University of Nairobi

UTILIZATION OF ANTENATAL CORTICOSTEROIDS FOR IMPROVING NEONATAL OUTCOMES IN KENYATTA NATIONAL HOSPITAL

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DECLARATION

I declare that this dissertation, 'Utilization of Antenatal corticosteroids for improving neonatal outcomes in Kenyatta National Hospital', a cross sectional prospective study, is my own original work and has not been submitted elsewhere for examination or award of degree. All resources and materials I have used or quoted have been indicated and acknowledged by means of reference. I further declare that this dissertation has not been submitted for the award of any other degree or to any university or institution.

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God bless you all.

DEDICATION

I dedicate this dissertation to the Almighty God for giving me life, health, strength, wisdom and the opportunity to pursue my dreams.

I also dedicate this work to my parents Mr. Timothy Mworia and Mrs. Anne Mworia for always remembering me in their prayers and being a constant source of inspiration, motivation and peace in my life. Thank you for all your guidance as I work to achieve my life's ambitions. God bless you abundantly.

To my grandparents for teaching me that the greatest blessing in life is the ability to be a source of peace and hope to everyone you meet. I hope to continue building on the legacy you established for me.

All praise belongs to Jehovah.

ABBREVIATIONS

ACOG - American College of Obstetricians and Gynecologists

ACS - Antenatal Corticosteroids

ANC - Antenatal Care

FIGO- International Federation of Obstetricians and Gynecologists

GA – Gestational Age

IVH – Intraventricular Hemorrhage

KNH – Kenyatta National Hospital

LMP – Last Menstrual Period

NBU – New Born Unit

NEC- Necrotizing Enterecolitis

NBS – New Ballard Score

NICU – Neonatal Intensive Care Unit

PROM – Pre-labour Rupture of Membranes

PPROM – Preterm Pre-labour Rupture of Membranes

RCOG – Royal College of Obstetricians and Gynaecologists

RDS - Respiratory Distress Syndrome

SVD - Spontaneous Vertex Delivery

UNCoLSC - United Nations Commission on Life-Saving Commodities

UON – University of Nairobi

WHO -World Health Organization

DEFINITIONS OF TERMS

Labour: Intermittent uterine contractions that increase in frequency and intensity and result in effacement and dilatation of the cervix and spontaneous bearing down effort leading to expulsion of the products of conception.

Preterm birth: All births before 37 completed weeks of gestation or fewer than 259 days since the first day of a woman's last menstrual period.

Gestational age: The post-conception age of the baby based on menstrual dates and confirmed by clinical assessment using the New Ballard Score.

New Ballard Score: A tool used to assess gestational age using various criteria divided into physical and neurological criteria.

Silverman Anderson Score: A score used to assess severity of respiratory distress in newborn and preterm infants without respiratory support

Low Birth Weight: Birth weight less than 2500 grams

Parity: The total number of times a woman has been pregnant regardless of the outcome.

Spontaneous preterm birth: Spontaneous onset of labor or labor following premature rupture of membranes (PROM)) occurring before 37 completed weeks of gestation.

Induced preterm birth: Induction of labor or elective Cesarean section before 37 completed weeks of gestation

One course of Antenatal Corticosteroids: Can be either two 12 mg doses of betamethasone given intramuscularly 24 hours apart or four 6 mg doses of dexamethasone given intramuscularly every 12 hours

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ABSTRACT:

Background: Antenatal corticosteroids (ACS) are well recognized as a key mediator in decreasing the adverse complications of preterm birth. Preterm newborns are more likely to experience both short-term and long-term morbidities, with RDS being one of the most serious. Only 35% of prenatal corticosteroids were used in Kenyatta National Hospital (KNH), according to Gwako et al. Guideline changes are expected to result in increased ACS use, however no follow up study has been done to assess the current utilization of antenatal corticosteroids at KNH and identification of factors that may affect its use.

Objectives: To determine the proportion of women who delivered in KNH between 24-37 weeks and received antenatal corticosteroids and to describe factors associated with its utilization as well as the neonatal short-term outcomes.

Study Methods: A cross-sectional descriptive study in Kenyatta National Hospital NBU/NICU and postnatal wards that recruited women and their preterm neonates delivered at Kenyatta National Hospital. Outcome measures included frequency of antenatal corticosteroids administration, need for NBU admission, need for respiratory support and prevalence of neonatal deaths. Factors associated with antenatal corticosteroid administration were determined by the calculation of the Risk Ratio (RR) and 95% confidence intervals (CI) with a level of statistical significance set at 0.05. Multivariate analysis was carried out to adjust for confounders.

Results: Of 384 women, 171 (45%) received antenatal corticosteroids (95% CI 39.6% - 49.5%). Antenatal corticosteroids were prescribed in 251 of women recruited, but was administered to 171 women .The greatest discrepancy between prescription and administration was seen in the 29–32-week group. Multivariate analysis to adjust for confounders revealed that women with a gestational age ≤34 weeks (ARR 2.37 95% CI 1.69 – 3.32; p=<0.001) and the presence of comorbidities (ARR 1.38 95% CI 1.10 – 1.75; p=0.006) were more likely to receive antenatal corticosteroids, while women who presented with the presence of labour at admission (ARR 0.74 95% CI 0.58 – 0.95; p=0.018) were less likely to receive antenatal corticosteroids and these were statistically significant In newborns exposed to prenatal corticosteroids, 93 % required admission to the NBU/NICU, 46 % required oxygen, 32 % required CPAP, 12 % required mechanical breathing, 23 % required surfactant, and 20 % of the neonates died during the first seven days of life.

Conclusion: Antenatal corticosteroids are underutilized in women who deliver preterm in KNH between 24-37 weeks. Fewer women receive antenatal corticosteroids than those to whom it is prescribed. Comorbid conditions and a gestational age of less than 34 weeks were linked to higher prenatal corticosteroid utilization, whereas labor at the time of admission was linked to lower antenatal corticosteroid utilization.

Recommendations: There is need to increase the utilization of antenatal corticosteroids in KNH. Further study is needed to identify gaps in administration of antenatal corticosteroids following its prescription.

CHAPTER ONE
1.0 INTRODUCTION

1.1 Background Details and epidemiology:

Preterm birth, which by definition refers to live births occurring before 37 full weeks of gestation, represents 10.6% of live births worldwide in 2014, totaling 14.84 million births. (1).

Prematurity is associated with increased mortality especially for those delivered before the expected date of delivery. Globally it is the main cause of mortality affecting children aged less than 5 years as reported in 2015 where 1.06 million deaths of the 5.9 million deaths in the age group were associated with premature birth and its complications. The risk of mortality and morbidity in premature newborns is significantly higher at lower gestational ages nevertheless there are still significantly higher risks for late premature infants compared to term babies (2).

It affects many countries worldwide with estimates from the World Health Organization (W.H.O) between 5-18% across 184 countries, the majority in the African and Asian continent. Preterm birth rates in India are 15%, according to Shubhada A et al, 16.8 percent in Zimbabwe, according to Feresu SA, and 16.3 percent in Malawi, according to Van den Broek NR et al. Wagura et al. reported that the preterm birth rate in KNH was 18.3 percent. In many developing countries use of antenatal corticosteroids remains low including in Cameroon (10%), Brazil (4%) and Ecuador (35%) and in Kenya the overall frequency of utilization was at 35% as reported by Gwako et al. This indicates multiple missed opportunities to provide this key treatment crucial for improving neonatal outcomes. (3-10).

The most common complication leading to mortality in premature neonates is respiratory distress syndrome which is a lung disease presenting acutely in neonates associated in particular with surfactant deficiency. There is an inverse relationship between gestational age and the prevalence and severity of respiratory distress syndrome (RDS). Antenatal corticosteroids given to expectant mothers at risk of preterm delivery are one of the mainstay treatments for improving newborn outcomes; this has been associated with a decrease in neonatal death. (5, 6, 11-14).

Gwako's study of the mothers who received ACS, 46% delivered before 34weeks while 26 % delivered after 34 weeks. Only 3% of the mothers with preterm labour received a complete course of ACS. Malawi reported similar findings, where only 4% of the mothers in preterm labour received a complete course of ACS (7). It was not clear as to why full doses of ACS were not administered but most often noted was that mothers were admitted in advanced labour

with no time to give the complete course or that there was a failure to capture the drug administration information following poor documentation. Other reasons included incorrect evaluation of gestational age, the diagnosis of inevitable abortion, obstetric emergencies requiring immediate delivery, refusal by expectant mothers to seek assistance at medical facilities and in some cases obstetricians overlooking a missed chance to administer antenatal corticosteroids (15-17).

1.2 Statement of the problem

Preterm birth is a problem in 184 countries, according to estimates from the World Health Organization (5–18%). According to local data, the incidence in Kenyatta National Hospital was 18.3%, and 35 percent of prenatal corticosteroids were used overall. Of those women who received ACS 46 % delivered before 34weeks while 26 % delivered after 34 weeks and as such highlights a gap in the management of preterm labor. Has there been an increase in utilization as a result of new updates to preterm labor management SOPs and antenatal corticosteroid use guidelines? There have been no additional studies conducted to examine the current utilization rates in our facility.

1.3 Justification and Utility of the Study

Improving antenatal corticosteroid utilization would improve the outcomes of preterm neonates leading to important cost saving to both households and the health system. There has been no recent study conducted to examine the current utilization rate in our facility. The study findings would act as a means of evaluation if there been an increase in utilization as a result of new updates to preterm labor management and antenatal corticosteroid use guidelines. Data generated from the study could be used to generate new hospital policy recommendations.

