RISK FACTORS FOR SEVERE EARLY NEONATAL MORBIDITY AMONG TERM NEONATES ADMITTED AT MUHIMBILI NATIONAL HOSPITAL, TANZANIA - A NESTED CASE CONTROL STUDY

Fatma Abdallah Lijohi, MD

MMed (Obstetrics and Gynaecology) Dissertation
Muhimbili University of Health and Allied Sciences
October, 2015

RISK FACTORS FOR SEVERE EARLY NEONATAL MORBIDITY AMONG TERM NEONATES ADMITTED AT MUHIMBILI NATIONAL HOSPITAL, TANZANIA -A NESTED CASE CONROL STUDY

By

Fatma Abdallah Lijohi, MD

A Dissertation Submitted in (Partial) Fulfillment of the Requirement for Degree of Master of Medicine in Obstetrics and Gynaecology of Muhimbili University of Health and Allied Sciences

Muhimbili University of Health and Allied Sciences
October, 2015

CERTIFICATION

The undersigned certify that they have read and hereby recommend for acceptance for examination by the Muhimbili University of Health and Allied Sciences a dissertation entitled: ***Risk Factors for Severe Early Neonatal Morbidity among Term Neonates Admitted at Muhimbili National Hospital, Tanzania-A Nested Case Control Study,*** in partial fulfillment of the requirements for the degree of master of medicine in Obstetrics and Gynaecology of the Muhimbili University of Health and Allied Sciences**.**

_____

Prof. Projestine Muganyizi
(Supervisor)
Associate Professor in Obstetrics and Gynaecology
MUHAS

Date_____

_____

Prof. Karim Manji
(Co supervisor)
Professor in Pediatrics
Department of Pediatrics and Child Health
MUHAS

Date_____

DECLARATION
AND
COPYRIGHT

I, **Dr. Fatma Abdallah Lijohi**, declare that this **dissertation** is my own original work, and that it has not been presented and will not be presented to any other university for a similar or any other degree award.

Signature ……..... Date …….

ACKNOWLEDGEMENT

The completion of this study would not have been possible without the dedicated supervision of my supervisor, Prof Projestine Muganyizi and co–supervisor Prof Karim Manji. I sincerely thank them for their guidance and timely corrections in preparation of the proposal and report writing. They played a very important role as my teachers and my supervisors; their contribution was invaluable and highly appreciated.

I extend my gratitude to staff of Muhimbili National Hospital neonatal and maternity wards for their tireless support and guidance to ensure the fulfillment and timely accomplishment of this study. Their support was invaluably throughout the course and during this dissertation. I convey my special thanks to Dr Adrian, Sr. Mvungi, Sr.Tibesigwa, Sr.Aweza,Sr I. R.Mlawa for their commitment during data collection.

Special thanks to the director of clinical services in Muhimbili national hospital and head of department of obstetrics and gynaecology of MNH for allowing me to conduct the research at MNH. Thanks to the government of Tanzania Ministry of health and social welfare for the financial support to enable this study.

I also wish to extend my special thanks to my family for their kindness, love, support and amazing understanding throughout the course and especially during conduction of this dissertation.

Lastly with all the weight I thank the Almighty God for giving me good health and ability to do the study.

DEDICATION

This work is dedicated to my mother, Mrs. Kuruthum S Ngalawa and to my loving and supportive husband Ismail.

ABSTRACT

Background

Early neonatal period is the first seven days of life, and the highest risky period for adverse neonatal outcome. Worldwide about 4 million neonatal deaths occur yearly, three quarters of these deaths occur in the first week. Neonates with severe morbidity are at increased risk of mortality than the rest. Studies addressing risk factors for severe early neonatal morbidity pay more attention to premature babies with less attention to term neonates. Risk factors could differ substantially because term neonates are expected to be healthier due to their physiological maturity.

Objective

The focus of this study was on term babies who were admitted at MNH Neonatal Care Unit within seven days of life with the objective to identify risk factors for their severe morbidity.

Methods

This was a nested case control study conducted on all term neonates who were admitted within seven days of birth during the study period from September to December. We adapted the MAIN score tool as a checklist during data collection and follow up, and presence of death or any one or more of the selected morbidity items within seven days of delivery was used to distinguish between severely morbid neonates and less severely morbid neonates. Data were obtained from review of neonatal unit case notes, review of RCH4 cards, delivery records and questionnaire interviews with the mothers. Using SPSS version 20 computer program, univariate regression models were run to determine Odds ratios and 95% Confidence Intervals as estimates of the risk for severe morbidity and clinical importance of the individual risk factors respectively. Multivariate analysis was then performed to determine the independent risk factors for severe morbidity in the final Model. In all analyses the p value of 0.05 or less were taken as statistically significant. Ethical clearance for this study was obtained from MUHAS Senate Research and Publication Committee and Muhimbili National Hospital.

Results

During the study period a total of 2104 newborns were admitted at MNH NCU. Of these 1624 did not meet the criteria for the study. The analysis was done on 463 term neonate of whom 220(47.5%) were diagnosed to have severe early neonatal morbidity. Incidence of early neonatal morbidity for term neonates was 255.7 per 1000 neonates. Low birth weight in term babies and urinary tract infections during pregnancy were independently associated with severe early neonatal morbidity. Severe early neonatal morbidity of a term neonate with no congenital anomaly was a serious adverse outcome with high proportion at MNH, and warrants further investigations. Furthermore studies are recommended for identifications of more risk factors.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF ABBREVIATIONS

ABD	Assisted Breech Delivery
HIV	Human Immunodeficiency Virus
IV	Intravenous
LSCS	Lower Segment Caesarean Section
MAIN	Morbidity Assessment Index for Newborn
MNH NCU	Muhimbili National Hospital Neonatal Care Unit
MNH	Muhimbili National Hospital
NCU	Neonatal Care Unit
NTISS	Neonatal Therapeutic Intervention Scoring System
PROM	Premature rupture of membranes
SVD	Spontaneous Vaginal Delivery
TISS	Therapeutic Intervention Scoring System
UN	United Nations
UTI	Urinary tract infections
WHO	World Health Organization

DEFINITIONS OF TERMS

Neonatal morbidity - A sick neonate admitted at neonatal unit was considered to have neonatal morbidity.

Early neonatal period- was defined as the period from delivery up to 7 days of life.

Severe early neonatal morbidity-This was diagnosed based on Modified Morbidity Assessment Index for Newborn(MAIN) tool items whereby the presence of DEATH or any of the following morbidity items within seven days of delivery was diagnostic: The items were:

1. Multiple convulsions
2. Cardiopulmonary resuscitation any time before discharge.
3. Apnea corrected by oxygen or by resuscitation.
4. Need for intubation at birth.
5. Hyperbilirubinemia bilirubin>250µmol/L (needing phototherapy or exchange transfusion).
6. Hypotonia.
7. Severe thrombocytopenia with or without bleeding disorder.
8. Stupor, obtundation or Coma.
9. Abnormal respiratory rate.
10. Need for blood transfusion.
11. Abnormal heart rate.

Antenatal factors- Factors or events during pregnancy such as antenatal care attendance, febrile illness in pregnancy, anemia, and pregnancy induced conditions or any other antenatal complication before labor

Intrapartum and immediate postpartum factors-in this study imply factors during labor and delivery. Includes obstructed labor, prolonged labor, hemorrhage, mode of delivery (vacuum, breech, SVD and caesarean section), assistance at delivery, place of delivery and complications immediate post-delivery.

Fetal and neonatal factors-includes birth weight, Apgar score, sex and duration post-delivery to referral or admission.

1 BACKGROUND

Introduction

Early neonatal period refers to the period before 7 completed days of age, a period during which most neonatal deaths occur (1). Worldwide, about 4 million neonatal deaths occur yearly, three quarter of deaths occur in the first week of life with the highest risk at the first day of life (2). Among under-five mortality, neonatal deaths increased from 37% in 2000 , 41% in 2008 to 44% 2012(1,3). Over 98% of these deaths occur in developing nations with the highest rates in Africa (4).

The United Nations (UN) estimates that 1.6 million babies are born each year in Tanzania. About 51,000 newborns die in Tanzania yearly, which places it among the top five countries with the most newborn deaths in sub-Saharan Africa (5). Neonatal mortality rate remains high at 32 per 1,000 live births, and accounts for 47% of the infant mortality rate in the country. The slow decline in neonatal mortality as compared to post-neonatal mortality calls for attention and efforts to reverse this trend (6).

Pregnancy and delivery complications were implicated in more than half of newborn morbidity (7). Intrapartum and immediate postnatal periods have always been important and can have a significant risk to both mother and her newborn neonate (8). Studies have shown that adverse intrapartum events were implicated in up to 23% of neonatal deaths, along with long-term impairment and disability worldwide (9). Every year, an estimate of 904000 intrapartum-related neonatal deaths occurs worldwide accounting for one-`third of the early neonatal deaths, contributing to 9 percent of all under-5 child mortality (8). In developing countries nearly two- thirds of all births occur at home, and in approximately half of deliveries, skilled care is not available making intrapartum related morbidity and mortality worse. Suspected factors includes maternal characteristics ,pregnancy complications, intrapartum events, lack of skilled birth attendants especially in developing countries and neonatal factors leading to early neonatal morbidity, mortality and long-term impairment and disability . In Tanzania, severe infections, birth asphyxia and preterm complications leading causes of newborn deaths (4,10) Neonates with severe neonatal morbidity are the one at highest

risk to mortality. It can be assumed that along with every case of neonatal mortality there are cases of morbidity as well. Interventions to reduce neonatal morbidity indirectly leads to reduction of neonatal mortality. Severe morbidity of a term infant without congenital malformations is an emotionally devastating outcome for both parents and caregivers and the community (11).

Magnitude of term neonatal morbidity admissions to NICU varies wordwide. In Canada incidence of admission is 14.4 percent, while in USA 5-18 percent of term babies get admitted in NICU and 40 percent of all admissions at higher level nurseries are term babies (12). In Northern Tanzania 15% gets admitted to neonatal care unit (NCU)(13). This includes both term, pre-term and post term. Among them neonatal deaths is around 15percent, the rest are treated with morbidity. At Muhimbili National Hospital an average of 500 neonates are admitted monthly. Reasons for admissions in MNH neonatal unit includes prematurity 21.7%, birth asphyxia 21.6%, septicemia 14%, Pneumonia 1.4%, congenital anomalies 1.48%, Anemia 0.2%, for routine care 31.8%, unknown 0.15, others 7.7% (MNH data base 2014). Some of these neonates recover quickly and get discharged within optimum time. But there were those who were born at term without congenital anomalies and still have delayed recovery and/or develop life threatening conditions resulting in higher rates of morbidity and mortality. Contrary to preterm and post term, most of neonates delivered at term do well and have a low prior probability of death and serious morbidity hence has drawn little research attention (11). It is rationale that this special group referred in this study as severe morbid term neonates is the group of interest (an outcome), of which risk factors or predictors associated with their morbidity needs to be established.

1.0 Literature review

1.0.1 Risk factors for neonatal morbidity:

Studies have shown associations between neonatal morbidity and some socio demographic, maternal medical conditions, antepartum, intrapartum and immediate postpartum factors. In social demographic factors, teenage mothers and those over 34 years of age have been found to have higher risks of having an unfavorable outcome such as small for gestation age and low birth weights (14,15). Large for gestation age and macrosomia increased with increasing maternal age (16). Recently a noted increase in the incidence of childhood type 1 diabetes could be explained by increase in maternal age (17). Mothers delivering for the first time were at higher risk for poor neonatal outcome than others (18)**.**Babies of single mothers were more likely to have neonatal morbidity as compared to babies of married mothers (13). The higher risk of maternal and neonatal morbidity was found among rural residence mothers due to the longer distance to access health care services and difficulty of transportation from living place to the hospital (19). Education levels were associated with better neonatal outcomes. More highly educated mothers were better in take care of themselves during pregnancy (20).

Elective caesarean section has been associated with increased risk of neonatal respiratory morbidity. This has been attributed to "iatrogenic prematurity" or lack of physiological changes related to labor. Babies delivered by elective caesarean section at 37 to 39 weeks' gestation were at two to fourfold increased risk of respiratory morbidity compared with babies delivered by intended vaginal delivery (21).

Many studies have shown an association between maternal diseases and neonatal morbidity, mothers with diabetes mellitus have risk of neonatal macrosomia, increased intensive care admission, prolongation of hospital stay and higher rates of neonatal hypoglycemia, neonatal asphyxia, birth trauma, hypocalcaemia, hyperbilirubinemia and respiratory distress (22,23).

Admission to neonatal intensive care unit and low Apgar scores are more frequent for infants of obese mothers, both after spontaneous and induced labor (24).

Intrapartum factors have also been associated with neonatal morbidity. Premature rupture of membranes and prolonged rupture of membranes could complicate to fetal distress, cord compression, deformation and altered pulmonary development leading to pulmonary hypoplasia and pulmonary hypertension and even infection (13,19). Poor monitoring during labor including poor fetal heart rate monitoring was indirectly associated with over 40 percent perinatal death. Issues like poor management of induction of labor and poor documentation as well as delayed management of pregnant women have been common in poor resource countries (25).

Women in labour with meconium stained amniotic fluid (MSAF) are at risk of having neonates with respiratory and neurodevelopment morbidity and mortality, and therefore longer hospitalization (26). Transfer or admission of newborns to neonatal care unit alone was found to have strong associations with classical neonatal risk factors for morbidity and mortality (13), some studies even used admission to intensive care neonatal unit as an indicator for severe neonatal morbidity (11). Studies have shown low birth weight, infections and birth asphyxia were interchangeably most common causes of neonatal morbidity (27,28).

