed the greater burden resulted from physical pain and referral, emergency nature of the deliveries, newborn care routine and separation strain, strenuous accommodation as well as poor communication and support from health workers.

Conclusion: Preterm birth mothers in Kenyatta National Hospital have high levels of psychosocial burden with a poorer quality of life in early postpartum period. Structured patient-focused psychological counseling and support may help mitigate this burden and improve the quality of life of the preterm birth mothers.

Keywords: Preterm birth; Psychosocial burden; Quality of life; Focused Group Discussion

CHAPTER 1: INTRODUCTION AND LITERATURE REVIEW

INTRODUCTION

Preterm birth poses a significant challenge in perinatology causing physical, psychosocial and economic burden for the baby, the mother, the community and the health system!(1–4). The global prevalence of prematurity is 11% and it's the leading cause of neonatal morbidity and mortality (1,5). Up to 85% of preterm births occur in Africa and Asia. Preterm neonates account for almost 70% neonatal mortality, 5-10% still births and 50% of long term neurologic sequelae (1,6–8). Despite advances in research and interventions to prevent preterm birth there has been a rising trend over the last two decades especially in LMIC(1,5).

Current research on preterm birth focuses on optimizing neonatal outcomes. However, the mothers of these neonates receive little attention beyond routine puerperal care (9). Mothers of preterm neonates are a unique cohort, as they serve as primary caregivers to their high-risk babies whilst simultaneously requiring medical attention. This may predispose them to psychosocial challenges that may translate into a decline in their quality of life (3,10–12). There is paucity of data locally and globally on the psychosocial well-being of these mothers.

This study sought to evaluate the psychosocial burden and quality of life of the mothers of preterm babies in comparison to mothers of babies born at term at the Kenyatta National Hospital to add to the little available data and provoke more research in this field to the overall development of informed comprehensive programmatic interventions for the preterm birth mothers and their newborns.

LITERATURE REVIEW

Pathophysiology of pre term births

A preterm birth (PTB), can be induced or spontaneous; 45-50% are idiopathic, 30% related to PPRM, 15-20% medically indicated/elective preterm deliveries (1). Spontaneous preterm births are those that occur without medical indications and are still not well understood hence the increase despite preventive interventions(1,13).

Induced preterm births are medically indicated for the benefit of the mother, fetus or both. Placental, maternal or fetal factors are considered in optimizing delivery (1,14). Obstetric complications such as placenta previa, preeclampsia, multiple gestation and multiple previous scars that increase the risks of morbidity and mortality through hemorrhage, uterus rupture and still births lead to induced preterm births (14). The advances in research that have improved neonatal survival especially in developed countries have led to an increase in induced preterm deliveries (14,15).

The exact cause of spontaneous preterm birth is unknown and the interplay of environmental, demographic, behavioral and medical characteristics with underlying genetic susceptibilities is associated with PTB (13). The following risk factors have been reported:

- ❖ Maternal age below 18 years and above 35 years
- ❖ Overweight or underweight mothers
- ❖ African race
- ❖ Short stature
- ❖ Women born preterm
- ❖ Previous preterm delivery
- ❖ Multiple gestation
- ❖ Low social economic status
- ❖ Physical stress (long standing hours, heavy manual work)
- ❖ Psychosocial stress
- ❖ Birth canal Infections

The mechanism of preterm birth

The complex interplay of molecular and biologic factors in the mother and fetus during pregnancy and parturition are yet to be fully understood hence the unclear pathophysiology of preterm delivery syndrome(13). Preterm birth mechanism has been explained from the following underlying factors:

- ❖ Birth canal infections and fetal inflammatory response syndrome (FIRS).
- ❖ Utero-placental ischemia
- ❖ Hormonal disorders (especially gestagens)
- ❖ Fetus as an Allograft theory & Allergy
- ❖ Uterine over distension
- ❖ Cervical insufficiency

Birth canal infection has been shown to trigger most preterm births mainly by inflammation (6,16). Women with genetic polymorphisms affecting the regulation of adaptive and innate immunity in pregnancy respond differently to infections triggering preterm birth. Polymorphisms promoting production of pro-inflammatory cytokines like TNF α , type 1 cytokines, interferon γ and interleukin 12 in response to infections lead to the inflammatory cascade that trigger parturition (13). Women with TNF α gene mutations are 10 times more likely to get preterm birth when infected with Bacterial vaginosis as opposed to their counterparts without the gene mutation (16). Stress and obesity also trigger inflammatory response (13).

The inflammatory cascade alters the balance and functioning of cytokines, matrix metalloproteinase and prostaglandins. The fetus inflammatory response syndrome (FIRS) may occur in absence of maternal response (6,13). Microbial invasion of amniotic cavity leads to acute cervical insufficiency (funneling and shortening). The resultant effect leads to uterine contraction and cervical changes (funneling and shortening) that lead to PROM and preterm delivery (6,16).

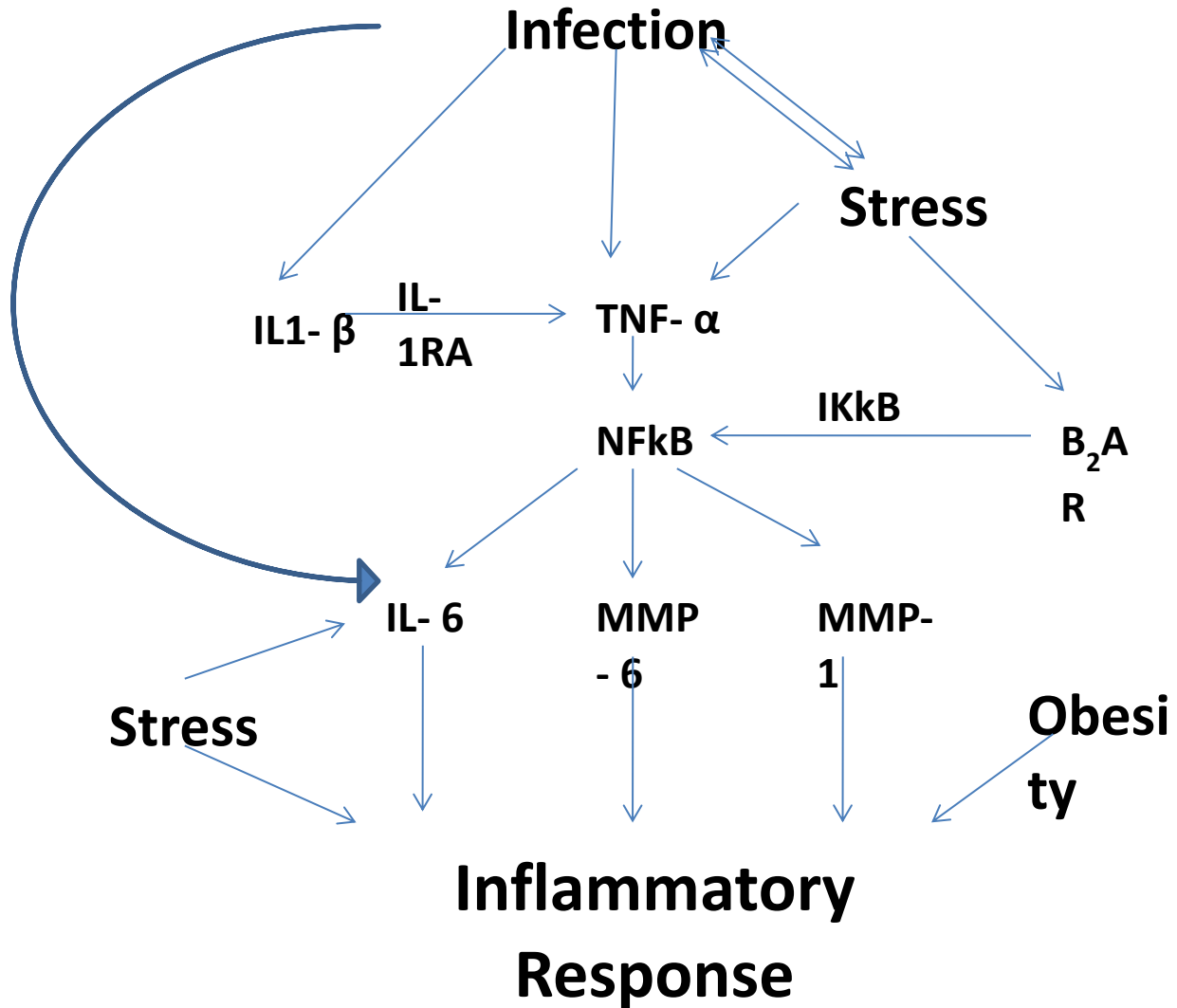


Figure 1: The inflammatory cascade in preterm labour, adapted from Crider KS et. al., 2005 (13).
 Footnote: *TNF*-tumor necrosis factor alpha, *NFκB*- nuclear factor kappa-B, *IL*- Interleukins, *MMP*- Matrix Metalloproteinases.

Utero-placental ischemia caused by thrombophilias compromise the placental microcirculation leading to production of oxidative products that interact with pattern recognition receptors (PRR) triggering inflammatory response like infections leading to preterm birth (16).

Hormonal disorders leading to an imbalance between the relaxing agents (progesterone and nitric (1) oxide) and the pro-contraction agents (estrogen, oxytocin, prostaglandins and CRH) are shown to stimulate early uterine contractions and preterm birth (9,16).

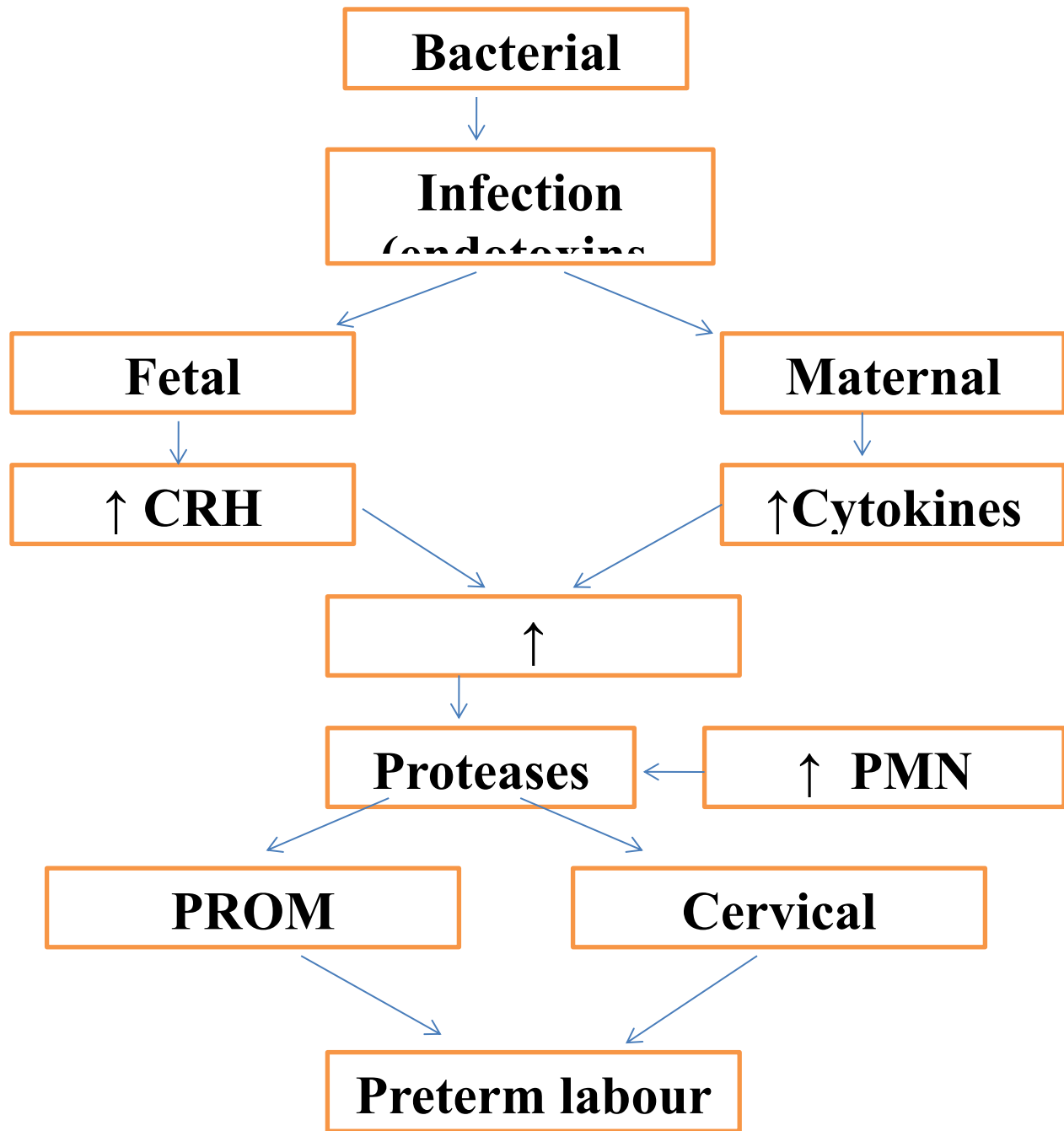


Figure 2: Flow chart showing the mechanism of preterm labour in bacterial infection, adapted from Pararas et. al., 2006 (6).

