7-DAY OUTCOME OF TERM NEONATES ADMITTED AT PUMWANI MATERNITY HOSPITAL NEWBORN UNIT WITH PERINATAL ASPHYXIA

BY

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DECLARATION

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

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ABBREVIATIONS

ANC	Antenatal Clinic
APH	Antepartum Haemorrhage
CM	Centimeter
DALYS	Disability Adjusted Life Years
ERC	Ethics and Research Committee
EEG	Electroencephalography
GoK	Government of Kenya
GM	Grammes
HIE	Hypoxic Ischemic Encephalopathy
IQR	Interquartile range
KNH	Kenyatta National Hospital
KG	Kilogram
MM	Millimeter
CM	Centimeter
MOH	Ministry of Health.
NICU	Neonatal Intensive Care Unit
NBU	Newborn Unit
PMH	Pumwani Maternity Hospital
PROM	Prolonged Rupture of Membranes
PMTCT	Prevention of mother to child transmission
SD	Standard deviation
SDG	Sustainable Development Goal
SOP	Standards of operating Procedures
UK	United Kingdom
UoN	University of Nairobi
UNICEF	United Nations Children Emergency Fund
WHO	World Health Organization

DEFINITION OF TERMS

Perinatal asphyxia: "Failure to initiate and sustain breathing at birth and clinical manifestation of hypoxic ischemic encephalopathy as described by Sarnat and Sarnat stage 1, 2 or 3 (appendix I).

Term newborn: Infants born at or after 37 completed weeks of gestation using Finnstrom score. The score is shown in appendix III.

Outcome by day 7 of life:

- Clinical improvement i.e without neurological sequelae
- Persistence of abnormal neurological signs by day 7 of life which include increased or reduced tone, altered grasp/nutritive suck/Moro reflex, altered level of consciousness and presence of Seizures.
- Death.

Adverse outcome:

- Persistence of abnormal neurological signs by day 7 of life.
- Death.

Neurologic sequelae: Persistence of abnormal neurological signs by day 7 of life which includes increased or reduced tone, altered grasp/nutritive suck/Moro reflex, altered level of consciousness, and presence of Seizures.

ABSTRACT

Background: Birth asphyxia still is a significant cause of newborn mortality and morbidity globally. There is paucity of data on short term outcomes of perinatal asphyxia in Africa and in particular Kenya.

Study objective: To find out 7-Day outcome and the factors contributing to adverse outcome in term newborns admitted at Pumwani Maternity Hospital newborn unit with perinatal asphyxia.

Methods: We conducted a short descriptive longitudinal study in Pumwani Maternity Hospital newborn unit between October 2020 to February 2021. Term newborns with perinatal asphyxia on the basis of failure to initiate and sustain breathing at birth with features of hypoxic ischemic encephalopathy admitted within 24 hours of birth were enrolled. Clinical evaluation was conducted daily within the first week of the newborn's life for the primary outcome i . e . persistence of abnormal neurologic signs, clinical improvement, or death.

RESULTS

Of 172 neonates enrolled into the study,15.1% died and 28.5% continued treatment and the rest (56.4%) discharged from hospital including 14.4 % being those discharged with neurological impairment. Prolong duration of resuscitation [*OR 2.2 (95% CI 1.7-3.3), p<0. 001],* presence of seizures [*OR 98.6(95% CI 23.6-411), p<0. 001]* and low Apgar score at 5 minutes [*OR 0.05(95% CI 0.01-0.23), p<0.001]* were associated with adverse outcome.

Breech vaginal delivery *[OR 21.3 (95% CI 3.1-147.8) p=0.002],* prolong duration of labor *[OR 1.3 (95% CI 1.1-1.4),p<0.001]* and prolong rupture of membranes [*OR 1.3 (95% CI 1.2-1.5),p<0.001]*were also associated with adverse outcome. Similarly, infants were more likely to die if they were delivered in facilities other than Pumwani Maternity hospital [*OR 28.8 (95% CI 3.4-252.5), p=0. 002].*

CONCLUSION

Perinatal asphyxia has remained significant contributor to newborn mortality and morbidity at Pumwani Maternity hospital. Improved quality of intra-partum care services aimed at monitoring mothers with prolong rupture of membranes and preventing prolong labor and fetal complications are needed.

1.0 INTRODUCTION

Perinatal asphyxia is among the leading cause of perinatal mortality worldwide. The World Health Organization definition of Perinatal asphyxia is "Failure to start and sustain breathing at birth.(1)

Birth asphyxia according to American Academy of Pediatrics is defined as having evidence of metabolic acidosis (pH<7) in a fetal umbilical arterial blood sample, presence of APGAR score between 0 to 3 more than 5 minutes and neonatal neurological consequences like seizures or coma, reduced tone and numerous organ involvements (2).

Annually about ten million newborns need support to begin breathing. Approximately 5 percent to 10% of all neonates who are delivered in facilities need some level of resuscitation like tactile stimuli, positioning with airway clearance while about 3%–6% need essential neonatal resuscitation which includes the initial stages of neonatal resuscitation and assisted ventilation and 2% require advanced resuscitation (3).

Perinatal asphyxia is still a major cause of mortality and morbidity in the neonatal period. It is responsible for about nine hundred twenty thousand neonatal deaths yearly and is linked to approximately a million intrapartum stillborn as well as unspecified burden of lifelong neurological disorder and impairment (4).The sum of disability adjusted life years(DALYS) due to perinatal asphyxia surpasses those caused by all childhood conditions avoidable by immunization (5).

According to United Nations Children Emergency fund(UNICEF) data on child survival and the Sustainable Development Goals (SDGs),it is projected that over 60 countries will fail to achieve Sustainable Development Goal in lowering neonatal deaths to or below twelve deaths per a thousand live births in 2030 (6).

In Kenya the infant mortality rate in 2014 was 39 per 1000 births while neonatal mortality rate was 22 for every a thousand live births with birth asphyxia contributing significant proportion (7).

Causes of perinatal asphyxia can be divided into antepartum, intrapartum, or the postpartum causes. The major manifestation of asphyxia results from diminished cerebral blood with corresponding systemic hypoxemia resulting in primary and secondary energy failure (8).

Clinical findings in infants who have hypoxic ischemic encephalopathy (HIE) had been utilized as indicators of significant asphyxia insults. Neurological status usually worsens within 24- 72 hours after perinatal asphyxia and its severity at this point can be used to predict neurological sequelae. The gravity of early neurologic dysfunction in term infants is commonly centered on clinical stages of HIE as depicted by Sarnat and Sarnat which is a very useful pointer of infants at risk of neurological consequence (9).

The predictive power of HIE based on Sarnat and Sarnat scale depends on its severity and the period of observed signs. Neonates with HIE Sarnat stage 1 usually have suffered mild asphyxia thus no significant long-standing neurodevelopmental consequences. About eighty percent of infants with severe HIE who survive suffer serious complications while those who survive moderate HIE 10-20% also develop serious complications. In severe encephalopathy mortality rate is about 25-50% (10).

Various modalities are available for use in the initial hours of life to identify neurological impairment and to measure the degree of HIE like magnetic resonance imaging, cerebral function monitoring, cranial ultrasound as well as Doppler flow ultrasound of middle cerebral artery.[10] Most of these techniques may nonetheless be inaccessible in several neonatal centers especially in developing nations (11).

2.0 LITERATURE REVIEW

Different findings were reported in studies done on perinatal asphyxia plus associated adverse outcomes both globally and locally.

Thonberg *et al* carried out a retrospective review of the clinical course together with outcome of perinatal asphyxia at a paediatric unit in Goteborg, Sweden that involved 227 infants. All the infants who developed severe encephalopathy died or acquired neurological impairment. A half of the infants who had moderate or mild HIE were noted as normal at discharge. Out of the 227 infants, Seizures occurred in 27 of which 18 of them seizures occurred within 12 hours of birth. No association was established regarding seizures onset and outcome (12).

In London, a study done by Azzopardi D *et al* to establish if 2-channel continuous electroencephalography (EEG) done within the first twelve hours of birth would foretell the gravity of neurological damage plus neurodevelopmental consequence after perinatal asphyxia. Continuous two-channel EEG was performed within 12 hours of birth in 22 infants who were suspected to have suffered birth asphyxia and 11 healthy control infants. It was found that 12 infants who were suspected to have asphyxia with mild HIE or remained well had normal EEG while Six out of nine infants who had moderate or severe HIE had abnormal EEG. All the 5 infants who passed on or developed neurodevelopmental sequalae had an abnormal EEG (13).

A prospective study was carried out by Finer N *et al to* evaluate factors which affect outcome of hypoxic ischemic encephalopathy. This involved forty-nine term infants who had neurological signs of HIE following perinatal asphyxia and were followed up in the neonatal period. Seizures developed in 34 infants with 25 of them, seizures occurring within 24 hours of life. Those with Sarnat stage I HIE were 7 while stages II and III were 41 and 1 respectively. Factors that significantly associated with adverse outcome were Sarnat stage as well as occurrence of intractable seizures (14).

A descriptive study was conducted by Massaro AN et al on Short-term outcomes after perinatal hypoxic ischemic encephalopathy: a report from the Children's Hospitals Neonatal Consortium HIE focus group involving nine hundred forty-five referred infants born at term with perinatal asphyxia within the first three days of life. It was reported that severity of HIE had direct correlation with Poor APGAR results, severe metabolic acidosis, protracted resuscitation at the time of birth, both clinical together with electroencephalographic (EEG) seizures and atypical background on EEG (15).

Helen Trotman *et al* did a retrospective study in West Indies to assess the predictors of outcome in term infants who developed HIE following birth asphyxia. Those who satisfied the inclusion criteria were ninety-five neonates. Out of these, twenty-nine (31%) had mild HIE while 41 (43%) and 25 (26%) had moderate and severe HIE, respectively. About half of the newborns with severe neonatal encephalopathy died before discharge which interpreted to 12% of the study population while Thirty-four (36%) of the them satisfied conditions for poor outcome (16).

Another study by Oswyn G *et al* to find out the incidence, outcome and associated factors of perinatal asphyxia, Papua New Guinea, reported that factors which significantly correlated with perinatal asphyxia were prior stillbirth or neonatal death, abnormal fetal heart rate, prolong rupture of membranes beyond 12 hours before birth, meconium-stained liquor, antepartum bleeding, maternal fever and delayed first and second phases of labour. All the infants with Sarnat stage III hypoxic ischemic encephalopathy (HIE) died or developed neurological damage (17).