Some of these morbid neonates recover quickly and get discharged home. On the other hand, a proportion of these neonates do presents with severe disease and remains admitted in hospital for longer periods (29). These neonates hence could result in longer hospital bed occupation, or suffer added complications that call for extra interventions and prolonged periods of medical and nursing attention, hence more resources and more time consumption.

Although previous studies have shown associations of socio-demographic, maternal, neonatal and intrapartum factors with neonatal morbidity, most of these studies do not make a distinction between premature and term neonates. (13,27,30) and many others were done on preterm neonates (31–33). Our study aims at determining obstetric predictors for severe morbidity including maternal, antenatal, intrapartum and immediate postpartum factors among term neonates.

1.0.2 Neonatal morbidity measures

In a simplest form, most common measures of neonatal morbidity used previously are conventional methods which have defined neonatal morbidity using a single item measure such as the gestation age (34,35) length of neonatal unit stay (29), Apgar score and birth weight , temperature instability, hypoglycemia and respiratory distress to predict morbidity (35). Although these conventional measures of morbidity covers large population of neonates and are readily available from routine records, alone fail to categorize morbid neonates into various spectrum of morbidity (severity) and have been blamed for failure to characterize the severity of morbidity after the first few moments of life (29,34).

Other alternative measures are:

Currently few tools of newborn morbidity have been optimized and standardized for use over the entire spectrum of severity, from minimal to severe, for use in perinatal population studies of early neonatal period. The measures include morbidity assessment index for newborn (MAIN) (34). Developed as a global measure of morbidity in the first week of life, for babies with no congenital anomalies delivered at a gestation age more than 28 weeks. MAIN score tool is based on items of routine clinical and laboratory examination of newborns. MAIN score tool had already been validated for use. Studies done to validate MAIN score tool of which "Conclusion: The MAIN score fulfills the need for a simple, universal, yet sensitive and robust tool to provide a numerical index of early neonatal outcomes of prenatal care and adverse prenatal exposures in babies delivered beyond 28 weeks gestation. The performance of the MAIN score agrees well with the current medical awareness regarding the impact of adverse prenatal exposures on newborn morbidity"(36).

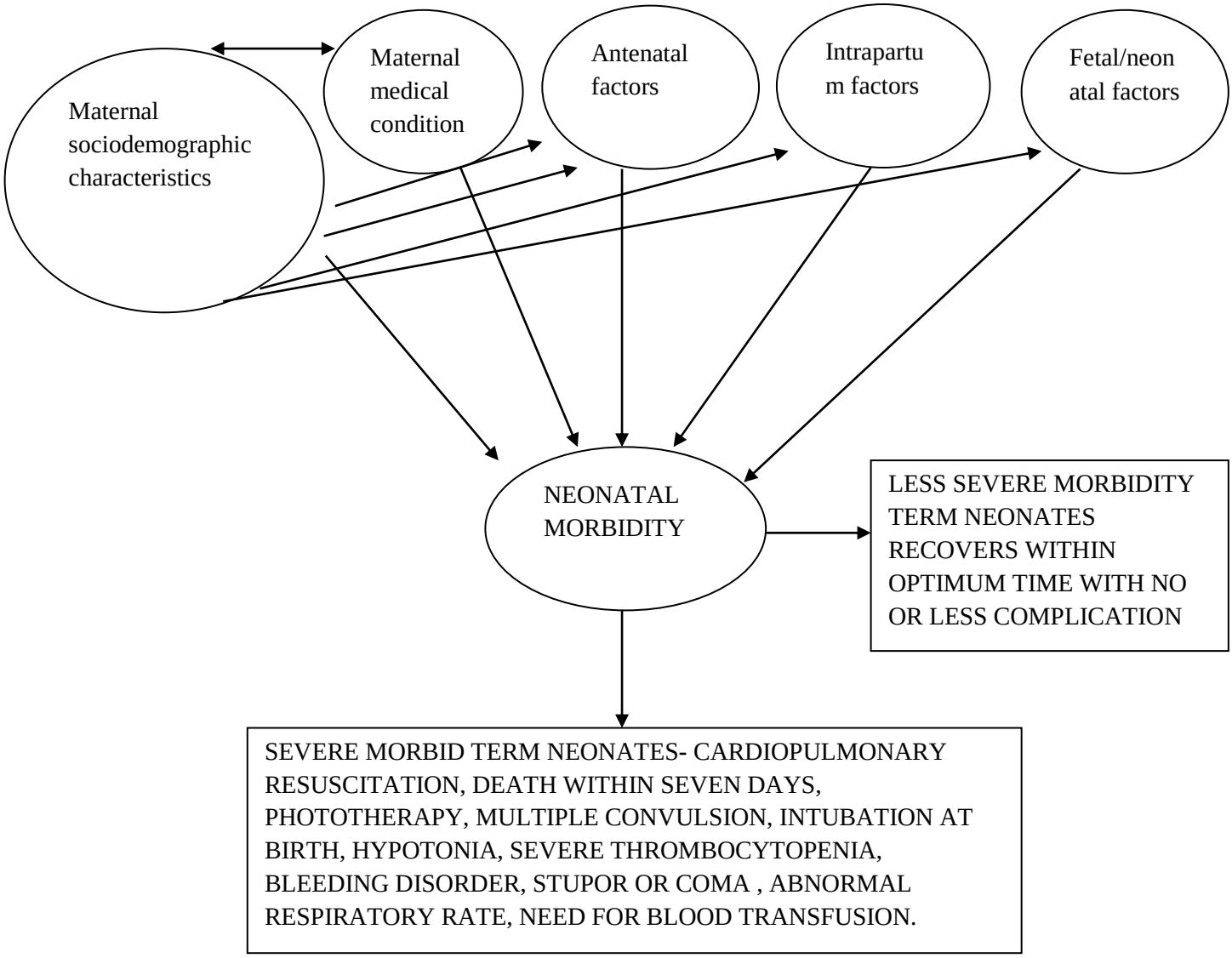
The Neonatal Therapeutic Intervention Scoring System (NTISS), is another standard measure that has been modified from the original adult severity of illness assessment tool, Therapeutic Intervention Scoring System (TISS) score of Cullen et al (1974 and 1983)(37) (Appended). Assesses severity of neonatal illness indirectly through the

therapy given, rather than through direct measurements of physiological status. This score can be easily abstracted from medical records and provides information beyond traditional measures such as birth weight. The disadvantage is that it appears to be problematic for infants who die within the first few hours of life.

The combination of standard measures by adaptation of morbidity assessment tools has also been used to define the spectrum of morbidity and found to be valid. A recent study done on term newborn severe morbidity in United States included seven criteria to define severe morbidity, where by a composite of neonatal morbidity included ≥1 cases of hypoxic ischemic encephalopathy, meconium aspiration with pulmonary hypertension, requirement of hypothermia therapy, respiratory distress syndrome, seizures, sepsis or suspected sepsis, or death as diagnostic for severe morbidity(12). A morbidity study done in Atlanta in 2006 used only three items and presence of one or more item was diagnostic for severe morbidity, newborn hospital stay more than 6 nights, any morbidity diagnostic code considered life threatening and infant death before hospital discharge as serious morbidity (29). These can be adopted with modification because of different hospital settings especially in low resource settings.

In our study we adapted MAIN score tool which was modified by deleting locally inapplicable items from the original MAIN tool and hence making a new designed tool termed Modified MAIN as a checklist during follow up of neonates. Categorization of neonates into severe morbidity was done by creation of a composite of neonatal morbidity whereby ≥1 item from modified MAIN tool was diagnostic. Our new Modified MAIN score tool could not be used directly to discriminate neonates into different degree of severity without this categorization as compared to original MAIN score tool , since it needs further validation and field testing.

Figure 1: CONCEPTUAL FRAMEWORK



Neonates with morbidity get admitted at neonatal care unit,among them are term neonates.These neonates have variable exposure characteristic**s** ,e.g. sociodemographic characteristics of women may affects the risk of medical conditions, maternal, antenatal, intrapartum and foetal/neonatal factors.Likewise maternal medical conditions like diabetes and sickle cell affect the indivdiual woman's parity and the like. The relationship can be

complex,bidirectional or unidirectional as shown in figure 1.Some of the neonates get treated and recover quickly and get discharged.On the contrary others develop severe life threatening complications and mortality.These severely morbid neonates will need extra care ,attention in terms of resources,time and bed occupation.They are the one who will need emergeny care,resuscitations,intubations and assistant ventilations which are limited in terms of staff and supplies ending up with poor quality of care and hence increse in short term and longterm morbidity and mortality. The prediction of the severity using a simple scoring tool is what we intended to undertake.

Statement of the problem

Severe morbidity and mortality of a term neonate without congenital anomaly is a devastating situation to caregivers and parents (Lefkowitz et al 2010, Evers 2009). Term neonates are expected to be healthy due to their low probability of serious morbidity (31). Although there are many morbid neonates admitted at Muhimbili National Hospital, some of them recover quickly and get discharged home, a proportion of them present with severe disease which is life threatening. Because of the severe morbidity these neonates demand extra care in neonatal unit, extra medical and nursing attention with prolonged stay. Having severe morbidity means more time, space and resources in an already resource poor setting**.** Suspected factors includes maternal demographic characteristics, pregnancy complications, intrapartum events, lack of skilled birth attendants especially in developing countries and neonatal factors. Moreover, severe morbidity for term neonates is likely to intensify the traumatic impact on parents and care givers whose expectations of a healthy baby after a term pregnancy were high. Despite all these potential impacts the literature on severe morbidity in term babies is scanty and currently there is no published study in Tanzania specifically aiming at morbidity of term neonates.

1.1 Rationale of the study

Number of neonatal admissions at Muhimbili National Hospital is high but the resources are limited. This study will describe neonates with severe morbidity at term who need extra care at MNH NCU and who increase costs and trauma to families. The findings of the study will inform policy makers on possible factors to which prevention can be focused. It will be useful for international comparisons and advance scientific knowledge on predictors of severely morbidity in term babies for future prevention.

1.2 Research question

What are the risk factors for severe early neonatal morbidity among term neonates admitted at MNH?

2 OBJECTIVES

2.1 Broad Objective

To determine predictors of severe early neonatal morbid outcome among term neonates admitted at neonatal unit in Muhimbili National Hospital

2.2 Specific Objectives

i. To determine the incidence of early neonatal morbidity at term among all admissions at MNH NCU

ii. To establish the proportion of babies with early neonatal morbidity at term with severe morbidity.

iii. To determine predictors of severe early neonatal morbidity among term babies admitted to MNH NCU.

METHODOLGY

2.0 Study design

A case control study nested in a cohort of term neonates whereby all term neonates admitted were followed up to their 7th day of birth, discharge, or death depending on which came first. Neonates were then screened for the indicators of severe morbidity during the period

2.1 Study setting

Study was conducted at Muhimbili National Hospital Neonatal Care Unit located at MNH maternity block. Maternity block receives most of obstetric and neonatal high risk cases from within the hospital and referrals from other hospitals both private and government from Dar es Salaam and nearby regions. It has a capacity of 356 beds where 130 were baby cots, 22 delivery beds, 8 maternal high dependent unit beds and 196 general beds.

Neonatal care unit at Muhimbili National Hospital admitts an average of 500 neonates monthly that is 10 to 17 per day of which sick term neonates are about 3 to 5. The unit has central oxygen supply as well as cylinders. Babies receive oxygen via nasal or hood masks. The unit has no mechanical ventilator or any continuous positive airway pressure machine**.** There is no devise available for neonatal blood pressure check. Babies in the unit are either fed on expressed breast milk if the mothers are around or formula in the absence of the mothers. Feeding is given either through nasal gastric tube, syringe or cup and spoon. For neonates with feeding difficulties, parenteral feeding with 10% dextrose is provided.

Neonatal ward has different rooms in which neonates are kept according to their birth weight, whether they have infectious disease or not. Assessment for maturity of babies was done during admission. First room was for premature or low birth weight less than 1500gms babies**.** Neonates in this room were kept in a room incubator at a higher temperature than the rest of the room. A room for neonates with >1500<2500grams, a room for neonates who have normal birth weight or big babies with neonatal morbidity

were also part of the neonatal ward. The explained setting was a ward regular practice not influenced by our study method requirement**.**

Neonates who had been discharged home after birth because they were healthy with no complication and suddenly developed morbidity at home which necessitated admission (from home) were also kept in a separate room.

Neonates who are normal and healthy admitted for care due to their mother's conditions (very sick mothers, orphans or abandoned and unknown neonates) are also kept in a separate room. Neonates get admitted for an average of two to seven days in neonatal unit, get well and discharged. In neonatal unit/ward neonates are brought by nurses from labor ward or from a referring hospital, they are received by ward nurse who quickly get collateral information of the neonate and quickly triage the baby into respective rooms. Resuscitation or any medical attention needed is immediately given to the child by the specific room nurse, like Intravenous cannula, oxygen, IV fluids if needed.

The newly admitted neonate is then immediately seen by a doctor where investigations and specific treatment are started right away. Ward rounds are conducted daily by general practitioners, pediatricians and neonatologists who review the neonates daily.

Mothers of neonates also get admitted in the maternity block wards located in the same building as the neonatal care unit. They visit their sick newborns every three hours in twenty four hours (8 times) for breast feeding and care.

Neonates who get well are discharged and seen at the neonatal clinic in two weeks' time for follow up.