Footnote: CRH- Cortisol Releasing Hormone, PMN- Polymorphonuclear cells, PROM- Premature Rupture of Membranes.

Fetus rejection may result from inappropriate up regulation and down regulation of the main MHC antigens. This is suggested by the increased preterm births in women with autoimmune disorders such as lupus erythematosus, ulcerative colitis and autoimmune thyroiditis. Allergy is postulated to be a contributor in some cases of preterm births after isolation of eosinophilic granulocytes from the amniotic fluid of preterm birth women. The high concentration of mast cells in the uterus upon degranulation increases the prostaglandins production which results in uterine contraction (16).

Excessive uterine distension in multiple pregnancy, congenital uterine disorders and polyhydramnios may overcome the relaxing agents and cause uterine contraction. Amniochorial expansion damages the chorions leading to PROM (16,17). Cervical insufficiency can occur from congenital causes (cervical hypoplasia, collagen defects and DES exposure in utero), acquired causes (conization and repeated dilations) and infectious causes (MIAC). This leads to second or third trimester deliveries (6,9,16).

Burden of pre term births

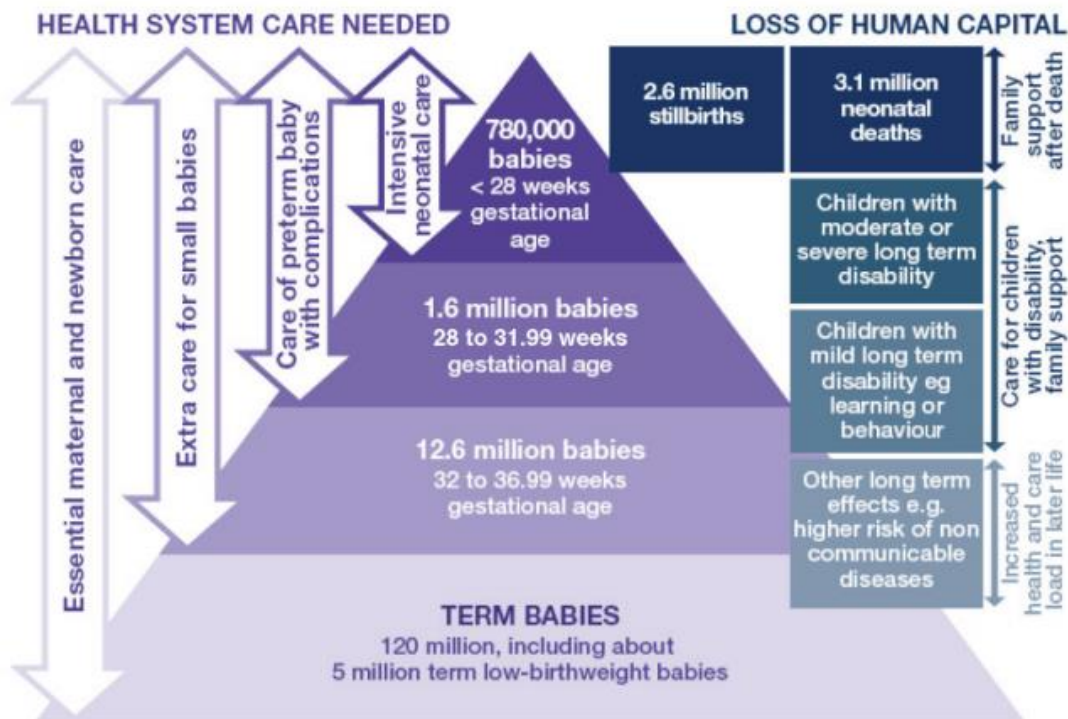


Figure 3: The composite burden of preterm births, adapted from Petrou S., 2003 (20)

PTB poses a great challenge to modern perinatology with a high neonatal mortality and morbidity associated with enormous physical, psychosocial and economic burden to the health system (1). Over 13 million babies are born preterm every year with over 11 million in low and middle income countries in Africa and Asia (1,15). The disparity in care and survival hence the morbidity and mortality burden between the developed and developing nations of 90:10 is alarming (5).

There has been a rise in the prevalence over the last two decades despite advancement in science (1,13). The medically induced preterm births are increasing with the aggressive policies for caesarean deliveries for poor fetal growth especially in developed countries and are predicted to follow suit in the developing countries as the neonatal survival improves (9,15). One third of the world births occur at home which only means the true burden of preterm birth in developing countries with poor records may be way higher than speculated (15).

Preterm birth is the leading direct cause of neonatal mortality worldwide and a significant indirect cause by respiratory infections, diarrhea and other infections which are four - eight times higher in preterm neonates compared to term neonates (12,15). Poorer access to health services and quality maternal and newborn care leads to higher cause specific death rates in low income countries (5,15). The mortality rate and disability worsens with decreasing gestation (1).

The morbidity and long term disability results from immature organs like hyaline membrane disease and medical interventions like retinopathy of prematurity from oxygen therapy. Preterm births cause 5-10% of still births and the ones that survive suffer from respiratory distress syndrome, necrotizing enterocolitis, intraventricular hemorrhage, retinopathy of prematurity, chronic lung disease and infections (5,12,15).

The neonates that survive to childhood are at a risk of long term complications like (3,12,18,19).

- Cognitive impairment: learning disabilities and mental retardation.
- Neuromotor impairment: cerebral palsy, hypotonia and severe motor disability.
- Sensory deficits: visual impairment (blindness, squint, refractive errors) and hearing loss (mainly sensori-neural hearing loss)
- Childhood under nutrition and
- Social disabilities with compromised education levels, income and establishment of families.

Economic burden of preterm birth

Prematurity is associated with a huge strain on the index family and public resources from the direct costs of hospitalization and indirect costs like loss of productivity and opportunity costs (10,20,21). Preterm births account for half the infant hospitalization costs and a quarter of the pediatric hospitalization costs (22). In 2005 the preterm birth associated cost from medical and educational expenses and loss of productivity were estimated to be >US\$ 26.2 billion in the USA (1). In England and Wales the incremental costs was £2.946 billion (US\$ 4.567 billion) per child with 92% of this cost mainly during the hospitalization after birth. The costs increase with decreasing gestation at birth (2).

Psychosocial burden of preterm birth

The intangible costs of PTB affect the overall care and eventual quality of life of the infant and caregiver. Preterm birth imposes a heavy emotional burden to the parents or caregivers which may adversely impact their quality of life. Self reproach, fear of mortality, fear of isolation, anxiety, maternal depression and prolonged hospitalization are some of the contributors of the emotional burden increasing the mother's psychological distress (3,10,21).

The see-saw interaction of the caregiver's well being and the child's well being demands a broader care approach to optimize the health of the mother and her baby. The burden is greater with the very preterm babies, immediately after birth then an increase is noted upon discharge during reintegration with the family/society(10,23–25).

There are few studies assessing the caregivers' psychosocial burden and quality of life hence lack of adequate evidence to convince policy makers on the seriousness of the maternal/caregiver psychosocial burden (10,26).

Multidisciplinary management of preterm births

Preterm birth is a global perinatal challenge demanding a concerted effort from everyone including the obstetricians, neonatologists, nursing team, administrators of service delivery, psychiatrists and clinical psychologists (27–29). The care is based on a four pronged approach:

- ❖ Identifying women at risk of preterm birth
- ❖ Risk reduction during antenatal care and preterm labour
- ❖ Care during the preterm labour and delivery

❖ Neonatal care tailored for the preterm neonate

During antenatal care, identification of women at risk of preterm birth are identified based on maternal characteristics (such as age, race, socioeconomic status, psychological stress, smoking and obesity), prior obstetric history (previous preterm births) and the medical (hypertension, diabetes) and pregnancy conditions (genital tract infections, recurrent UTI's, multiple gestation, ART, polyhydramnios) (27).

Reduction of risk mainly targets the causal pathways of preterm birth which include counseling, gestagens, cervical cerclage, treating of genital tract infections like Bacterial vaginosis and treating urinary tract infections. The mother is also counseled and followed up in a hospital facility that is equipped to handle very preterm newborns and other perinatal complications anticipated (27–29).

Women presenting with preterm labour and premature rupture of membranes are managed with the key intention of buying more time to institute interventions that would improve neonatal outcome. Tocolytics are used to allow 48 hours for antenatal corticosteroids use. The antenatal corticosteroids are administered to reduce the risk of RDS, IVH, NEC and accelerate fetal lung maturity (27,29). Magnesium sulphate is administered within 4-6 hours of planned or expected delivery in preterm births below 32 weeks for neuroprotection of the neonate(27).

Antibiotics are used especially in PROM to prevent neonatal infections (27,28). No consensus has been arrived at in terms of mode of delivery and as such individualization of cases especially for the very preterm is recommended. The use of antenatal corticosteroids and antibiotics has been shown to improve neonatal outcomes in both high and low income countries (9).

Neonatologist and NICU nurses at delivery are required to institute specialized preterm neonate care. Care is targeted against the main killers at delivery which include hypothermia (thermal care), infections (proper cord care and antibiotics), hypoglycemia (early and exclusive breastfeeding, cup and spoon or breast milk substitutes as appropriate) and hypoxia (resuscitation immediately after birth, use of oxygen and ventilator if necessary). The very premature infants with complications may require nursing in NICU (Neonatal Intensive Care Unit) (30,31).

Assessment of quality of life

The WHO defines health as “a state of complete physical, mental and social well-being not merely the absence of disease or infirmity”(32). The state of ‘well-being’ can be assessed by the perceived or actual improvement in the quality of life of the individual.

“Quality of life is an individual’s perception of their position in life in the context of the culture and value systems in which they live in and in relation to their goals, expectations, standards and concerns” (32). Quality of life is the resultant output of the complex interaction of the person’s physical state, psychological state, social relationships and salient environmental features (33).

WHOQOL-BREF

This is a quality of life assessment tool developed by WHO in over 15 international field centers that assesses the four domains (physical, psychological, social and environmental) that influence the quality of life (33,34). It is an internally and externally valid tool that can be comparable across different cultures. The WHOQOL-BREF is a shortened sound version of the WHOQOL-100 for use in clinical and field research. It has good discriminant and content validity as well as test-retest reliability (33–35).

Assessment of psychosocial burden

Care of a preterm neonate poses great physical, financial, social and psychological challenges to the caregiver which may impact negatively on the caregivers’ social, occupational and personal roles (10). Inadequate adjustment by the caregiver can lead to a huge psychosocial burden and eventually a mental illness.

Zarit Burden Interview (ZBI)

This is a validated tool for assessment of the psychosocial burden on caregivers. It measures the subjective burden of caregivers by use of subjectively worded items to evoke an affective response from the caregiver. The responses are graded on a 5 point Likert scale. A higher score suggests a higher burden and imply need for special care for the particular caregiver to institute appropriate adjustments. It is a valid and reliable tool for assessing caregivers’ burden (36,37).

PROBLEM STATEMENT

Preterm birth has a high prevalence globally (11%) and locally (12.9%) and has been on a rising trend despite scientific advances in research and intervention especially in LMIC like Kenya (1,5). The psychosocial burden has been less studied especially locally influence policy. This is further evidenced in the four prong approach in management of preterm births. The seriousness of the influence of maternal mental health and its effect on the care of the newborn and the burden posed by preterm birth is yet to be fully evaluated (10). Most studies focus on neonatal care and financial burden. More studies are needed to provide adequate evidence to show the psychosocial burden and inform pragmatic policies and programmatic interventions.