A prospective study was carried out by Seyal *et al* to determine factors associated with adverse outcome among neonates with perinatal asphyxia in the newborn unit of Paediatrics department, Sir Ganga Ram Hospital, Pakistan. The study involved one hundred forty-four consecutive asphyxiated neonates who were admitted in the newborn unit and satisfied the inclusion criteria. Out of 144 neonates who fulfilled inclusion criteria, 59.7% of them were discharged successfully while 40.3% succumbed. The predisposing factors which remarkably correlated with adverse outcome was delayed arrival to the hospital as well as severe perinatal asphyxia (18).

A descriptive, prospective study have been conducted by Qureshi AM *et al* in Abbottabad to determine the risk factors of perinatal asphyxia, common presentation as well as association of APGAR scores with stages of HIE. Those who were eligible for the study were 181 neonates with neurological signs of hypoxic-ischemic encephalopathy. Maternal history, APGAR scoring and neurological grading were carried out to assess for brain damage. It was found that 22.6% had mild HIE while those with moderate and severe were 38.7% each. Hypoxic ischemic encephalopathy related Mortality was at 16%. Factors which contributed significantly to neonatal mortality were lack of antenatal visits, toxemia in pregnancy and protracted labour (19) .

Retrospective observational study was conducted in a tertiary Centre in Bangalore; India by Siva Saranappa S B *et al* on Clinical profile and outcomes of term asphyxiated newborns. Of the 60 neonates recruited into the study 31.7% had hypoxic ischaemic encephalopathy (HIE) of whom 52.6% had Sarnat stage I HIE while 31.5% and 15.7% of the infants had HIE Sarnat stages II and III respectively. Of the 60 neonates enrolled into the study, 40% had meconium-stained liquor, 11.6% had premature rupture of membranes while 5% was cord prolapse. All babies with severe HIE died. (20).

In Nigeria, a descriptive, retrospective study was carried out by Egharevba OI *et al* of newborns who have been admitted into the special care baby unit with perinatal asphyxia. Data was collected from babies' and mother's case records. The outcome was categorized as survived or died. Birth asphyxia accounted for forty-five out of three hundred forty-seven (13%) of admissions during the review period. Mortality rate was 31.1% and the factors associated significantly with mortality were lack of antenatal care as well as severe HIE stage (21).

A case-control study was conducted by Lisanu Wosenu *et al* on the determinants of perinatal asphyxia among live birth infants at Gondar referral hospital, northwest Ethiopia. The Cases were newborns with an APGAR score of less than 7 at 5 minutes of birth and the controls were newborns with an APGAR score of 7 at 5 minutes. The main determinants of perinatal asphyxia included prolong labor, meconium-stained liquor, Caesarean section delivery, fetal distress, and low birth weight (22).

A prospective study was conducted by Irene N *et al* on the prevalence, severity, and early outcomes of HIE among neonates at a referral hospital in Tanzania involving 201 babies with perinatal asphyxia. Using Sarnat and Sarnat score, severity of birth asphyxia was categorized and a follow up for 7 days or until discharge conducted. Mortality as a result of HIE was 9.1% and it was higher among neonates who had grade III HIE (84.2%) as opposed to moderate HIE (1.4%).Abnormal neurological signs observed were weak/absent reflexes (46.0%), hypotonia (43.3%) and lethargy (42.2%) (23) .

A prospective study conducted in Muhimbili National Hospital, Tanzania, on prevalence as well as immediate outcomes of hypoxic Ischemic encephalopathy (HIE) involving 112 infants with birth asphyxia revealed that most of the neonates with HIE Sarnat grade 1 (92.3%) had favorable outcome and were discharged while most of those with HIE Sarnat grade III (51.6%) passed on. Overall mortality due to HIE was 27.2% (24).

Hellen Namusoke *et al* carried out a prospective study at St. Francis Hospital in Kampala, Uganda, on the incidence as well as short-term outcomes of term newborns with HIE. The inclusion criteria were term neonates more than 2000grammes and born at St. Francis Hospital. Clinical evaluation was done on all neonates within 48 hours of life, for signs of encephalopathy. Significant proportion of babies with intrapartum asphyxia got HIE. Newborns with signs of Hypoxic Ischemic Encephalopathy were followed up by a daily clinical examination then short-term outcome recorded on day seven. It was found that 10 (43.5%) of neonates had mild HIE while 8(34.8%) and 5(21.7%) had moderate and severe HIE, respectively. Mortality due to HIE was 26% with two thirds being infants with grade III HIE. Common complications by day 7 of life were absent suck reflex, weak Moro reflex and need for respiratory assistance. Factors significantly correlated with HIE included prolong labour, prolong rupture of membranes, referred mothers, antepartum haemorrhage, Ceasarian delivery and prime parity (25).

A prospective cohort study by CallyJ.Tann *et al*, on early childhood outcomes following neonatal encephalopathy in Uganda, reported that death and neurodevelopmental impairment following neonatal encephalopathy were common. They also found that neonatal clinical seizures, cranial ultrasound abnormalities and nasogastric feeding at discharge increased the risk of neurodevelopmental consequences (26).

Here in Kenya, Maalim et al conducted a hospital based short longitudinal survey on short term outcome and factors contributing to adverse outcome in term neonates admitted with birth asphyxia at the Kenyatta National hospital (KNH) Newborn Unit (27).

It was reported that by day 7 of life, 31.1% died while 31.1% continued with treatment and the rest of the infants (37.8%) were discharged with 6.7%of them discharged with neurologic impairment. Delivery outside KNH, prolong labour, lack of resuscitation and presence of seizures had association with adverse outcome (27).

In summary, from these studies birth asphyxia remains significant contributor to mortality and morbidity in the neonatal period. Most of the studies have demonstrated the utility of Sarnat & Sarnat HIE stages in forecasting outcome. The predictive power of HIE as per Sarnat and Sarnat scale depends on its severity and the period of observed signs. Neonates with HIE Sarnat stage 1 usually have suffered mild asphyxia thus no significant long-standing neurodevelopmental consequences. Majority of infants with severe HIE die while those who survive suffer serious complications and a good proportion of those who survive moderate HIE develop complications.

From these studies, factors reported that were significantly associated with adverse outcomes included prolong labor, presence of seizures, low Apgar score at 5 minutes and referrals.

3.0 STUDY JUSTIFICATION

Pumwani maternity hospital (PMH) is among the largest maternity hospitals in Kenya with average monthly deliveries of 1500.The hospital is in a low-cost setting with majority of the clients being from low socioeconomic status. Significant proportion of emergency deliveries are secondary to fetal distress which is an important determinant for birth asphyxia. However, the outcomes of neonates managed for birth asphyxia at PMH Newborn Unit remains unknown.

It's also important to identify factors that may contribute to adverse outcomes, and this will go a long way in aiding decision making with regards to management of perinatal asphyxia among neonates. Moreover, the findings from this study will inform the hospital administration, county government and Ministry of Health on the disease burden and requisite prioritization of resources for neonatal resuscitation and provision of new treatment modalities like therapeutic hypothermia.

The study results can be used as a guide for other studies on outcome of perinatal asphyxia in PMH Newborn Unit (NBU).

4.0 STUDY OBJECTIVES

4.1 Primary objective

- To determine 7-day outcome of term newborns with perinatal asphyxia admitted at PMH NBU.
- Expected outcomes:
  I. Clinical improvement i.e without neurological sequelae
  II. Persistent abnormal neurological signs by day 7 of life which includes increased or reduced tone, altered grasp/nutritive suck/Moro reflex, altered level of consciousness and presence of Seizures.
  III. Death.

4.2 Secondary objective

- To outline maternal and neonatal factors related to adverse outcomes in newborns admitted at PMH NBU with perinatal asphyxia.

5.0 METHODOLOGY

5.1 Study Design

Hospital based short descriptive longitudinal study.

5.2 Study Area

This study has been carried out at Pumwani maternity hospital (PMH) newborn unit, a maternity referral hospital, located in Nairobi County, Kamkunji constituency, Pumwani ward with a bed capacity of 268 and baby cots of 150. It's among the largest maternity hospitals in Kenya with average monthly deliveries of 1500.The hospital is in a low-cost setting with majority of the clients being from low socioeconomic status.

It offers antenatal and postnatal services, maternity, newborn care, maternal and neonatal child health, comprehensive care centre, Prevention of mother- child transmission (PMTCT) and rehabilitation services. The hospital is run by various healthcare personnel including medical officers, obstetricians/gynaecologists, paediatricians, clinical officers, nurses, pharmacists, pharmaceutical technologists, physiotherapist and occupational therapists among others.

5.3 Study Population

Term neonates admitted at PMH NBU within 24hours of birth with perinatal asphyxia in the course of the study period.

Inclusion criteria:

- Term neonate based on gestational age assessment using Finnström score admitted at PMH NBU with perinatal asphyxia for the first 24 hours of birth.
- Informed consent by caregiver.

Exclusion criteria:

1. Neonates with gross congenital abnormalities.
2. Preterm.

5.4 Sample Size

According to health records estimates in PMH, an average of 60 infants are admitted in the NBU due to perinatal asphyxia every month. This translates to approximately 720 infants per year. The study shall be performed over 6 months hence the attainable population shall be 360 infants admitted with perinatal asphyxia. A representative sample will be taken from this finite population and sample size will be determined as shown below:

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

Where

n' = sample size with finite population correction,

N = size of the target population = 360

Z = Z statistic for 95% level of confidence = 1.96

P = Estimated proportion of death among infants with perinatal asphyxia admitted in NBU = 31.1% (Maalim et al)

d = margin of error = 5%

$$= \frac{360 \text{ x } 1.96^2 \text{ x } 0.311 \text{ x } 0.689}{0.05^2 \text{ (360-1)} + 1.96^2 \text{ x } 0.311 \text{ x } 0.689}$$

n = 172

A minimum of 172 infants with perinatal asphyxia will be sampled to estimate 7-day outcomes within 5% level of precision.

5.5 Sampling Technique

Term babies who satisfied the inclusion criteria were recruited into the study through consecutive sampling.

5.6 Study Period

October 2020 to February 2021.

5.7 Study Procedure

Recruitment of the study participants was conducted at the Pumwani Maternity Hospital newborn unit. Term babies admitted at PMH NBU with perinatal asphyxia were assessed for birth asphyxia as per Sarnat & Sarnat and those who satisfied the inclusion criteria enrolled into the study after informed consent by their caregivers. They were then categorized into HIE stages using Sarnat and Sarnat staging as shown in appendix I.