Participants

Target population: All ill neonates who were born at term and were admitted at MNH Neonatal care unit and implicitly their mothers were the target population

Accessible population: All term neonates admitted at MNH Neonatal care unit and implicitly their mothers who were admitted between September and December 2014.

Study population: All term neonates admitted at MNH Neonatal care unit and implicitly their mothers who were admitted between September and December, 2014.Consented and who met the criteria for inclusion.

2.2 Sampling procedure

All neonates were consecutively scrutinized for eligibility and the eligible ones enrolled until sample size was reached. Recruitment was done daily from the admission book.

2.3 Inclusion criteria

All term neonates admitted at Muhimbili National Hospital due to sickness.

2.4 Exclusion criteria

Term neonates admitted at Muhimbili National Hospital with:

1. Gross congenital malformations
2. Neonates whose maternal details are not available–death, abandoned babies,
3. unknown

2.5 Sample size

One of the important intrapartum predictor variables is delivery by Caesarean Section (CS) at MNH where most of the neonatal admissions emanate, CS prevalence is around 50 percent. According Hansen & Wisborg (2007) babies delivered by elective caesarean section at 37 to 39 weeks' gestation are at two fold to four fold increased risk of respiratory morbidity compared with babies delivered by intended vaginal delivery. Our assumption is that at MNH, NICU CS prevalence will be generally slightly lower due to admissions from outside MNH and much lower for the severely morbid due to delayed intervention, say 40%. Thus among the babies with severe morbidity, 60% will not have been exposed to CS (i.e. p1=0.6)

Taking a risk estimate of 2 (odds =2: for developing severe morbidity once exposed to CS (the minimum risk by Hansen & Wisborg, 2007), power of 80% a calculated sample size is 330 (165 on each arm) using Fleiss formula (reference) below:

$$n = \frac{\left[z_{\alpha/2}\sqrt{(r+1)\bar{p}\bar{q}} + z_{1-\beta}\sqrt{rp_1q_1 + p_2q_2} \right]^2}{r(p_1 - p_2)^2}$$

Reference: **(**Fleiss J.L. *Statistical Methods for Rates and Proportions.* John Wiley & Sons, 1981. Print.**)**

Where:

n =165	number of sample size for each arm
$z_{\alpha/2}$ = 1.96	z-score for two-tailed test based on α level=95%
$_{1-\beta}$ = 0.80	z-score for two -tailed test based on β level (=80%)where
r = 1:1	**Unexposed to caesarean section: exposed to caesarean section**
	n= 330(165 on each arm)

Adding 20% non-response/loss to follow, the calculated minimum sample size is 399 which is rounded up to 400

2.6 Study duration

Study was conducted for a period of four months from September to December 2014.

2.7 Research assistants

There were five research assistants. One student of school of medicine fifth year who together with the principal investigator located at neonatal ward and four nurses working in obstetric wards one located in each ward (there were four obstetric wards). Principal investigator trained the research assistants on purpose of the study, methods of data collection and use of collection tools for one day for the ward nurses and three days for research assistant located in neonatal ward. A research assistant in the neonatal ward helped with case recruitment according to eligibility criteria, coding the neonates, identify maternal ward location for each neonate selected, filling neonatal checklists with information from case notes and physical examination of neonates on daily bases.

Research assistants in obstetric wards helped with locating selected mothers and filling maternal questionnaire. Once mother was located and gave consent, information was communicated to Principal investigator for commencing of study in the respective neonate.

2.8 Pilot study

Pilot study was conducted where 40 neonates and their mothers were recruited and followed up. This familiarised the research assistants with working tools, flow of patients and convenience time for working. Evening hours were selected for recruitment and follow ups when routine neonatal ward activities were at minimum. An average of 2-5 eligible neonates were found to be admitted daily. Queries in the tool were identified and amendment on the tool were done and adjusted accordingly. Original MAIN score tool was used in a pilot study, where some items were removed from it because they were not applicable at our setting. This resulted in a modified MAIN score tool named as neonatal morbidity severity assessment tool (appended index 4).

2.9 Data collection

Sick term neonates together with their mothers admitted on a daily bases were studied. A checklist was created (modified MAIN score tool) and daily progress of the sick neonate was noted using checklist for seven completed days, discharge or death whichever came first. Mothers of neonates were interviewed during admission. A written consent was obtained from mother participants prior to the interview. For very sick mothers admitted in Intensive care unit or eclamptic mothers who could not communicate consent was taken from next of kin and maternal information was taken from them, while the intrapartum information was obtained from ward case notes. A semi structured questionnaire as primary data was used. Mothers also were asked to provide their antenatal visit card to supplement information such as date of first ANC visit, immunization history, malaria prophylaxis, history of drugs, illnesses recorded during follow up, weight at first ANC visit, number of ANC visits. Referral note to MNH together with labor record (partograph) were also used when available.

Maternal questionnaire consisted of four parts where the first part was demographic characteristics which included age of mother, address, marital status, education level and occupation.

Second part asked about reproductive information. Third part included maternal medical conditions which were hypertension, tuberculosis, sickle cell, HIV, diabetes, renal disease and others. Fourth part consisted of questions reflecting antepartum, intrapartum and immediate postpartum events.

Neonatal checklist

In order to measure severe morbidity among neonates, characteristics of neonates during first seven days needed to be captured. A checklist from the Morbidity Assessment Index for Newborn (MAIN) score was adapted which was used for follow up of neonates during the study .The original MAIN score index had 47 items that were reliably used in assessing severity of newborn illness based on clinical and laboratory findings. The MAIN Score had been tested and found to be a simple, universal, yet sensitive and robust tool to provide discrimination of disease severity among new born population(36) . In this study a modified tool with 37 items was made excluding ten items that were either difficult to measure or unreliable in our setting. Some of the excluded items were:

1. Apgar score at 10 minutes- had 3items
2. Altered color
3. Systolic blood pressure- has 2 1tems
4. Urine output
5. Mechanical ventilation
6. Intraventricular hemorrhage-has 2 items

Then, the modified tool with 37 items was again re- tested and more items were removed from the modified tool due to unreliability and lack of consistency. The items removed from the modified tool were flaccidity, drowsy, lethargic, poor sucking, and meconium below cords, persistent vomiting, birth trauma, hypoglycemia, sepsis and use of antibiotics.

All of the excluded items, however, would still be reflected in the retained 27 items.
Neonates were followed daily and presence or absence of any condition from the checklist items was noted

Measure of severe morbidity

In this study, a composite of neonatal morbidity was created from the modified tool items, where *a neonate with death within the seven days of life* OR *any of the following was considered to have severe morbidity:*

1. Multiple convulsions
2. Cardiopulmonary resuscitation any time before discharge
3. Apnea corrected by oxygen or by resuscitation
4. Need for intubation at birth
5. Hyperbilirubinemia bilirubin of >250µmol/L (needing phototherapy or exchange transfusion)
6. Hypotonia
7. Severe thrombocytopenia with or without bleeding disorder
8. Stupor, obtundation or Coma
9. Abnormal respiratory rate persisting for 2 days or longer
10. Need for blood transfusion
11. Abnormal heart rate.

This new tool was considered adequate in our setting and was reviewed and accepted as feasible by the Neonatologists at MNH, NCU (personal communication**)**

2.10 Data analysis

Data was entered in EPI info and transferred to SPSS computer program version 20 for analysis. An association of individual co-variates with the primary outcome (Presence of severe morbidity Yes/No) was determined on bivariate analysis. Multivariate analysis was performed to determine independent predictors of severe morbidity for term neonates by including in the final model predictor variables with a p value of 0.1 or less

on bivariate analysis .In all analyses the p value of 0.05 or less was taken as statistically significant.

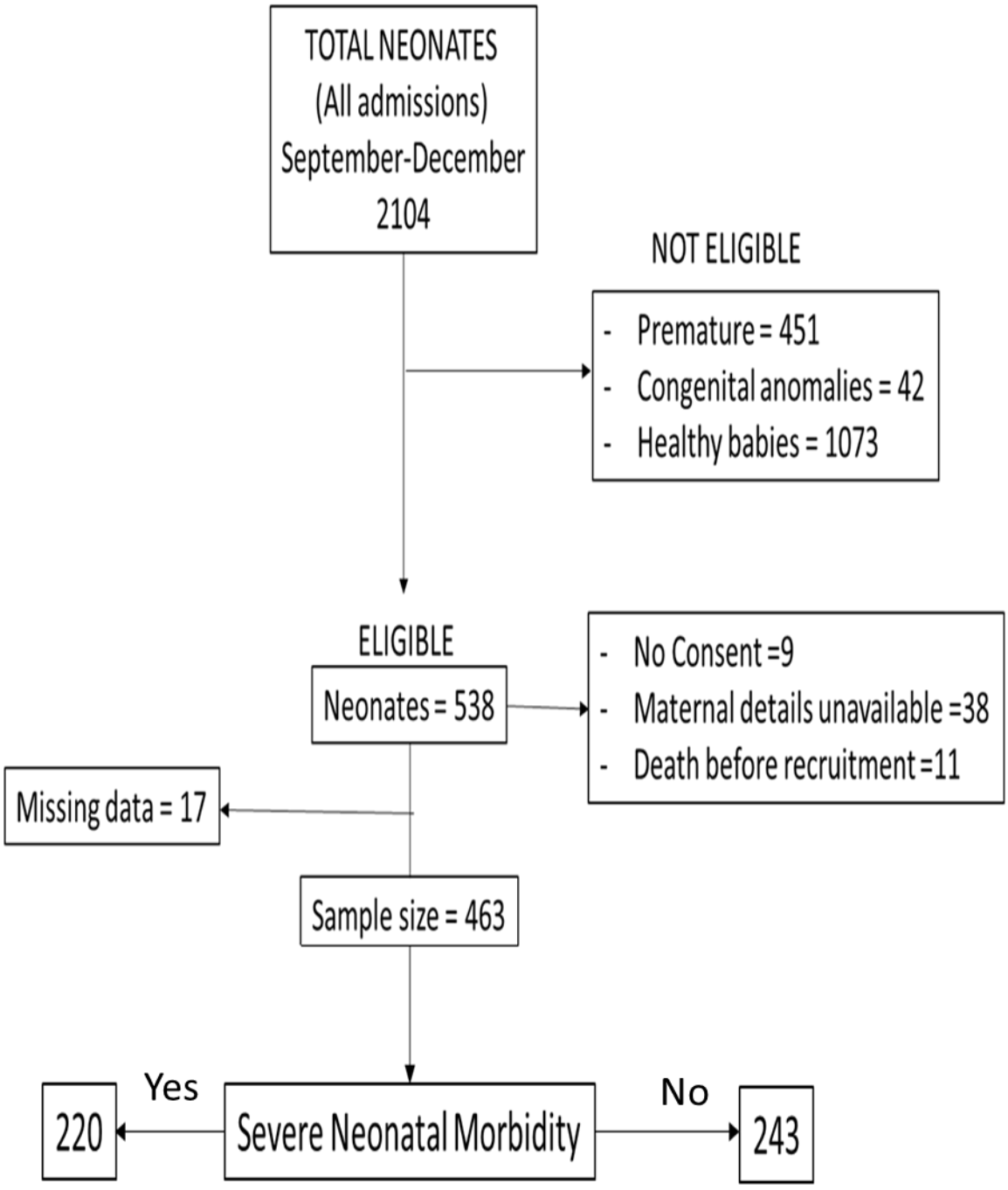
2.11 Ethical clearance

Was sought from Muhimbili University of Health and allied sciences senate, Research and publication committee and the study began after the permission to conduct study was granted by the Muhimbili National Hospital.

Ethical issues

This study was based upon early neonatal period of seven days. All information was secured by the investigator and reassurance was given to the participant mothers. Neither the neonates nor the mothers were denied treatment because of refusal to participate. Neonatal check listing by investigator did not interfere with management. Data collection was done when all admission procedures were completed and treatment commenced. Mothers of neonates or clinicians attending neonates signed consent form for the neonates. Mothers signed their own written consent form.

Figure 2: Sampling process



Note:- Exposures were the term newborns admitted at MNH shortly after delivery. Outcome was development of severe morbidity

RESULTS

During the study period 2104 neonates were admitted at MNH neonatal unit. Premature neonates were 451(21.4%) and 1653(78.6%) were neonates born at term. Among them 1073 (51%) neonates were healthy babies admitted for care due to their mother's condition. Therefore the 538 neonates met the recruitment criteria into the study.