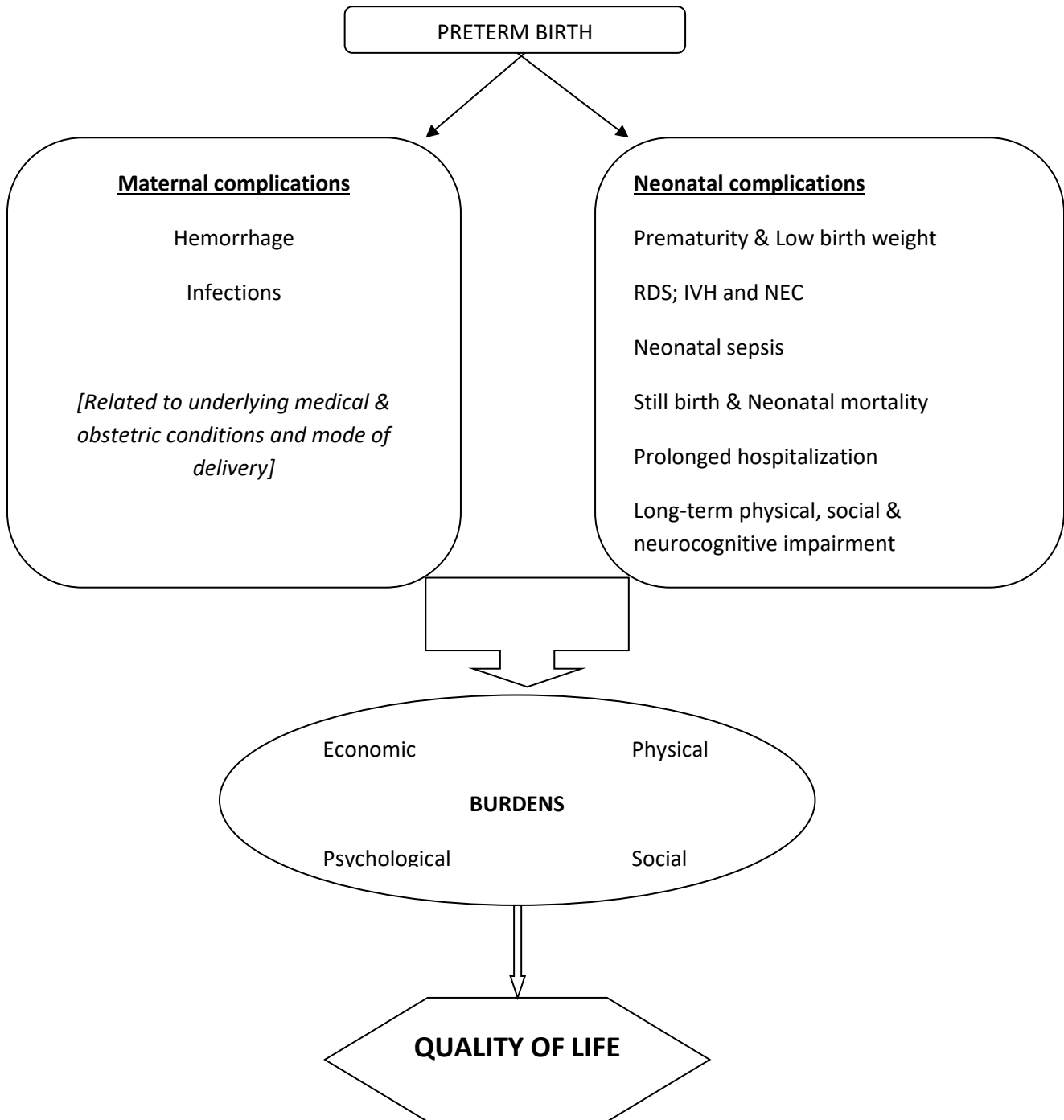
STUDY JUSTIFICATION

Preterm birth is a global perinatal challenge with physical, social and economic implications resulting from the high neonatal morbidity and mortality coupled with the many complications of prematurity. The rising trend despite advances in research and the strain on healthcare demands a pragmatic approach in programmatic interventions in preterm birth management.

The increased demands in the care of a preterm neonate are exhausting physically, emotionally and financially on the mother as the primary caregiver. The mental health of the caregiver influences the level and adequacy of care offered to the neonate. The psychosocial burden on the mothers with preterm birth and the consequent impact on their quality of life are not known.

This study evaluated the psychosocial burden and the consequent impact on the quality of life of mothers with preterm birth compared to their counterparts with term deliveries. The results of this study will add to the pool of research and attract more research in mental health of mothers to influence policies on pragmatic programmatic interventions that improve newborn survival and the maternal mental health.

CONCEPTUAL FRAMEWORK



Preterm birth is accompanied by maternal and neonatal complications. The neonatal complications are demanding physically, economically and psychosocially to the caregivers and may affect their psychosocial wellbeing and consequently their quality of life.

RESEARCH QUESTION

Is there a difference in the psychosocial burden and quality of life among mothers with preterm birth versus term birth at Kenyatta National Hospital?

HYPOTHESIS

H₀: There is no difference in the psychosocial burden and quality of life between mothers who deliver preterm and mothers who deliver at term.

OBJECTIVES

Broad Objective

To compare the psychosocial burden and quality of life of mothers with preterm birth versus term mothers at the Kenyatta National Hospital

Specific Objectives

1. To compare the demographic and clinical characteristics of mothers with preterm birth and mothers with term deliveries in Kenyatta National Hospital
2. To determine the psychosocial burden of mothers with preterm birth and mothers with term birth in Kenyatta National Hospital
3. To evaluate the quality of life of mothers with preterm birth and mothers with term birth in Kenyatta National Hospital
4. Evaluate the psychosocial stressors, burden and coping from the preterm birth mothers' perception at Kenyatta National Hospital

CHAPTER 2: METHODOLOGY

Study design

This was a mixed methods study:

- Quantitative aspect: Descriptive cross-sectional study in which 267 mothers with preterm birth were compared with 814 mothers with term birth and their psychosocial burden and quality of life determined.
- Qualitative aspect: Focused Group Discussions were used to obtain more information on the psychosocial burden and quality of life of preterm mothers that was not available in the quantitative data assessment tools.

Study site and setting

The study was carried out at the Kenyatta National Hospital, a national teaching and referral hospital with a countrywide catchment area. It has a well equipped comprehensive reproductive health unit, newborn unit with neonatal intensive care unit (NICU) and specialists in various disciplines making it an ideal destination for referral of preterm birth mothers and premature neonates. It is a public hospital mainly attending to low and middle income earners.

The KNH new born unit has preterm and term neonates delivered in KNH and those referred after delivery. Averages of 5 preterm neonates are admitted daily. The NBU has a NICU area (with a 10 bed capacity) and the general ward. There is a special Kangaroo Mother Care room where preterm birth mothers take care of their infants. The mothers and neonates in NBU receive a standard care with no specific routine counseling or specialized services tailored for the preterm birth mothers.

The mothers with children in NBU live either in the mother's hostel or in the post natal wards of KNH. In these wards the mothers share rooms (12-20 per room) with other postpartum mothers before discharge. No specific segregation and care is offered to any specific group of mothers.

Study population

The study included the mothers in Kenyatta National Hospital who delivered 24 -37+0 weeks within their first week of puerperium to represent the preterm birth mothers and women who delivered at a gestation of more than 37+0 weeks to represent the term mothers (comparison group). The mothers who delivered preterm and term were all given the same standard treatment

with no specialized care fashioned for the special circumstances of preterm delivery. There were on average 50 term deliveries and 5 preterm deliveries in the maternity wing daily.

Inclusion criteria

1. Women with preterm birth (delivery between 24 – 37 weeks gestation) within the first week of puerperium.
2. Women with term deliveries as the comparison group.
3. Women who voluntarily consent to participate in the study

Exclusion criteria

1. Mothers below 18 years
2. Mothers who didn't understand English or Kiswahili
3. Mothers with severe co morbid conditions that rendered them bedridden (paralyzed and ICU admission)
4. Chronic physical or mental disease, disability or illnesses
5. Crises pregnancy mothers (e.g. rape victims)
6. History of infertility or previous pregnancy losses ('precious baby')
7. Mothers who delivered before arrival at KNH.

Sampling and sample size

Consecutive sampling method was used for the preterm birth mothers and simple random sampling for term mothers where all who were sampled and met the criteria and consented to the study were recruited until the desired sample size was achieved.

There were three term mothers (comparison group) recruited for every preterm birth mother recruited. Each day the ratio of term to preterm deliveries in KNH approximated 4:1 and with exclusion of patients with severe morbidity, those who delivered before arriving to KNH and the mothers who were discharged before being included in the study the ratio settled on was 3:1. This ensured all mothers who deliver at around the same period got an equal chance to participate in the study.

This being a cross-sectional study with qualitative variables (psychosocial burden and quality of life), the following formulae was used to calculate the sample size. The main outcomes were

psychosocial burden with estimated Odds ratio of 2.10 (1.30-3.39) and prevalence of 12% vs 6% for preterm and term mothers respectively in previous studies (38,39).

Sample size was calculated using the difference in proportions - Fleiss JL formula (Statcalc epi-infoTM) as outlined below. The following assumptions were considered during the calculation:

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

n = sample size per group

r = ratio of term to preterm birth mothers, 3:1 taken to maintain the power of the study at 80% and also to be able to conduct a multi-variate analysis of the different variables

P₁= proportion of mothers with preterm babies with high psychosocial burden post partum, in this study 12%

P₂= proportion of mothers with term babies with high psychosocial burden post partum, in this study 6%

\bar{p} = measure of variability, taken as $12+6/2=9$

Z_β= Value corresponding to the power of the study, in this study 80% = 0.80

Z_α = Value corresponding to the normal standard deviate at 95% C.I in this study = 1.96, with 0.05 level of significance

P₁- P₂ = effect size (difference in proportions)

Odds ratio to be detected of 2.1

Applying this in the Statcalc epi info software gives a value of 234.

The sample size for this study was **257 preterm birth and 769 term birth mothers.**

(Ratio of Preterm birth mothers: Term Mothers being 1:3)

Recruitment and consenting

The mothers were recruited from labour ward and postnatal wards. The study was explained to them individually, the benefits, harm and procedure including the final results dissemination.

Informed written consent was administered and only those who consented and met the study criteria were included in the study.

Exposed: Mothers with preterm birth (<37 weeks gestation) were recruited by consecutive sampling where all the women who consented and met the inclusion criteria were recruited until the sample size was achieved.

Unexposed (Comparison) group: Mothers with term birth (≥ 37 weeks gestation). They were recruited by simple random sampling using random tables. Each day there were more than three times term deliveries compared to preterm deliveries. They were recruited from the same pool that preterm birth mothers were recruited.

The postnatal mothers in KNH were accommodated at the labour ward in the first few (4-8) hours after delivery and then transferred to the post natal wards where they stayed until both the mother and the newborn were discharged. Each postnatal ward received mothers from labour ward twice per week.

The study participants in each ward were informed about the study and recruited for interviews at their convenience. Mothers from each ward were interviewed just before they were discharged and the remaining mothers were not included in the study. This was done to avoid contamination by the participants discussing the study and their answers with the group not interviewed. The files of each participant interviewed were marked with a code to avoid re-interviewing.

Focus Group Discussion:

Preterm birth mothers who were not interviewed were recruited for Focused Group Discussions. They were randomly sampled using simple random tables into groups of 5-10. The study was explained to them and an informed consent administered. The discussions were scheduled at a convenient time for the group participants. The interviews were conducted by research assistants guided by clinical psychologists with recording of the interviews using the EVISTR digital voice recorder (8GB saving every 5 seconds – serial number X001QYJFOH).

The recruitment and FGD were done bi-weekly to avoid contamination. The women targeted for the FGD were recruited from the postnatal wards.

Variables and Confounders

The demographic and obstetric characteristics of the study participants were analyzed. The main variables in this study were qualitative variables;

Psychosocial burden of preterm birth mothers: This was assessed by the semi-structured interview described in the Zarit Burden Interview. The participants' perception on how the situation had affected their lives was assessed with graded answers ('never' 'rarely' 'sometimes' 'quite frequently' and 'nearly always') to the 22 questions and finally interpreted as little, mild, moderate or severe burden depending on the aggregated score of 0 – 88.

Quality of life of preterm birth mothers: The four main domains of quality of life (physical, psychological, social relationship and environment) and the overall quality of life were assessed using the WHOQOL-BREF with a 5 point Likert scale graded answers. The final score of 0 - 100 was used to interpret the quality of life.

Focus Group Discussions: The oral responses from the participants were used as the qualitative data that were transcribed, translated and analyzed into broad themes.

Confounders: Chronic mental or physical illness, diseases and disabilities are likely to increase the psychosocial burden and worsen quality of life. Other expected confounders included severe co-morbidities, prior history of infertility and crisis pregnancies. These were excluded from the study (as per the exclusion criteria) to eliminate their confounding effect.

Data on previous and current neonatal outcomes, maternal age, education level, marital status and occupation which were likely to be confounders were adjusted for during analysis by multiple linear regression analyses.