CHAPTER TWO

2.0 LITERATURE REVIEW

2.1 Introduction

W.H.O defines preterm birth as delivery which occurs before 37 completed weeks of gestation or fewer than 259 days since the first day of a woman's last menstrual period. (18).

2.2 Causes and Risk Factors

Preterm births can be categorized as either spontaneous or induced. Spontaneous preterm births are the outcome of spontaneous early labor (40–45%) or the premature rupture of the membranes (20-25 percent). Preterm deliveries that are induced account for 30–35 percent of preterm births and are performed for obstetrical conditions such pre-eclampsia, eclampsia, hemorrhage, and acute or chronic fetal compromise. Premature labor was prevalent in 15.6 percent of cases, according to a cross-sectional study done at KNH in 2001.It also found no associated factor in 52% of the preterm deliveries while 26.6% were due to PPROM and 8.5% due to pre-eclampsia, among other factors. Gwako et al in 2014 found strong association in the occurrence of preterm delivery with presence spontaneous preterm labour; hypertension and PPROM were the which is a similar finding to Pattanittum et al. In KNH 28.5% of preterm births occurred at 28-30 weeks with 41.5% at 34-36 weeks this is in contrast to the USA where 5% of preterm deliveries occurred before 28 weeks and 60-70 % of preterm babies were delivered at 34- 36 weeks.

Broncho-pulmonary dysplasia, hypothermia, respiratory distress syndrome, , intraventricular hemorrhage and newborn sepsis are among the morbidities linked to preterm birth. Long-term morbidities include the emergence of cerebral palsy, mental impairment, and retinopathy of prematurity (18-23).

2.3 Respiratory Distress Syndrome

More than 10% of all newborns born weighing less than 2500 g are likely to be adversely affected by neonatal respiratory distress syndrome, which can be decreased or prevented in the majority of cases by giving pregnant women who are about to deliver prematurely prenatal steroids. (7).

Respiratory distress syndrome (RDS) is caused by inadequate lung structure, concomitant surfactant insufficiency, and a lack of associated surfactant protein production. It begins shortly after birth with the acute illness' clinical presentation lasting about 2 to 3 days. The clinical signs of tachypnea, tachycardia, and chest tightness, as well as the chest x-ray, which shows lower lung capacities, distinct, uniform infiltrates, and air-bronchograms, are used to diagnose RDS. Mechanical ventilation, supplementary oxygen use, and Continuous Positive Airway Pressure (CPAP) are all possible RDS management strategies.. Exogenous surfactant should be given via endotracheal tube in extreme preterm infants and those manifesting severe cases followed by respiratory support. The incidence of RDS and its complications, such as chronic lung diseases metabolic disorders , patent ductus arteriosus, hypotension and intracranial hemorrhage, have been significantly decreased as a result of accurate gestational age estimation techniques, such as early gestation sonography and the regular use of corticosteroids. Following administration, prenatal corticosteroids show their greatest effects after 24 hours, peaking at 48 hours, and continuing to be efficacious for at least a week (13, 22, 24-29).

2.4 Guidelines on Antenatal Corticosteroid Use

In 2012, the United Nations Commission on Life-Saving Commodities (UNCoLSC) listed antenatal corticosteroids as one of its 13 lifesaving commodities. Therapy using ACS is thought to follow two mechanisms of action that aim to improve lung functionality. The first is by promoting the growth of type 1 and type 2 pneumocytes. The second is by biochemical maturation following phospholipid synthesis in type 2 pneumocytes after the induction of lung enzymes.

Corticosteroids have also been postulated to be efficacious at later gestational ages of more than 34 weeks by increasing epithelial sodium channels expression, enhancing the alveoli absorption of sodium and fluid instead of active fluid secretion which results in fetal lung fluid reduction.

A complete course comprising of 4 doses of dexamethasone each at 6 mg should be administered intramuscularly twice daily are recommended by both the American College of Obstetricians and Gynaecologists (ACOG) and The Royal College of Obstetricians and Gynaecologists (RCOG) in mothers at risk of preterm delivery between 24 and 34 weeks of

gestation, It is worth noting that the Royal College of Obstetricians and Gynecologists (RCOG) guidelines state in all cases of planned elective caesarean section before 39 weeks of gestation, mothers should receive ACS. as studies found this to reduce the rate of admission for RDS among this group of neonates. Antenatal corticosteroid use is recommended by the ACOG and FIGO Working Group on Good Clinical Practice in Maternal-Fetal Medicine in patients between 34 and 37 weeks of gestation. The current preterm labor and preterm PROM protocol in KNH (SOP/KNH/OBS/GYN/059) does not explicitly state the antenatal corticosteroids to be administered or the dosage. Expectant women at risk of premature delivery before 34 weeks of gestation are given antenatal corticosteroids. In the absence of precise LMP dates or fetal lung maturity testing, anecdotal evidence suggests that for women whose delivery is between 34- and 37-weeks gestational age; a single course of antenatal corticosteroids is administered to improve the outcome of the neonate, with the choice being based on the obstetrician's personal preference and experience, based on these aforementioned international guidelines. On this matter, there are no clear hospital guidelines. (14, 30-32).

2.5 Antenatal corticosteroid utilization and outcomes

In the study carried in KNH by Gwako et al, the overall frequency of utilization of antenatal corticosteroids was only at 35%. The study showed that of those who received antenatal corticosteroids 46% of women delivered before 34 weeks while 26% delivered after 34 weeks. Only 40% of women who gave birth before 34 weeks gestation received prenatal corticosteroids, according to a study by Pattanittum P et al. Most of the women (81%) gave birth fewer than 48 hours after receiving the medication, while only 19% gave birth more than 48 hours after receiving it.. Despite the minority of mothers receiving a complete course of antenatal corticosteroids, there was a marked decrease in both morbidity and mortality of the neonates. Although the majority of the women were hospitalized long enough for the prenatal corticosteroids to be given, it was not clear why they didn't receive the full doses. According to Gwako et al, in preterm neonates below 34 weeks gestation the development and severity of RDS was substantially reduced with antenatal corticosteroids exposure. The study also found that antenatal corticosteroids exposure reduced premature neonatal mortality rates throughout all gestational ages with a greater impact on premature neonates delivered within 34 weeks of 11.5% compared to those who were born after 34 weeks of 5.8% (4, 21).

2.6 Late preterm and antenatal corticosteroids exposure

A global study of over 29 million infants found that late premature birth was associated to a rise in mortality as compared to newborns delivered at term with exposure to antenatal corticosteroids marginally reduced the incidence of RDS in neonates born after 34weeks. It

was also associated with fewer neonates requiring oxygen therapy and mechanical ventilation in this age group contrasted with newborns who weren't exposed (33).

2.7 Study Objectives

2.7.1 Broad Objective

- To ascertain the proportion of women who deliver preterm between 24-37 completed weeks of gestation in KNH and receive antenatal corticosteroids, the factors associated with antenatal corticosteroids utilization and the short-term outcomes in these neonates.

2.7.2 Specific Objectives

- To ascertain the number of women who deliver between 24-37 weeks of gestation and receive antenatal corticosteroids
- To determine the factors associated with utilization of antenatal corticosteroids (gestational age, presence of comorbidities, history of pregnancy loss, number of ANC visits and presence of labor at admission)
- To determine short-term outcomes in preterm neonates exposed to antenatal corticosteroids including need for admission, need for oxygen, need for CPAP, need for mechanical ventilation, need for surfactant and neonatal mortality.

CHAPTER THREE

3.0 RESEARCH METHODOLOGY

3.1 Study Design

A cross-sectional study was conducted at Kenyatta National Hospital because it required less time and was more cost effective, giving an opportunity to look at the various objectives and collect data for all variables at a single point in time.

3.2 Study site and setting

The study was carried out at the Newborn Unit (NBU)/Neonatal Intensive Care Unit (NICU) and postnatal units at Kenyatta National Hospital. The Kenyatta National Hospital is a tertiary facility serving as a national referral facility as well as a teaching hospital for the University of Nairobi, College of Health Sciences. Its location 4 kilometers west of Nairobi's Central Business District provides access to medical care to the low and medium socioeconomic population. This is linked to referrals from other hospitals in the nation and the larger region of Eastern Africa. The hospital has a busy maternity unit providing delivery services to over 1300 women per month and a NBU which offers specialized neonatal care. Based on their gestational age, vital signs, the health of the fetus, and diagnoses, women are given a priority status for admission to the birthing unit. The first dosage of dexamethasone may be administered to the patient, if necessary, as determined by the last regular period and verified by an early prenatal ultrasound. The standard procedure is to give two doses of 12 mg dexamethasone intramuscularly 12 hours apart., if unsure of dates tests should be conducted to assess fetal lung maturity however these may be unavailable or delayed leaving the decision to the obstetrician's own discretion based on other recognized guidelines.

Neonates in the following categories are admitted to KNH NBU: • All preterm neonates born with birthweights under 2000 grams

• Neonates with RDS, birth asphyxia, jaundice, or congenital abnormalities who weigh more than 2000 g at birth

• The state of the mother, such as if the mother is admitted to intensive care for whatever reason; neonates whose mothers have diabetes mellitus and rhesus negative blood groups

When the low-birth-weight newborns are stable and have gained 1800 grams in weight, they are discharged from the hospital. Babies delivered preterm but have a weight greater than 2000g and have no other indication for admission to NBU are accommodated in the postnatal wards with their mothers until discharge.

3.3 Study Population

The population of the study comprised of 384 women and their neonates delivered preterm at Kenyatta National Hospital between 24 weeks and 37 weeks of gestation.

The gestational age was defined using the New Ballard's score for gestational age assessment as seen in Appendix VI (34).