5.8 Study Procedure Diagram

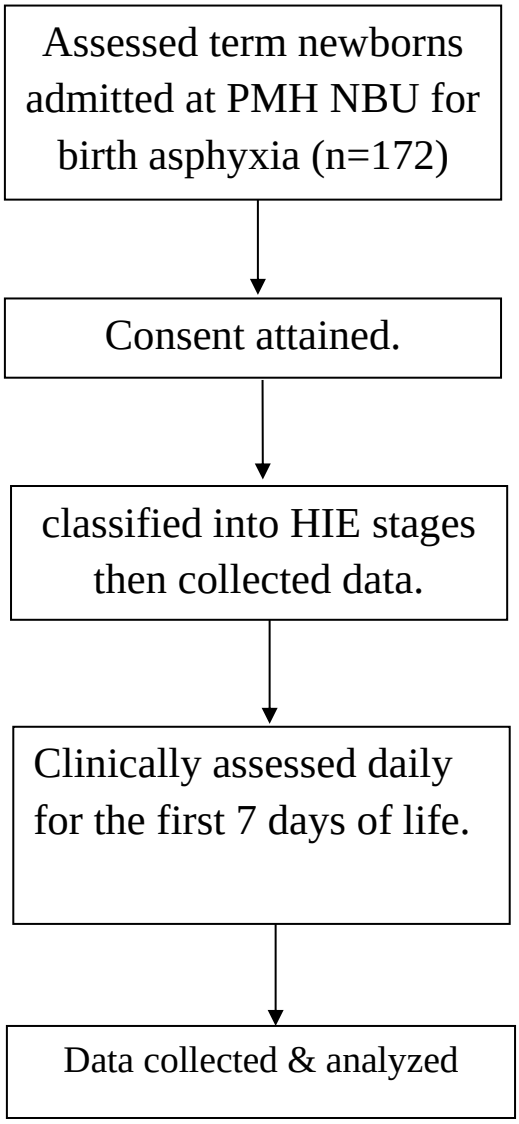


Figure 1: study procedure

5.9 Data collection

Term babies admitted at PMH NBU with perinatal asphyxia were screened and those who satisfied the inclusion criteria enrolled into the study after informed consent by their caregivers. The principal investigator conducted daily clinical examination of the neonates for the first seven days of newborn's life and the results entered in a standard tool (as per appendix II). Measurements of head circumference, body weight and length of the newborn were taken according to the standard operating procedures indicated in appendix IV.

The caregivers were interviewed, their antenatal records examined to ascertain their socio-demographic characteristics and obstetric history as per appendix II.

6.0 DATA MANAGEMENT AND ANALYSIS

Data obtained from the questionnaires was coded, entered then cleaned in Microsoft Excel. Data analysis was performed by using SPSS version 17.0 software. Demographic as well as clinical characteristics of the infant and the mother was summarized and presented as percentages and means or medians for categorical and continuous data, respectively. The HIE stage of the infants at admission was categorized as mild, moderate, and severe and presented as percentages. The 7-day outcome was analyzed then presented as percentages.

The 7-day outcome of perinatal asphyxia was tested for association with infant and maternal characteristics to determine the risk factors. Chi square test was used to test the association between categorical variables and 7-day outcome. ANOVA test was used to compare means across the three outcomes (death, discharged and continued treatment) at day 7 of follow up. Odds ratios were calculated for unfavorable outcomes (death and continuing treatment) in comparison to the infants who were discharged. Multivariate analysis was done by using logistic regression model for assessing factors which are independently associated with mortality and continuing treatment while controlling for confounding variables. All the statistical tests were interpreted at 5% level of significance (p value less or equal to 0.05).

7.0 ETHICAL CONSIDERATIONS

7.1 Ethics and Research Committee approval

Authorization to do the study was sort from Kenyatta National Hospital and university of Nairobi ethics and research committee as well as Pumwani Maternity Hospital management.

7.2 Consent for questionnaire

Prior to administering the questionnaire, an informed consent was taken from the caregivers. The objective of the study was well clarified, and confidentiality guaranteed with the data collected being accessible to the research team alone. Anonymity of the participants was ensured throughout by use of serial numbers rather than their names. Participants were informed of their right to refuse to take part in the study.

8.0 RESULTS

Infants with perinatal asphyxia in this study were one hundred and seventy-two (172) of whom 53.5% were male. The average clinical gestation and birth weight were 38.8 weeks and 3000grams respectively while mean length and head circumference were 49.4 and 35.5 centimeters respectively. The median Apgar score was 6 at 5 minutes as shown below (table 1).

Table 1: Characteristics of the newborn

Variable	**Frequency (%)**
Gender Male Female	 92 (53.5) 80 (46.5)
Clinical gestation in weeks Mean (SD)	38.8 (1.2)
Birth weight in grams Mean (SD)	3000.1 (513.6)
Length in centimeters Mean (SD)	49.4 (1.1)
Head circumference in centimeters Mean (SD)	35.5 (1.7)
Apgar score at 5 minutes Median (IQR)	6 (5 – 7)

Table 2: Delivery characteristics

Variable	Frequency (%)
Place of delivery	
PMH	161 (93.6)
Other health facilities	11 (6.4)
Mode of delivery	
Vertex vaginal	113 (65.7)
Breech vaginal	8 (4.7)
C/S	51 (29.7)
Duration of labor in hours	
Mean (SD)	15.8 (5.0)
Duration of rupture of membrane	
Mean (SD)	9.9 (3.8)
Amniotic fluid color	
Clear	140 (81.4)
Green	29 (16.9)
Not known	3 (1.7)
Resuscitation with BVM	141 (82.0)
Duration of resuscitation in minutes	
Median (IQR)	5 (3 – 10)
Intubation/mechanical ventilation	0

Of the 172 infants,93.6% were born in PMH. Majority (65.7%) were born via Spontaneous vertex vaginal. Median duration of labour and rupture of membranes was 15.8 and 9.9 hours respectively. Amniotic fluid color was clear in 81.4% of the women with meconium-stained liquor being 16.9%.

Majority of the infants were resuscitated via bag valve mask (82%) and median period of resuscitation was 5.0 minutes as shown in table 2 above.

Table 3: Maternal characteristics

Variable	Frequency (%)
Age	
Mean (SD)	25.2 (5.0)
Parity	
Category, n (%)	
0	79 (45.9)
1	36 (20.9)
2	35 (20.3)
3+	22 (12.8)
Marital status	
Single	7 (4.1)
Married	164 (95.3)
Separated	1 (0.6)
Occupation	
Salaried formal employment	27 (15.7)
Self-employment	14 (8.1)
Casual worker	47 (27.3)
Unemployed	84 (48.8)
Level of education	
None	24 (14.0)
Primary not completed.	15 (8.7)
Primary completed.	44 (25.6)
Secondary not completed.	32 (18.6)
Secondary completed.	39 (22.7)
Tertiary and beyond	18 (10.5)
Antenatal clinic visit	172 (100.0)
Number of times visit to antenatal clinic.	
Once	71 (41.3)
Twice	49 (28.5)
More than twice	52 (30.2)
Maternal fever a week before delivery	3 (1.7)
Antepartum hemorrhage	2 (1.2)
High blood pressure	2 (1.2)
Convulsion during pregnancy	1 (0.6)
Other chronic diseases	8 (4.7)
Disease (n=8)	
Asthma	3 (37.5)
HIV	5 (62.5)

The caregivers interviewed were all biological mothers. Their mean age was 25.2 years with majority (95.3%) being married while primigravidae were 45.9%. Majority of the mothers (48.8%) were unemployed, however, only 14% were illiterate.

Majority (58.7%) of the mothers attended more than one antenatal clinic visit.

Maternal fever and antepartum hemorrhage was reported in 1.7% and 1.2% of the mothers respectively while high blood pressure and convulsions during pregnancy were 1.2% and 0.6% respectively. Other chronic diseases such as HIV and Asthma was reported among 4.7% as shown in table 3 above.

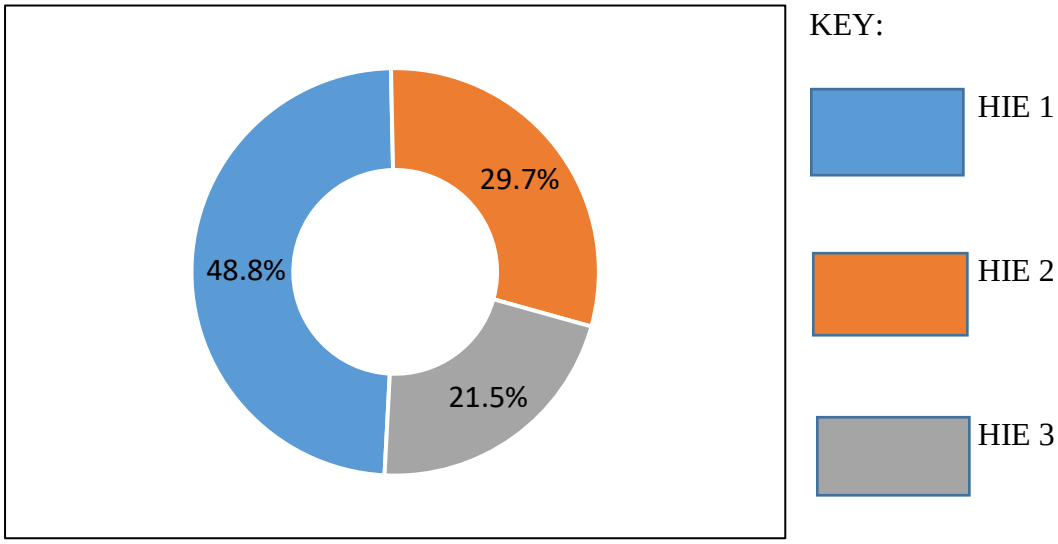


Figure 2: Hypoxic ischemic encephalopathy (HIE) stage at admission.

The severity of asphyxia was determined by use of Sarnat & Sarnat scoring of Hypoxic Ischemic Encephalopathy (HIE) at admission. Most of the neonates (48.8%) had stage one HIE while (29.7%) and 21.5% had stage two and three respectively as shown in figure 2 above.

Table 4: Outcome by day 7 of life

Variables	**Frequency (%)**	**HIE stage**		
		1	2	3
Outcome				
Died	26 (15.1)	0	0	26 (70.3)
Continued treatment.	49 (28.5)	16 (19.0)	25 (49.0)	8 (21.6)
Discharged	97 (56.4)	68 (81.0)	26 (51.0)	3 (8.1)
Neurologic sequelae	**(n=97)**	**(n=68)**	**(n=26)**	**(n=3)**
With sequelae	14 (14.4)	2 (2.9)	9 (34.6)	3 (100.0)
No sequelae	83 (85.6)	66 (97.1)	17 (65.4)	0

Of 172 infants enrolled into the study,15.1% died and 28.5% continued treatment while 56.4% were discharged with 14.4 % being those discharged with neurologic impairment.