	Independent	Dependent
Objective 1	Maternal age	
	Parity	
	Marital status	
	Occupation	
	Educational level	
	Inter-pregnancy interval	
	Mode of delivery	
	Previous pregnancy outcome	
	Complication preceding delivery	
	Postpartum complication	
	Neonatal Outcomes: Immediate neonatal outcome: live or still birth APGAR score Birth weight Congenital anomalies NBU admission	
Objective 2	Mothers with preterm birth	Psychosocial burden
	Mothers with term birth	
Objective 3	Mothers with preterm birth	Quality of life
	Mothers with term birth	

Table 1: Dependent and independent variables of the postpartum women recruited in the study.

Data collection

Recruited participants were scheduled for interviews at their convenience. Information on the demographic and obstetric characteristics of the participant as well as the outcome of the delivery was obtained from the records in labour ward and cross checked with antenatal wards details and the files of the mother and neonate.

The data obtained from the file were verified by cross checking with the participant as she settled for the interview. Each participant was interviewed in a quiet room where the assessment tools were administered and when completed all the data from that participant were enveloped, sealed and labeled for confidentiality and quality assurance.

Mothers with preterm birth who did not participate in the questionnaires were recruited by simple random sampling and interviewed in focused groups of 5 – 10 and their responses recorded on a voice recorder. Each participant was given a code name (identifier) and an equal controlled opportunity to speak by the moderator. For the questions with cross cutting answers the participants were asked to write their responses on a paper then each discussed and expounded their answer to the group verbally. The group comments and responses were transcribed and grouped per question to collate all answers of a particular question together for picking main quotations and themes for further analysis. The Consolidated criteria for Reporting Qualitative Study (COREQ) guidelines were used.

Study participants only participated in the study once and participants from each ward were interviewed once with the data collection spread over at once a week (to afford spatial separation as the approximate duration of stay was one week) till required sample size was achieved. This was done to avoid contamination (by avoiding interaction of the interviewed participants with the others) and also avoided re-interviewing of the participants.

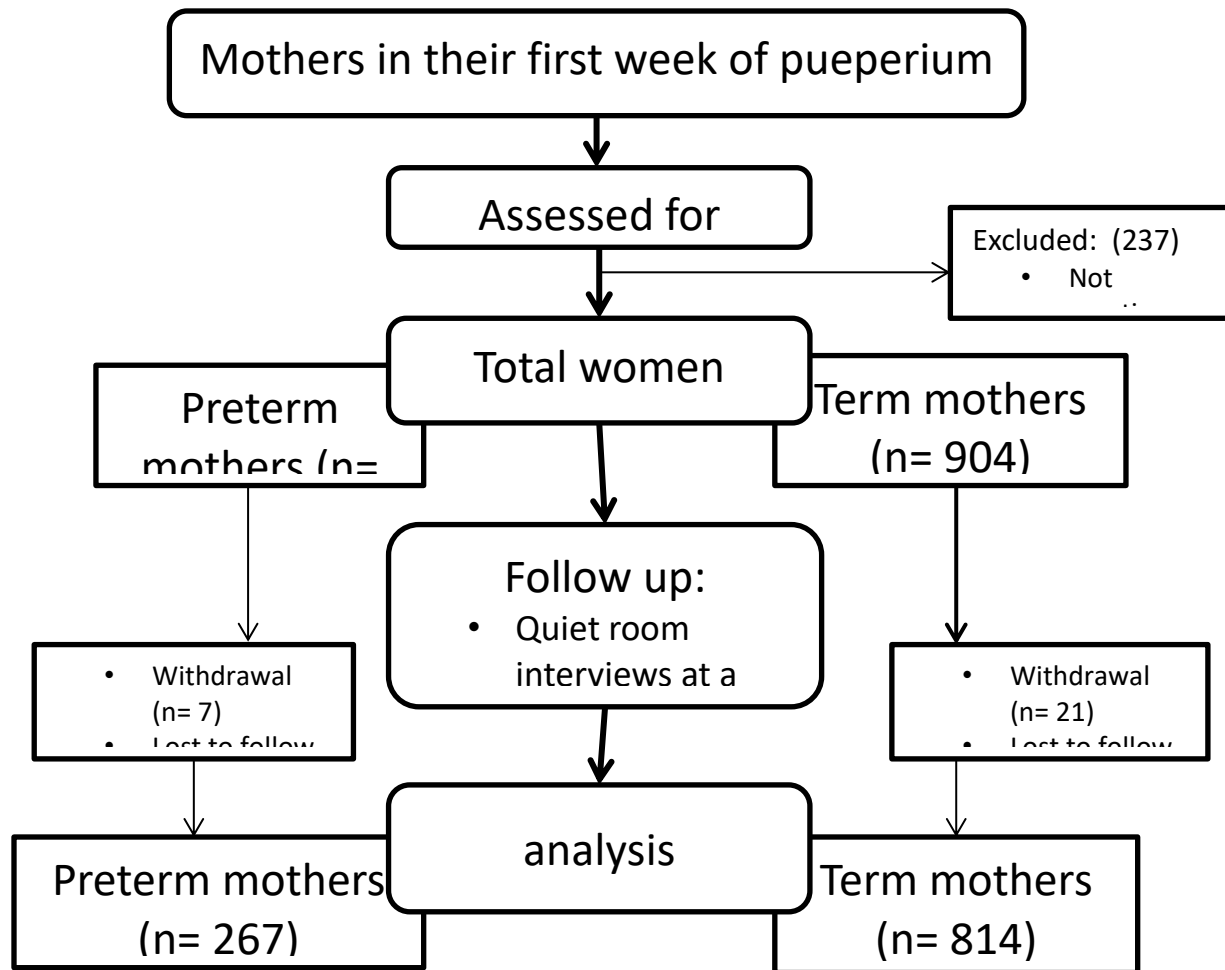


Figure 4: Figure showing the consort study flow diagram.

Materials

Stationery, voice recorders, questionnaires, data storage files, password protected computers, hard drives and flash drives.

Quality assurance

The following measures were taken for quality assurance through all the stages of the study.

- a) Data obtained from the records and files were confirmed from the participants and relevant health care providers.
- b) Data were stored in password protected computers, hard drives and flash drives to ensure confidentiality and accessible to only the principal investigator, supervisors and statistician.

- c) Qualified clinical psychologist's guidance was embraced throughout the study planning, execution and closure.
- d) Quiet comfortable rooms were used for the interviews at the participant's convenience.
- e) The participants were interviewed using Kiswahili, English or both to facilitate understanding and accurate responses.

Ethical considerations

The study was reviewed and approved by the Kenyatta National Hospital/ University of Nairobi ethics review committee (KNH/UON ERC) commencing the recruitment. Permission was also granted by the University of Nairobi department of Obstetrics & Gynecology and the KNH administration before the study commencement.

The following ethical issues were anticipated for and response measures put in place:

- Participants encountered during the study with severe psychosocial disturbance bordering mental illness were to be referred to a clinical counselor and a psychiatrist for care.
- Confidentiality was maintained to ensure mothers don't feel like they are 'bad' mothers hence avoiding self blame and stigma.
- Study interviews were scheduled at the convenience of the mothers to avoid disrupting Kangaroo mother care, breastfeeding or other care for the neonate.
- The mothers were counseled on preterm births and prematurity to enable closure and alleviate self blame (e.g. I was working too much that's why the baby came early).

Data management and analysis

Data were entered in excel sheets and cleaned up with cross checking with the recorded interviews to ensure accurate information. The incomplete data was excluded from the analysis. These were stored in password protected hard drives and limited access computers.

Comparison of socio-demographic and clinical characteristics of the mothers gave birth to term and preterm babies were done using a chi-square test for the categorical variables and two sample t-tests for the continuous variables. A two sample t-test compared the means of the two populations to establish whether they differed significantly from each other. Two sample t-tests was used to compare mean age of the mothers at birth, mean duration from last birth, mean duration of hospital stay and mean fetal birth weight of the two treatment groups.

The psychosocial burden of mothers with preterm birth and mothers with term deliveries in Kenyatta National Hospital was determined using the Zarit Burden Interview (ZBI) score. The interview consisted of 22 questions with scores ranging from 0 to 4 as follows; 0 – never, 1- rarely, 2- sometimes, 3 - quite frequently and 4 - nearly always. The aggregate scores for each mother were computed by summing up the individual scores for each of the 22 questions. The mothers were then classified into four psychosocial burden groups based on their aggregate scores as follows; 0 - 21 (little or no burden), 22 - 40 (mild burden), 41- 60 (moderate burden) and 61 - 88 (severe burden).

Proportional odds (ordinal) logistic regression model was preferred in the assessment of the psychosocial burden between the term and preterm birth mothers. The model is an extension of the logistic regression model that takes into account the ordinal nature of the response variable by modeling the upwards cumulative probabilities of the outcome variable. The model also assumes a constant relationship across the groups within the response variable hence the assumption had to be verified for the results to be valid.

Univariate proportional odds model were fitted to the data using psychosocial burden and the treatment groups as the outcome and main exposure respectively. Other univariate models featuring psychosocial burden and each of the maternal and neonatal socio-demographic and clinical characteristics were also fitted. These yielded unadjusted odds ratios and their respective confidence interval.

Further analysis was done by fitting a multivariate model that included the entire maternal and neonatal socio-demographic and clinical characteristic that showed significance in the univariate analysis. This model yielded the adjusted odds ratios and confidence intervals.

The proportional odds assumption was confirmed to hold by fitting a multinomial logistic model to the dataset. This gave four slopes hence nesting the proportional odds model. Likelihood ratio test was then used to compare whether the two models were statistically different hence ascertaining the assumption.

The quality of life of mothers with preterm birth and mothers with term deliveries in Kenyatta National Hospital was evaluated using the WHOQOL-BREF. The data was first checked for missing data. This was followed by reversal of three negatively stated items i.e. WHOQOL3,

WHOQOL4 and WHOQOL26. Computation of raw scores for each of the four domains was then done by aggregating the individual scores for questions that fell in each domain. The maximum and minimum aggregate scores were identified after which the raw aggregate scores were transformed into percentages using the formula below.

$$\textit{Transformed Scale} = \frac{(\textit{Actual Raw score} - \textit{Lowest Possible RawScore})}{\textit{Possible Range of Raw Score}} \times 100$$

One-Way Analysis of Variance (One-Way ANOVA) model was used to model the association between the domain scores and the treatment groups. The model suited the data because of the continuous nature of the response variable after transformation. The assumption of linearity, independence and constancy of variance must hold for the results of the ANOVA model to be valid. Normality and constancy of variance assumption was confirmed to hold through a Kolmogorov Smirnov and Levene test respectively. Pearson's correlation was used to check independence assumption.

Like in the second objective, both univariate and multiple ANOVA models were fitted to the data. The multiple ANOVA models only involved maternal and neonatal characteristics that had shown significance in the univariate analysis.

All the analyses were done in R-Studio Version.

Qualitative data analysis (FGD):

The study involved a qualitative analysis of ten room interviews which were conducted on mothers who had given birth to preterm babies; and the babies were being taken care of in the nursery at Kenyatta National Hospital. The analysis process was characterized by five major steps namely transcription of the interviews, translation of the transcribed data, understanding the data to obtain a detailed insight into the concepts being explored, development of a coding system for the data and lastly linking of the codes to form concepts which led to the development of the major discussion points (themes).

The focused group interviews were all conducted in the same room hence one question may have more than one response. The interviews were both done in Swahili and English languages. Some subjects occasionally responded in Sheng' (a corrupted version of Swahili local slung). The interviews were transcribed in the original language of the response after which it was translated to English. Unsaid thoughts were expressed in parenthesis.

The translated responses were then broken down into phrases and sentences. Each of the phrases and sentences was considered to identify keywords that were used as the codes. The significant and repeating themes were then identified. This involved sorting and filtering the phrases and sentences to bring out the types, classes, sequences, processes and patterns of interest in the data. Lastly, similar categories were brought together by linking them into broader themes.

CHAPTER 3: RESULTS

The study had qualitative and quantitative data that were analyzed. The following results were obtained.

Quantitative Data Results:

The objectives were investigated and the following findings described.

Demographic and clinical characteristics of mothers with preterm and term deliveries in Kenyatta National Hospital

We screened 1434 mothers and after excluding 237 who did not meet inclusion criteria 1197 were interviewed. 116 incomplete files were excluded and the remaining 1081 were included in the final analysis, 267 preterm mothers and 814 term mothers as shown in the study flow chart in Figure 5.