In our study total of 480 neonates were recruited. Among them seventeen (17) neonates had missing data and were excluded. Therefore the sample size included in our study was 463, in which 267(57.7%) were male and 196(42.3%) were female**.** The median age of neonates was 1 day (Range 1-3) with SD 1.77. Also the Mean weight was 3237.62gms (Range 2100-5000) with SD 526.62. Three hundred and fifteen 315(68%) were born at MNH and 148(32%) from other hospitals outside MNH. In all recruited 257(55.5%) were born by caesarean section and 344(74.2) were from Dar es Salaam. Majority of mothers in the study 381(82.3%) were married, multipara 266(57.5%) with primary education 244(52.5%) who were either housewives or petty trader 277(59.8). All attended ANC of which 342(73.8%) attended four or more times. See table 1 below

Table 1: Socio demographic characteristics of study participants N=463

Variable		Frequency	Percentage
Age	< 19	38	8.2
	20-34	362	78.2
	35+	63	13.6
Marital status	single	82	17.7
	married/cohabiting	381	82.3
Address	Temeke	127	27.4
	Kinondoni	108	23.3
	Ilala	109	23.5
	Pwani Districts	29	6.3
	Others	89	19.2
Occupation	House wife	163	35.2
	Non employed	53	11.4
	Peasant	24	5.2
	petty trader	114	24.6
	Bussiness	43	9.3
	Employed	66	14.3
Education	No formal education	16	3.5
	Primary Education	244	52.7
	Secondary Education	132	28.5
	College/University	71	15.3
Delivery place	MNH	315	68.0
	Peripheral Hosp	148	32.0
Neonatal Characteristics			
Neonatal sex	Male	267	57.7
	female	196	42.3
Neonatal weight	2000-2499gms	18	3.9
	2500-3999gms	394	85.1
	4000gms	51	11.0

INCIDENCE AND PROPORTION

Total admission was 2104 neonates. Total number of neoates who had morbidity at term with no congenital anomalies were 568.Therefore Incidence of early neonatal morbidity at term among all admissions at Muhimbili National Hospital neonatal unit was (538/2104)x1000= 255.7 per 1000 neonates. Neonates with severe morbidity were 220. Term neonates with morbidity who participated in the study were 463.Therefore proportion of babies with early neonatal morbidity at term with severe morbidity was 47.5 percent.

RISK FACTORS FOR SEVERE EARLY NEONATAL MORBIDITY AMONG TERM NEONATES ADMITTED AT MNH NEONATAL UNIT.

TABLE 2: Association between maternal socio demographic characteristics with severe neonatal morbidity among neonates admitted at MNH neonatal unit from Sept-Dec 2014. N=463.

	Severe morbidity		
Variable	**NO N (%)**	**YES N (%)**	**P value**
Age Group			
15-19	14(36.8)	24(63.2)	
20-34	201(55.5)	161(44.5)	0.035
35+	28(44.4)	35(55.6)	
Marital status			
Single	39(47.6)	43(52.4)	0.447
Married/cohabit	204(53.5)	177(46.5)	
Education level			
No formal education	6(37.5)	10(62.5)	
Std seven	126(51.6)	118(48.4)	
Secondary	71(53.8)	61(46.2)	0.568
College	40(56.3)	31(43.7)	
Occupation			
House wife	89(54.6)	74(45.4)	
Non employed	26 (49.1)	27 (50.9)	
Peasant	6 (25)	18(75)	0.06
Petty trader	60(52.6)	54(47.4)	
Business	28 (65.1)	15 (34.9)	
Employed	34 (51.5)	32 (48.5)	

Table 2:.Neonates with severe morbidity were higher in teenage mothers than the rest age groups. P value=0.035.Majority of neonates with severe morbidity their mothers were single, peasants with no formal education although this was statistically not significant.

TABLE 3: Association of Maternal Reproductive Information with severe neonatal morbidity of term neonates admitted at MNH neonatal unit. N = 463.

	Severe morbidity		
Variable	**NO N (Col %)**	**Yes N (Col %)**	**P value**
Parity			
Primiparas	107(48.4)	114(51.6)	0.094
Multiparas	136(56.2)	106(43.8)	
Number of parity before index			
No	107(48.40)	114(51.60)	
1-4	131(56.20)	102(43.80)	0.246
5+	5(55.60)	4(44.40)	
Previous child death			
No	199(51.8)	185(48.2)	
1	33(57.9)	24(42.1)	0.852
2+	12(50.0)	12(50.0)	
Abortion			
No	203(52.6)	183(47.4)	0.918
Yes	40(51.9)	37(48.1)	

Table 3: above shows that primiparas had more neonates with severe morbidity (51.6%) than those who delivered before. Mothers with previous child deaths of two or more (50%) and those women with previous abortion (48.1%) had more babies with severe morbidity. However none of the reproductive characteristics were statistically significant.

TABLE 4: Association of Maternal medical conditions with severe neonatal morbidity of term neonates admitted at MNH neonatal unit from Sept to Dec 2014

	Severe morbidity		
Variable	**No N (Col %)**	**Yes N (Col %)**	**P value**
Hypertension			
No	237(52.3)	216(47.7)	0.63
Yes	6(60.0)	4(40.0)	
Sickle cell			
No	242(52.6)	218(47.4)	0.505
Yes	1(33.3)	2(66.7)	
HIV			
No	236(52.3)	215(47.7)	0.681
Yes	7(58.3)	5(41.7)	
Diabetes mellitus			
Yes	1(20.00)	4(80.00)	0.196
No	242(52.8)	216(4)	
Others			
Yes	13(46.4)	15(53.6)	0.285
No	230(52.9)	205(47.1)	

Table 4 above shows mothers with sickle cell and non-gestational diabetes had higher severe morbid neonates (66.7% and 80%). However the results were statistically insignificant.

*Others include asthma, genital lesions, cardiac diseases, fibroid, burkitt lymphoma, previous scar, hearing disorders, scoliosis, psychosis, anemia, skin diseases, teeth ache, and peptic ulcer disease.

TABLE 5: Association of Maternal Antepartum factors with severe neonatal morbidity among term neonates admitted at MNH neonatal unit from Sept-Dec 2014

	Severe morbidity		
Variable	**No N (Col %)**	**Yes N (Col %)**	**P value**
SP given			
No	1(20.00)	4(80.00)	0.606
Yes	242(52.8)	216(47.2)	
Dewormed			
No	76(56.7)	58(43.3)	0.244
Yes	167(50.8)	162(49.20)	
ANC Attendant			
Doctor	66(60.6)	43(39.4)	0.053
Nurse of any cadre	177(50.0)	177(50.0)	
Pre-eclampsia			
No	222(51.9)	206(48.1)	0.354
Yes	21(60)	14(40)	
Eclampsia			
No	226(51.7)	211(48.3)	0.175
Yes	17(65.4)	9(34.6)	
Watery discharge			
Yes	20(66.7)	10(33.3)	0.108
No	223(51.5)	210(48.5)	
UTI			
Yes	5(20)	20(80)	0.001
No	238(54.3)	200(45.7)	
Vagina Bleeding			
Yes	10(43.5)	13(56.5)	0.375
No	233(53)	207(47)	
Malaria			
Yes	38(49.4)	39(50.6)	0.547
No	205(53.1)	181(46.9)	

Anaemia			
Yes	4(50)	4(50)	0.887
No	239(52.5)	216(47.5)	
Worm infestation			
Yes	3(30)	7(70)	0.15
No	240(53)	213(47)	
Diabetes			
Yes	5(62.5)	3(37.5)	0.567
No	238(52.3)	217(47.7)	

Table 5 above shows those attended by a doctor at ANC had less neonates with severe morbidity than those seen by nurses of any cadre (P value 0.053) .Mothers who had upper urinary tract infections during pregnancy had higher neonates with severe morbidity than those who did not have UTI. p=0.001

TABLE 6: Association of Intrapartum events and immediate postpartum factors with severe neonatal morbidity among term neonates admitted at MNH neonatal unit from Sept-Dec 2014

	Severe morbidity		
Variable	**No N (Col %)**	**Yes N (Col %)**	**P value**
Mode of delivery			
SVD	85(45.7)	101(54.3)	
LSCS	150(58.4)	107(41.6)	0.009
ABD	6(60)	4(40)	
VACCUM	2(20)	8(80)	
Assistant at delivery			
Doctor	163(57.6)	120(42.4)	0.01
Nurse/Midwife	80(44.9)	98(55.1)	
Relative	0(0)	2(100)	
Place of delivery			
Muhimbili National Hospital	190(60.3)	125(39.7)	0.000
Peripheral Hospitals	53(35.8)	95(64.2)	
Problem during/just after delivery			
Headache			
Yes	17(73.9)	6(26.1)	0.042
No	226(51.4)	214(48.6)	
Prolonged labor			
Yes	30(41.1)	43(58.9)	0.035
No	213(54.6)	177(45.4)	
Referral duration			
Not applicable(from MNH)	191(60.4)	125(39.6)	
Within 24 hours	22(28.2)	56(71.8)	0.000
Beyond 24hours	30(43.5)	39(56.5)	

Table 6 above shows mothers who delivered by low cavity vacuum extraction (LCVE) those assisted at delivery by relative/untrained personnel and mothers who had prolonged labor had more neonates with severe morbidity. The analysis above for the association between mode of delivery and risk of severe neonatal morbidity needs to be repeated. Chi square for homogeneity analysis gives a corrected chi square value of 1.9 and a 2 tailed Fisher exact p value of 0.7 hence no association. Mothers who delivered their neonates at peripheral hospital had more neonates with severe morbidity than those delivered at MNH, p 0.009. Neonates who were referred within 24 hours had more severe morbidity p=0.000 (what was the strength of the association therein?).

Table 7: Neonatal factors associated with severe morbidity of term neonates admitted at MNH neonatal care unit

Variable	Non severe N (Col %)	Severe N (Col %)	P value
Neonatal Sex			
Male	125(46.8)	142(53.2)	0.004
Female	118(60.2)	78(39.8)	
Apgar score			
less than seven	229(52.8)	205(47.2)	0.639
more than seven	14(48.3)	15(51.7)	
Neonatal weight (gm)			
2000-2499	5(27.)	13(72.2)	0.014
2500-3999	204(51.8)	190(48.2)	
4000+	34(66.7)	17(33.3)	

Majority of neonates with severe morbidity had low birth weight had (72.2%) than those with normal or heavy weight p=0.014 Refer to the table number when running the commentary. What were the Odds ratio and the corresponding 95% confidence interval for the association between neonatal sex and weight and severe neonatal morbidity?

Table 8: Multivariate analysis for factors associated with severe morbidity of term neonates admitted at MNH neonatal intensive care unit. n=463

Variable	AOR	95% CI	P value
Age group			
<=19	2.27	0.19-27.14	0.028
20 – 34	.859	0.08 – 9.54	0.902
35+		1	
Occupation			
Employed			0.178
Housewife	0.725	0.26 – 2.06	0.546
Non employed	0.503	0.04 – 5.87	0.546
Peasant	3.9	0.82 – 18.52	0.087
Petty trader	0.64	0.22 -1.92	0.428
Business	0.68	0.19 – 2.45	0.556
Parity			
Primipara	1.08	0.25 – 4.69	0.921
Multipara		1	
ANC ATTENDANT			
Doctor	0.89	0.42 – 1.9	0.761
Nurse (any cadre)	1		
Watery discharge			
Yes	2.12	0.65 – 6.96	0.215
No			
UTI			
Yes	16.31	1.65 – 161.43	**0.017**
No			
Mode of delivery			
Vacuum		1	0.610
SVD	0.111	0.002 – 6.49	0.289
LSCS	.09	0.001 – 6.19	0.261
ABD	0.038	0.0 – 4.732	0.184

Assistant At Delivery			
Relative		1	0.950
Doctor	1.22	0.02 – 96.84	0.930
Nurse	0.977	0.016 – 59.27	0.991
Delivery place			
MNH	0.584	0.085- 3.99	0.583
Peripheral hospital	1		
Headache			
No	2.351	0.542 – 10.20	0.254
Yes			
Prolonged labour			
Yes	0.781	0.322 – 1.898	0.586
No	1		
Time to referral			
Beyond 24 hours			0.286
Not referred	0.966	0.13 – 7.17	0.973
Within 24 hours	2.148	0.54 – 10.20	0.132
Sex (Neonate)			
Male	1.572	0.864 – 2.859	0.138
Female	1		
Weight(grams)			
>= 4000	1		0.064
2000 – 2499	7.58	1.297 – 44.31	**0.025**
2500 – 3999	2.104	0.85 – 5.208	0.108

In table 8 above, factors which had P value of 0.1 or less in bivariate analysis were entered in multivariate logistic regression .Weight of the neonate (AOR; 7.58 95%CI 1.30-44.31), and UTI in pregnancy AOR; 16.32%CI (1.65–161.43) remained independently associated with severe morbidity.

DISCUSSION

Morbidity Assessment Index for Newborn (MAIN) was developed as a global measure of morbidity in the first week of life, for babies with no congenital anomalies delivered at a gestation age more than 28 weeks. MAIN score tool is based on items of routine clinical and laboratory examination of newborns. MAIN score tool had already been validated for use. (34) However, this tool is not applicable in resource poor settings.

In this study MAIN score index items were adapted and re-adapted , from 47 items to 37 and later to 27 clinically relevant items and a modified MAIN tool was developed . A check-list of all these 27 items was administered daily for 7 days. . Use of modified MAIN tool solely as measure of severe morbidity was avoided since the new modified tool's performance was yet to be identified that is its sensitivity, specificity and both the positive and negative predictive values as compared to original MAIN tool. A composite of neonatal morbidity was created and neonates were assigned in their appropriate severity status.

Our study revealed that the incidence of early neonatal morbidity at term among all admissions at MNH Neonatal unit during a period of four months was **(538/2104) x1000= 255.7 per 1000 neonates**. This finding is far higher than other published studies. In a study of severe neonatal morbidity of term neonates without congenital anomalies in Netherlands, incidence was 3-4 neonates per 1000 term neonates (11). This could be due to differences in neonatal unit set ups. Only neonates who have life threatening conditions were admitted in level three neonatal care units and hence low in number. In our setting all sick neonates were mixed in the same neonatal unit. In another study which was comparing morbidity of term and late pre term neonates the incidence of term neonates was found to be (0.3/1000) in Atlanta (29). Developed countries are far better in quality of care than developing countries due to availability of equipment

and expertise hence, less complication during antenatal, intrapartum and immediate postpartum are expected. This could be another reason for low incidences of severe morbidity in these two studies as compared to the findings noted. The alarming higher incidence of neonatal morbidity of term neonates at MNHNCU was also due to the fact that, there is scarcity of functioning neonatal care units at peripheral hospitals in the region and nearby regions necessitating most cases being referred to this center. Lack of specialists, expertize, drugs and equipments for neonates are partly the reasons for more referral for neonatal care at MNH. The studies referred above had similar methodology in discriminating neonates into severe morbidity using one or more of the selected items as severe morbidity.