3.4 Eligibility Criteria

3.4.1 Inclusion Criteria

The following requirements had to be met by each participant that was selected in order for them to be considered for the study.

a. All women who delivered live preterm babies in KNH and their neonates with a documented (written) between 24 weeks and 37 weeks of gestation, using the New Ballard score taken within 48 hours of delivery.
b. Documented (written) informed consent from mother was obtained

3.4.2 Exclusion Criteria

Participants who fulfilled the following criteria were excluded from the study

a. All women who had stillbirths and women who did not give consent
b. Neonates with an identified major or lethal congenital fetal anomalies
c. Neonates from multiple gestation
d. Neonates older than 48 hours with no documented New Ballard Score
e. Any mother with documented contraindications to antenatal corticosteroid administration or on corticosteroid treatment aside from that of preterm labor management

3.5 Sample Size Determination

The sample size was determined by applying the Fischer's Formulae;

$$n = \frac{Z_{\alpha}^2 \, p \, (1-p)}{d^2}$$

$Z_{\alpha} = 1.96$

- n = estimated sample size
- p =expected proportion in population
- Z_{α} = Standard normal deviate for 95% CI (1.96)
- d = precision level (set at 5%)

$$n = \frac{(1.96)^2 \times 0.50 \times 0.50}{(0.05)^2}$$

n = 384 mother-baby pairs

The value of p that maximizes p (1-p) is p=0.5 because the current population percentage expected for all objectives was unknown., this would generate the most conservative sample size to meet all objectives. The largest sample size of 384 was generated from p (expected proportion in population) of 50%.

3.6 Study period

The study was carried out between the months of July to November 2021.

3.7 Sampling Method

Mothers and their preterm infants were recruited by consecutive sampling from the NBU/NICU and postnatal wards, until the target sample size is reached.

3.8 Study Personnel and Recruitment of Participants

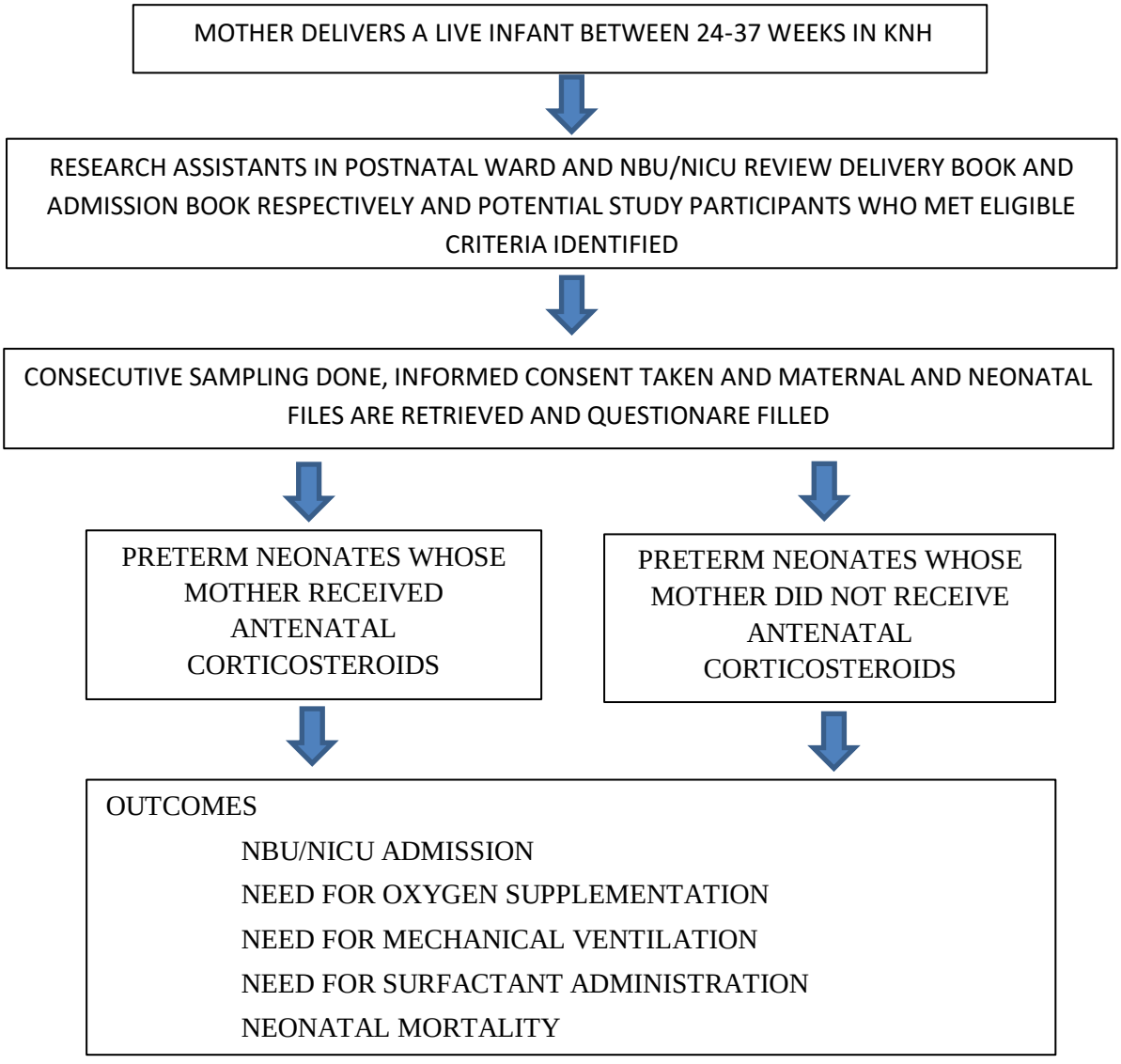
Research Assistants recruited to work in the study were two qualified clinical officers with experience working in KNH-NBU, each of who was assigned to the respective study locations in the NBU/NICU and postnatal wards. Permission from the relevant authorities was sought by the principal investigator (PI) who then orientated the research assistants around the units as they were introduced to the in-charges in the respective departments. Training of the research assistants was done by the primary investigator on how the study was to be carried out including how to carry out the New Ballard's score, review maternal and neonatal records for information and filling of the questionnaire. Daily follow up supervision of the research assistants, entry and back up of the data collected on a daily basis was the responsibility of the principal investigator.

Recruitment of participants was done daily by the research assistants. A customized data collection form was used for ease of analysis. Neonates meeting the eligibility criteria were to be identified and recruited through perusal of NBU/NICU and maternal postnatal ward's - Admission Book and files. The perusal involved confirmation of KNH delivery and the documentation of the New Ballard Score (NBS) of those neonates born between 24 to 37 weeks of gestation, taken within 48 hours of delivery. Women who would satisfy the inclusion criteria were made aware of the study's goals and the need for their consent. Mothers who provided the study with their informed consent, along with their neonates. In cases where New Ballard Score is not documented in the file and the baby was <48 hours, the principal investigator or research assistant would conduct a NBS and the patient will be recruited, however in cases where New Ballard Score is not documented in the file and the baby was >48 hours, the patient would not be recruited. Following recruitment, the participant's admission (in-patient) number was entered into a register and serialized in a bid to prevent double participant recruitment; the Research Assistant would then administer the pre–tested structured questionnaire that had both open-ended and closed-ended questions. The mother's prenatal record and/or file contained additional information about the mother's history. Neonates were followed until the 7th day of life or discharge or death whichever preceded the other. The obstetrician treating the patient was in charge of deciding whether to recommend prenatal corticosteroids or not. While the use of supplemental oxygen indicated the requirement for respiratory support. The decision to

prescribe surfactant was the responsibility of the registrar or neonatologist managing the patient as guided by the NBU-SOP on surfactant administration.

The process was carried out as shown in the figure below.

Figure 1: Sampling, Recruitment and Data collection Flowchart



3.9 Measurements

3.9.1 Gestational Age Assessment

In our set up despite access to early obstetric ultrasound, a large proportion of mothers who deliver at our facility are not followed up here at the ANC clinics, thus have no early obstetric scan performed. The New Ballard Score was used to estimate gestational age as it achieved greater accuracy especially in extremely premature neonates, as seen in Appendix VI (34).

3.10 Study Outcomes

For the broad objective the outcome was the proportion of women documented to have received antenatal steroids.

For the specific objectives the outcomes included: factors associated with utilization of ACS (presence of comorbidities, history of pregnancy loss, the number of ANC visits and presence of labor at admission) neonatal mortality and the following interventions: need for oxygen therapy, need for CPAP, need for mechanical ventilation, and need for surfactant administration.

3.11 Data Collection instruments

Following recruitment of the study participants and obtaining consent from the caregiver, the Research Assistant administered a pre–tested structured questionnaire that had both open-ended and closed-ended questions.

3.12 Data management and quality

Two registered clinical officers with experience working at KNH-NBU were hired as research assistants. Before data collection began, the primary investigator trained the research assistants on the study protocol and procedures in order to help with data management tasks like data collecting and entry. This was done the week before data collection began and continued until the lead researcher was certain that the assistants had received adequate training in data collecting.

The research assistants worked with the primary investigator to fill out data retrieval forms (data entry), collect data from patient case notes, including information on neonatal outcomes and exposure to dexamethasone, and make sure the health records were only utilized for study. Once the lead investigator had received approval from the relevant KNH departmental heads, the research assistants did not require permission to access the patients' records.

The study instrument and data abstraction method were explained to research assistants, who were then closely supervised by the lead investigator until they were comfortable with the procedure. This ensured quality control during data collection. Together with the research assistants, the principal investigator completed 50 data retrieval forms and used the chance to check the data retrieval forms' questions for clarity. Patient and neonatal records, along with case notes, were acquired outside of the study period and used for training.