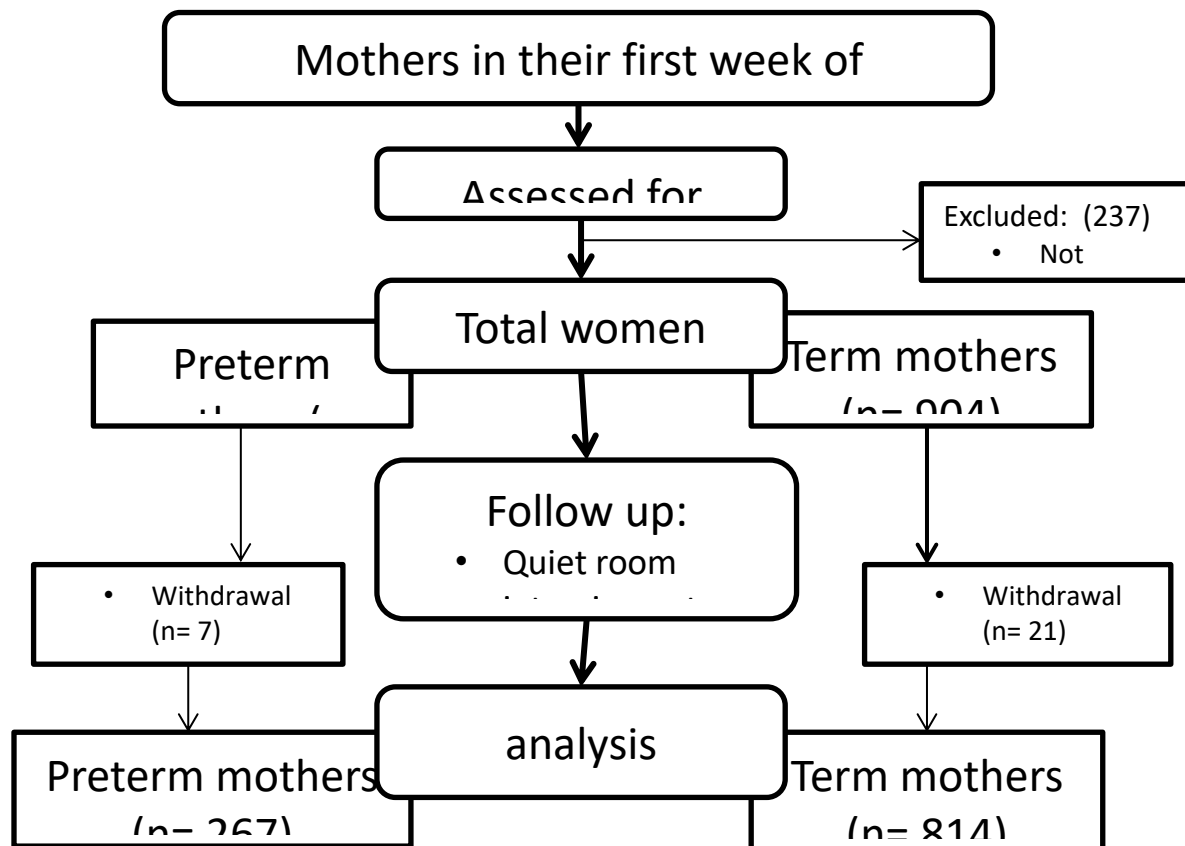


Figure 5: The study flow diagram of the recruitment and assessment of psychosocial burden and quality of life at KNH in 2018-2019.

Age, marital status, parity, inter-pregnancy interval, mode of delivery and postpartum complications were similar in the two groups. Preterm birth mothers were less likely to be educated and to have formal employment compared to the term birth mothers 27.7% vs. 39.4%

($p < 0.0001$) and (14.2% vs. 24.7%, $p < 0.0002$) respectively. The modes of delivery were comparable with only a lower rate of elective CS in the preterm birth mothers. Preterm neonates had poorer outcomes; birth weight, APGAR scores and higher NBU admissions. The preterm birth mothers took longer to initiate and maintain breastfeeding and had prolonged hospital stay compared to the term birth mothers (9.9 days vs. 4.3 days, $P < 0.0001$). These are summarized in table 2.

Table 2: Maternal and Neonatal characteristics comparing Term and Preterm Birth Mothers assessed for Psychosocial burden and Quality of life in KNH in 2018-2019.

Variable	Term delivery (n = 814)	Preterm delivery (n = 267)	p value
MATERNAL CHARACTERISTICS			
Age ($\bar{x} \pm sd$) (years)	27.32 (5.84)	27.64 (6.01)	0.4590
Marital Status			
<i>Married</i>	696 (85.5%)	224 (83.9%)	0.3760
<i>Separated</i>	14 (1.7%)	3 (1.1%)	0.3760
Education			
<i>Secondary</i>	340 (41.8%)	111 (41.6%)	0.0046
<i>Tertiary</i>	321 (39.4%)	74 (27.7%)	<0.0001
<i>Primary/None</i>	153 (18.8%)	82 (30.7%)	0.0001
Occupation			
<i>Formal</i>	201 (24.7%)	38 (14.2%)	0.0002
<i>Contractual</i>	122 (15.0%)	36 (13.5)	0.1676
<i>Unemployed</i>	491 (60.3%)	193 (72.3%)	
Interpregnancy interval (Weeks)	60.8 (42.2)	62.7 (39.6)	0.5950
Post Partum Complications	19 (7.1%)	59 (7.2%)	0.9420
Mode of delivery			
<i>Elective CS</i>	154 (18.9%)	6 (2.2%)	< 0.0001
<i>Emergency CS</i>	390 (47.9%)	137 (51.3%)	0.0684
<i>SVD</i>	270 (33.2%)	124 (46.5%)	
Duration of hospital stay (Days)	4.3 (4.2)	9.9 (12.6)	< 0.0001
NEONATAL CHARACTERISTICS			
Birth weight (Kgs)	3.31 (0.49)	2.05 (0.69)	< 0.0001
NBU Admission	93 (11.4%)	184 (68.9%)	<0.0001
Breast Feeding	777 (95.5%)	165 (61.8%)	< 0.0001
APGAR scores			
<i>1 Minute (<7)</i>	50 (6.1%)	69 (25.8%)	< 0.0001
<i>5 Minutes (<7)</i>	14 (1.7%)	24 (9.0%)	< 0.0001
<i>10 Minutes (<7)</i>	14 (1.7%)	24 (9.0%)	< 0.0001

Key: CS – Caesarean section; NBU – Newborn Unit; SVD – Spontaneous Vaginal delivery

The Psychosocial burden of mothers with preterm and term deliveries in Kenyatta National Hospital

In total, 817 (75.6%) of the patients reported little or no psychosocial burden while 29 (2.7%) reported moderate psychosocial burden. No patient reported severe psychosocial burden (aggregated ZBI score > 60). The minimum and maximum aggregate ZBI scores were 0 and 56 respectively. Preterm birth mothers reported higher psychosocial burden compared to their term counterparts: Little/No burden (74.14% vs. 76.0%); Mild to moderate burden (22.5% vs. 21.5%); and Moderate to severe burden (3.4% vs. 2.5%) as illustrated in the grouped bar graph in the Figure 2.

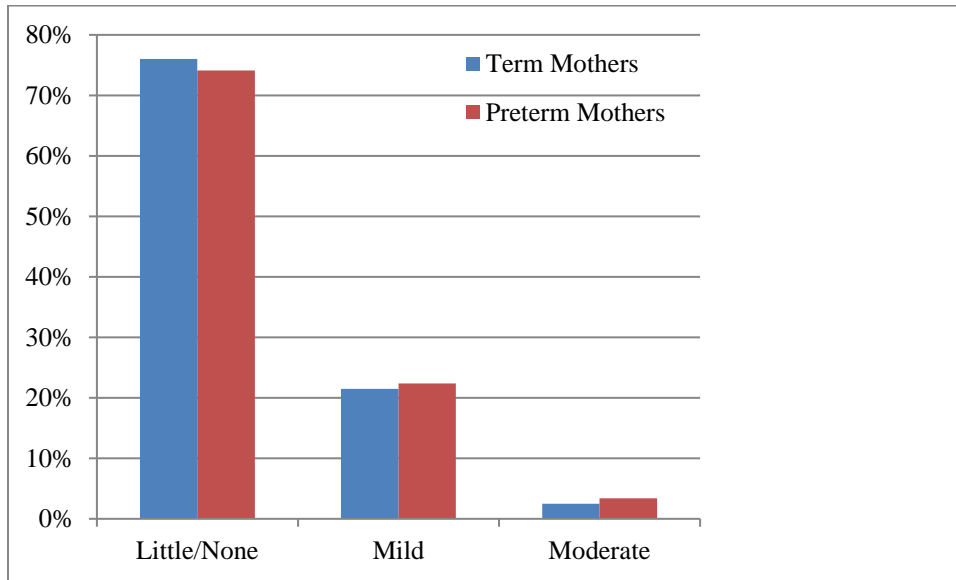


Figure 6: Psychosocial Burden among Term and Pre-Term Birth Mothers in KNH in 2018-2019.

The results obtained from fitting a proportional odds model to the data depicted the odds of mothers who gave birth to preterm babies experiencing greater psychosocial burden was 12 % higher compared to that of mothers who gave birth to term babies (OR = 1.12, 95% C.I. 0.81-1.53, $p = 0.4977$). Preterm mothers were more likely to experience greater psychosocial burden compared to the term mothers but the difference was not statistically significant. This is summarized in the table 3.

Further independent analysis of the association between the psychosocial burden and other socio-demographic and clinical characteristics revealed significant effects of age, occupation and mode of delivery as shown in Table 3. Age was significantly associated with psychosocial burden ($p = 0.0059$) with an estimated odds ratio of 0.97. This meant that for every unit increase in the age of the expectant mother the odds of experiencing a greater psychosocial burden reduced 0.97 fold. Younger women were therefore more likely to experience greater psychosocial burden compared to the older ones.

The occupation of the mother showed the strongest association with psychosocial burden. The odds of formally employed mothers experiencing greater psychosocial burden was 0.52 times that of the unemployed ones (OR = 0.52, 95% C.I. 0.37- 0.77, p = 0.0008). Unemployed mothers therefore were likely to report higher scores of psychosocial burden compared to the formally employed ones.

The same trend was also observed in mothers employed under contract. The odds of mothers on contract scoring highly on psychosocial burden was 0.43 times that of unemployed mothers (OR = 0.43, p = 0.0005). Unemployed mothers therefore were likely to report higher scores of psychosocial burden compared to the contractually employed ones.

There was a significant association between mode of delivery and psychosocial burden. The odds of a mother who delivered via emergency CS having a greater psychosocial burden was 0.72 times that of those who delivered via SVD (OR = 0.72, p = 0.0338). Emergency CS mothers were therefore more likely to score high on psychosocial burden compared with the SVD mothers.

None of the neonatal characteristics showed a significant association with the score of psychosocial burden. This is however expected because the test on psychosocial burden was conducted on the mothers and not the newborns. The variables were therefore independent from each other.

Lastly, the association between psychosocial burden and the gestation of the mother at the time of birth remained non significant when a multivariate proportional odds model was fitted to control the effects age, occupation and mode of delivery (OR = 1.02, p = 0.8472).

Table 3: Psychosocial Burden between Term and Preterm Mothers in KNH in 2018-2019.

Psychosocial Burden	General (n=1081)	Term (n = 814)	Preterm (n = 267)	OR (95 % CI)	P-Value
Little/ None	817 (75.6%)	619 (76.0%)	198 (74.1%)	1.12 (0.81, 1.53)	0.4977
Mild	235 (21.7%)	175 (21.5%)	60 (22.4%)		
Moderate	29 (2.7%)	20 (2.5%)	9 (3.4%)		

Note: The proportional odds model fits a common slope across the groups using cumulative probabilities.

Quality of life of mothers with preterm birth and mothers with term deliveries in KNH

Results of the one way ANOVA models fitted on each of the quality of life domains showed significant association between preterm birth and poorer quality of life. Preterm birth mothers quality of life was poorer by 2.18 (0.36 – 4.0) P = 0.0187 in the physical domain and 2.73 (1.04- 4.42) P = 0.0014 in the environmental domain as summarized in Table 3. Further analysis showed that mothers who breastfed their babies had a better quality of life in the environment domain (-2.39, p = 0.0314).

Table 4: Difference in Quality of Life between Preterm and Term Birth Mothers in KNH in 2018-2019 (N = 1081).

Domain	Min(%)	Max (%)	Preterm (%)	Term(%)	Mean Dif. (95% CI)	P-Value
Physical	10.71	82.14	50.12	52.30	2.18 (0.36-4.00)	0.0187
Psychological	16.67	100.00	73.97	74.95	0.97 (0.61-2.56)	0.2280
Social	0.00	100.00	73.76	75.46	1.70 (0.51-3.93)	0.1320
Environmental	15.62	100.00	62.30	65.03	2.73 (1.04-4.42)	0.0014
Overall	15.62	100.00	65.58	66.39	0.80 (0.51-2.12)	0.2290

The quality of life in the preterm and term mothers differed significantly in the Physical and Environmental domains as shown:

Physical domain:

There was a significant association between the scores of quality of life in the physical domain and the gestational period of the mother at birth (-2.18, 95% C.I. 0.36-4.00, $p = 0.0187$). Shifting status from term to preterm birth the mean quality of life score reduced by 2.18. This in effect shows that, physically, the mothers who gave birth to preterm babies had a poorer quality of life compared to their counterparts who gave birth to term babies.