This study found the proportion of neonatal severe morbidity at term was 47.5 percent. This finding is higher than other few studies on severe morbidity available. Study done in Atlanta, had proportion of 2.5 percent (29). Study done in Netherlands found the proportion of 17.1 percent (11). A recent study done in Washington 5-18 percent (12). The proportions are lower compared to our study due to similar reasons as could be due to differences in study settings. They are high level neonatal units with less referrals as compared to our setting and hence fewer admissions. Low proportion of severe neonatal morbidity in developed countries may also be due to availability of equipments and expertise. Few studies on severe morbidity of term neonates are available in developing countries to compare with our study. Study done in Northern Tanzania (KCMC)(13) looked for risk factors for neonatal admission to ICU. Proportion of neonates admitted was 15 percent however methodology was different ,although diagnostic criteria was admission to neonatal intensive care unit, it was a disease specific study and term neonates were not dealt separately as in our study.

Urinary tract infection was found in this study to be independently associated with severe early neonatal morbidity of term neonates admitted at MNH neonatal care unit. These neonates were about 16 times at higher risk of getting severe early neonatal morbidity. This outcome was also similar to a study done in UK by Murphy et al (38) and other study by Osorno et al (39) even though these related to just poor outcome among the neonates and not severe morbidity. This could be due to differences in study

setting as well as the methodology used. Another study done in Israel showed that Maternal UTI is independently associated with pre-term delivery, pre-eclampsia, intra-uterine growth restriction (IUGR) and caesarean deliveries (CD). Nevertheless, it was not associated with increased rates of perinatal mortality compared with women without UTI (40).

Many other studies associated UTI with adverse pregnancy and neonatal outcomes including low birth weight, premature rupture of membranes, intrauterine growth restriction, and even death (41–43). Mechanism of UTI causing PROM was believed to be release of metalloproteinases by macrophages via cytokines which degrade the membranes in a similar way as do collagenases and phospholipase issued from bacteria (42).Maternal UTI was also associated with neonatal sepsis (44). This study also observed that those neonates who were born with birth weight below 2500 grams were independently associated with severe early neonatal morbidity. These infants were classified as having low birth weight (45). This is also strengthen by another observation in a setting in Nigeria that showed birth weight was a significant predictor of neonatal mortality (46,47).Similar findings in a setting in Canada where morbidity and mortality were found to increase among term neonates who were born with a birth weight below 3rd percentile of their gestation age. The study further showed low birth weight related to lower five minute Apgar score, high incidence of seizures in firs 24 hours of life, increased risks of need for intubation at delivery room, increased risk for neonatal sepsis and mortality (42).

CONCLUSION

Incidence of early neonatal morbidity at term among all admissions at Muhimbili National Hospital neonatal unit was high (538/2104) x1000= 255.7 per 1000 neonates.

Proportion of babies with severe morbidity among those with early neonatal morbidity at term was high at 47.5 percent..

This study revealed that, severity of illness of early neonatal period is independently associated with maternal urinary tract infection during pregnancy and low birth weight of term neonates

LIMITATION AND MITIGATIONS

Unavailability of a neonatal morbidity score tool for developing countries was a challenge. Unavailability of investigations and equipments in our neonatal units makes original MAIN tool inapplicable at present. . We therefore modified and designed our tool which could be easily used in primary care settings as well. This tool cannot be compared with the MAIN tool, since they are different by 20 items. We have only used this Modified tool for research purpose and its clinical application will require large studies for validation. . Discrimination of neonates to severe morbidity was done by creating a composite of neonatal morbidity obtained from modified MAIN tool items where presence of 1 or more items was diagnostic.

Intrapartum predictor assessment for mothers who delivered their baby outside MNH may be limited since some were not referred with their partograph and had poorly filled or no referral letter at all, but this was controlled by inclusion of items in the questionnaire which captured the information needed. .

RECOMMENDATIONS

Severe early neonatal morbidity of a term neonate with no congenital anomaly has a very high incidence at MNH, and warrants further investigations of morbidity rather than only mortality and different factors associated must be analyzed in depth using audit and longer term outcome measures

Hospitals referring neonates to MNH should be empowered with equipments and expertise so as less severe morbid neonates are managed at the respective centers and give chance to severe morbid neonates to effective care and reduce the congestion in this neonatal ward.

Further studies should be done to increase insight for morbidities of term neonates and identification of more risks factors. In further studies involvement of healthy neonates is advised as control group.

This Modified MAIN tool needs to be further validated in low resource settings. In that context, comparing the performance (sensitivity, specificity, negative and positive predictive value) of the modified tool used in this study to the original MAIN tool is needed and can only be done in centers where both can be compared.

In longterm, developing countries including MNH needs to invest in laboratory infrastructure and equipments.

REFFERENCES

1. WHO. Guidelines on Maternal, Newborn, Child and Adolescent Health [Internet]. Geneva; 2012. Available from: http://www.who.int/maternal_child_adolescent/documents/guidelines-recommendations-newborn-health.pdf

2. Zupan J. Perinatal mortality in developing countries. N Engl J Med [Internet]. 2005 May 19;352(20):2047–8. Available from: http://www.ncbi.nlm.nih.gov/pubmed/15901857

3. Black RE, Cousens S, Johnson HL, Lawn JE, Rudan I, Bassani DG, et al. Global, regional, and national causes of child mortality in 2008: a systematic analysis. Lancet [Internet]. Elsevier Ltd; 2010 Jun 5 [cited 2014 Feb 26];375(9730):1969–87. Available from: http://www.ncbi.nlm.nih.gov/pubmed/20466419

4. J Lawn and K Kerber. Opportunities for Africa ' s Newborns [Internet]. 2006. Available from: http://www.who.int/pmnch/media/publications/oanexecsum.pdf

5. Kinney M V, Kerber KJ, Black RE, Cohen B, Nkrumah F, Coovadia H, et al. Sub-Saharan Africa's mothers, newborns, and children: where and why do they die? PLoS Med [Internet]. 2010 Jun [cited 2014 Feb 6];7(6):e1000294. Available from: http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=2888581&tool=pmcentrez&rendertype=abstract

6. Manji K. Situation analysis of newborn health in Tanzania [Internet]. Dar es Salaam; 2009. Available from: http://www.countdown2015mnch.org/documents/2012Report/Tanzania_Situation Analysis_Newborn.pdf

7. Moss W, Darmstadt GL, Marsh DR, Black RE, Santosham M. Research priorities for the reduction of perinatal and neonatal morbidity and mortality in developing country communities. J Perinatol [Internet]. 2002 Sep [cited 2014 Jan 29];22(6):484–95. Available from: http://www.ncbi.nlm.nih.gov/pubmed/12168128

8. Lawn JE, Cc A, Kinney M, Sibley L, Carlo WA, Paul VK, et al. International Journal of Gynecology and Obstetrics Two million intrapartum-related stillbirths

and neonatal deaths : Where , why , and what can be done ? Int J Gynecol Obstet [Internet]. International Federation of Gynecology and Obstetrics; 2009;107:S5–19. Available from: http://dx.doi.org/10.1016/j.ijgo.2009.07.016

9. Kigenyi O, Tefera GB, Nabiwemba E, Orach CG. Quality of intrapartum care at Mulago national referral hospital , Uganda : clients ' perspective. BMC Pregnancy Childbirth [Internet]. BMC Pregnancy and Childbirth; 2013;13(1):1. Available from: BMC Pregnancy and Childbirth

10. Lawn JE, Cousens S, Darmstadt GL, Paul V, Martines J. Why are 4 million newborn babies dying every year? Lancet [Internet]. 2004;364(9450):2020. Available from: http://www.ncbi.nlm.nih.gov/pubmed/15582058

11. Evers ACC, Hope. Perinatal mortality and severe morbidity of term infants [Internet]. Utrecht University; 2012. Available from: http://dspace.library.uu.nl/bitstream/handle/1874/242464/evers.pdf?sequence...

12. Spain JE, Tuuli MG, Macones G a, Roehl K a, Odibo AO, Cahill AG. Risk factors for serious morbidity in term nonanomalous neonates. Am J Obstet Gynecol [Internet]. Elsevier Inc.; 2015 Jan 26 [cited 2015 May 1];(4):1–7. Available from: http://www.ncbi.nlm.nih.gov/pubmed/25634367

13. Mmbaga BT, Lie RT, Kibiki GS, Olomi R, Kvåle G, Daltveit AK. Transfer of newborns to neonatal care unit : a registry based study in Northern Tanzania. BMC Pregnancy Childbirth. BioMed Central Ltd; 2011;11(1):68.

14. Carolan M, Frankowska D. Advanced maternal age and adverse perinatal outcome: a review of the evidence. Midwifery [Internet]. 2011 Dec [cited 2014 Mar 4];27(6):793–801. Available from: http://www.ncbi.nlm.nih.gov/pubmed/20888095

15. Kenny LC, Lavender T, McNamee R, O'Neill SM, Mills T, Khashan AS. Advanced maternal age and adverse pregnancy outcome: evidence from a large contemporary cohort. PLoS One [Internet]. 2013 Jan [cited 2014 Feb 28];8(2):e56583. Available from: http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=3577849&tool=pmcentrez&rendertype=abstract

16. Callaway LK, Prins JB, Chang AM, Mcintyre HD. The prevalence and impact of overweight and obesity in an Australian obstetric population. Med J Aust [Internet]. 2006;184(2). Available from: https://www.mja.com.au/system/files/issues/184_02_160106/cal10167_fm.pdf

17. Cardwell CR, Stene LC, Joner G, Bulsara MK, Cinek O, Rosenbauer J, et al. Maternal Age at Birth and Childhood Type 1 Diabetes : A Pooled Analysis of 30 Observational Studies. Diabetes Journals [Internet]. 2010;59(February). Available from: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2809958/pdf/zdb486.pdf

18. Shin YH, Choi S, Kim KW, Yu J, Ahn KM, Kim HY, et al. Association between Maternal Characteristics and Neonatal Birth Weight in a Korean Population Living in the Seoul Metropolitan Area , Korea : A Birth Cohort Study (COCOA). J Korean Med Sci [Internet]. 2013;580–5. Available from: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3617312/pdf/jkms-28-580.pdf

19. Tongkumchum P, Saelim R, Makaje N, Phon-on A. Democratic Confidence Intervals for comparing two Proportions. Songklanakarin J Sci Technol [Internet]. 2013;35(2):235–41. Available from: http://rdo.psu.ac.th/sjstweb/journal/35-2/35-2_235-241.pdf

20. Rachatapantanakorn O. A Method on Assessing Complication-Base Risk Factors for Neonatal Morbidity : Application for Pattani Hospital Delivery. Glob J Health Sci [Internet]. 2009;1(1):60–8. Available from: http://www.ccsenet.org/journal/index.php/gjhs/article/view/1137/1202

21. Anne Kirkeby Hansen, Kirsten Wisborg NU. Risk of respiratory morbidity in term infants delivered by elective caesarean section : cohort study. Br Med J [Internet]. 2007;1–7. Available from: http://www.bmj.com/content/bmj/336/7635/85.full.pdf

22. Al-Khalifah R, Al-Subaihin A, Al-Kharfi T, Al-Alaiyan S, M. K, AlFaleh, et al. Neonatal Short-Term Outcomes of Gestational Diabetes Mellitus in Saudi Mothers : A Retrospective Cohort Study. J Clin Neonatol | [Internet]. 2012;1(1):29–33. Available from: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3761990/

23. R. Al-Kalifah, A. Al-Subaihin, T. Al-Alaiyan KMA. O riginal A rticle ››› Neonatal Short-Term Outcomes of Gestational Diabetes Mellitus in Saudi Mothers : A Retrospective Cohort Study. 2013;29–33.

24. Minsart A, Buekens P, Spiegelaere M De, Englert Y. Neonatal outcomes in obese mothers : a population-based analysis. Biomed Cent Pregnacy Childbirth [Internet]. 2013;2–7. Available from: http://www.biomedcentral.com/content/pdf/1471-2393-13-36.pdf

25. Kidanto HL, Mogren I, Roosmalen J Van, Thomas AN, Massawe SN, Nystrom L, et al. BMC Pregnancy and Childbirth Introduction of a qualitative perinatal audit at Muhimbili National. 2009;10:1–10.