Before entering the data, the primary investigator checked each questionnaire for accuracy. Any blanks were filled in by consulting the medical records again.

The acquired information was all de-identified and made anonymous. A Microsoft Excel spread sheet with built-in consistency and validation checks was used to enter the data after that. By checking each variable in the database for completeness, validity, and cross-validation of entries in related variables, it was cleaned using statistical tools..

3.13 Data Storage

The completed questionnaires were kept in a drawer that could be locked. Only the statistician, the primary investigator, and the supervisors had access to the data, which was kept on an external storage device that required a password to access it.

3.14 Data Sharing and Access

Discretion was exercised in sharing this material. The study results will be published once they have been processed, and this can be seen on the websites of medical journals.

3.15 Data Analysis

STATA and SPSS were used to analyze the data.. Maternal socio-demographic characteristics were measured using continuous variables and summarized using tables and charts. Neonatal demographic characteristics such as gestational age and birth weight were measured using continuous variables and summarized as mean and a measure of variation with findings then being summarized using tables and charts. The calculation of the Risk Ratio (RR) and 95 percent confidence intervals (CI) with a level of statistical significance set at 0.05 was used to identify factors associated with antenatal corticosteroid administration between the antenatal corticosteroid exposed and non-antenatal corticosteroid exposed groups. Multivariate analysis using log binomial regression model to adjust for confounders was then carried out. The short-term neonatal outcomes were then summarized in tables.

3.16 Control of errors and bias

The following actions were done to minimize various biases and errors.

1. Data were uploaded into a computer on a regular basis, and daily cross-checks confirmed the accuracy of the data collected.
2. The questionnaire was pre-tested to reduce on insensitive measure bias thus ensured that questions were sensitive enough to detect what might be important differences in the variable of interest.
3. Explanation on the definitions of the terms used in the questionnaires was done by the principal investigator to ensure similar interpretation when collecting data.
4. The principal investigator supervised data entry to ensure validity of the collected data.

5. The New Ballard Score was used to estimate gestational age as it achieves greater accuracy in extremely premature neonates (Ballard)
6. In cases where there was no documented Antenatal Corticosteroids prescription by a clinician in file or treatment sheet, the nurses' cardex was reviewed for such information. Lack of documentation was taken as 'No Antenatal Corticosteroids was prescribed"
7. In cases where there was no documentation of Antenatal Corticosteroids administration in file or in the treatment sheet, the nurses' cardex was reviewed for such information. Lack of documentation was taken as 'No Antenatal Corticosteroids was administered'

3.17 Ethical considerations

Ethical approval was sought and approved from University of Nairobi ethics research committee (P116/02/2021) and Kenyatta National Hospital to carry out the study involving the collection and analysis of data as part of thesis dissertation. Informed consent was obtained only after the study's purpose was clearly explained to the participant. Informed that their possible departure from the study at any point would not affect the care of their newborns, mothers were given the option to accept or reject participation in the study. There was no issuance of rewards or inducements in a bid to recruit participants to join the study. Strict confidentiality was observed throughout the entire study as no personal identification data was recorded, with the study participants assigned study identification numbers. Every piece of data gathered was specifically used for research. The subjects suffered no bodily injury because no intrusive procedures were performed. In view of the Covid-19 pandemic, contact was limited to during consent approval, questionnaire administration and while conducting a NBS. All this was in accordance with Ministry of Health protocols and guidelines.

3.18 Study limitations

The limitation of this study was the documentation of New Ballard (NBS) and the documentation of antenatal corticosteroids administration. The challenge was overcome by the research assistant or investigator conducting a NBS when the baby was <48 hours and by reviewing maternal file, nurses cardex and treatment records to determine antenatal corticosteroid administration.

CHAPTER FOUR

4.0 RESULTS

384 mother-baby pairs with neonates delivered between 24 and 37 weeks of gestation at KNH between July and November 2021 were included in the study.

4.1 Maternal socio-demographic and reproductive characteristics

The mean maternal age for women recruited was 29.3 years (SD±5.7) while the mean birth weight for all neonates recruited were 1941grams (SD±790).

Majority of the women (30%) were between 25-29 years, were multigravida (83%) and had secondary education (52%). The most common mode of delivery (58%) was Caesarean section, and the majority of the women (77%) had no history of pregnancy loss or comorbidities (65%). In those women with comorbidities pregnancy induced and essential hypertension (74%) was the most frequent, followed by HIV at 14% and diabetes at 12%. Most women (97%) had visited ANC clinics however 77% had less than 4 visits. In terms of the duration between the first dose and delivery, 30% of mothers delivered within 12 hours, 30% between 12 and 24 hours, and 40% delivered within 24 hours of receiving the first dose.

Variable	Frequency	Percent
Maternal age (years)		
18-24	84	22
25-29	116	**30**
30-34	101	26
>35	83	22
Education Level		
No formal education	4	1
Primary	58	15
Secondary	199	**52**
Tertiary	123	32
Gravidity		
1	66	17
2-5	302	**79**
>5	16	4
Mode of Delivery		
SVD	160	42
CS	224	**58**
History of pregnancy loss		
Yes	90	23
No	294	**77**
Presence of Comorbidities		
Yes	133	35
No	251	**65**
Comorbidities		
Diabetes	18	12
HTN	107	**74**
HIV	20	14
ANC attendance		
Yes	374	**97**
No	10	3
Number of ANC visits		
0-4	295	**77**
>4	89	23
Time elapsed between the first dose and delivery (hours)		
<12 hours	51	30
12-24 hours	51	30
>24 hours	68	40

Table 1: Maternal socio-demographic and reproductive characteristics of women who delivered in KNH

As shown below in figure 1, neonatal characteristics of those recruited revealed there were more male neonates (51%) delivered than female neonates (49%).

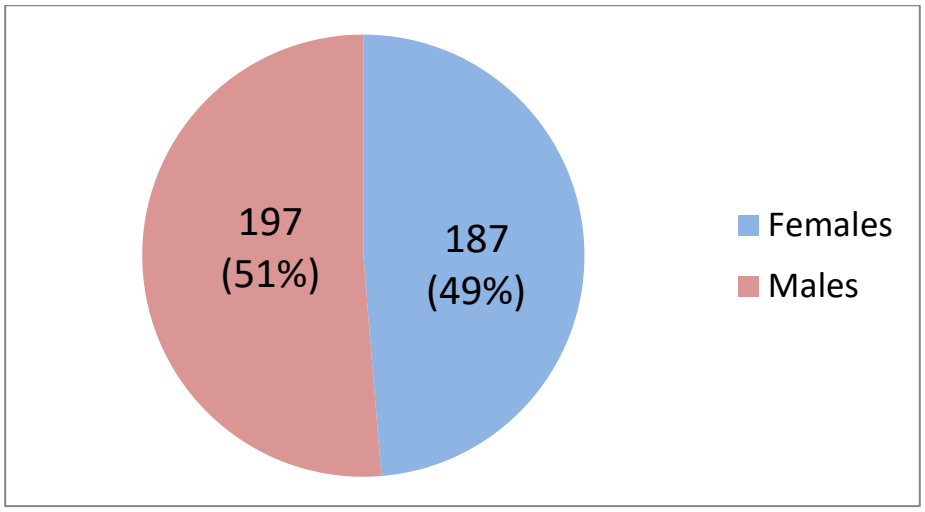


Figure 2: Distribution of neonates according to sex

The highest frequency according to gestational age (142) was seen in the 33–36-week group as shown in figure 4 below.

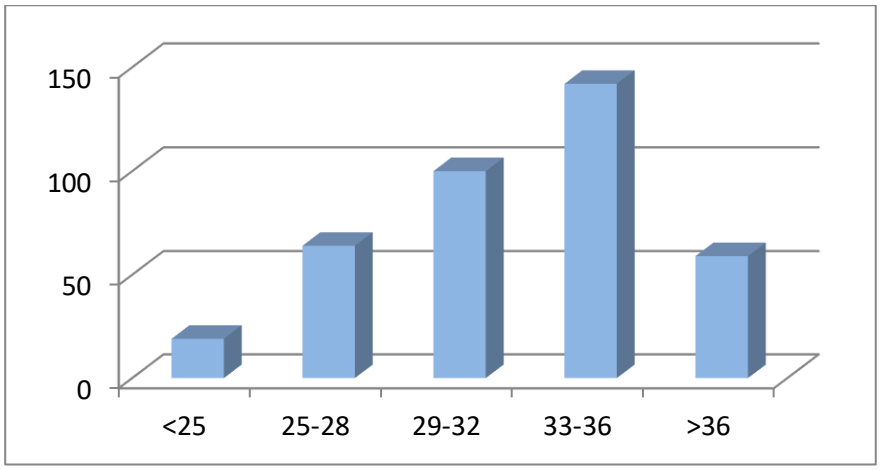


Figure 3: Distribution of neonates according to gestational age

4.2 Proportion of women who received antenatal corticosteroids

Figure 4 shows that 45% (171) women who delivered between 24-37 weeks received antenatal corticosteroids (95% CI 39.6% - 49.5%)