Subanalysis revealed that marital status and mode of delivery also significantly affected the quality of life in the two groups. Shifting marital status from single to separated, the mean quality of life score increased by 6.82, 95% C.I. 0.20-13.43, ($p = 0.0434$). This in effect shows that the mothers who had separated from their spouses reported better quality of life compared to their counterparts who had never been married before (single). There was a difference of 0.18 ($p = 0.1837$) in the mean quality of life score of the married and single mothers in relation to physical domain. The difference was, however, not statistically significant.

There was also a strong associated between the scores of quality of life in the physical domain and the mode of delivery of the mother (2.42, 95% C.I. 0.71-4.14, $p = 0.0056$). The mean QOL score for mothers who delivered normally (SVD) was lower by 2.42 compared to their counterparts who delivery through emergency CS. There was no significant difference in the mean quality of life score of the mothers who gave birth via elective CS and those who gave birth via SVD.

Physical Domain			
Variable	Category	Estimate (95% CI)	P-Value
Maternal Factors			
Gestation Period at Birth	< 37 weeks	-2.18 (-4.00, -0.36)	0.0187
Age	>= 35 Years	0.08 (-4.05, 0.28)	0.0891
Marital Status	Married	0.18 (-0.74, 3.88)	0.1837
	Separated	6.82 (0.20, 13.43)	0.0434
Education	Secondary	-0.15 (-2.23, 1.92)	0.8820
	Tertiary	1.34 (-0.77, 3.47)	0.2140
Occupation	Formal	-0.37 (-3.02, 2.26)	0.7794
	Contractual	-2.11 (-4.39, 0.16)	0.0685
Delivery Mode	Elective CS	1.41 (-1.00, 3.83)	0.2510
	Emergency CS	2.42 (0.71, 4.14)	0.0056
Post Partum Complication	Yes	1.55 (-1.48, 4.59)	0.3160
Neonatal Factors			
Birth Weight	Grams	0.00 (-0.00, 0.00)	0.0930
NBU Admission	Yes	-1.21 (-3.01, 0.58)	0.1870
Breast Feeding	Yes	0.87 (-1.47, 3.22)	0.4650
APGAR 1 Minute	< 7	0.85 (-1.66, 3.36)	0.5070
APGAR 5 Minute	< 7	0.41 (-3.85, 4.68)	0.8500
APGAR 10 Minute	< 7	0.41 (-3.85, 4.68)	0.8500

Table 5: Table on the effect of maternal and neonatal factors on the Physical Domain of QoL of preterm vs. term birth mothers in KNH, 2018-2019

Environmental domain:

There was a significant associated between the scores of quality of life in the environment domain and the gestational period of the mother at birth (2.73, 95% C.I. 1.04-4.42, p = 0.0015). Shifting status from preterm to term birth, the mean quality of life score decreased by 2.73. This

in effect shows that the mothers who gave birth to preterm babies had poorer environmental quality of life compared to their counterparts who gave birth to term babies.

Further analysis showed that mothers who breastfed their babies had a better quality of life in the environment domain (-2.39, 95% C.I. 4.56-0.21, $p = 0.0314$). This in effect shows that the mothers who gave birth to preterm babies were more associated with poor quality of life compared to their counterparts who gave birth to term babies since a bigger proportion of preterm babies were not breastfeeding.

There was no significant association between the gestational age and the transformed scores in both social relationships and psychological domains ($p = 0.2280$ and 0.1320 respectively). The mean difference in the overall quality of life for preterm and term mothers was not significant (0.2290).

Environmental Domain			
Variable	Category	Crude OR (95% CI)	P-Value
Maternal Characteristics			
Gestation Period at Birth	< 37 weeks	2.73 (1.04, 4.42)	0.0015
Age	>= 35 Years	0.53 (-1.48, 2.55)	0.6010
Marital Status	Married	0.76 (-1.38, 2.91)	0.4843
	Separated	5.59 (-0.56, 11.74)	0.0748
Education	Secondary	0.08 (-1.84, 2.01)	0.9300
	Tertiary	-0.35 (-2.32, 1.62)	0.7280
Occupation	Formal	-1.75 (-4.21, 0.70)	0.1612
	Contractual	-2.06 (-4.18, 0.05)	0.0558
Delivery Mode	Elective CS	-1.35 (-3.60, 0.89)	0.2380
	Emergency CS	-0.01 (-1.61, 1.57)	0.9800
Post Partum Complication	Yes	1.38 (-1.43, 4.20)	0.3370
Neonatal Characteristics			
Birth Weight	Grams	-0.00 (-0.00, 0.00)	0.0623
NBU Admission	Yes	1.09 (-1.09, 3.29)	0.3270
Breast Feeding	Yes	-2.39 (-4.56, -0.21)	0.0314
APGAR 1 Minute	< 7	0.43 (-1.89, 2.76)	0.7150
APGAR 5 Minute	< 7	0.09 (-3.86, 4.06)	0.9610
APGAR 10 Minute	< 7	0.09 (-3.86, 4.06)	0.9610

Table 6: Table on the effect of maternal and neonatal factors on the Environmental Domain of QoL of preterm vs. term birth in KNH, 2018-2019

Qualitative Data Results:

12 focused group discussions were conducted, 2 were incomplete and 10 recordings were forwarded for analysis. The Focused Group Discussions yielded the following broad themes addressing the psychosocial burden and quality of life experienced by mothers who gave birth to preterm babies in Kenyatta National Hospital.

1. Physical Pain and Medical Treatment;
2. Emergency Nature of Preterm Birth and the Subsequent Nursery Care;
3. Perception around Safety of the just concluded and Future Pregnancies;
4. Communication and Information gap together with Safety of Physical Environment; and
5. Coping with Stress and Possible Changes at Kenyatta National Hospital.

Physical Pain and Medical Treatment

Physical pain and medical treatment came out as one of the broad themes in the psychosocial burden and quality of life of mothers with preterm birth in Kenyatta National Hospital. Most mothers who had given birth to preterm babies cited several symptoms as the main alert that made them seek medical attention from the hospital. These included headaches that ranged from mild to severe, fainting, pain, bleeding, swelling of the leg, uncontrolled blood pressure and premature rupture of membrane (breaking the water). The latter was the most mentioned among the stated reasons. Some also mentioned the presence of other diseases such as tuberculosis.

Medical treatment appeared through the mention of referral systems from peripheral facilities. Most mothers had found themselves in KNH due to lack of well equipped peripheral facilities and expertise to offer the medical services that they needed. Physical pain and lack of access to medical treatment when needed can contribute immensely to psychosocial burden and quality of life. Below are some of the translated responses from the mothers.

It started with a headache (after which) I fainted immediately. I was (then) taken to Kitui General (Hospital). They (the doctors) said I needed an operation but they could not do it there because my (blood) pressure was very low. I was then referred to KNH.

I started feeling pain when I was admitted (in hospital). I was taken to the labour (ward) where I delivered a 1.5 kg baby.

My legs started swelling when I was 7 months (pregnant). I was not in pain but this continued until last Thursday

I had been bleeding for four months until I gave birth. I started feeling ill after I got pregnant. I got admitted in hospital for 2 weeks. I contracted TB (tuberculosis). I had oxygen (therapy) and I got well. (However) the blood had traces of water (amniotic fluid) in it.

They told me that my pregnancy (gestational period) was too young and their incubator was non-functional hence they sent me to KNH.

Emergency Nature of Preterm Birth and the Subsequent Nursery Care

The fact that preterm births come as medical emergencies and almost always caught the victims unaware also came out as one of the major themes that contributed to psychosocial burden and quality of life among mothers who gave birth to preterm babies. Most mothers admitted that they felt stressed when they learnt that they would give birth prematurely. The burden appeared to have been caused by the unexpected delivery time. Premature delivery meant that the mothers had not prepared psychologically. Moreover, the premature babies also presented with more challenges compared to their mature counterparts. The mothers cited having to stay in hospital to take care of the baby, breastfeeding after every three hours, expressing milk; which occasionally fail to come out because of the prevailing circumstances, lack of bonding due to being separated from their babies among the main challenges. Below are some of the sampled responses from the mothers.

I felt stressed. I was not expecting the baby to come at that time. You expect (the baby) at a certain time but it comes earlier. I am not prepared and the baby comes with more challenges.

I have to stay in the hospital and care for my baby every minute. (After) every three hours you are there (nursery). Expression of milk, sometimes the milk does not come out because I was not ready (for the delivery).

I started bleeding at 7 months. I was asleep when it started. I delivered two days later. The baby was 2.2 kg at birth. It was taken to the nursery for him to gain some strength.

I was asleep too when the bleeding started. My kid was 1.9 kg (at birth but) it fell sick and refused to breastfeed.

I felt bad because those (mothers who gave birth to term babies) who we were admitted with were discharged after delivery (while) I have had two weeks of pure stress.

Perception around Safety of the just concluded and Future Pregnancies

Most mothers admitted that they felt stressed and full of fear when they learnt that they would give birth prematurely. Their fear ranged from the decision point, the actual birth process, the thought of their baby being in the nursery, their separation from the newborn baby and the lengthy

separation from their families. The latter was mostly fronted by mothers who had left other children at home. The mothers shared a general perception that the nursery was not safe. Most of them seemed worried that they would give birth after which their baby would definitely die. Preterm birth can be considered as a life defining moment hence can result in total change in perception towards future pregnancy. This may result from the psychosocial burden and adjusted quality of life that are associated with pre-term birth and the challenges that accompany it. Nevertheless, most of the mothers seemed engrossed in the current situation to an extent of not willing to express their thoughts about their next pregnancy. The aspect of financial safety surrounding preterm birth also came up. Most mothers, however, thought that finances were not a major concern if the baby would make it out of the nursery alive. These are some of the sampled response from the mothers.

I was sad (and) worried about the nursery ... worried about their survival

It (the thought of premature birth) was painful and it hurt me so much. I fear for my baby

I was so shocked and scared. I had the feeling that I would give birth after which the baby would die but God saw me through.

I feel scared whenever I hear that babies are dying in the nursery. I feel very uncomfortable

I am worried about the bill. I was discharged yesterday but I was in so much pain that I couldn't stand without support. I went to the nursery and told them that NHIF (insurance) would foot the bill. When I went back was told it was not possible because I did not include the name of the baby ... that I should have done so after 24 hours but I thank God the baby is alive.

My fear is the hospital bill and whether the baby will survive.

Communication and Information gap together with Safety of Physical Environment

Poor communication by the health care providers to their patients also manifested as a major theme. Most of the mothers did not know the actual reason why they were admitted in hospital. There was no proper communication on what possibly may have caused the preterm birth. Most mothers stated the symptoms that made them seek medical attention. After which they stated the verdict of having to deliver their babies prematurely. A few of them stated preeclampsia and inability to carry a pregnancy to term based on previous pregnancies as the cause of their pre-term birth. Generally, whenever there is a gap in communication fear is generated because the patient tends to fill the gap with other thoughts. This, in effect, may contribute to psychosocial burden and affect quality of life of the mothers. These are some of the responses that were sampled from the mothers.

I heard doctors saying that a 33- week pregnancy has very low chance of survival hence I was very worried as I headed to theatre. I was anaesthetized and when I gained consciousness I inquired where my baby was and they (the nurses) said they don't know. I concluded that it died.

It is not anyone's wish. Bleeding and prematurely breaking the water. I don't know why it came earlier (than expected).

I didn't attend the (ANC) clinic hence the kid was (later) diagnosed with Spina bifida

Pre- eclampsia, swelling of the legs and uncontrolled (blood) pressure ... blood pressure and fainting (but) I don't know what caused the (rise in) blood pressure

The baby swallowed a lot of amniotic fluid when the CS was being conducted hence developed breathing problems.

I was so worried. My Hb was low, 9 instead of 12. I was so stressed. I would even faint hence I may have hurt myself in the process.

Seems like my womb cannot carry a pregnancy to term because the first (previous) pregnancy aborted after 6 months; same to this one.

The state of the physical environment surrounding the mother and her preterm baby can also contribute immensely to the psychosocial burden and quality of life of the mother. When the mothers are out of the nursery they may not be aware of the on goings in the nursery and this may cause a lot of stress. The situation is made worse by the fact that the babies share the cot despite their age and gravity of their condition. The babies are also too young hence they may pull out branulars and oxygen pipes from themselves or each other hence causing more harm.