26. Jyoti C, Devi, Uma. U R. Risk Factors for Meconium Aspiration and Mas (Meconium Aspiration Syndrome) in Neonates Born Through Meconium Stained Amniotic Fluid (Msaf) in a Tertiary Care Centre in Malabar (Kerala). J Evol Med Dent Sci [Internet]. 2013;2(48):9489–95. Available from: http://www.ncbi.nlm.nih.gov/pubmed/21477569

27. Length F. Pattern of morbidity and mortality in the newborn special care unit in a tertiary institution in the Niger Delta region of Nigeria : A two year prospective study. Glob Adv Res J Med Med Sci [Internet]. 2015;1(6):133–8. Available from: http://garj.org/full-articles/pattern-of-morbidity-and-mortality-in-the-newborn-special-care-unit-in-a-tertiary-institution-in-the-niger-delta-region-of-nigeria-a-two-year-prospective-study.pdf?view=inline

28. Mmbaga BT, Lie RT, Olomi R, Mahande MJ, Kvåle G, Daltveit AK. Cause-specific neonatal mortality in a neonatal care unit in Northern Tanzania: a registry based cohort study. BMC Pediatr [Internet]. BMC Pediatrics; 2012 Jan [cited 2014 Feb 28];12(1):116. Available from: http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=3469393&tool=pmcentrez&rendertype=abstract

29. Shapiro-mendoza CK, Tomashek KM, Kotelchuck M, Barfield W, Nannini A, Weiss J, et al. Effect of Late-Preterm Birth and Maternal Medical Conditions on Newborn Morbidity Risk. Off J Am Acad Pediatr [Internet]. 2008;121(2). Available from: http://pediatrics.aappublications.org/content/121/2/e223.full.pdf+html

30. Carolan MC, Davey M, Biro M, Kealy M. Very advanced maternal age and morbidity in Victoria , Australia : a population based study. 2013;

31. Araújo BF De, Zatti H, Madi JM, Coelho MB, Olmi FB, Canabarro CT. Analysis of neonatal morbidity and mortality in late-preterm newborn infants. J Pediatr (Rio J) [Internet]. 2012;88(3):259–66. Available from: http://www.scielo.br/pdf/jped/v88n3/en_v88n03a13.pdf

32. Carrie K S, Tomashek KM, Kotelchuck M, Barfield W, Nannini A, Weiss J, et al. Effect of Late-Preterm Birth and Maternal Medical Conditions on Newborn Morbidity Risk. Off J Am Acad Pediatr [Internet]. 2014; Available from: http://pediatrics.aappublications.org/content/121/2/e223.full.pdf+html

33. Fernanda M, Almeida B De, Guinsburg R, Martinez FE, Procianoy RS, Leone CR, et al. Perinatal factors associated with early deaths of preterm infants born in Brazilian Network on Neonatal Research centers. J Pediatr (Rio J) [Internet]. 2008;84(4):300–7. Available from: http://www.jped.com.br/conteudo/08-84-04-300/port.pdf

34. Donna Strobino. Measures of Neonatal Morbidity Donna Strobino , PhD Bloomberg School of Public Health [Internet]. 2006. Available from: http://ocw.jhsph.edu/courses/PreventingInfantMortality/PDFs/Lecture9.pdf

35. Dorling JS, Field DJ, Manktelow B. Neonatal disease severity scoring systems. Arch Dis Child Fetal Neonatal [Internet]. 2005;11–6. Available from: http://fn.bmj.com/content/90/1/F11.full.pdf+html

36. Verma A, Weir A, Drummond J, Mitchell BF. assessment index for newborns. J Epidemiol Community Heal [Internet]. 2005;59:420–6. Available from: http://www.ncbi.nlm.nih.gov/pmc/articles/ PMC1733084/ pdf/v059p00420.pdf

37. Gray JE, Richardson DK, Mccormick MC, Workman-daniels K, Richardson K, Gray E, et al. Neonatal Therapeutic Intervention Scoring System : A Therapy-Based Severity-of-Illness Index and Donald A . Goldmann The online version of this article , along with updated information and services , is located on the World Wide Web at : Illinois , 60007 . 2014;

38. Murphy HR, Steel SA, Roland JM, Morris D, Ball V, Campbell PJ. Europe PMC Funders Group ,Obstetric and perinatal outcomes in pregnancies complicated by Type 1 and Type 2 diabetes : influences of glycaemic control , obesity and social disadvantage. Diabet Med. 2012;28(9):1060–7.

39. Osorno Covarrubias L(1), Watty Cáceres C, Alonzo Vázquez F, Dávila Velázquez J EEM. Maternal history impact in neonatal mortality [Internet]. 2008. p. 730–8. Available from: http://www.ncbi.nlm.nih.gov/pubmed/ 19149402

40. Efrat Mazor-Dray, Amalia Levy, Francisc Schlaeffer and ES. Maternal urinary tract infection: is it independently associated with adverse pregnancy outcome? [Internet]. 2009. p. 124–8. Available from: http://www.tandfonline.com/doi/pdf/10.1080/14767050802488246#.Vg69B32IGTE

41. Practice C, Lee M, Bozzo P, Einarson A. Urinary tract infections in pregnancy. Can Fam Physician [Internet]. 2008;54:853–4. Available from: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2426978/pdf/0540853.pdf

42. Bérard A, Santos F, Ferreira E, Perreault S. Urinary Tract Infections During Pregnancy. 2011; Available from: http://cdn.intechweb.org/pdfs/20569.pdf

43. Bolton M, Horvath DJ, Li B, Cortado H, Newsom D, White P, et al. Intrauterine growth restriction is a direct consequence of localized maternal uropathogenic Escherichia coli cystitis. PLoS One [Internet]. 2012 Jan [cited 2015 Mar 20];7(3):e33897. Available from: http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=3309957&tool=pmcentrez&rendertype=abstract

44. Emamghorashi F, Mahmoodi N, Tagarod Z. Maternal Urinary Tract Infection as a Risk Factor For Neonatal Urinary Tract Infection. Iran J Kidney Dis [Internet]. 2012;6(3):178–80. Available from: http://www.ijkd.org/index.php/ijkd/ article/view/561/404

45. Cintire DDM, Bloom SL, Casey BM, Leveno KJ. Birth Weight in Relation to Morbidity and Mortality Among Newborn Infants. N Engl J Med [Internet]. 1999;340(16). Available from: http://www.nejm.org/doi/pdf/10.1056/NEJM199904223401603

46. Muhammad T, Khattak AA, Shafiq-ur-Rehman, Khan MA, Khan A, Khan MA. Maternal Factors Associated With Intrauterine Growth Restriction. J Ayub Med Coll Abbottabad [Internet]. 2010;22(4):64–9. Available from: http://ayubmed.edu.pk/JAMC/PAST/22-4/Taj.pdf

47. Onwuanaku CA, Okolo SN, Ige KO, Okpe SE, Toma BO. The effects of birth weight and gender on neonatal mortality in north central Nigeria. BMC Res Notes [Internet]. BioMed Central Ltd; 2011;4(1):562. Available from: http://www.biomedcentral.com/1756-0500/4/562

48. Stewart A. Adolescent pregnancy. Lancet. 1990;335:356.

49. McIntyre(WHO) P. Pregnant Adolescents - Delivering on Global Promises of Hope. World Health [Internet]. 2006;1–31. Available from: http://apps.who.int/iris/bitstream/10665/43368/1/9241593784_eng.pdf

50. Dennis JA. Young maternal age and low birth weight risk: An exploration of racial/ethnic disparities in the birth outcomes of mothers in the United States. Soc Sci J [Internet]. 2013;50(4):625–34. Available from: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4199306/pdf/nihms581376.pdf

51. Ferraro AA, Cardoso VC, Barbosa AP, Da Silva AAM, Faria CA, De Ribeiro VS, et al. Childbearing in adolescence: intergenerational dejà-vu? Evidence from a Brazilian birth cohort. BMC Pregnancy Childbirth. 2013;13:149.

52. Zwane E. Socioeconomic And Maternal Determinants Of Infant Mortality: An Analysis Using The Swaziland Demographic Health Survey 2007. 2012.

53. Lama L, Shrestha S, Sharma A, Upadhyay S PM. Immediate neonatal outcome of adolescent pregnant mother at Nepal Medical College Teaching Hospital. Nepal Med Coll J [Internet]. 2013;117–21. Available from: http://www.ncbi.nlm.nih.gov/pubmed/24696930

54. Pun KD and Chauhan M. Outcome of adolescent pregnancy at Kathmandu University Hospital, Dhulikhel, Kavre. Kathmandu Univ Med J (KUMJ). 2011;9(33):50–3.

55. Kumar A, Singh T, Basu S, Pandey S B V. Outcome of teenage pregnancy. Indian J Pediatr. 2007;74(10):927–31.

56. Sharma V, Katz J, Mullany LC, Khatry SK, Leclerq SC, Shrestha SR, et al. NIH Public Access. 2009;162(9):828–35.

57. Markovitz BP, Cook R, Flick LH, Leet TL. Socioeconomic factors and adolescent pregnancy outcomes: distinctions between neonatal and post-neonatal deaths? BMC Public Health. 2005;5:79.

58. Cunnington a J. Margaret Jackson prize essay 2000. What's so bad about teenage pregnancy? J Fam Plan Reprod Heal Care. 2001;27(1):36–41.

59. Theresa O Scholl, Mary L Hediger and IGA. Maternal growth during pregnancy and decreased infant birth weight. Heal (San Fr. 1990;790–3.

INDICES

Index 1: Neonatal severity assessment tool

No _____. Baby of _____.BWT_____Grams.

Age in days _____5 minute Apgar score _____(99 if not known).

Delivered at:

1. MNH

2. Referral from peripheral hospital.

3. Referred on ---------- hours post delivery

Mode of delivery:
1. SVD
2. CS
3. ABD
4. Vacuum

	Indicators	**DAY 1**		**DAY 2**		**DAY 3**		**DAY 4**		**DAY 5**		**DAY 6**		**DAY 7**	
Item		**yes**	**no**	**yes**	**no**	**yes**	**no**	**yes**	**no**	**yes**	**no**	**yes**	**no**	**yes**	**no**
Within 24 hours of birth															
1.1	**Resuscitation at birth**														
1.2	Intubation														
	Apgar score (5 min)														
2	score 4-7														
3	score 1-3														
4	score<1														
	Respiratory rate														
5	<30 or >60 at 3-24 h														
6	>100 between 3-24 h														
	With seven days of birth														
	Heart rate/min*														
7	160-200 beat														
8	>200 beat														
9	<100 beat														
	Posture														
	Hypotonia														
10	Present at 1-120 h of age														
11	Present beyond 120 h of age														
	Flaccidity														
12	Present at 1-120 h														

	Apnea*														
13	Apnea corrected by oxygen														
14	Apnea corrected by resuscitation														
	Bleeding disorder														
15	Thrombocytopenia with or without bleeding disorder(GI/lungs/skin)														
16	Need for transfusion due to anemia or item 20														
	Seizures														
17	Tremors/single seizure														
18	Multiple seizures														
19	If >2 drugs used for seizures														
	Level of consciousness*														
20	Drowsy/lethargic														
21	Stupor/obtundation/coma														
	Oral feeding difficulties*														
22	Poor sucking within 24 h														
23	Poor sucking at 24 h-7 days														
24	Muconeum below cords														
25	Persistent vomiting														
	Need for Oxygen supplement over 24hrs														
26	Oxygen over 24 h														
	Birth trauma														
27	Bone fracture-long bone/clavicle/skull														
28	Nerve injury (facial/peripheral)														
	Hypoglycaemia (lowest level)														
29	Blood glucose <2.2 mmol/l														
	Hyperbilirubinaemia, mmol/l (peak level)														
30	Serum bilirubin >250/phototherapy														
31	Serum bilirubin >340/exchange transfusion														
	Bacterial culture/Presumed sepsis/use of Antibiotic														
32	Blood positive														
33	CSF positive														
34	Use of antibiotic														
	Cardiopulmonary resuscitation														
35	Any time before discharge														

Index 2: Maternal Questionnaire (English Version)

MATERNAL QUESTIONNAIRE

MUHIMBILI NATIONAL HOSPITAL

Admission no _____ Interviewer's name _____

Hello. My name is _____ and I am working with the Muhimbili National Hospital. We are conducting a study that asks about mothers and neonatal health issues. We would very much appreciate your participation in this study. This information will help the government to improve women's and child health services. The interview will take just a few minutes to complete. Participation in this study is voluntary, and if we should come to any question you don't want to answer, just let me know and I will go.
Signature of interviewer:_____ Date: _____
To the next question; or you can stop the interview at any time. However, we hope that you will participate in this survey since your information is important.
At this time, do you want to ask me anything about the study?
May I begin the interview now?

RESPONDENT AGREES TO BE INTERVIEWED Yes □ No □

Demographic information

1. Date of birth _____.
2. Living area: Region _____ District_____.
3. Weight _____kg. Height ____cm.
4. Marital status_____
5. Blood group _____

6. Education level _____.

7. Occupation_____

Reproductive Information.

8. Parity-Have you ever given birth before this? Yes □ No □.

9. If yes how many _____.

10. Gravidity- How many pregnancies you have had_____

11. How many children are alive _____,

12. How many died _____.If non, go to QN 14

13. Do you know why they died?

14. Abortions- Have you ever had a miscarriage? That is, have you ever lost a pregnancy?

Yes □ No □, If yes how many _____.

15. Have you suffered from any of the following before pregnancy?

A. hypertension	yes	no
B. renal disease	yes	no
C. diabetes mellitus	yes	no
D. tuberculosis	yes	no
E. sickle cell	yes	no
F .HIV	yes	no

G. Any other specify _____

QN 15-25 CONFIRM WITH ANTENATAL CARD

16. At what gestation age was the first booking_____

17. How many times attended antenatal clinic? _____

18. Did you receive antimalarial during pregnancy? Yes no

If yes

19. How many times did you receive Antimalarial? ----------

20. During this pregnancy did you take drugs for increasing Haemoglobin?

Yes □ No □.

21. If yes a: How many types?

b: How regularly?

22. During this pregnancy, did you take any drug for intestinal worms? Yes □ No □.

23**.** Did you see anyone for antenatal care during this pregnancy? Yes □ No □.