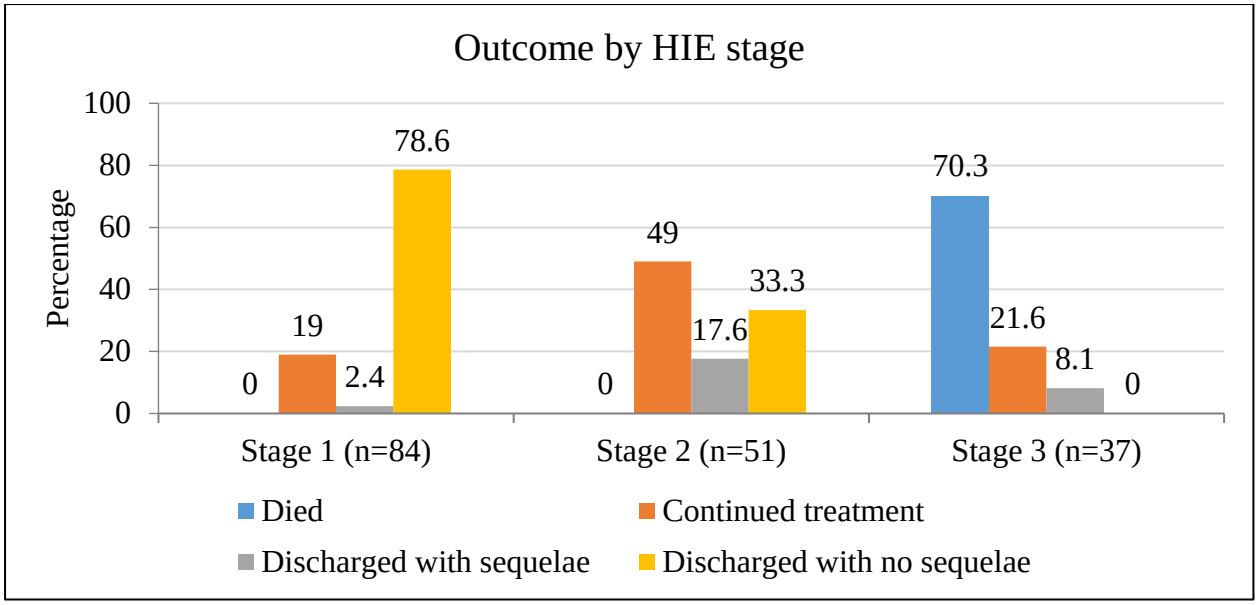


Figure 3: Outcomes associated with HIE stage.

Among the neonates with HIE stage three,70.3% died with 21.6% continuing treatment past day 7 of life. Of the infants admitted with HIE stage two,49% continued treatment while 33.3% were discharged without neurologic sequelae. Majority of the infants with HIE stage one (78.6%) were discharged without sequelae with only 2.4% having neurologic sequelae. A considerable proportion of those discharged with neurological sequelae were admitted with HIE stage 2 as shown in figure 3 above.

Outcomes over the 7 days follow up period.

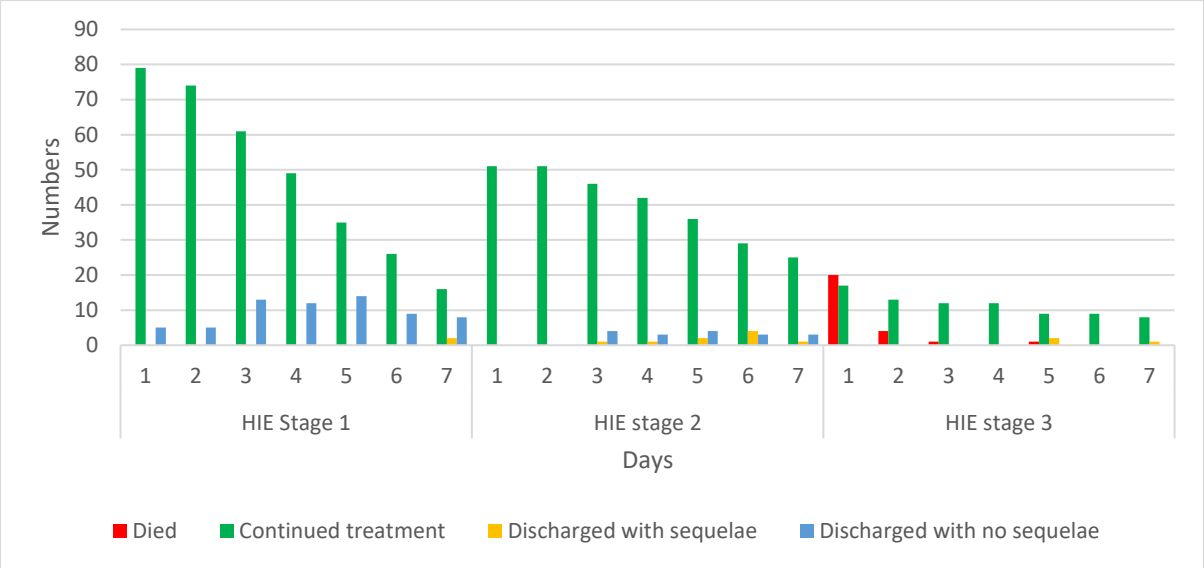


Figure 4: Outcomes over the 7 days follow up period.

Most of infants admitted with HIE stage three died with majority of the deaths occurring within 72hours of life. Majority of infants who were discharged with neurologic sequelae had HIE stage two. Infants with HIE stage one had favorable outcome with most being discharged without sequelae as shown in figure 4 above.

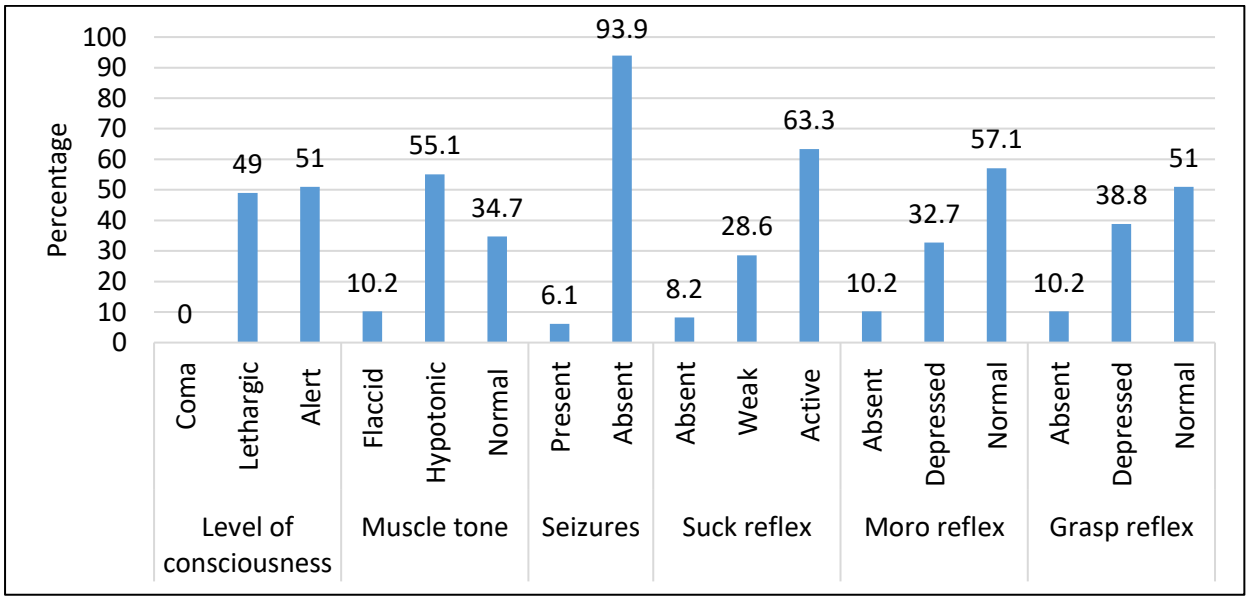
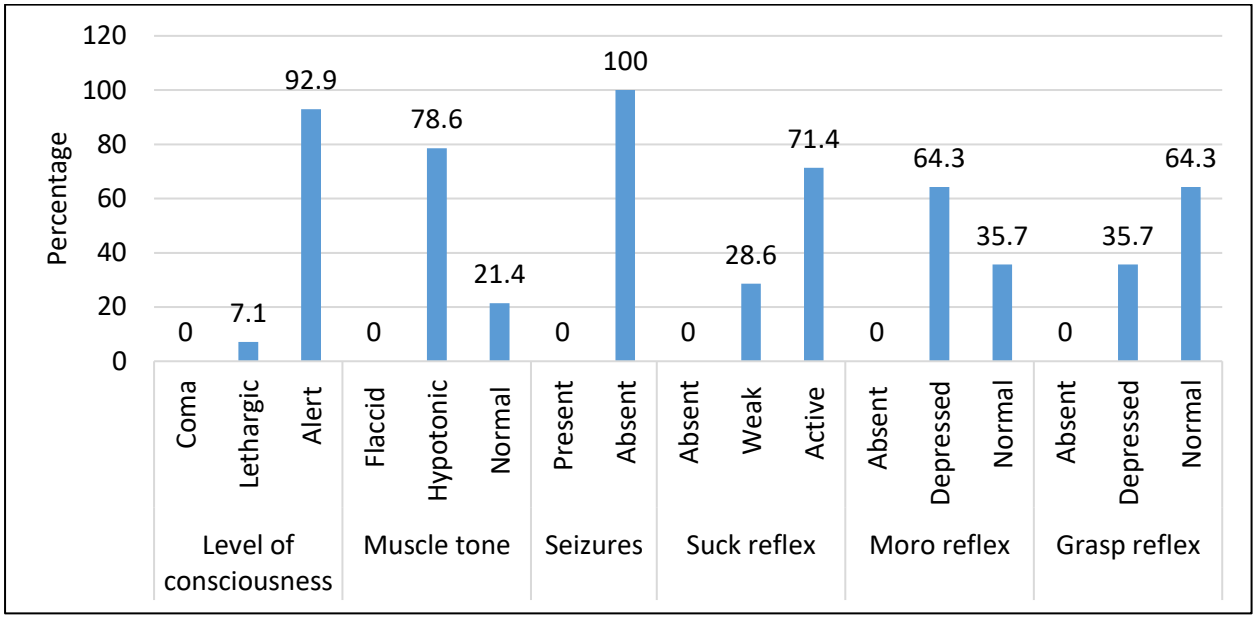


Figure 5: Clinical status of those who continued treatment.