I went to the nursery and found that the baby had pulled off the oxygen pipe. I could not tell when he did that. He had also removed the branular from the head hence the medication was flowing to his head and back. I keep asking myself if they (the nurses) would have noted it had I not gone to the nursery. The fact that my baby is there raises my fear.

Coping with Stress and Possible Changes at Kenyatta National Hospital

Coping with stress can help one reduce her psychosocial burden hence improving her quality of life. Mothers who were interviewed admitted to getting rid of their stress in different ways. These included crying, talking to friends and counseling. Some also acknowledged that talking to others patients about their situation helped them understand and appreciate that they were not in that situation all by themselves hence making them feel better. They said that they counseled each other but would appreciate if they would have gotten the same as a group from a qualified counselor. In the same breathe; some seemed to have resigned to fate.

I had to cry so that I could heal. I was in denial initially.

You just stick with the problem within you until that time when changes will occur. I am confused. I just pray to God.

I get relief from God (praying), from friends and counseling ... through sharing with other patients. When one tells you about her problems you gain strength because (you realize that) you share the same situation with many other people.

We counsel ourselves. We would appreciate if we had a counselor. It will be much better if counseled as a group.

We would appreciate if we would be put in the same room (away from term mothers) so that we can share our experiences and encourage each other.

The mothers also gave several suggestions on the possible changes that can be made to improve service delivery in KNH. Babies should be separated on need basis. Those with more severe conditions should be separated from those with less severe ones. There should be improved communication among the health care providers and patients. This includes proper communication on the condition of the babies, reasons for their admission to the nursery, their medical progress and if possible expected date of discharge. The number of nurses attending to babies in the nursery should be increased to counter shortage. Close monitoring of the babies when their mothers are not in the nursery to avoid danger that may arise from how the babies interact with each other in the nursery. Warm water and sufficient food should also be made available to the mothers because they help in increasing milk production. If food is served when the mothers are in the nursery then some should be reserved and served to them later. Alternatively, the time for serving food to the mothers should be changed altogether. Mothers should also be allowed ample time to bond with their babies. Time allocated to the mothers to breastfeed their babies should be reserved for exactly that. It should not be used as a teaching session to students. The number of beds and mosquito nets in the wards should be increased to allow ample room for the mothers to have adequate rest whenever they are not attending to their babies in the nursery. Furthermore, the hospital should provide an extra room away from the wards to allow the mothers to bond with the rest of their kids since kids are not allowed into the wards. The following are sampled responses from the mothers.

When the baby is fine you have peace mind. The needs of a premature baby cannot be compared to that of a baby with minor problems such as failing to suckle. When they are put together in the nursery the premature babies get less attention hence more stress to the mother. Premature babies should be given more attention.

The babies spend in the same place despite having different conditions. Some nurses respond rudely to us. Some kids do not breastfeed yet there is no nurse who shows concern

More nurses should be recruited in case there is a shortage. Each nurse should monitor one or two babies. Increase the number of beds in the wards, and give us mosquito nets.

The doctor should have a one on one dialogue with the patients before discharging them so as to know how she feels about her condition. I would rather one stays in the ward if she feels that she is not yet well.

You return from the nursery only to find that there is no food reserved for you. You sleep hungry despite being a breastfeeding mother. Reserve food for us or serve food when we are not in the nursery.

The mothers also pointed to the attitude of healthcare workers as an area that needs improvement. Some patients expressed their frustration concerning the attitude of healthcare workers. They also noted that the behavior of nurses changed significantly in the presence of senior doctors compared to when they were absent. They also thought it wise for nurses to respond to their questions rather than brushing them off.

Nurses should communicate to the patients. The patient should get a response to the questions they ask; not being told to ask or wait for his doctor yet one is seen by different doctors.

Whenever the senior doctors are around, the nurses react (to our concerns). They (nurses) pretend to be more caring ... the ones who come at night behave totally different from those who come during the day; they seem not to care.

You (health workers) are here because of me but I feel that you are here for the salary because I am not satisfied by the way I am treated ... if I ask a question I should get an answer. Pay attention, listen then act.

CHAPTER 4: DISCUSSION

The aim of this study was to evaluate and compare the psychosocial burden and quality of life of mothers who deliver preterm and those who deliver at term. Maternal and neonatal characteristics, psychosocial burden and quality of life as well as the subjective reporting of burden by the mothers were evaluated and analyzed. Preterm birth mothers had lower socioeconomic status, higher odds of psychosocial burden and poorer quality of life. The reported burdens majored around physical pain and referral, emergency nature of the deliveries, newborn care routine and separation strain, strenuous accommodation as well as poor communication and support from health workers.

Preterm mothers had a lower socioeconomic status evidenced by the lower education levels and employment levels among them compared to the term mothers. This is comparable with other studies which showed a higher preterm birth prevalence by 1.9% in the lower socioeconomic groups (40–42) . Some studies that contradicted these findings suggested that strenuous working conditions (over 42 hours a week or >6 hrs of standing) would also lead to preterm birth but most studies that mirrored our findings linked employment and education as indicators of well being, health status & social support hence lower preterm birth prevalence (41–43). Our study setting was a public hospital serving low and middle income earners who were the study participants.

The preterm neonates had poorer outcomes with lower birth weight, lower APGAR scores, higher NBU admissions, delayed breastfeeding initiation and maintenance, consequently leading to the prolonged hospital stay of the preterm mothers compared to the term mothers. These were similar to several studies and were presumed basis of the higher burden in the preterm mothers right from when the decision of delivery is made to the time of discharge from the hospital and even higher parental burden after discharge from the hospital (11,44,45).

Preterm mothers had 12% higher odds of having a higher psychosocial burden compared to their term counterparts. The overall difference in the psychosocial burden was not statistically significant. This differed with other studies which reflected a higher burden, Carson et al. 12% vs. 6% at one year after birth and Singer et al. 13% vs. 1% at 1 month and similar burdens at 14 years (10,26,38,46). Our study interviewed the mothers before they left the hospital when the burden was comparable to the term mothers who were still in the hospital hence facing similar

challenges hence the disparity on the burden levels with the studies done at one month and one year and at discharge as per the other studies (10,26,38).

The quality of life of preterm mothers was poorer than that of term mothers in the physical and environmental domains. The demands of taking care of a preterm neonate would result in energy drain, disturbed sleep, fatigue, poor rest, change in environment while caring for the neonate and lack of freedom, all impacting on the physical health and environmental domains. Availability of family support may explain the lack of association between psychological and social domains with the experience of preterm birth. This shows their quality of life was affected from early on in the care of their newborn. The overall quality of life was however not significantly different from the term mother. This reflected the changes observed in QoL in Amorim et al. which was done four months after delivery where the physical domain and environmental domain were prominently affected. The overall quality of life of our participants scored lower than for Amorim et al. maybe explained by the recent birth trauma, different socioeconomic levels and support systems in the two countries (47). A cohort follow up study of the mothers may reveal at what point the burden increases and the quality of life worsens significantly from the term mothers (26,46,47).

Marital status, mode of delivery and breastfeeding status also affected the quality of life. Breastfeeding was noted to improve the quality of life. This matched previous studies that showed early parental involvement and avoiding separation from the mother increasing bonding time reduced the burden and improved the quality of life (10,11,44,48). The separated women had a better quality of life maybe generated from the lack of expectation of social/financial support from their partner compared to the married and single women. The perceived better quality of life noted in emergency c/s patients would be explained by the less strenuous more comfortable accommodation offered to them compared to their counterparts who delivered vaginally.

The Focused Group Discussions revealed the psychosocial stressors and concerns that burdened and consequently worsened the quality of life of preterm mothers in five broad themes; Physical Pain and Medical Treatment; Emergency Nature of Preterm Birth and the Subsequent Nursery Care; Perception around Safety of the just concluded and Future Pregnancies; Communication

and Information gap together with Safety of Physical Environment; and Coping with Stress and Possible Changes at Kenyatta National Hospital.

The physical pain during preterm labour and lack of access to medical treatment leading to referral was a stressor reported. The emergency nature of preterm birth caught them unaware with no psychological, financial nor birth plan preparedness. The strenuous care of the baby at NBU with 3 hourly breastfeeding, separation and longer hospital stay weighed heavily on the mothers. Fear of the birth process, baby's survival and well being, lengthy separation from families as well as prognosis of future pregnancies dominated the mothers' perception around safety of current and future pregnancies.

Communication gap that was filled with negative thoughts/fears by the mothers also came out as a great stressor. The preterm mothers lamented healthcare providers not updating the mothers on their progress and that of the babies as well as the physical environment of the NBU (overcrowding).

The following coping strategies were employed by the mothers; crying, praying, talking to friends, self counseling and encouraging one another. They felt they would really benefit from a qualified counselor and structured support groups as well as improved communication and accommodation in the hospital.

These were similar to stressors observed in different group of preterm mothers where they reported surveillance, sleep disturbance, non-supportive healthcare, lack of social support and accessibility to quality healthcare as main stressors (47). Gangi et al. noted that early mothers involvement in the newborn care improved bonding and consequently reduced the post traumatic stress in preterm mothers (44,48). Counseling, psychoeducation, structured psychological interventions and as well as positive coping strategies were instrumental in improving the overall burden (37.5% vs. 25.2%) and QoL (11,26,46,49).

Our study findings mirrored other studies emphasizing on the early stressors (physical pain, fear of baby's well being, accommodation strain, newborn care routine, separation) and the need to address them from as early as before delivery with counseling and decision aids and continuous structured psychological interventions and support to ensure the psychosocial burden is reduced and subsequently mitigate the effect on quality of life of the preterm mothers (11,50).

Strength of the study:

The large sample size and the use of validated data collection tools was one of the strengths of this study as it enabled the translation and comparison of our study findings with similar studies.

The use of a mixed methods study design enabled our study to evaluate the mothers' perception on their psychosocial burden and QoL which complemented to the study tools.

Study limitations:

Long term follow-up to assess the burden and QoL after discharge and during child development was not possible due to the time limitations of the study. The participants would sometimes become emotional and breakdown during the interviews and as such some of the interviews were prolonged and took more than one session to complete. These did not affect our results as the interviews were stopped and continued at a later time and the incomplete sessions were not analyzed.

CONCLUSION

The preterm and term mothers in our study had high levels of psychosocial burden. Preterm mothers have a poorer quality of life in the physical and environmental domains as well as unique psychosocial stressors affecting their psychosocial well being. The preterm mothers have unique care needs that are not being met and need care tailored specific to them.

RECOMMENDATIONS

We recommend adjustments in the care of the preterm mothers to address the psychosocial stressors reported such as accommodation strain and long separation from neonates as well as improving communication and support from the health care workers. Structured patient-focused psychological counseling and support may help mitigate the burden and subsequently improve the mental health of the mothers with preterm birth.

We recommend further studies to assess the psychosocial wellbeing of mothers with preterm birth after discharge and for a longer duration as well as studies to evaluate psychological interventions to improve maternal psychological wellbeing.

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ANNEXES

Annex 1: Approval from Ethics Review Committee

Annex 2: Approval from Kenyatta National Hospital

Annex 3: Consent Form/ Fomu ya Idhini

Study title:

THE PSYCHOSOCIAL BURDEN AND QUALITY OF LIFE OF MOTHERS WITH PRETERM BIRTH IN KENYATTA NATIONAL HOSPITAL.

Principal investigator: Dr. Douglas Kamunya Mwaniki

Introduction:

I Dr. Douglas Mwaniki, a postgraduate student at the Department of Obstetrics & Gynaecology, University of Nairobi, am conducting a study on The psychosocial burden and quality of life of mothers with preterm birth in Kenyatta National Hospital. You are hereby requested to participate in the study.

This information will help you make a decision on whether to participate in the study or not. You may ask any questions about the study or anything in this form that is not clear.

Purpose of the study:

Preterm delivery involves a lot of psychological and physical changes that may impact on the quality of life of the mother. The extra burden borne by the mothers who deliver preterm compared to those who deliver term is not known.

This study will evaluate the psychosocial burden and quality of life of women who deliver preterm compare to those who deliver term to establish if there's a significant extra burden and impact on quality of life in the mothers who deliver preterm.

Benefits:

Your participation in the study will help us obtain this information that will be used to tailor pragmatic interventions to cushion the women against psychological distress and subsequent mental illness by early counseling and support. This study is expected to benefit your household, the local community, Kenya and mothers globally.

Possible risks:

The study will have no invasive procedures and you'll only be required to answer a few questions. There will be no added risks to you standard care as that accorded to other patients.

Voluntarism:

This is a voluntary exercise and you can withdraw at any point during the study with no repercussions. The management you receive at the hospital will be standard and not influenced by your decision.

Compensation:

No compensation will be offered for participation in the study.