24.Did you receive tetanus toxoid? how many doses

25. If yes, who did you see?

a. Health personnel □ Doctor, □ Nurse/midwife,

b. Other person □ Trained traditional birth attendant.

□ Untrained traditional birth attendant.

□ Other (specify) _____

26. What problems did you have when you were pregnant?

□ Headache □ Blurry vision □ Edema/pre-eclamsia □ vaginal bleeding □Tetanus
□ Convulsions/eclampsia □ Watery discharge □ Lower abdominal pain □ Anemia
□ Baby movement was low □ varicose vein □ Excessive vomiting UTI
□ Other (specify) _____ Add bleeding in early pregnancy

27. At what gestation age did you have the problem in QN24 above?

28. Were you investigated or treated for any medical condition during pregnancy? Name it---------

29. Have you suffered from any of the following during pregnancy?

1. Malaria yes no

2. Anemia yes no

3. Worm infestation yes no

4. Hypertension yes no

5. Diabetes yes no

6. Eclampsia yes no

7. Hemorrhage yes no

8. Any other specify _____

30. How long did your labor pains persist? (Count from time she started true labor to delivery to confirm)----------

31. Were any of the following procedures performed at the time of delivery?

□ Forceps □ vacuum delivery □ caesaren □ SVD

32. Were the following given during labor or immediate post-delivery?

□ Blood transfusion □ Intravenous fluid □oxytocin

33. Who assisted you during delivery?

c. Health personnel □ Doctor, □ Nurse/midwife, □ Auxiliary midwife

d. Other person □ Trained traditional birth attendant.

□ Untrained traditional birth attendant.

□ Relative/Friend

□ Other (specify)_____.

34. Where did you give birth?

a. Home □ Respondent's home □ Other home.
b. Public sector MNH □ Govt. Regional Hospital □ Govt. District Hospital □ Govt. Health center □ Govt. Dispensary.
c. Private Medical center □ Pvt. Hospital/Clinic □ Maternity home □ Other (Specify) _____

35. At any time just before, during or after the delivery did you suffer from any of the following problems?

□ Headache □ Blurry vision □ Edema/pre-eclamsia □ Excessive bleeding □Convulsions/eclamsia □ Foul-smelling discharge □ Baby movement was low
□ Baby's hands/feet came out first □ Prolonged labor □ Obstructed labor □ Torn uterus
□ Placenta praevia/retained □ High fever □ Fistula □ Did not have any problems
□ Other (specify) _____.

36. Where were you treated for the problems occurred Q34?

a. Home □ Respondent's home □ Other home.
b. Public sector □ Govt. Regional Hospital □ Govt. District Hospital □ Govt health
center □ Govt. Dispensary.
c. Private Medical center □ Pvt. Hospital/Clinic □ Maternity home □ Other (Specify) _____.

38. How long after baby was delivered did you stay there?

____Hours, _____days, _____Weeks

Index 3. Dodoso la mama (Swahili Version)

DODOSO LA MAMA

HOSPITALI YA TAIFA YA MUHIMBILI

Namba ya usaili ya mhojiwa _____Jina la anayehoji _____

Habari. Naitwa_____ nafanya kazi na hospitali ya Taifa ya Muhimbili. Tunafanya utafiti ambao utahusisha kukuuliza baadhi ya maswali ya husuyo afya yako na mtoto wako. Tutafurahi kama utakubali kushiriki katika utafitihuu. Taarifa zitakazopatikana kutokana na utafiti huu zitasaidia hospitali ya Muhimbili pamoja na serikali kuboresha huduma ya afya ya mama na motto. Mahojiano haya yatatumia dakika kadhaa. Na ushiriki wako ni hiari na uko huru kuamua kutoshiriki kwasasa au wakati wowote tukiwa tunaendelea na usaili utaniarifu name nitaondoka.

Sahihi ya mhojiwa:_____ Tarehe: _____

Pamoja na hayo, nimatumaini yetu utashiriki kikamilifu katika usaili huu kwa kuwa ushiriki wako ni muhimu sana katika utafiti huu.

Je una swali lolote linalohusu utafiti huu kwa sasa?

Naweza kuendelea kukuhoji?

MAMA AMEKUBALI KUHOJIWA? Ndio □ Hapana□

---

1. Tarehe yakuzaliwa _____.
2. Mahali unapoishi: Mkoa _____ Wilaya_____.
3. Uzito _____kg.
4. Urefu ____cm.
5. Hali yandoa_____
6. Kundi la damu _____
7. Elimu _____.
8. Kazi_____

Taarifa za Uzazi.

9. Umeshawahi kuzaa kabla ya mtoto huyu? Ndio □ Hapana □.

10. Kama ndio, mara ngapi?_____.

11. Umeshawahi kubeba ujauzito mara ngapi?_____

12. Una watoto wangapi walio hai? _____,

13. Je kuna mtoto/watoto aliyefariki. _____.Kama hakuna nenda swali la 15

14. Je unafahamu kwanini walikufa?

15. Je ulishawahi kupata ujauzito na ukatoka/ukaharibika?

Ndio □ Hapana □,

16. Kama ndio ni mimba ngapi zilizoharibika?_____.

17. Kabla ya kuwa mjamzito ulikuwa na

A. shindikizo la damu	Ndio	Hapana
B. figo	Ndio	Hapana
C. kisukari	Ndio	Hapana
D. kifuakikuu	Ndio	Hapana
E. sickle cell/Seli mundu	Ndio	Hapana
F. VVU	Ndio	Hapana
G.Ugonjwa mwingine taja	_____	

QN 18-27 (HAKIKI KWENYE KADI YA KLINIKI)

18. Wakati wa mimba ya mtoto huyu was asa, Je? Ulianza kliniki mimba ikiwa na umri gani? _____
19. Uliendaklinikijumlayamarangapi? _____
20. Je wakati wa ujauzito ulipata dawa za kumkinga mtoto na malaria akiwa tumboni? Ndio □ Hapana□

    Kama ndio
21. Ukiwa mjamzito ulipewa dawa hizo mara ngapi? ----------

22. Wakati wa ujauzito huu ulitumia dawa za kuongeza damu?
    Ndio □ Hapana □.

23. Kama ndio

    a: Je ni aina ngapi?

    b: Ulikuwa unakunywa kutwa mara ngapi??

24. Wakati wa ujauzito wa mtoto huyu wa sasa ulitumia dawa kwa ajili ya minyoo?
    Ndio □ Hapana□.

25. Wakati wa ujauzito ulichoma sindano ya pepopunda? kama ndio ulichoma mara ngapi?

26. Je wakati ukienda kliniki ulikuwa ukihudumiwa/ukipimwa maendeleo yako na mtoto na mtaalamu yupi wa afya?
    a) Wataalamu wa afya □ Dakitari □ Nesi
    b) Wengine □ Mkunga wa jadi aliyesajiliwa
    □ Mkunga wa jadi asiyesajiliwa
    □ Mwingine (taja) _____

27. Wakati wa ujauzito ulikuwa na tatizo lipi la kiafya
    1.□ maumivu ya kichwa 2. □ macho kuona giza 3. □ kutokwa na damu kabla ya miezi saba (wiki 28) 4. □ kutokwa na damu baada ya miezi saba ya ujauzito 5.□Tetanus 6.□ kifafa cha uzazi 7. □ kupasua chupa kabla ya uchungu 8.□Maumivu makali ya tumbo chini ya kitovu
    9.□ mtoto alikuwa hachezi vizuri tumboni 10.□ kutapika sana hadi ukahitaji matibabu 12. □ Other (nyingine taja) _____

28. Tatizo la kiafya ulilolipata hapo juu swali no26 ulilipata mimba ikiwa na umri gani ?

29. Je umewahi kuumwa na kutibiwa maradhi ya fuatayo ukiwa mjamzito

1. Malaria	ndio	hapana
2. upungufuwadamu	ndio	hapana
3. minyoo	ndio	hapana

4. magonjwa ya shindikizo la damu wakati wa ujauzito ndio hapana

5. kisukari cha ujauzito ndio hapana

6. kifafa cha mimba ndio hapana

7. Kumwagadamu ndio hapana

8. Ugonjwa mwingine taja _____

30. Ulikuwa kwenye Uchungu kwa muda gani kabla ya kujifungua?.....

31. Je ulipewa matibabu yoyote kati ya yafuatayo wakati wa uchungu?

□ Dripu ya maji □ Dripu ya maji ya uchungu □ Kutundikiwa damu □ sikupewa □ sifahamu

32. Nani alikuzalisha wakati wa kujifugua

A. Mtaalamu wa afya □ Dakitari □ muuguzi □ sijui

B. Mtu mwingine □ Mkunga wa jadi aliyesajiliwa.
□ Mkunga wa jadi asiyesajiliwa
□ Ndugu/rafiki/jirani
□ Mwingine taja_____.

33. Ulijifugua kwa njia gani? (msaidie mama kuelewa)

□ Kawaida (SVD) □ Kwa msaada mkubwa wa mtaalamu wa afya kwa kuwa hakutanguliza kichwa (ABD) □ kwa kutumia vifaa kama mikasi mikubwa (forceps) □ kwa kuvutwa na kifaa kama chupa na mipira (vacuum extractor)
□ upasuaji tumboni

34. Umejifungulia wapi?

a) Nyumbani □ Nyumbani kwangu □ Nyumba nyingine

b) Hospitali ya serikali □Muhimbili hospitali □ hospitali ya mkoa
□ Hospitali ya serikali ya wilaya □ kituo cha afya □ zahanati ya serikali

c) Private Medical center □ hospitali binafsi □ kliniki binafsi za kujifungulia
□ Nyengine taja _____

35. Je ulipata matatizo yafuatayo muda mfupi kabla ya kujifungua, wakati wa kujifungua au muda mfupi baada ya kujifungua?

□ maumivu ya kichwa □ macho kuona giza □ □ kumwaga damu nyingi □Degedege□ kutokwa na uchafu unaonuka □ mtoto alipunguza kucheza □ mtoto alitanguliza mikono/miguu □ uchungu muda mrefu □ uzazi pingamizi □ kuchanka kizazi □ kondo kubakia □ Homa kali □ mkojo au choo kutoka bila kujitambua □ sikua na tatizo lolote □ Jengine taja _____.

36. Ulitibiwa wapi kwa tatizo lako hapo juu Q34?

a) Nyumbani □ kwangu □ nyumba nyingine
b) Serikalini □Hospitali ya serikali □Hospitali ya wilaya □kituo cha afya □ zahanati
c) Kituo binafsi □ Hospitali binafsi □ kliniki binafsi ya kujifungulia □ kwengine taja (nyingine taja) _____.

37. Ulikaa kwa muda gani huko uliko jifungua kabla ya kuletwa hapa____saa, _____ siku_____ juma

Index 4: Main score

MAIN SCORE

Item	Morbidity attribute	Discrimatory index	χ^2‡	Scale
MAIN score, sum of the scale values of all checked items. †Discriminatory index, this is an indicator of discriminative capability of an item to capture various different grades of morbidity on the morbidity continuum. ‡χ^2, this statistic reflects fitness of observed on predicted test score distributions. Scale, relative scale values derived from item response analyses that provide weighting to the item(s) reflecting its contribution to the overall morbidity score. NA, not available because of small number of subjects for χ^2analysis. All statistical parameters are derived fitting two parameter item analysis model using BILOG-W software.				
Within 24 hours of birth				
	Cord blood Ph			
1	7.1	0.50	6.7	151
	Resuscitation at birth			
2	Intubation	0.88	6.5	127
	Meconium			
3	Meconium below cords	0.35	12.7	155
	Apgar score (5 min)			
4	score 4–7	0.47	13	125
5	score 1–3	0.97	0.8	162
6	score<1	1.6	0.3	193
	Apgar score (10 min)			
7	score 4–7	1.4	2	154
8	score 1–3	1.7	0.4	183
	Altered colour*			
9	Dusky/central cyanosis	0.74	2.2	145
	Respiratory rate/min*			
10	<30 or >60 at 3–24 h	0.54	5.3	131
11	>100 between 3–24 h	0.58	11.5	140

Within seven days of birth					
	Heart rate/min*				
12	160–200 beat		0.54	10.3	120
13	>200 beat		0.67	NA	183
14	<100 beat		0.5	3.1	157
	Hypotonia*				
15	Present at 1–120 h of age		1.0	1.5	129
16	Present beyond 120 h of age		1.36	9.2	156
	Flaccidity*				
17	Present at 1–120 h		1.07	7.4	154
	Apnea*				
18	Apnea corrected by oxygen		1.26	10.8	115
19	Apnea corrected by resuscitation		1.04	2.2	140
	Bleeding disorder				
20	Thrombocytopenia with or without bleeding disorder(GI/lungs/skin)		0.84	0.5	147
21	Need for transfusion due to anemia or item 20		1.1	0.2	170
	Systolic BP (mean, mm of Hg)*				
	28–32 weeks	32–42 weeks			
22	<30	<40	0.85	3.4	136
	Urine output*				
23	Low (<2 ml/kg/h)		1.25	7.1	141
	Seizures				
24	Tremors/single seizure		0.81	4.5	137
25	Multiple seizures		1.67	1.7	155
26	If >2 drugs used for seizures		1.94	1.0	183
	Level of consciousness*				
27	Drowsy/lethargic		0.92	4.2	137
28	Stupor/obtundation/coma		1.75	0.6	187

	Oral feeding difficulties*			
29	Poor sucking within 24 h	1.04	10.2	81
30	Poor sucking at 24 h–7 days	1.32	8.0	98
31	Poor sucking beyond 7 days	1.04	22.6	119
32	Persistent vomiting	0.62	13.9	136
	Respiratory status—assisted ventilation*			
33	Assisted ventilation beyond 24 h	0.66	30.8	117
	Respiratory status—mechanical ventilation*			
34	Mechanical ventilation within 24 h	1.09	5.5	130
35	Mechanical ventilation at 24 h–7 days	1.4	6.2	135
36	Mechanical ventilation beyond 7 days	1.16	2.6	162
	Birth trauma			
37	Bone fracture—long bone/clavicle/skull	0.7	NA	176
38	Nerve injury (facial/peripheral)	0.49	NA	183
39	Subdural or intracerebralhaematoma	0.71	NA	179
	Hypoglycaemia (lowest level)			
40	Blood glucose <2.2 mmol/l	0.44	1.6	151
	Hyperbilirubinaemia, mmol/l (peak level)			
41	Serum bilirubin >250/phototherapy	0.37	28.9	103
42	Serum bilirubin >340/exchange transfusion	0.42	NA	179
	Bacterial culture			
43	Blood positive	0.86	1.8	162
44	CSF positive	0.93	0.1	187
	Intra-ventricular haemorrhage			
45	Grade 1 or 2	0.86	0.6	152
46	Grade 3 or 4	1.84	0.8	186
	Cardiopulmonary resuscitation			
47	Any time before discharge	2.06	2.6	162

Index 5. Neonatal Consent form (English Version)

ID NO……

PERMISSION FOR A CHILD TO TAKE PART IN RESEARCH

Study title: **OBSTETRIC PREDICTORS OF SEVERE EARLY NEONATAL OUTCOME AMONG TERM NEONATES ADMITTED AT MUHIMBILI NATIONAL HOSPITAL, TANZANIA**

Introduction: Your child is being asked to take part in this study because we are going to follow him/her up until seventh day after delivery to assess the severity of her/his illness

Your decision whether or not to allow your child to take part will have no effect on the quality of your child's medical care. Please ask questions if there is anything about this study you do not understand.