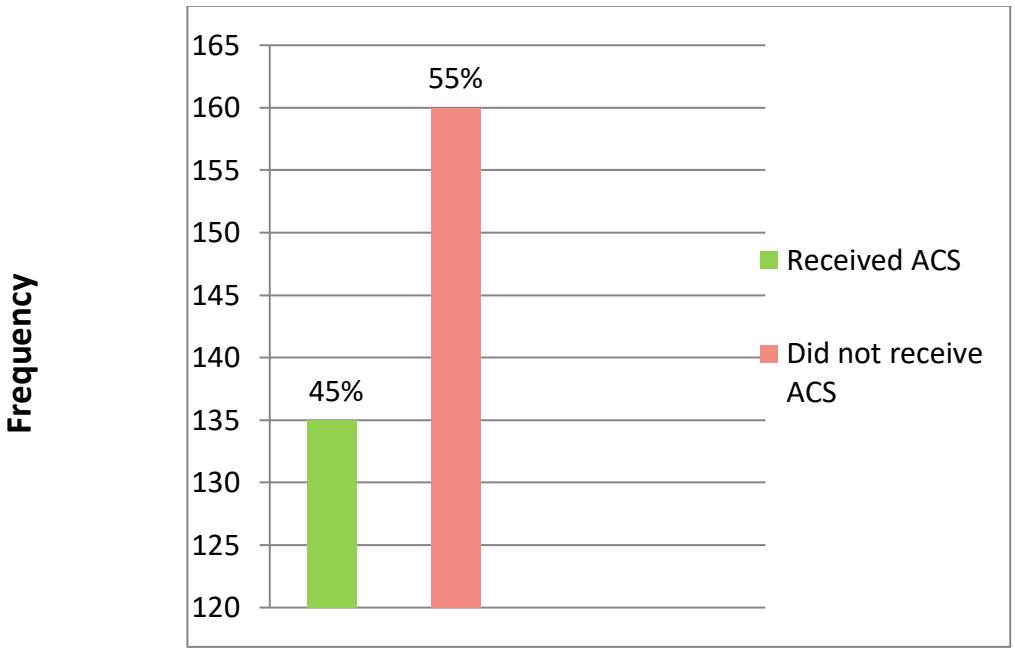


Figure 4: The proportion of women who received antenatal corticosteroids who delivered between 24-37 weeks

Antenatal corticosteroids were prescribed in 251 of women recruited, but was administered to 171 women .The greatest discrepancy between prescription and administration was seen in the 29–32-week group as seen below in figure 5. In majority (74%) of women there was no documented reason for not administering ACS while in 15% ACS was documented to have been administered prior to referral and in 11% precipitant labour was noted as the reason for not administering ACS.

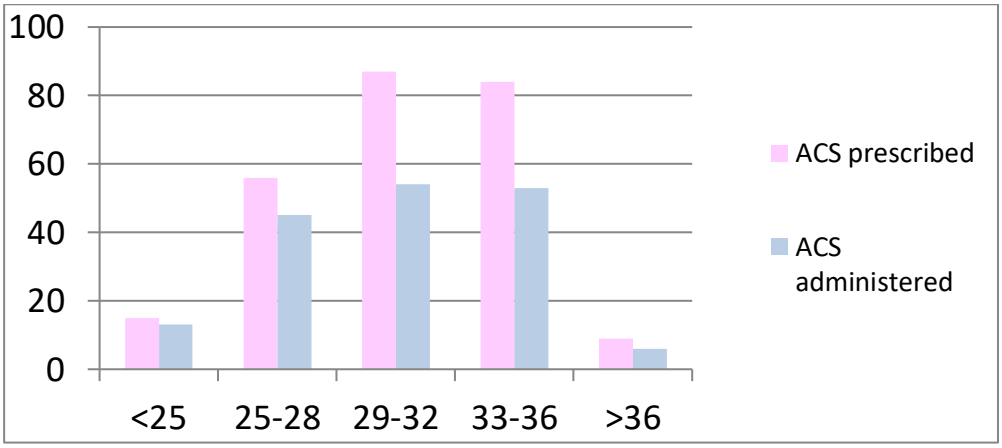


Figure 5: Frequency of antenatal corticosteroid prescription and administration according to gestational age

4.3 Factors associated with antenatal corticosteroid utilization

Women with history of pregnancy loss (RR 1.21 95%CI 0.96 to 1.53; p=0.031), those with comorbidities (RR 1.40 95%CI 1.10 to 1.78; p<0.001) and those with gestational age ≤34 weeks (RR 2.66 95%CI 1.89-3.73; p=<0.001) were associated with increased antenatal corticosteroids utilization and this was found to be significant. Women who had <4 ANC visits (RR 1.37 95%CI 1.04 to 1.81; p=0.170) was associated with increased antenatal corticosteroids utilization although this was found not to be significant. The presence of labor at admission was associated with decreased antenatal corticosteroids utilization (RR 0.66 95%CI 0.51 to 0.85; p<0.001) and this was significant.

Table 2: Factors associated with antenatal corticosteroid utilization

Variable	**Received ACS (Exposed) n=171**	**Did not receive (Not Exposed) n=213**	**RR (95% CI)**	**p-value**
History of pregnancy loss				
Yes	49 (28.7)	41 (19.2)	1.21 (0.96-1.53)	**0.031**
No	122 (71.3)	172 (80.8)	1.0	
Presence of comorbidities				
Yes	80 (46.8)	53 (24.9)	1.40 (1.10-1.78)	**<0.001**
No	91 (53.2)	160 (75.1)	1.0	
Gestational age				
≤34 weeks	142 (83.0)	107 (50.2)	2.66 (1.89 – 3.73)	**<0.001**
>34 weeks	29 (17.0)	106 (49.8)	1.0	
Number of ANC visits				
0-4	137 (80.1)	158 (74.2)	1.37 (1.04 - 1.81)	0.170
≥4	34 (19.9)	55 (25.8)	1.0	
Presence of labor at admission				
Yes	73 (42.7)	144 (67.6)	0.66 (0.51- 0.85)	**<0.001**
No	98 (57.3)	69 (32.4)	1.0	

Multivariate analysis to adjust for confounders revealed that gestational age ≤34 weeks (ARR 2.37 95% CI 1.69 – 3.32; p=<0.001) and the presence of comorbidities (ARR 1.38 95% CI 1.10 – 1.75; p=0.006) made it more likely for women to receive antenatal corticosteroids and these were statistically significant. Following multivariate analysis, the history of pregnancy loss was shown to be non-significant. This could be due to the presence of confounders or the study's power being insufficient to detect stated significance.

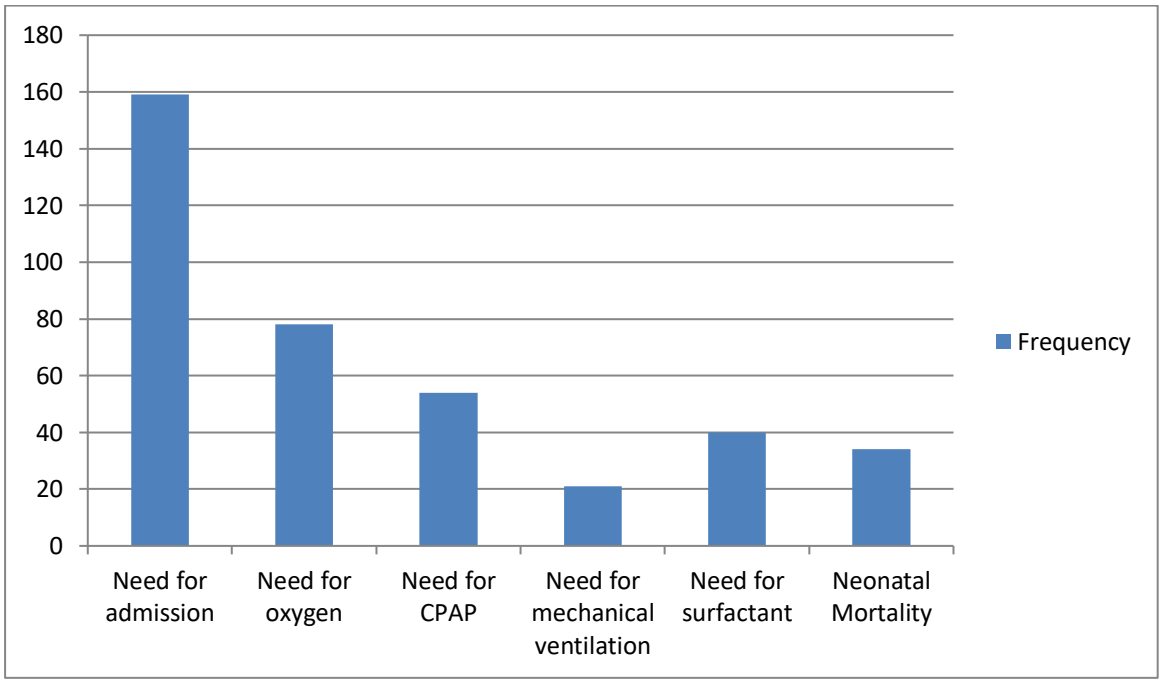
The presence of labour at admission (ARR 0.74 95% CI 0.58 – 0.95; p=0.018) made it less likely for a woman to receive antenatal corticosteroids and this was statistically significant.