Of the infants who continued treatment by day 7 of life,49% had altered level of consciousness with 65.3% having abnormal tone. Seizure was present among 6.1%, with 36.8% having absent/weak suck reflex as well as 42.9% and 49% having absent/depressed Moro & grasp reflex respectively as shown in figure 5 above.



F*igure 6: Clinical status among those discharged with neurologic sequelae.*

Among infants discharged with neurologic sequelae, 7.1% had altered level of consciousness with 78.6% having abnormal tone and 28.6% had weak suck reflex. Depressed Moro and grasp reflex was present in 64.3% and 35.7% respectively as shown in figure 6 above.

Table 5: Infant characteristics associated with the 7-day outcome.

Variable	Died	Discharged	Continued treatment	P value
Gender Male Female	 14 (53.8) 12 (46.2)	 49 (50.5) 48 (49.5)	 29 (59.2) 20 (40.8)	 0.611
Clinical gestation in weeks, mean (SD)	38.7 (1.2)	38.8 (1.2)	38.8 (1.4)	0.944
Birth weight in gm, mean (SD)	3019.2 (539.6)	3026.5 (533.9)	2927.3 (480.7)	0.540
Length in cm, mean (SD)	49.5 (1.1)	49.4 (1.2)	49.5 (1.1)	0.701
Head circumference in cm, mean (SD)	35.4 (1.0)	35.5 (2.1)	35.5 (0.8)	0.963
Apgar score at 5 minutes, median (IQR)	3 (2-4)	7 (6-7)	6 (5-7)	<0.001
Duration of resuscitation in minutes, mean (SD)	15.7 (4.5)	4.6 (2.5)	7.5 (5.2)	<0.001
Seizures Present Absent	 23 (88.5) 3 (11.5)	 7 (7.2) 90 (92.8)	 28 (57.1) 21 (42.9)	 <0.001

As shown in table 5 above, gender, clinical gestation, birth weight, length and head circumference were not significantly associated with adverse outcome *(p>0.05).*

Apgar score at 5 minutes was significantly lower (median 3) in infants who died compared to median of 7 and 6 in those who were discharged and continued treatment respectively *(p <0.001).* Similarly, duration of resuscitation was significantly longer (Mean 15.7 min) in patients who died compared to those discharged (Mean 4.6 min) and continued treatment (Mean 7.5mins), *p<0.001.* Also, Seizures were significantly correlated with mortality with 88.5% of infants who died having seizures compared to 7.2% of those discharged, *p value <0.001*.

Table 6: Maternal and delivery characteristics associated with the 7-day outcome.

Variable	Died	Discharged	Continued treatment	P value
Mean age (SD)	26.4 (5.9)	24.9 (4.7)	25.0 (5.0)	0.398
Parity				
0	14 (53.8)	44 (45.4)	21 (42.9)	0.648
1	2 (7.7)	21 (21.6)	13 (26.5)	
2	6 (23.1)	19 (19.6)	10 (20.4)	
3+	4 (15.4)	13 (13.4)	5 (10.2)	
Marital status				
Single	2 (7.7)	3 (3.1)	2 (4.1)	0.430
Married	24 (92.3)	94 (96.9)	46 (93.9)	
Separated	0	0	1 (2.0)	
Occupation				
Salaried formal employment	5 (19.2)	17 (17.5)	5 (10.2)	0.755
Self-employment	1 (3.8)	10 (10.3)	3 (6.1)	
Casual worker	6 (23.1)	25 (25.8)	16 (32.7)	
Unemployed	14 (53.8)	45 (46.4)	25 (51.0)	
Level of education				
None	8 (30.8)	8 (8.2)	8 (16.3)	0.191
Primary	7 (26.9)	36 (37.1)	16 (32.7)	
Secondary	9 (34.6)	41 (42.3)	21 (42.9)	
Tertiary and beyond	2 (7.7)	12 (12.4)	4 (8.2)	
Number of ANC visits				
Once	14 (53.8)	35 (36.1)	22 (44.9)	0.125
Twice	6 (23.1)	34 (35.1)	9 (18.4)	
More than twice	6 (23.1)	28 (28.9)	18 (36.7)	
Place of delivery				
PMH	20 (76.9)	96 (99.0)	45 (91.8)	<0.001
Other health facilities	6 (23.1)	1 (1.0)	4 (8.2)	
Mode of delivery				
Vertex vaginal	17 (65.4)	61 (62.9)	35 (71.4)	0.010
Breech vaginal	5 (19.2)	2 (2.1)	1 (2.0)	
C/S	4 (15.4)	34 (35.1)	13 (26.5)	
Duration of labor in hours, mean (SD)	20.7 (4.9)	14.5 (4.7)	15.6 (4.3)	<0.001
Duration of rupture of membrane, mean (SD)	13.4 (4.3)	9.1 (3.5)	9.8 (3.0)	<0.001
Amniotic fluid color				
Clear	3 (11.5)	19 (19.6)	7 (14.3)	0.531
Green	23 (88.5)	77 (79.4)	40 (81.6)	
Not known	0	1 (1.0)	2 (4.1)	
Maternal fever	0	2 (2.1)	1 (2.0)	1.000
Antepartum hemorrhage	0	1 (1.0)	1 (2.0)	1.000
High blood pressure	0	1 (1.0)	1 (2.0)	1.000
Convulsion during pregnancy	0	1 (1.0)	0	1.000
Other chronic diseases	0	4 (4.1)	4 (8.2)	0.299

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As shown in table 6 above, Age, parity, marital status, occupation, level of education, ANC visits, amniotic fluid color, maternal fever, antepartum hemorrhage, high blood pressure and convulsions were not significantly associated with adverse outcome.

However, place of delivery had significant correlation with adverse outcome (*p<0.001).* There was a higher proportion of infants (23.1%) referred from other health facilities among infants who died. In addition, 8.2% of those who continued treatment were from outside PMH with only 1% contributing to the number of infants discharged from the facility. Mode of delivery had significant association with adverse outcome with breech delivery being more common (19.2%) in infants who died but less frequent in those who were discharged (2.1%) or continued treatment (2.0%), p value= 0.010.

In addition, the duration of labor was shown to be significantly longer (mean 20.7 hours) in the infants who died compared to a mean of 14.5 hours in those who were discharged and a mean 15.6 hours in those who continued treatment (*p<0.001).*

Similarly, duration of rupture of membranes was significantly prolonged in infants who died (mean 13.4 hours) compared to those discharged (mean 9.1 hours) and continued treatment (mean 9.8 hours), *p<0.001.*

Table 7: Multivariable Analysis

Variable	Discharged	Died					Continued treatment				
	n (%)	n (%)	Crude OR (95% CI)	P value	Adjusted OR (95% CI)*	P value	n (%)	Crude OR (95% CI)	P value	Adjusted OR (95% CI)*	P value
Gender Male Female	49 (50.5) 48 (49.5)	14 (53.8) 12 (46.2)	1.1 (0.5-2.7) 1.0	0.763	4.1 (0.2-103) 1.0	0.389	29 (59.2) 20 (40.8)	1.4 (0.7-2.8) 1.0	0.322	1.5 (0.6-3.8) 1.0	0.408
Apgar score at 5 minutes, median (IQR)	7 (6-7)	3 (2-4)	0.05 (0.01-0.23)	<0.001	0.12 (0.02-0.79)	0.027	6 (5-7)	0.61 (0.43-0.86)	0.005	1.0 (0.6-1.6)	0.882
Duration of resuscitation in minutes, mean (SD)	4.6 (2.5)	15.7 (4.5)	2.2 (1.7-3.3)	<0.001	1.7 (1.0-3.0)	0.050	7.5 (5.2)	1.2 (1.1-1.4)	0.001	1.1 (0.9-1.2)	0.389
Seizures Present	7 (7.2) 90 (92.8)	23 (88.5) 3 (11.5)	98.6 (23.6-411.0)	<0.001	-	-	28 (57.1) 21 (42.9)	17.1 (6.6-44.5)	<0.001	11.1 (4.1-29.8)	<0.001
Place of delivery Other health facilities	96 (99.0) 1 (1.0)	20 (76.9) 6 (23.1)	28.8 (3.4-252.5)	0.002	35.0 (0.3-4625) 1.0	0.153	45 (91.8) 4 (8.2)	8.5 (0.9-78.5)	0.058	3.3 (0.2-44.5) 1.0	0.367
Mode of delivery Vertex vaginal Breech vaginal CS	61 (62.9) 2 (2.1) 34 (35.1)	17 (65.4) 5 (19.2) 4 (15.4)	1.0 2.4 (0.7-7.6) 21.3 (3.1-147.8)	0.148 0.002	62.3 (0.5-7730) 0.2 (0.0-9.9)	0.093 0.444	35 (71.4) 1 (2.0) 13 (26.5)	1.5 (0.7-3.2) 1.6 (0.1-15.7)	0.297 0.832	0.5 (0.0-12.0) 1.2 (0.4-3.3)	0.662 0.734
Duration of labor in hours, mean (SD)	14.5 (4.7)	20.7 (4.9)	1.3 (1.1-1.4)	<0.001	1.3 (0.9-1.8)	0.207	15.6 (4.3)	1.1 (1.0-1.1)	0.178	1.0 (0.9-1.2)	0.517
Duration of rupture of membrane, mean (SD)	9.1 (3.5)	13.4 (4.3)	1.3 (1.2-1.5)	<0.001	1.0(0.6-1.6)	0.929	9.8 (3.0)	1.1 (1.0-1.2)	0.191	0.9 (0.7-1.1)	0.225

All significant factors were adjusted using stepwise logistic regression model to obtain predictors of death and continuation of treatment past 7 days.