Procedure:

As a study participant, the researcher and research assistant will obtain some information from your medical records and conduct a short interview with you and your responses filled in a questionnaire. Some of the conversation may be recorded for quality purposes.

Confidentiality:

The information from you and from the medical records will be confidential. No names nor any information identifying you will be included in the questionnaires and the final report.

Contact information:

If you have any questions regarding the study, you can contact Dr. Douglas Mwaniki through telephone number 0723 849902. You may also contact the KNH/UoN/ERC Committee-0735-274288/0721-665077.

Or

The chairperson,

KNH/UON Ethics and Research Committee

P.O. Box 20723-00202, Nairobi.

Telephone number: (254-020) 2726300-9 Ext 44355

Email:uonknh_erc@uonbi.ac.ke

Your participation in the study will be highly appreciated.

Consent:

I _____ hereby voluntarily consent to participate in the study. I acknowledge that a thorough explanation of the nature of the study has been given to me by Dr/Mr./Mrs. _____. I clearly understand that my participation is completely voluntary.

Signature of Participant _____ Date _____

Signature of Researcher/ Assistant _____ Date _____

Fomu ya Ithini:

KICHWA CHA UTAFITI:

MZIGO WA KISAIKOLOJIA NA UBORA WA MAISHA YA MAMA WALIOZAA KABLA YA KUFIKISHA MASIKU KATIKA HOSPITALI YA TAIFA YA KENYATTA.

Mtafiti Mkuu: Dkt. Douglas Kamunya Mwaniki

Utangulizi:

Mimi Dkt. Douglas Mwaniki, mwanafunzi wa shahada katika Idara ya Obstetrics & Gynecology, Chuo kikuu cha Nairobi, ninafanya utafiti juu ya mzigo wa kisaikolojia na ubora wa maisha ya mama waliozaa kabla ya kufikisha masiku katika Hospitali ya Taifa ya Kenyatta. Unashauriwa kushiriki katika utafiti huu.

Maelezo haya yatakusaidia kufanya uamuzi juu ya kushiriki katika utafiti huu. Unaweza kuuliza swali lolote kuhusu utafiti au chochote katika fomu hii kukuwezesha kuelewa zaidi.

Kusudi la utafiti:

Kuzaa kabla ya masiku kufika huleta mabadiliko mengi ya kisaikolojia na ya kimwili ambayo yanaweza kuathiri ubora wa maisha ya mama. Mzigo wa ziada unaobebwa na mama waliozaa kabla ya masiku ikilinganishwa na wenzao waliozaa wakati unaofaa haujulikani.

Utafiti huu utatathmini mzigo wa kisaikolojia na ubora wa maisha ya wanawake ambao huzaa kabla ya masiku na kulinganisha na wale ambao huzaa wakati unaofaa.

Faida:

Ushiriki wako katika utafiti utatusaidia kupata habari hii ambayo itatumika kuunda hatua za kuzuia wanawake dhidi ya dhiki ya kisaikolojia na ugonjwa wa akili baadae kwa kuwapa msaada wa mapema. Utafiti huu unatarajiwa kufaidi familia yako, jamii yako, nchi na wamama duniani.

Hatari zilizowezekana:

Utafiti huu hautakuwa na athari zozote kwako na utahitajika tu kujibu maswali machache. Hakutakuwa na hatari zaidi ya huduma ya kawaida kama ile iliyopewa wagonjwa wengine.

Hiari:

Hili ni zoezi la hiari na unaweza kujiondoa wakati wowote wakati wa utafiti bila lawama. Usimamizi unaopokea kwenye hospitali utakuwa wa kawaida na hautaathiriwa na uamuzi wako.

Fidia:

Hakuna fidia itatolewa kwa kushiriki katika utafiti huu.

Utaratibu:

Kama mshiriki wa utafiti, mtafiti na msaidizi wa utafiti watapata maelezo kutoka kwenye kumbukumbu zako za matibabu na kufanya mahojiano mafupi nawe. Baadhi ya mazungumzo yatarekodiwa kwa madhumuni ya ubora.

Usiri:

Taarifa kutoka kwako na kutoka kwa kumbukumbu za matibabu itakuwa siri. Hakuna majina wala maelezo yoyote ya kukutambulisha yatakayonukuliwa kwenye ripoti ya utafiti huu.

Maelezo ya mawasiliano:

Ukiwa na swali lolote kuhusu utafiti huu, unaweza kuwasiliana na Dkt. Douglas Mwaniki kupitia namba ya rununu 0723 849902. Unaweza pia kuwasiliana na KNH / UoN / ERC Committee kupitia nambari 0735-274288 / 0721-665077.

Ama:

Mwenyekiti,

KNH / UON Kamati ya Maadili na Utafiti

S. L. P. 20723-00202, Nairobi.

Nambari ya simu: (254-020) 2726300-9 : 44355

Barua pepe: uonknh_erc@uonbi.ac.ke

Tutakushukuru sana kwa ushiriki wako katika utafiti huu.

Idhini:

Mimi _____ nimeamua kwa hiari yangu mwenyewe kushiriki katika utafiti huu baada ya maelezo ya kina kutoka kwa Dkt. / Bwana / Bi. _____. Ninaelewa wazi kwamba ushiriki wangu ni kwa hiari.

Sahihi ya Mshiriki _____ Tarehe _____

Saini ya Mtafiti / Msaidizi _____ Tarehe _____

Annex 4: Questionnaire/Focused Group Discussion

Date:

Participant's code:

A: SOCIODEMOGRAPHIC AND CLINICAL CHARACTERISTICS

1. Age (years):

2. Marital status:

Single Married Divorced Separated

3. Educational level:

Primary Secondary Tertiary None

4. Occupation:

Formal Casual Unemployed

5. Parity: (using the format Para.....+.....).....

6. Duration in months from the last delivery?

7. Gestation in weeks at last delivery.....

8. If Preterm: Induced Spontaneous

9. Mode of delivery: Elective CS Emergency CS SVD

10. Any obstetric complication preceding delivery (indicate):

.....

11. Post partum complications: None Yes

If yes to 12 above, state the complication:

.....

12. Immediate neonatal outcome: Live birth Still birth

13. Apgar score (/10):.....

14. Birth weight (gm):.....

15. Congenital anomalies: None Single Multiple

16. Admission to NBU: Yes No

17. Breastfeeding: Yes No

Articles\ZBI-22.pdf

Articles\WHOQOL-BREF with scoring instructions Updated 01-10-14.pdf

FOCUSED GROUP INTERVIEW: (5-10 participants)

1. Participants Bio-data

Serial number	Age	Sex	Residence	Marital status	Religion	Level of education

2. Facilitator's welcome, introduction, instructions to participants and consent explanation/form.

Welcome and thank you for volunteering to take part in this focus group. You have been asked to participate as your point of view is important. I appreciate your time and willingness to participate.

Introduction: This focus group discussion is designed to assess your current thoughts and feelings about how your current delivery has affected your psychological wellbeing and quality of life. The focus group discussion will take no more than one hour. May I tape the discussion to facilitate its recollection? (If yes, switch on the recorder)

Anonymity: Despite being taped, I would like to assure you that the discussion will be anonymous. The tapes will be kept safely in a locked facility until they are transcribed word for word, then they will be destroyed. The transcribed notes of the focus group will contain no information that would allow individual subjects to be linked to specific statements. You should try to answer and comment as accurately and truthfully as possible. I and the other focus group participants would appreciate it if you would refrain from discussing the comments of other group members outside the focus group. If there are any questions or discussions that you do not wish to answer or participate in, you do not have to do so; however please try to answer and be as involved as possible.

Consent explanation/form: Thank you for participating in this study. We will have an open discussion where everyone will be allowed to air their views to give information that may help improve the care of mothers with preterm birth. This discussion will be recorded for further analysis and dissemination of the findings. Confidentiality will be maintained at all levels of information processing. Your participation is voluntary, feel free to answer or remain quiet and to quit at any particular stage without fear of any victimization. Thank you again for being part of this study.

3. Ground rules

- The most important rule is that only one person speaks at a time. There may be a temptation to jump in when someone is talking but please wait until they have finished.
- There are no right or wrong answers
- You do not have to speak in any particular order
- When you do have something to say, please do so. There are many of you in the group and it is important that I obtain the views of each of you
- You do not have to agree with the views of other people in the group
- Does anyone have any questions? (answers)
- OK, let's begin

4. Warm up

- First, I'd like everyone to introduce themselves. Can you tell us your name?

5. Introductory question

I am just going to give you a couple of minutes to think about your experience during delivery and child birth. Is anyone happy to share his or her experience?

6. Guiding questions (these to be answered by any member of the team as they feel comfortable)

Can anyone share how they felt when she discovered she was having a preterm birth?

Does anyone have an opinion what caused the preterm birth?

Does everyone feel well cared for and supported here in KNH?

How would KNH make preterm mothers more comfortable?

Let's hear your fears concerning your babies and yourselves?

Who will tell us how they plan to cope with their fears?

Who among you feels stressed? And what is stressing you?

7. Concluding question

Of all the things we've discussed today, what would you say are the most important issues you would like to express about this checklist?

8. Conclusion

- Thank you for participating. This has been a very successful discussion
- Your opinions will be a valuable asset to the study
- We hope you have found the discussion interesting
- If there is anything you are unhappy with or wish to complain about, please contact the local PI or speak to me later

- I would like to remind you that any comments featuring in this report will be anonymous
- Please, write your report based on the results of the focus group. Please remember to maintain confidentiality of the participating individuals by not disclosing their names.

Annex 5: Referral Letter for further Psychiatry and Mental Health care.

REFERRAL LETTER

Dr. Douglas Mwaniki,
Resident Obstetrics & Gynecology Department,
University of Nairobi.

Date:

To:

The Chairperson,
Department of Psychiatry and Mental Health,
Kenyatta National Hospital.

Dear Sir/Madam,

RE: MRS. XYZ

In our study on “The psychosocial burden and quality of life of preterm birth mothers in KNH”, the above named study participant was found to have significant psychosocial burden and would require further evaluation, management and follow up at your department.

Attached are her clinical details and records for your perusal and the KNH consultation form.

Thank you for your continued cooperation and support.

Yours

Dr. Douglas Mwaniki

OBS/GYN Resident- UON.

Annex 6: ISSM - COREQ Checklist

Annex 7: Study timeline

	Sep 2017	Oct 2017	Nov 2017	April 2018	July 2018 - Feb 2019	March – April 2019	May – June 2019
Concept development							
Proposal development							
Ethical approval							
Data collection							
Data analysis							
Dissertation write up							

Annex 8: Study Budget



KNH Research and Programs

Awards are limited to a maximum of Kshs. 400,000.00

Components	Unit of Measure	Duration/ Number	Unit Cost (Kshs)	Total Cost (Kshs)
Personnel				
Research Assistant	1 Person	74 days	1,500.00	111,000.00
Statistician				30,000.00
Transcribing Fee	10 Transcripts	1	2,000.00	20,000.00
Printing	Copies	Pages		
Consent Form	1	5	10.00	50.00
Assent Form				
Questionnaires	1	11	10.00	110.00
Interview Guide	1	2	10.00	20.00
Final Report (Coloured)	6	6	20.00	720.00
Final Report(Black & White)	1	74	10.00	740.00
Photocopying				
Consent Form	1,050	3	3.00	9,450.00
Questionnaires	1,050	11	3.00	34,650.00
Interview Guide	10	2	3.00	60.00
Final Report- Black & White	5	74	3.00	1,110.00
Final Report Binding	6 books	1	500.00	3,000.00
Other costs				

ERC Fees	1	1	2,000.00	2,000.00
Poster Printing	1	1	2,500.00	2,500.00
Batteries	2 pairs	1	200.00	400.00
Stickers	11 pieces	1	30.00	330.00
Total				216,140.00

Budget items Justification:

1. Research Assistant:
1 research assistant is able to interview 16 participants a day. To achieve the sample size of 1026 we need 64 days. We will add 1 research assistant for 10 days to conduct focussed group discussions (FGDs) giving us a total of 74 days.
2. Transcribing fee: **This will be a one off fee for the transcription of the 10 recorded FGDs sessions.**
3. Statistician: **This will be a one off payment to the statistician for data analysis.**
4. Printing and Photocopying: **Will print one copy of each of the study tools and photocopy the rest. The coloured copies will all be printed. An extra 24 copies will be photocopied to take care of possible spoilt ones.**
5. Batteries: **2 pairs of batteries will be bought for use with the voice recorder that will be provided by the research department.**
6. Stickers: **stickers will be bought to identify patient files. Each batch has 100 stickers hence 11 batches will be needed.**
7. Poster Printing: **The results will be presented in form of poster presentation at the end of the study.**