Variable	**ARR (95% CI)**	**p-value**
Gestational age		
≤34 weeks	2.37 (1.69 – 3.32)	**<0.001**
>34 weeks	1.0	
Presence of comorbidities		
Yes	1.38 (1.10 – 1.75)	**0.006**
No	1.0	
History of pregnancy loss		
Yes	1.15 (0.93 – 1.43)	0.194
No	1.0	
Presence of labor at admission		
Yes	0.74 (0.58 – 0.95)	**0.018**
No	1.0	

Table 3: Multivariate analysis of factors associated with antenatal corticosteroid utilization

4.4 Short term interventions and mortality in neonates exposed to antenatal corticosteroids

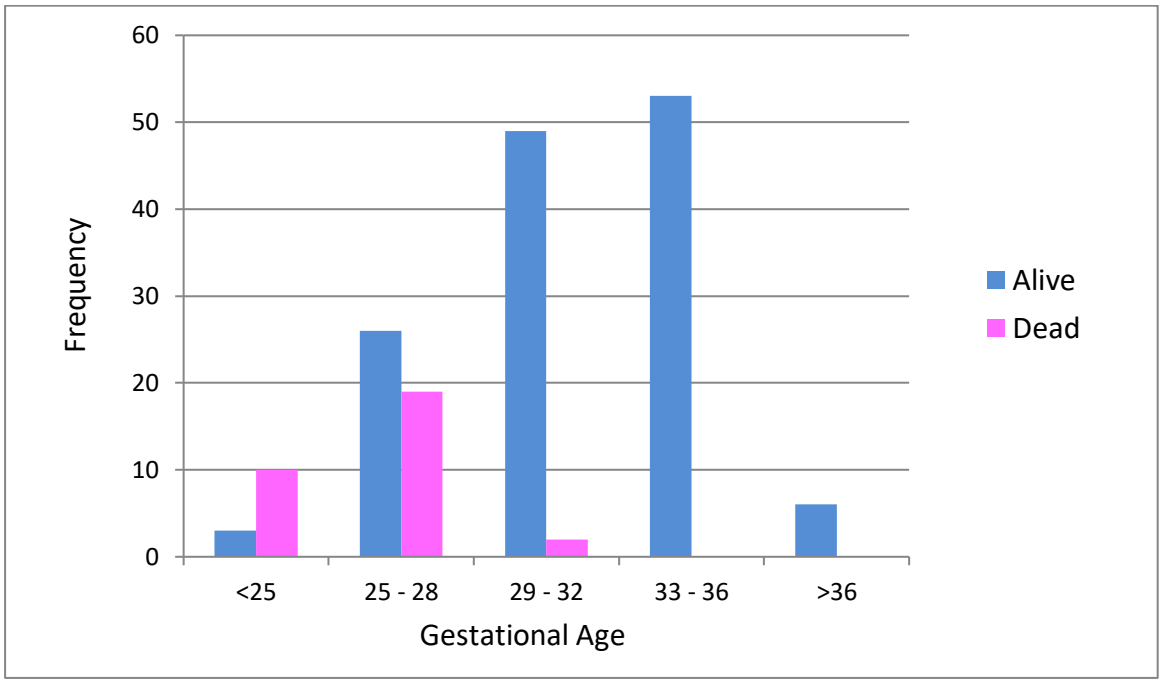
Figure 6: Short term outcomes in neonates exposed to antenatal corticosteroids



As shown above in Figure 6 among neonates exposed to antenatal corticosteroids there was need for NBU admission in 159(93%), need for oxygen in 78(46%), need for CPAP in 54(32%), need for mechanical ventilation in 21(12%), need for surfactant in 40(23%) and neonatal mortality at 34(20%) of the neonates.

Overall mortality according to gestational age in neonates exposed to antenatal corticosteroids was seen to be reduced in frequency except in the <25-week group. This is shown in the Figure 7 below.

Figure 7: Overall neonatal mortality according to gestational age



CHAPTER FIVE

5.0 DISCUSSION

A total of 384 mother-baby pairs were recruited for this prospective cross-sectional study. The majority of the women were between the ages of 25 and 29, multigravida, and had completed secondary school. The most common mode of delivery was Caesarean section, and the majority of the women had no history of pregnancy loss or comorbidities. In those women with comorbidities pregnancy hypertension was the most frequent followed by HIV and diabetes. Majority of the women had attended at least one antenatal care clinic however most of these women had less than four total visits. A higher proportion of women gave birth less than 24 hours after receiving their first dose, while 40% gave birth more than 24 hours after receiving their first dose. Neonatal characteristics of those recruited revealed there were more male neonates delivered than female neonates, with the highest frequency in the 33–36-week gestational age group.

The presence of comorbidities and a gestational age of 34 weeks were associated with increased antenatal corticosteroid utilization, which was similar to the findings of Pattanitum et al. However, the presence of labor at the time of admission was associated with decreased antenatal corticosteroid utilization in our study. (21). Given that this is the recommended age range for intervention in the guidelines, women whose gestational ages were 34 weeks or less were twice as likely to undergo ACS. The existence of comorbidities would heighten the need for follow-up at ANC clinics, increasing the chance of identifying risk factors, detecting potential complications and initiating early therapies, therefore increasing ACS utilization. Those with a history of pregnancy loss were more likely to receive antenatal corticosteroids because they required closer monitoring and early intervention to prevent recurrence of pregnancy loss. Following multivariate analysis, the history of pregnancy loss was shown to be non-significant. This could be due to the presence of confounders or the study's power being insufficient to detect stated significance. Though this did not achieve statistical significance, women who went to fewer ANC clinic visits were more likely to obtain ACS after preterm labor. This could be because identification of risk factors, follow-up, or intervention could not be carried out due to a lack of interaction with trained health care staff in the ANC clinic. Women were less likely to receive ACS if they presented in labor at the time of admission. This could be because they would arrive in advanced stages of labor or be referrals requiring emergency delivery, limiting the window for ACS administration and its effectiveness.

Dexamethasone is the steroid of choice at KNH. Dexamethasone is chosen in our facility despite studies showing that both betamethasone and dexamethasone are equally effective in lowering respiratory morbidity (4). Dexamethasone 6 mg given 12 hours apart over the course of two days constitutes a complete course of prenatal corticosteroids. The benefits of antenatal corticosteroids are at their highest 24 hours after administration, extend for at

least 7 days, but in our study, the majority of women gave birth before the first dose of dexamethasone was administered. Furthermore, fewer women received antenatal corticosteroids than those who had documented prescription, out of the total women recruited, 251 had a documented prescription of antenatal corticosteroids however only 171 of them received it, while 80 mothers did not receive antenatal corticosteroids despite prescription. . In 74% of women there was no documented reason for not administering ACS while in 15% ACS was documented to have been administered prior to referral and in 11% precipitant labor was noted as the reason for not administering ACS, highlighting a gap in antenatal corticosteroid prescription and administration. In majority of women there was no documented reason for not administering ACS other reasons for lack of administration included prior administration before referral and presence of precipitant labour.

Women who gave birth at KNH between 24- and 37-weeks' gestation used prenatal corticosteroids 45% of the time on average. According to a W.H.O. survey of low-income nations, 32% of Kenya's pregnant women use prenatal corticosteroids. (36), while local data by Gwako et al revealed that utilization of antenatal corticosteroid in KNH previously stood at 35% (4). Prenatal corticosteroid use is still uncommon in many poor nations, such as Cameroon (10%), Brazil (4%), and Ecuador (35%) but is still low compared to research conducted in the USA in 2003, which found that the prevalence of antenatal corticosteroid use was 75%. (35).

Need for oxygen, CPAP, mechanical ventilation, and surfactant were all seen to be low in frequency among neonates exposed to ACS, but NBU/NICU admissions were not. This may be the case because some of the neonates were admitted for conditions unrelated to the use of prenatal corticosteroids, such as prematurity, low birth weight, birth asphyxia, neonatal sepsis, or poor maternal health. Within the first 7 days of life, newborn mortality was decreased in all gestational age groups of those who were exposed to ACS, with the exception of neonates less than 25 weeks old. This could be because antenatal corticosteroid exposure greatly lowers the risk of respiratory morbidity, IVH, and NEC, all of which are major causes of mortality in these preterm newborns.

Possible imitations in this study including incomplete filling of questionnaires and gestational age estimation were overcome by using a prospective study design, by reviewing maternal file, nurses cardex and treatment records to determine antenatal corticosteroid administration and by conducting a New Ballard's score when the baby was less than 48 hours old.

Further larger prospective studies should be conducted to determine reasons for the low utilization and discrepancies between prescription and administration rates of antenatal corticosteroids in women who deliver preterm.

CHAPTER SIX

6.0 CONCLUSIONS

Antenatal corticosteroids are underutilized in women who deliver preterm in KNH between 24-37 weeks. Women with gestational age ≤34 weeks, presence of comorbidities, history of pregnancy loss and those with history of <4 antenatal clinic visits were associated with increased ACS utilization, while the presence of labor at time of admission was associated with reduced antenatal corticosteroids utilization. Multivariate analysis revealed that women with gestational age ≤34 weeks and presence of comorbidities, presence of labor at time of admission were able to achieve statistical significance. Fewer women received antenatal corticosteroids than those to whom it was prescribed.

CHAPTER SEVEN

7.0 RECOMMENDATIONS

Improved antenatal corticosteroid use in KNH among women who deliver preterm is required to increase preterm neonatal survival and morbidity. Routine education on antenatal corticosteroid to staff and documentation of antenatal steroid use should be advocated to facilitate regular audit. Further study is needed to identify gaps in administration of antenatal corticosteroids following prescription.

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APPENDICES

APPENDIX I: Time Frame

The following is the expected time frame of the study process:

Number	Activity	Estimated Time
1.	Development of Proposal and presentation	November 2019
2.	Proposal Submission for ethical approval	December 2020
3.	Data Collection	July-November 2021
4.	Data Analysis	November 2021
5.	Thesis Writing	December 2021
6.	Poster Presentation	January 2022
7.	Thesis Submission	February 2022

APPENDIX II: Study Budget

The following is the estimated budget cost for the study.