Risk factors of death

As compared to the infants who were discharged, those who died were more likely to be admitted with lower Apgar scores hence higher scores at admission was associated with reduced likelihood of death, *OR 0.05(95% CI 0.01-0.23), p<0.001 (as per table 7 above).* In addition, longer duration of resuscitation was associated to higher likelihood of death, *OR 2.2 (95% CI 1.7-3.3), p<0. 001.*

Having seizures was also associated with higher risk of death. Comparing with infants who were discharged by day 7, those who died were more likely to have seizures, *OR 98.6(95% CI), p<0. 001.*

Similarly, infants were more likely to die if they were delivered in facilities other than PMH [*OR 28.8 (95% CI 3.4-252.5), p=0. 002]*, breech deliveries *[OR 21.3 (95% CI 3.1-147.8),*

p=0.002], had prolong duration of labor *[OR 1.3 (95% CI 1.1-1.4),p<0.001] or* had prolong duration of rupture of membranes [*OR 1.3 (95% CI 1.2-1.5),p<0.001].*

However, logistic regression model showed that the factors independently associated with death were lower Apgar score at 5 minutes [adjusted OR 0.12 (95% CI 0.02-0.79, *p*=0.027)] and longer duration of resuscitation [adjusted OR 1.7 (95% CI 1.0-3.0), *p*=0.050].

Risk factors of continuing treatment

Infants who were admitted with higher Apgar scores at 5 minutes were less likely to continue treatment beyond 7 days, OR 0.61 (95% CI 0.43-0.86), *p*=0.005 while infants who had prolong resuscitation were more likely to continue treatment *OR 1.2 (95% CI 1.1-1.4), p=0.001.* Similarly, those who continued treatment had a significantly higher risk of seizures in comparison to those discharged, *OR 17.1(95% CI 6.6-44.5), p<0.001.*

But logistic regression model revealed that the factors independently associated with continuing treatment was having seizures [adjusted OR 11.1 (95% CI 4.1-29.8, *p*<0.001)].

9.0 DISCUSSION

The goal of this study was to ascertain short term outcomes and factors that contribute to adverse outcomes among term neonates with birth asphyxia at Pumwani Maternity hospital.

Short-term outcome of hypoxic ischemic encephalopathy

Of 172 newborns enrolled into the study,15.1% died and 28.5% continued treatment while 56.4% were discharged with 14.4 % being those discharged with neurologic impairment. Other studies reported various results.

For instance, Maalim et al on short term outcome and factors contributing to adverse outcomes amongst term babies admitted at Kenyatta National hospital (KNH) NBU with perinatal asphyxia, reported mortality rate of 31.1% with 31.1% continuing treatment past day 7 and the rest 37.8% discharged home. Mortality was higher than in our study. The difference can be due to KNH is the only tertiary referral health institution in Nairobi city and gets referrals from other health facilities with severe birth asphyxia.

Other studies like ours have revealed the value of Sarnat &Sarnat HIE stages in predicting outcome [9]. Infants with HIE stage three either died (70.3%) or continued treatment (21.6) while majority of infants with HIE stage two continued treatment (49%) past day 7 of life. Majority of the infants with HIE stage one had favorable outcome with 78.6% discharged without sequelae. A considerable proportion of infants discharged with neurological sequelae were admitted with HIE stage two.

Most of infants with HIE grade III died within 72 hours of admission into the unit. This is consistent with findings from a prospective study done in Tanzania [24], on prevalence as well as immediate outcomes of HIE in babies with birth where most of the babies with HIE grade three passed on. Majority of mortality occurred within the first 72 hours of life. This shows that neurological status of babies with HIE generally worsen within 24- 72 hours following perinatal asphyxia and its severity at this point can be utilized to foretell neurological sequelae. Birth asphyxia thus is preventable but if it occurs, its management will be basically supportive

Other studies had similar results. Thonberg *et al* [12] in a retrospective review of the clinical course together with outcome of perinatal asphyxia at a paediatric unit in Sweden reported that all the neonates with severe HIE died or acquired neurological impairment.

Factors associated with adverse outcome.

In our study, there was significant association between five-minute Apgar score with adverse outcome, which is in keeping with a study by Massaro AN *et al* [15]. In our study, Apgar score at 5 minutes was significantly lower (median 3) in infants who died compared to median of 7 and 6 in those who were discharged and continued treatment respectively, *p <0.001.* Compared to those discharged, Infants with a higher Apgar score were less likely to die, *OR 0.05(95% CI), p<0.001.*

Other studies have reported that presence of seizures plus timing of onset of seizures were useful in predicting outcome[15].In our study, there was apparent relationship between presence of seizures and adverse outcome. Seizure was significantly linked to mortality with 88.5% of infants who died having seizures compared to 7.2% of those discharged, *OR 98.6(95% CI) p value <0.00I.* Similarly, those with seizures were more likely to continue treatment as compared to those discharged. This association between seizures & mortality is expected considering that seizures are largely found among infants with moderate or severe HIE thus it's severity in babies with birth asphyxia is associated with brain injury hence increasing their mortality and morbidity.

Other factors associated with adverse outcome were place of delivery, duration of labour, duration of rupture of membranes, mode of delivery and duration of resuscitation. This is also the case with the study by *Maalim et al* at Kenyatta National Hospital [27].

In our study, infants delivered in other health facilities were more likely to die (23.1%) than discharged (1%) or continue treatment 8.2%, p< 0.001. This could be explained by the fact that most asphyxia referrals to PMH newborn unit are from lower-level health facilities such as health centers where there is lack immediate proper interventions of babies born with perinatal asphyxia and late referrals.

The duration of labour was significantly correlated with adverse outcome. The infants who died had significantly longer duration of labor (Mean 20.7) when compared to those who were discharged (Mean 14.5) and continued treatment (Mean 15.6), *p<0.001.* Similarly, duration of rupture of membranes was significantly prolonged in infants who died (mean 13.4 hours) compared to those discharged (mean 9.1 hours) and continued treatment (mean 9.8 hours), *p<0.001.*

This is like a study by Oswyn G *et al* that reported factors that significantly correlated with perinatal asphyxia being prolonged rupture of membranes, meconium-stained liquor, antepartum bleeding, maternal fever and delayed first and second phases of labour. However, from our study, maternal factors like meconium-stained liquor, antepartum bleeding, maternal fever, and convulsions during pregnancy had no significant correlation with adverse outcome.

The duration of resuscitation had significant correlation with adverse outcome. It was significantly longer (Mean 15.7 min) in patients who died compared to those discharged (Mean 4.6mins) and continued treatment (Mean 7.5mins), $p<0.001$.

Maternal factors like age and parity had no significant association with adverse outcome. This is also the case from a study by Seyal *et al* to determine factors associated with adverse outcome among neonates with perinatal asphyxia in Pakistan which reported maternal factors like gestational age and parity were not significantly associated with adverse outcome [16].

Study by Maalim et al on short -term outcomes of perinatal asphyxia and factors associated with adverse outcome reported that maternal factors such as education, occupation and antenatal clinic visits were found to be significantly linked to adverse outcome [27]. However, our study had no significant association.

CONCLUSION

Perinatal asphyxia still remains a significant cause of neonatal mortality and morbidity in Pumwani Maternity Hospital. Improved quality of intra-partum care services aimed at monitoring mothers with prolong rupture of membranes and preventing prolong labor and fetal complications are needed.

STUDY STRENGTHS

PMH NBU is managed by experienced medical officers with the help of senior paediatricians who have the requisite knowledge and expertise on identification and management of various neonatal conditions including perinatal asphyxia hence reducing variations in supportive management of perinatal asphyxia. The entire staff of the unit was cooperative and professional with proper documentation of their clinical work, and this has eased data collection during the study period.

LIMITATIONS

Pumwani Maternity Hospital is a level IV public maternity hospital, and these results may not be generalized to a higher health facility.

Clinical assessment only has been used to classify the gravity of HIE in this study. Future studies may complement the clinical evaluation with arterial blood gas (ABG) analysis or EEG for complete monitoring as well as examination of newborns with HIE.

RECOMMENDATIONS

Effort should be made by PMH administration to enhance the quality of intra-partum care services to avoid fetal complications associated with prolong labor and make a strict monitoring of mothers with Prolong rupture of membranes.

Efforts should be put in place by the County government of Nairobi and PMH administration to introduce new modalities in the management of perinatal asphyxia like therapeutic hypothermia.

There is need to have county and national register to follow up these infants to their school age.

Follow up study need to be done on the long -term outcome of infants with moderate to severe birth asphyxia discharged from the newborn unit.

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11.0 APPENDICES

APPENDIX I
SARNAT AND SARNAT CLINICAL STAGING OF HYPOXIC ISCHEMIC ENCEPHALOPATHY.

Variable	**Stage 1**	**Stage 2**	**Stage 3**
Level of consciousness	Alert	Lethargy	Coma
Muscle tone	Normal	Hypotonia	Flaccidity
Reflexes			
Suck	Normal	Weak	Absent
Moro	Normal	incomplete	Absent
Grasp	Normal	Weak	Absent

APPENDIX II
OUTCOMES OF PERINATAL ASPHYXIA STUDY QUESTIONNAIRE:

Questionnaire Serial Number

1.0 Registration					
1.1 Questionnaire Serial No.		**1.2 Patient's Hospital No.**		**1.3 Date (dd/mm/yy)**	
2. 0 Personal details					
2.1 Gender	[_0_] Male		[_1_] Female		
2.2 Date of birth (dd/mm/yy)					
2.3 Time of admission into NBU (24 hr clock)					
2.4 Clinical gestation in weeks					
2.4 birth weight in grams					
2.5 Length in centimeters					
2.6 Head circumference in centimeters					
2.8 Apgar score at 5 minutes	❑ Don't know				
2.9. Resuscitation with BVM	❑ Don't know		[_0_] No [_1_] Yes		
	2.9.1 *If yes for 2.9, what was the duration* in minutes?				
3.0 Intubation+ mechanical ventilation	[_0_] No [_1_] Yes				
4.0 Sarnat and Sarnat clinical staging of HIE					
4.1 Level of consciousness 2(alert), 1(lethargic),0(coma)					
4.2 Muscle Tone 2(normal),1(hypotonic),0(flaccid)					
4.3 Suck reflex 2(Normal),1(weak),0(absent)					
4.4 Moro reflex 2(Normal),1(incomplete), 0(absent)					
4.5 Grasp reflex 2(normal), 1(weak) 0(absent)					