What is the purpose of this study?

The purpose of this study is to learn more about the severity of neonates illnesses and if the severity of their illnesses can be predicted from their mothers health . Neonates with severe morbidity spend more resources and also has traumatic impact to parents.

Will you benefit from taking part in this study?

Your child will be a volunteer and might not personally benefit from being in this research study. However, we hope to gather information that may help other children in the future.

What does this study involve?

Your child's evaluation as part of this study will be done during admission days in the ward up to seventh day, or discharge whatever comes first. Your child will be followed up closely and different changes on his/her health, medication given will be recorded in a sheet of paper for use in our study. No new or added medication will be given for the purpose of the study. Your child will receive proper medication same wise as other neonates who are not in the study.

What are the options if you do not want to take part in this study?

Your child's participation in this study is completely voluntary. Your child will continue to receive regular care at the clinic regardless of whether he/she participates in the study.

What are the risks involved with taking part in this study?

These study no risks for your child, because no interventions will be done as part of study.

You can report any problems to your doctor or to the director of this study**:**

Dr. Fatma Lijohi 0713153207

• **Leaving the study:** You may choose to stop taking part in this study at any time for any reason. If you decide to stop taking part, it will have no effect on your child's medical care.

• **New Information:** New information related to this study and specifically new information about your child will be made known to you when it becomes available.

How will your privacy be protected?

The information you and your child provide will be kept strictly confidential. The study information will be stored in protected computer files and in paper records stored in locked filing cabinets. Only study staff will have access to the information.

The information will be maintained indefinitely.

Who may use or see your health information?

By signing this form, you allow the research team to use your child's health information and give it to others involved in the research. The research team includes the study director plus others working on this study at MUHAS.

Your permission to use your child's health information for this study will not end until the study is completed. You may ask for your child's study data at any time.

It is possible for a court or government official to order the release of study data including information about your child.

What if you decide not to give permission to use and share your personal health information?

If you do not allow use of your child's health information for this study, you may not take part in this study.

If you choose to stop taking part in this study, you may cancel permission for the use of your child's health information. You should let the researcher know if you want to cancel your permission. The study team will assist you in putting your wishes in writing. Information collected for the study before your permission is cancelled will continue to be used in the research.

Whom should you call about this study?

If you have questions about this study or need to report a study related injury, you can call your doctor or the research director for this study: Dr.Fatma Lijohi during normal working hours.

If Dr. Fatma Lijohi is not available, other staff members at will be available to answer your questions during normal business hours.

What about the costs of this study?

There will be no costs for you if you agree to have your child participate in the study. All study costs will be supported by

Will you be paid to take part in this study?

There will be no payment to you or your child for participation in the study.

What happens if you get sick or hurt from taking part in this study?

The sponsor of this research is the Ministry of health and social welfare. We expect no injuries. If you develop an illness or have an injury related to the study MOSW will pay for the reasonable costs of medical treatment.

If you have any questions or concerns about the legal responsibility of these organizations, please call the Chairman, MUHAS Research Ethics Committee (255 22 215 2489) during normal business hours.

If you agree that your child take part in this study and you sign this consent form, you are not giving up any of your legal rights.

Your responsibilities as a person taking part in this study

(1) Be aware it is important for your safety that the study team knows about your child's medical history and current condition.

(2) Notify the study team immediately if your child suffers any injury.

CONSENT

I have read the above information about study on "**Risk Factors for Severe Early Neonatal Morbidity among Term Neonates Admitted at Muhimbili National Hospital, Tanzania- Prospective Cohort Study"** and have been given time to ask questions. I agree to take part in this study and I have been given a copy of this signed consent form.

SIGNATURE

_____ _____

Researcher or Designee Signature and Date Name

_____

Legally Authorized Representative (Parent/legal guardian) and Date Name

Index 6: RIDHAA YA KUSHIRIKI KWENYE UTAFITI HUU

Namba ya Utambulisho……

Study title: Viashiria vya afya ya uzazi vinavopelekea afya duni ya mtoto mchanga ndani ya siku saba toka kuzaliwa kwa watoto waliolazwa katika wodi maalum ya watoto wachanga Hospitali ya Taifa ya Muhimbili.

Utangulizi: Mtoto wako anaombwa kushiriki katika utafiti kwa sababu tunafanya uchunguzi wa magonjwa katika afya ya mama na mtoto.Atakua akirekodiwa maendeleo ya afya yake mpaka siku ya saba ya kuzaliwa.

Uamuzi wako wa kumruhusu au kutomruhusu mtoto wako kushiriki hautakua na athari zozote kwenye ubora wa huduma ya mtoto wako. Tafadhali uliza swali kama kuna kitu usichokielewa kuhusu utafiti huu.

Je dhumuni la utafiti huu nilipi?

Dhumuni la utafiti huu ni kuchunguza mtoto wako anaumwa kiasi gani na kama kuna uhusiano wowote kati ya mtoto wako kuumwa zaidi na afya ya mama pamoja na huduma zinazotolewa kabla na wakati wa kujifungua. Kujua viashiria vya watoto kuumwa sana ndani ya siku saba za mwanzo baada ya kujifungua itasaidia kuepuka mapema au kuwahi tiba ili kupunguza vifo vya watoto wengine kupunguza gharama za matibabu na kupunguza mlundikano wa watoto wagonjwa katika wodi hii.

Je utafaidika kwa mwanao kushiriki kwenye utafiti huu?

Mtoto wako atafuatiliwa kwa kurekodiwa maendeleo yake kwa ridhaaa yako na inawezekana kuwa binafsi asifaidike kwa kuwepo kwenye utafiti huu. Zaidi tunatarajia kukusanya taarifa amabazo zitawasaidia watoto wengine siku za mbeleni.

Je Utafiti huu unahusisha nini?

Ufuatiliaji wa mtoto wako kama sehemu ya utafiti utafanyika wakati akiwa amelazwa kwenye wodi ya watoto wachanga kwa siku saba tu au mpaka akiruhusiwa kutegemeana kipi kitatangulia ..Mtoto wako atafuatiliwa kwa karibu na mtafiti kuhusu mabadiliko ya afya yake katika siku zilizochaguliwa, matibabu atakayopewa na hata baadhi ya vipimo

atakavyopata akiwa hospitali vitarekodiwa na mtafiti ndani ya siku saba .Mtafiti hatoongeza tiba wala kupunguza au kubadilisha matibabu anayostahili mtoto wako kwa namna yoyote ile. Ikimaanisha kwamba mtoto wako atapata matibabu sawa na watoto wengine ambao hawashiriki katika utafiti kwa kadiri atakavyostahili.

Je itakuwaje kama hutataka kushiriki kwenye utafiti huu?

Kushiriki kwa mtoto wako kwenye utafiti huu ni hiari kabisa. Mtoto wako ataendelea kupata huduma katika wodi hii bila kujali kama ameshiriki kwenye utafiti ama la.

Je kuna athari gani za kushiriki katika utafiti huu?

Utafiti huu hauna hatari kwa mtoto wako kwa kuwa utafiti hauhusishi kuongeza au kupunguza chochote katika tiba yake.Mtafiti atarekodi maendeleo ya mtoto tu.

Unaweza kuripoti matatizo yoyote kwa daktari wako au kwa mwendesha utafiti huu: **Dr. Fatma Lijohi**

Kuondoka kwenye utafiti: unaweza kuamua kusitisha mtoto wako kuendelea kushiriki kwenye utafiti huu muda wowote na kwa sababu yoyote. Kama utaamua kuacha kushiriki hautaathiri huduma za afya kwa mtoto wako.

Maelezo mapya: Maelezo mapya kuhusiana na utafiti huu na hasa maelezo mapya kuhusu mtoto wako utajulishwa mara tu ya takapokuwa yamepatikana.

Utunzaji wa siri

Habari utakazotoa wewe pamoja na taarifa za mtoto zitakazorekodiwa zitatunzwa kwa usiri mkubwa. Habari zihusuzo utafiti zitatunzwa kwenye kompyuta zenye ulinzi na rekodi zilizopo kwenye makaratasi zitatunzwa kwenye makabati yanayofungwa. Ni wafanyakazi wanao husika na utafiti tu ndio watakaoweza kuona taarifa, na taarifa hizi zitatunzwa siku zote.

Nina nia naweza kutumia au kuona taarifa zako za afya?

Kwa kuweka sahihi kwenye fomu hii umeruhusu watafiti kutumia taarifa za afya za mtoto wako na kuwapatia wengine wanaohusika na utafiti huu. Watafiti ni pamoja na mwendesha utafiti pamoja na wengine wanao husika na utafiti huu ambao wapo chuo kikuu cha Muhimbili pamoja na wizara ya afya.

Ruhusa ya kutumia taarifa za afya za mtoto wako itaisha wakati utafiti utakapokamilika. Unaweza kuomba taarifa za mtoto wako wakati wowote.

Inawezekana mahakama au afisa wa serikali akaamuru kuonyeshwa kwa taarifa za utafiti ikiwa ni pamoja na taarifa za mtoto wako

Je itatokea nini kama utaamua kutotoa ruhusa ya kutumia na kushirikisha wengine taarifa zako za afya?

Kama hautaturuhusu taarifa ya afya ya mtoto wako zitumike, hautaweza kushiriki kwenye utafiti huu.

Kama utachagua kuacha kushiriki katika utafiti huu, unaweza kufuta ruhusa ya matumizi ya taarifa za afya za mtoto wako. Watafiti watakusaidia kuweka matakwa yako kwenye maandishi. Taarifa zitakazo kuwa zimekusanywa kabla ya kufuta ruhusa zitaendelea kutumika kwenye utafiti.

Je utampigia nani kuhusu utafiti huu?

Kama una maswali kuhusu utafiti au ukiwa na haja ya kuripoti athari zitokanazo na utafiti, unaweza kumpigia daktari wako au mwendesha utafiti huu: **Dr Fatma Lijohi muda wa masaa ya kazi.**

Je kuna gharama juu ya tafiti huu?

Hakuna gharama kama utakubali mtoto wako ashiriki kwenye utafiti huu. Wizara ya afya itasaidia gharama zote za utafiti .

Je utalipwa kwa kushiriki kwenye utafit:

Hapatakuwa na malipo kwako au mtoto wako kwa kushiriki kwenye utafiti

Kama unamaswali kuhusu wajibu wa kisheria wa vyuo hivi tafadhali piga simu Kwa Mwenyekiti wa kamati ya maadili ya tafiti chuo kikuu cha muhimbili (MUHAS) (255 22 215 2489) wakati wa saa za kazi .

Kama utakubali mtoto wako ashiriki kwenye utafiti huu na ukasaini fomu hii ya ridhaa, haujiondolei haki yoyote ya kisheria.

Wajibu wako kama mshiriki wa utafiti huu

(1) Ufahamu kuwa ni muhimu kwa usalama wako na kwa watafiti kujua kuhusu taarifa za kimatibabu za mtoto wako na matatizo ya hivi karibuni.

Ridhaa

Nimesoma maelezo hapo juu kuhusu utafiti unaohusu Viashiria vya afya ya uzazi vinavopelekea afya duni ya mtoto mchanga ndani ya siku saba toka kuzaliwa . na nimepewa muda wakuuliza maswali. Nakubali kushiriki katika utafiti huu na nimepewa fomu ya ridhaa hii iliyowekwa sahihi.

Sahihi

_____

sahihi ya mtafiti au kaimu na tarehe Jina kamili

_____

sahihi ya mwakilishi wa kisheria (mzazi / mlezi) na tarehe Jina kamili