Category	Remarks	Units	Unit Cost	Total (Ksh.)
Proposal Development	Printing drafts	1000 pages	5	5000
	Proposal copies	8 copies	1000	8000
ERC	Application fees	1	2000	2000
Data Collection	Stationery pack (Pens, paper etc.)	400	50	20000
	Training research assistants	2	2500	5000
	Research Assistants	16 weeks	2000 X 2	64000
Data Entry	Data Clerk	1	10000	7000
Data Analysis	Statistician	1	35000	35000
Thesis Write up	Printing drafts	1000 pages	5	5000
	Printing Thesis	10 copies	1500	15000
Total				**166,000**

APPENDIX III: QUESTIONNAIRE

INSTRUCTIONS TO INTERVIEWERS

i. Ensure respondents to this questionnaire are the biological mothers of the child who delivered in KNH.

ii. For questions with alternatives fill in the number bearing the response in the dash (___) provided at the end of each question as appropriate.

iii. Don't suggest responses for the respondent.

Questionnaire No _____ Initials _____

Study No. _____ Date of Interview _____

SECTION A: DEMOGRAPHIC INFORMATION

1. Maternal Age _____ (in years)

2. Marital status ( )

1= Single (never married) 3= Divorced/separated

2= Married 4= Widowed

3. Highest level of maternal educational attained ( )

1= No formal education 3= Secondary

2= Primary 4= College/university education

4. Maternal Occupation ( )

1= Employed 4= Retired

2= Self-employed 5= Student

3= Unemployed

5. Religion. ( )

1= Catholic. 3= Muslim

2= Protestant. 4= Others (specify).....

SECTION B: OBSTETRIC INFORMATION

Part 1: Information from the mother

6. When was your LMP? .....

7. Gestation by dates .....(to the nearest week as per LMP)

8. When did you deliver your baby? (Dd/mm/yr).....

9. Do you have any co-morbidities (can select more than one option) ( )

1= Diabetes 4= Epilepsy

2= Hypertension 5= Other (specify).....

3= HIV

10. Previous history of pregnancy loss? .....

1= Yes 2= No

11. If yes to No. 11 How many? _____ Miscarriage _____ Stillbirth

Part 2: Information from the antenatal card or mother's file

12. Date of admission (Dd/mm/yr)……

13. Parity (documented) ……

14. Any documented maternal co-morbidities (can select more than one option) ( )

1= Diabetes 4= Epilepsy

2= Hypertension 5= Other (specify).....

3= HIV

15. Did the mother attend ANC clinic ( )

1= Yes 2= No

16. If YES to No.16, what was the number of visits? _____

17. Was mother a referral to our facility? ( )

1= Yes 2= No

18. If YES to No.18 what was the duration between referral and admission to KNH? (In hours) _____

19. Was mother in labour at admission? ( )

1= Yes 2= No

20. If YES to No. 20, what was the stage of labour? ( )

1= Latent 2= Active

21. Onset of labour ( )

1= Spontaneous 2= Induced

22. Mode of delivery ( )

1= Spontaneous Vertex Delivery 3= Caesarean Section

2= Assisted Vaginal Delivery

23. Documentation of prescription of ACS ( )

1= Yes 2= No

24. Documentation of administration of ACS ( )

1= Yes 2= No

25. If YES to No. 25, What was the duration between first dose and delivery (in hours)

_____

26. If YES to No. 25, Number of doses of Dexamethasone administered?

_____

27. If NO to No. 25, Why was antenatal corticosteroids not administered ( )

1= Drug stock out 3= No documented reason

2= Precipitant labour 4= Other (specify) _____

SECTION C: NEONATAL OUTCOME

28. Neonate sex ( )

1=Male 2= Female

29. Birth weight in grams? _____

30. New Ballard Score _____ Gestational Age _____

31. Need for admission to NBU ( )

1= Yes 2= No

32. Need for oxygen supplementation ( )

1= Yes 2= No

33. Need for CPAP ( )

1= Yes 2= No

34. Need for intubation for mechanical ventilation ( )

1= Yes 2= No

35. Need for surfactant ( )

1= Yes 2= No

36. Status of baby on day 7 or discharge (whichever precedes)

1= Alive 2= Dead

END

APPENDIX IV: CONSENT FORM FOR THE PARTICIPANTS

Study number……. Date……

Questionnaire No _____

Study title: Utilization of antenatal corticosteroids for improving neonatal outcomes in Kenyatta National Hospital, Nairobi, Kenya.

Investigator: Dr. Angela Nkirote Mworia, Postgraduate student, Department of Paediatrics, University of Nairobi.

Supervisors:

1. Prof. D. Wamalwa, Department of Paediatrics, University of Nairobi

2. Prof. Fred Were, Department of Paediatrics, University of Nairobi

3. Dr. George Gwako, Department of Obstetrics, University of Nairobi

Investigator's statement

We are requesting you and your baby to participate in a research study.
The purpose of this consent form is to give you information you will need to help you decide whether to participate in the study or not. You may ask questions on the risks and benefits of the study on your baby and yourself.
(Please read or listen to the information from this form carefully).

Introduction

Preterm birth is defined as birth occurring before 37 completed weeks of gestation.
About 15 million babies are born into the world before the right time and over 1 million of these babies die each year and others develop long term complications that impair their growth. In addition, the number of such births is increasing worldwide.
Antenatal corticosteroid use remains a key element in prevention and reduction of severe complications following prematurity. The purpose of this study is to determine the utilization of antenatal corticosteroids and the factors that influence its use among women who deliver preterm in Kenyatta National Hospital.

The benefits of the study

Your participation in this study will help us identify the factors that influence antenatal corticosteroids use in mothers with preterm delivery.
This will help in developing measures to reduce missed opportunities, so as to ensure as many babies the therapeutic benefits of antenatal corticosteroids.

The risks of the study

No harm will be caused to you or your baby.

Information about confidentiality

All the information obtained will be held in strict confidentiality. No information of any kind will be released to any other person or agency without your permission expressed in writing. We will not publish or discuss in public anything that will identify you or your baby.

Participation

Participation is entirely voluntary and you may refuse or withdraw your consent at any stage without it influencing the care you and your baby are given in any way.

If you **AGREE** to take part in the study, please sign below.

Signed …… Date……

Name of Researcher/ Research Assistant……..

Signed…… Date……

For any questions or clarifications on the study please contact

Researcher

Dr. Angela Nkirote

Tel: 0720900100

Email: angienkirote@gmail.com

Lead supervisor

Prof. Dalton Wamalwa

Tel: 0721239493

Email: dalton.wamalwa@uonbi.ac.ke

KNH UoN ERC- Secretary

Tel: (020) 2726300 ext 44102 Email: uonknh_erc@uonbi.ac.ke

APPENDIX V: CONSENT FORM (KISWAHILI)

FOMU YA KUTOA IDHINI YA KUSHIRIKI KATIKA UTAFITI

Nambari ya utafiti..... Tarehe.....

Nambari ya dodoso.....

Kichwa cha Utafiti

Matumizi wa dawa za corticosteroids kwa wamama wajawazito kuboresha matokeo ya watoto wanaozaliwa hospitali kuu ya Kenyatta, Nairobi

Mtafiti Mkuu:

Dr. Angela Nkirote Mworia , mwanafunzi wa shahada kuu ya matibabu maalum ya watoto,

Chuo Kikuu cha Nairobi.

Wasimamizi wa Utafiti:

1. Profesa D. Wamalwa, Profesa wa matibabu maalum ya watoto, Chuo Kikuu cha Nairobi.

2. Profesa Fred Were, Profesa wa matibabu maalum ya watoto , Chuo Kikuu cha Nairobi.

3. Daktari George Gwako, Mhadhiri, Idara ya Matibabu ya vizuizi vya uzazi na ugonjwa wa uzazi, Chuo Kikuu cha Nairobi.

Taarifa ya Mtafiti Mkuu

Tunakuuliza kushiriki katika utafiti tunaofanya kuhusu utumizi wa dawa inayotumika kuboresha matokeo kwa watoto wanaozaliwa kabla ya wakati unaofaa, hii dawa inatambulika kama corticosteroid. Kadhalika tunauzitafuta changamoto zinayokumba utumizi wa hii dawa huku KNH. Kusudi ya fomu hii ni kukupa wewe habari muhimu itakayokuwezesha wewe kufanya uamuzi iwapo wewe na mwanawe uliyejifungua mutashiriki kwenye utafiti au la. Unaweza kuuliza maswali yoyote kuhusu utafiti huu hasa kuhusu faida au dhuruma zozote za utafiti huu kwako au kwa mtoto wako. **(Tafadhali soma au sikiza kwa maakini yaliyomo kwenye fomu hii).**

Utangulizi

Kujifungua mapema kuliko wakati unaofaa ina maana kuwa mama mja mzito anajifungua kabla ya mimba kukamilisha wiki 37 baada ya siku ya kwanza ya muda aliyopata damu yake ya mwezi kwa mara ya mwisho kabla ya kupata mimba. Watoto takribani milioni kumi na tano huzaliwa kote duniani kila mwaka kabla ya wakati unaofaa huku watoto zaidi ya milioni moja wakifa kila mwaka kwa sababu ya kuzaliwa mapema kuliko inavyostahili ilhali wengine wengi hawakuui ipasavyo kutokana na matatizo yanayohusiana na kuzaliwa kabla ya wakati unaofaa. Idadi ya watoto wanaozaliwa kabla ya wakati unaotarajiwa inazidi kuongezeka duniani kila mwaka na sababu mbalimbali zinahusishwa na hali hii. Utafiti huu unalenga kudadisi utumizi wa dawa ya ACS

unaopunugza matatiza yanaohusiana na kuzaliwa kabla ya wakati unaofaa. Kadhalika unaangazia sababu mbalimbali yanyokumba matumizi miongoni mwa akina mama wanajifungulia katika hospitali kuu ya Kenyatta.