4.6 HIE stage	

5.1 Date of birth (dd/mm/yy) Enter at least year	❑ Don't know	[__|__]-[__|__]-[__|__]
5.2 Relationship to the newborn.	❑ Non-relative	[_1_] Mother [_2_] Father [_3_] Sibling [_4_] Grandparent [_5_] Other relative
5.3 Parity	❑ Don't know	
5.4 Marital status	❑ Don't know	[_1_] single [_2_] Married [_3_] Separated [_4_] Widowed
5.5 Occupation	❑ Don't know	[_1_] Salaried formal employment [_2_]Informal employment [_3_] Self employment [_4_] Casual worker [_5_] Unemployed
5.6 Level of education	❑ Don't know	[_1_] None [_2_] Primary not completed [_3_] primary completed [_4_] Secondary not Completed [_5_] Secondary completed [_6_] Tertiary and beyond
5.7 Antenatal clinic visits	❑ Don't know	[_0_] No [_1_] Yes
5.7.1	*If yes for 5.7 how many times?*	[_1_] Once [_2_] Twice [_3_] more than twice
5.9 Place of delivery		[_1_] Home [_2_] PMH [_3_]Other health facility [_4_] On way to health facility
6.0 Mode of delivery		[_1_] Vertex vaginal [_2_] Breech vaginal [_3_] C/S [_4_] Vacuum Extraction
6.1 Maternal fever (within one week before delivery)	❑ Don't know	[_0_] No fever [_1_] Fever
6.2 Ante partum haemorrhage	❑ Don't know	[_0_] No bleeding [_1_] Bleeding
6.3 High blood pressure (Mother's case record)	❑ No information	[_0_] NO [1_] YES
6.4 Convulsion during pregnancy	❑ Don't know	[_0_] NO [_1_] YES
6.5 Other chronic diseases	❑ Don't know	[_0_] NO [_1_] YES
6.5.1	*If yes for 6.5 what disease*	
6.6 Duration of labour	❑ Not known	
6.7 Duration of rupture of membranes	❑ Not known	
6.8 Amniotic fluid colour	❑ Not known	[_0_] Green [_1_] Clear

6.0	CLINICAL ASSESMENT							
Time after initial assessment **Sign**	Day 1 Date: Time:	Day 2 Date: Time:	Day 3 Date: Time:		Day 4 Date: Time:	Day 5 Date: Time:	Day 6 Date: Time:	Day 7 Date: Time:
6.1 Level of consciousness 2(alert),1(lethargic),0(coma)								
6.2 Muscle tone 2(normal), 1(hypotonic), 0(flaccid)								
6.3 Seizures 1(absent), 0(present)								
6.4 Suck reflex 2(active),1(weak), 0(absent),								
6.5 Moro reflex 2(normal) 1 (depressed), 0(absent),								
6.6 Grasp reflex 2(normal),1(depressed), 0(absent),								

APPENDIX III
FINNSTRÖM SCORE.

Examine the baby and tick the most appropriate for each of the categories of assessment. The scores will be a = 1 b = 2 c = 3 d = 4.

1. ***Breast size.***

Measure the transverse diameter of each breast with a sliding calliper and record.

Right breast _____ mm Left breast _____ mm.

Categorize the largest value registered into either a, b or c and assign a score.

(a) below 5 mm.
(b) 5 to 10 mm.
(c) more than 10 mm.

2. ***Nipple formation***.

Inspect the nipple and assess whether it is visible, whether there is an areolar and characteristics of the areolar in relationship to the nipple. Tick the category that best describes the nipple and then assign a score:

(a) nipple barely visible, no areola.
(b) Nipple well defined, areola present but not raised.
(c) Nipple well defined; edge of the areola raised above the skin.

3. ***Skin opacity***.

Inspect the skin and assess the visibility of the blood vessels. Tick the category that best describes visibility of the blood vessels and then assign a score.

(a) numerous veins, tributaries and venules are clearly seen, particularly over the abdomen.
(b) veins and tributaries are seen.
(c) a few large blood vessels are clearly seen over the abdomen.
(d) a few large blood vessels are seen indistinctly over the abdomen, or no blood vessels are seen.

4. Scalp hair.

Inspect the scalp hair and describe the texture and tick the category that best describes it then assign a score.

(a) fine hair, woolly or fuzzy, individual strains difficult to distinguish.

(b) Hair coarse and silky.

(c) Each hair appears as a single strand.

5. Ear cartilage.

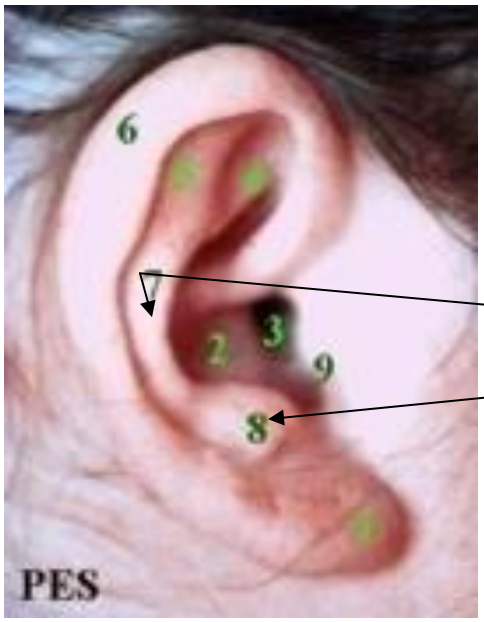
Palpate both ears to estimate the distribution of ear cartilage. In case there is a difference between the two ears, your judgment is based on the most "mature" ear:

(a) no cartilage is felt in antitragus.

(b) cartilage is felt in antitragus.

(c) cartilage is present in anthelix.

(d) Cartilage formation is completed in helix (i.e. cartilage can be palpated in the dorsal-cranial part).



1 Lobe or lobule
2 Concha Bowl
3 External Acoustic meatus
4 Triangular fossa
5 Scapha
6 Helix
7 Antihelix
8 Antitragus
9 Tragus

6 . Finger nails.

Inspect the finger nails and palpate the finger tip letting the nail scratch the hand of the examiner. Tick the category that best describes the nails and then assign a score.

(a) the nails do not reach the fingertips.
(b) the nails reach the fingertips.
(c) the nails reach or pass the finger tips, distal edge of the nail is distinct and relatively firm (i.e. the edge of the nail can easily be felt if the nail scratches the hand of the examiner).

7. Plantar skin creases.

Inspect the sole of the foot and only assess the relatively broad creases. Fine superficial lines may be present especially if the skin is dry but usually disappear if the sole is stretched from toes to heel. Categorize the skin creases and then assign a score:

(a) no skin creases are present.
(b) anterior transverse creases only are present.
(c) occasional creases are seen on the anterior two-thirds of the sole.
(d) the whole sole is covered with creases, i.e. also the heel.

Calculation of the Gestational age.

Add the scores and then correlate with the table below for a determination of the gestational age.

Total score _____

GESTATIONAL AGE BASED ON 7-ITEM CHART.

TABLE FOR GESTATIONAL AGE ESTIMATION BASED ON THE FINNSTRÖM SCORE.

Maturity score	Gestational age (in weeks)
7	27
8	28
9	29
10	30
11	31
12	32
13	33
14	34
15	35
16	36
17	36.5
18	37.5
19	38.5
20	39.5
21	40
22	41
23	42

APPENDIX IV
STANDARDS OF OPERATING PROCEDURES.

Standards of operating procedures for the measurement of weight, length and head circumference.

Weight**:**

Babies will be weighed in the newborn unit in a warm environment using a basin scale with high sides to ensure baby's safety. Before weighing the baby, the weighing scale will be calibrated to zero using a standard weight of two kilograms. The hospital infection prevention control standards shall be observed all the time. Three readings shall then be taken and average weight taken to the nearest 0.1grams (gm).

Length:

The length will be measured with the help of an assistant using a stadiometer. Three supine measurements will be taken and the average recorded to the nearest 0.1 centimeter (cm).

Head circumference:

Head circumference will be measured using a tape measure. Three occipitofrontal circumference measurements will be taken and the average recorded to the nearest 0.1cm.

APPENDIX V
CONSENT FORM

7-DAY OUTCOME OF TERM NEONATES ADMITTED AT PUMWANI MATERNITY HOSPITAL NEW BORN UNIT WITH PERINATAL ASPHYXIA.

Informed Consent form for _____ _____

The principal investigator is Dr. Bashir Dekow under supervision from Professor A. Wasunna, Dr. Nyambura Kariuki, Dr. Diana Marangu and Dr. Mary Waiyego on a study to determine 7-Day outcome and the factors associated with adverse outcomes in term babies with perinatal asphyxia at Pumwani Maternity Hospital Newborn Unit. The study is being done under the department of Paediatrics and Child Health at the University of Nairobi.

This Informed Consent Form has two parts:

- Information Sheet (to share information about the research with you).
- Certificate of Consent (for signatures if you agree to take part).

You will be given a copy of the full Informed Consent Form.

Introduction.

I am a Student currently doing my Masters in Paediatrics and Child health at the University of Nairobi. I am doing a study to determine 7-Day outcome and the factors associated with adverse outcomes in term babies with perinatal asphyxia at Pumwani Maternity Hospital Newborn Unit. Information will be given to you and feel free to ask questions before participating in the research. There may be some words that you do not understand. Please ask me to stop as we go through the information and I will take time to explain. If you have questions later, you can ask them to me.

Purpose of the research.

Perinatal asphyxia is defined as Failure to initiate and sustain breathing at birth. Perinatal asphyxia contributes significantly to neonatal mortality and accounts for 23% of neonatal deaths globally. Besides mortality, it is also associated with significant morbidity like cerebral palsy. Studies done on perinatal asphyxia and factors associated with adverse outcomes have reported different results. There is paucity of data on short term outcomes of perinatal asphyxia in Africa and in particular Kenya.

Risks.

There will be no experimental investigations or treatments in this study. All information given will be treated with utmost confidentiality.

Benefits.

The study will improve patient management and follow up.

Participant selection.

All term newborns admitted within 24hours of delivery to PMH NBU with perinatal asphyxia.

Voluntary Participation.

Your participation in this research is entirely voluntary and as such, no remuneration or compensation will be offered to the participants of the study. Whether you choose to participate or not, all the services you receive at this unit will continue and nothing will change.

Procedures and Protocol:

Description of the Process;

Once consented, a set of questions will be presented to you. Thereafter clinical examination of the study subjects will be carried out by the investigator every 24hours for the first 7 days of newborn's life.

Duration.

I require about 15 minutes of your time to gather information from you after which I will proceed to clinical assessment of the baby.

Confidentiality.

This research will improve patient management and follow up. The identity of those participating in the research will not be shared.

The information that will be collected from this research project will be kept confidential. Information about you and your child that will be collected during the research will be put under utmost confidentiality and no-one but the researcher will be able to see it. Any information about you and your child will have a number on it instead of your names. Only the researcher will know what your number is and it will not be shared with or given to anyone except the department of Paediatrics and Child Heath at the University of Nairobi.