Faida ya Utafiti huu

Kushiriki kwako katika utafiti huu kutatuwezesha kudadisi sababu zinazoweza kuhusishwa na matumizi ya corticosteroid. Hii itasaidia kubuni mikakati mwafaka ya kusaidia kuongeza umatumizi ya hii dawa, ili kuhakikisha watoto wengi iwezekanavyo wanaozaliwa kabla wakati wapate ubora wa hali ya afya kutokana na matumizi ya hii dawa

Dhuruma ya Utafiti huu

Hakuna jambo la kukudhuru wewe au mtoto wako litakalofanywa kwenye utafiti huu, hakuna dhuruma yoyote inayotarajiwa.

Usiri wa habari za utafiti

Tutaajibika kulinda habari zote tutakozopata kuhusu wewe na mtoto wako wakati na baada ya utafiti huu ili kuhakikisha habari hizo ni siri kati yetu na wewe. Hakuna watu au idara zozote zitakazopata habari hizo bila ya idhini yako. Pia tutahakikisha kuwa habari zinazoweza kukutambulisha wewe au mtoto wako hazinakiriwi kamwe katika ripoti za utafiti huu.

Kushiriki Utafiti

Kushiriki utafiti huu ni kwa hiali yako mwenyewe. Una haki ya kukataa kushiriki au hata kujiondoa kutoka utafiti huu wakati wowote. Kukataa kushiriki au kujiondoa kwako hakutaadhiri huduma zitakazotolewa kwako au kwa mtoto wako.

Ikiwa **UNAKUBALI** kushiriki utafiti huu, tafadhali weka sahihi hapa chini.

Sahihi..... Tarehe.....

Jina la Mtafiti/Mtafiti msaidizi.....

Sahihi..... Tarehe.....

Kwa maswali yoyote au ufafanuzi kuhusu huu utafiti tafadhali wasiliana na

Mtafiti

Dr. Angela Nkirote

Simu: 0720900100

Barua pepe: angienkirote@gmail.com

Msimamizi kiongozi

Prof. Dalton Wamalwa

Simu: 0721239493

Barua pepe: dalton.wamalwa@uonbi.ac.ke

KNH UoN ERC - Katibu

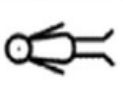
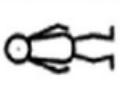
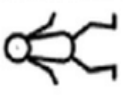
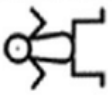
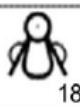
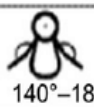
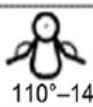
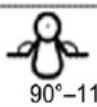
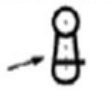
Simu: (020) 2726300 ext 44102

Barua pepe: uonknh_erc@uonbi.ac.ke

APPENDIX VI

New Ballard's Score for gestational age assessment

Neuromuscular Maturity

Score	-1	0	1	2	3	4	5
Posture							
Square window (wrist)	 >90°	 90°	 60°	 45°	 30°	 0°	
Arm recoil		 180°	 140°–180°	 110°–140°	 90°–110°	 <90°	
Popliteal angle	 180°	 160°	 140°	 120°	 100°	 90°	 <90°
Scarf sign							
Heel to ear							

Physical Maturity

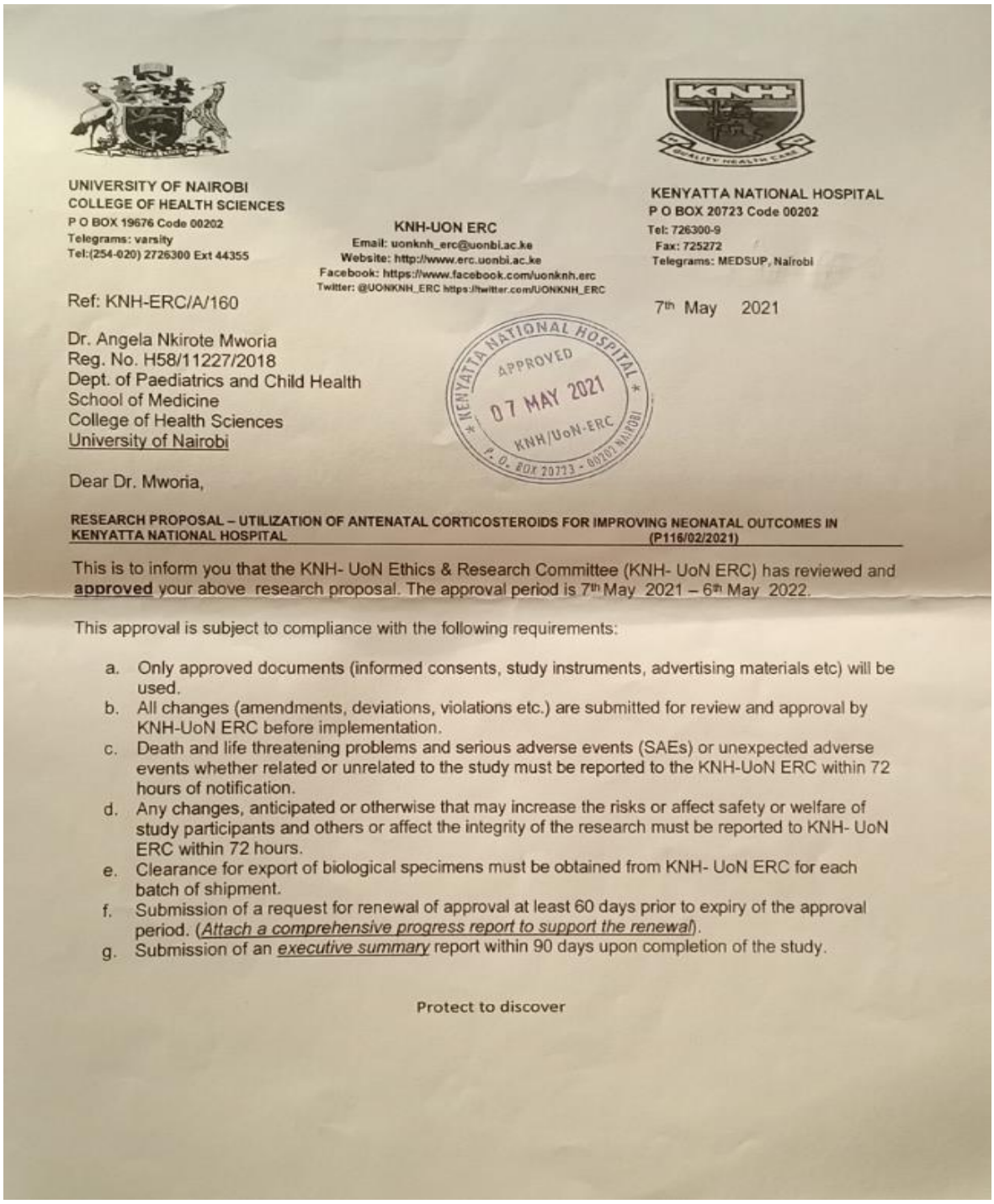
Skin	Sticky, friable, transparent	Gelatinous, red, translucent	Smooth, pink; visible veins	Superficial peeling and/or rash; few veins	Cracking, pale areas; rare veins	Parchment, deep cracking; no vessels	Leathery, cracked wrinkled
Lanugo	None	Sparse	Abundant	Thinning	Bald areas	Mostly bald	
Plantar surface	Heel-toe 40-50 mm: –1 <40 mm: –2	>50 mm, no crease	Faint red marks	Anterior transverse crease only	Creases anterior ⅔	Creases over entire sole	
Breast	Imperceptible	Barely perceptible	Flat areola, no bud	Stippled areola, 1–2 mm bud	Raised areola, 3–4 mm bud	Full areola, 5–10 mm bud	
Eye/Ear	Lids fused loosely: –1 tightly: –2	Lids open; pinna flat; stays folded	Slightly curved pinna; soft; slow recoil	Well curved pinna; soft but ready recoil	Formed and firm, instant recoil	Thick cartilage, ear stiff	
Genitals (male)	Scrotum flat, smooth	Scrotum empty, faint rugae	Testes in upper canal, rare rugae	Testes descending, few rugae	Testes down, good rugae	Testes pendulous, deep rugae	
Genitals (female)	Clitoris prominent, labia flat	Clitoris prominent, small labia minora	Clitoris prominent, enlarging minora	Majora and minora equally prominent	Majora large, minora small	Majora cover clitoris and minora	

Maturity Rating

Score	Weeks
-10	20
-5	22
0	24
5	26
10	28
15	30
20	32
25	34
30	36
35	38
40	40
45	42
50	44

APPENDIX VII

KNH-UON Ethics Review Committee approval



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Telegrams: MEDSUP, Nairobi

Ref: KNH-ERC/A/160

7th May 2021

Dr. Angela Nkirote Mworia
Reg. No. H58/11227/2018
Dept. of Paediatrics and Child Health
School of Medicine
College of Health Sciences
University of Nairobi

KENYATTA NATIONAL HOSPITAL APPROVED 07 MAY 2021 KNH/UoN-ERC P. O. BOX 20723 - 00202 NAIROBI

Dear Dr. Mworia,

RESEARCH PROPOSAL – UTILIZATION OF ANTENATAL CORTICOSTEROIDS FOR IMPROVING NEONATAL OUTCOMES IN KENYATTA NATIONAL HOSPITAL (P116/02/2021)

This is to inform you that the KNH- UoN Ethics & Research Committee (KNH- UoN ERC) has reviewed and **approved** your above research proposal. The approval period is 7th May 2021 – 6th May 2022.

This approval is subject to compliance with the following requirements:

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

Protect to discover