Right to Refuse.

You do not have to take part in this research if you do not wish to do so and refusing to participate will not affect your treatment and care of your child at this unit in any way.

This proposal has been reviewed and approved by the department of Paediatrics and Child health as well as the Ethics and research committee in Kenyatta National Hospital, which is a committee whose task it is to make sure that research participants are protected from any harm.

You can ask me any more questions about any part of the research study, if you wish to. Do you have any questions?

Questionnaire serial Number:

Outcome of Perinatal asphyxia study

I, being a guardian of _____ (name of Newborn) have had the research information explained to me. I understand that I can withdraw my child from the study at any point and this will not affect my baby's care in any way.

☐ I agree to allow my baby to take part in this research and for the collection of clinical data.

Parents/guardian's signature: _____ Date: _____

Parent/guardian's name: _____ Time: _____

I certify that I have explained to the parent/caregiver the research information. Investigator's signature: _____ Date: _____

investigator's name: _____ Time: _____

Only necessary if the parent/guardian cannot read:

I* attest that the information concerning this research was accurately explained to and apparently understood by the parent/guardian and that informed consent was freely given by the parent/guardian.

Witness' signature: _____ Date: _____

Witness' name: _____ Time: _____

*A witness is a person who is independent from the trial or a member of staff who was not involved in gaining the consent.

Thumbprint of the parent as named above if they cannot write.

Who to Contact?

If you have any questions you may ask them now or later, even after the study has started. If you wish to ask questions later, you may contact any of the following:

Name: Dr. Bashir Dekow (Principal Investigator).

Mobile Number: 0722-415896

Email: bashirdekow2014@gmail.com

Name: Professor A. Wasunna

Mobile Number: 0722700444

Email: wasunnabill@gmail.com

Name: Dr Nyambura Kariuki

Mobile Number: 0722679119

Email: kariukin1@yahoo.co.uk

Name: Dr Diana Marangu

Mobile Number:0721282815

Email: marangud@gmail.com

Name: Dr Mary Waiyego

Mobile Number: 0721612393

Email: mawaiyego@yahoo.com

Kenyatta National Hospital/University of Nairobi Ethics and Research Committee

College of Health Sciences

P. O. Box 19676 00202 Nairobi

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

Email: **uonknh_erc@uonbi.ac.ke**

APPENDIX V
IDHINI

Matokeo ya siku ya 7 ya watoto wachanga waliokamilisha wakati halisi ya kuzaliwa waliolazwa katika hospitali ya pumwani na utambuzi wa pumu ya kuzaliwa.

Fomu ya Idhini ya _____ _____

Mpelelezi mkuu ni Dkt. Bashir Dekow chini ya usimamizi wa Profesa A. Wasunna, Dkt.Nyambura Kariuki, Dkt. Diana Marangu and Dkt.Mary Waiyego katika utafiti wa Matokeo ya siku ya 7 ya watoto wachanga waliokamilisha wakati halisi ya kuzaliwa waliolazwa katika hospitali ya Pumwani na utambuzi wa pumu ya kuzaliwa.

Utafiti itafanyika chini ya Idara ya Afya ya Watoto katika Chuo Kikuu cha Nairobi.

Hi fomu ya idhini ina sehemu mbili:

- Sehemu ya Maelezo (kukuelezea zaidi kuhusu utafiti).
- Shahada ya Idhini (sahihi ikiwa umekubali kujihusisha na utafiti huu).

SEHEMU YA I: Maelezo.

Mimi ni mwanafunzi katika chuo kikuu cha Nairobi, ninasomea shahada kuu kwenye Idara ya Afya ya watoto. Ningependa pamoja na wasimamizi wangu kutafiti Matokeo ya siku ya 7 ya watoto wachanga waliokamilisha wakati halisi ya kuzaliwa waliolazwa katika hospitali ya pumwani na utambuzi wa pumu ya kuzaliwa. Kando na haya utapewa maalezo zaidi kuhusu mada na pia una uhuru wa kuuliza maswali yoyote ili kuelewa utafiti huu zaidi.

Nia.

Pumu ya kuzaliwa ni kutoanzisha kupumua na kuendeleza kupumua baada ya kuzaliwa. Pumu ya kuzaliwa huchangia asilimia 23 ya vifo vya watoto wachanga duniani. Mbali na hilo, husababisha unyevu kama ugonjwa wa kupooza kwa ubongo. Utafiti kuhusu ugonjwa wa pumu ya kuzaliwa pamoja na sababu zinazohusiana na matokeo mabaya ya ugonjwa huu iliripotiwa na matokeo tofauti. Kuna uhaba wa matokeo ya muda mfupi ya pumu ya kuzaliwa katika bara la Afrika hasa nchi ya Kenya.

Hatari.

Hakutakuwa na uchunguzi au matibabu ya majaribio katika utafiti huu. Habari yote iliyotolewa itahifadhiwa kwa usiri mkubwa.

Faida ya Utafiti.

Utafiti huu utasaidia kuboresha maisha ya wagonjwa hasa watoto na matibabu yao.

Wanaoalikwa kujihusisha na Utafiti.

Watoto wote wachanga waliokamilisha wakati halisi ya kuzaliwa waliolazwa katika hospitali ya Pumwani na utambuzi wa pumu ya kuzaliwa ndani ya masaa 24.

Kushiriki.

Kushiriki utafiti huu utakuwa kwa njia ya kujitolea na kwa hivyo hakuna malipo yoyote atakayolipwa mshiriki wa utafiti huu. Iwapo hungependa kushiriki uamuzi huu hautakuathiri kwa njia yoyote iwe matibabu yako au utakavyohudumiwa.

Maelezo kuhusu mchakato.

Iwapo utakubali kushiriki, utaulizwa maswali chache kuhusu mama na mtoto. Kisha uchunguzi ya mwili ya mtoto itafanywa na mpelelezi mkuu kila masaa 24 kwa siku 7 za kwanza ya mtoto.

Wakati utakaotumika.

Nahitaji kama dakika 15 ya muda wako.

Usiri.

Matokeo ya utafiti huu yatawekwa siri wala hayatapatiwa mtu yeyote asiyehusika na utafiti huu. Zaidi ya hayo badala ya jina lako au ya mtoto, nambari zitatumiwa kutambulisha majina yenu. Mpelelezi pekee ndiye atajua nambari hizo na hazitashirikiwa kwa mtu yeyote isipokuwa Idara ya Afya ya Watoto katika Chuo Kikuu cha Nairobi.

Haki ya kutoshiriki.

Kushiriki utafiti huu ni kwa kujitolea na iwapo hungependa kushiriki, uamuzi wako utaheshimiwa na pia hautaathiri kwa njia yoyote matibabu yako na ya mtoto. Bali utaendelea kupokea matibabu na huduma ya hospitali hii kama hapo awali.

Pendekezo hili limeangaliwa na kuidhinishwa na Idara ya afya ya watoto ya Chuo kikuu cha Nairobi na kamati ya maadili ya utafiti katika hospitali ya Kenyatta inayohakikisha kuwa haki za wanaoshiriki utafiti wowote nchini zinazingatiwa**.** Iwapo utakuwa na swali lolote kumbuka una uhuru kuuliza. Una swali lolote?

SEHEMU YA II: Shahada ya idhini

Matokeo ya utafiti wa Pumu ya kuzaliwa

Mimi kama mzazi/ mlezi wa _____ (jina la Mzaliwa mpya) nimekuwa na habari ya utafiti ambayo nimeelezewa. Ninaelewa kuwa ninaweza kumwondoa mtoto wangu kutoka kwa utafiti wakati wowote na hii haitaathiri utunzaji wa mtoto wangu kwa njia yoyote.

☐ Ninakubali kumruhusu mtoto wangu kushiriki katika utafiti huu na ukusanyaji wa ripoti ya kliniki.

Saini ya mzazi / mlezi: _____ Tarehe: _____

Jina la mzazi / mlezi: _____ Saa: _____

Ninathibitisha kwamba nimeelezea mzazi / mtunzaji habari ya utafiti.

Saini ya mchunguzi: _____ Tarehe: _____

Jina la mchunguzi: _____ Saa: _____

Ikiwa mzazi / mlezi hawezi kusoma:

Ninathibitisha kwamba habari kuhusu utafiti huu ilielezewa kwa usahihi na inaeleweka kwa mzazi / mlezi na kwamba idhini iliyo na ukweli ilitolewa bure na mzazi / mlezi.

Saini ya Shahidi: _____ Tarehe: _____

Jina la Shahidi: _____ Wakati: _____

* Shahidi ni mtu ambaye amekuwa huru kutoka kwa utafiti huo au mfanyikazi ambaye hakuhusika katika kupata idhini hiyo.

Picha ya kidole ya mzazi kama ilivyotajwa hapo juu ikiwa hawawezi kuandika.

Kwa maelezo zaidi hata baada ya utafiti huu una uhuru wakuwasiliana na watu wafuatao kupitia anwani na numbari za simu zilizoandikwa hapa chini.

Jina: Dkt.Bashir Dekow (Mtafiti mkuu).
Numba ya simu: 0722-415896
Barua pepe: bashirdekow2014@gmail.com

Jina: Profesa A. Wasunna
Namba ya simu: 0722700444
Barua pepe: wasunnabill@gmail.com

Jina: Dkt Nyambura Kariuki
Namba ya simu: 0722679119
Barua pepe: kariukin1@yahoo.co.uk

Jina: Dkt Diana Marangu
Namba ya simu: 0721282815
Barua pepe: marangud@gmail.com

Jina: Dkt Mary Waiyego
Namba ya simu: 0721612393
Barua pepe: mawaiyego@yahoo.com

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Barua pepe: **uonknh_erc@uonbi.ac.ke**

APPENDIX VI
BUDGET

Category	**Remarks**	**Units**	**Unit Cost (KShs)**	**Total (KShs)**
Proposal Development	Printing drafts	500 pages	5	2500
	Proposal Copies	10 copies	600	6,000
Data Collection	Stationery			5,000
Data Analysis	Statistician	1		30,000
Thesis Write Up	Computer Services			5,000
	Printing drafts	1000 pages	5	5,000
	Printing Thesis	10 copies	600	6,000
Contingency funds				10,000
Total				**69,500**

APPENDIX VII
WORK PLAN

	Months 1 -2	Months 3-4	Months 5-10	Month 11	Months 12-13	Month 14	Month 15
Development of Proposal							
Proposal submission to Ethics							
Data collection							
Data analysis							
Thesis Writing							
Poster Presentation							
Thesis Submission							