USE OF ANTENATAL CORTICOSTEROIDS PRIOR TO PRETERM DELIVERY: THE PRACTICE AT MUHIMBILI NATIONAL HOSPITAL, DAR ES SALAAM.

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By

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

Muhimbili University of Health and Allied Sciences

November 2012

CERTIFICATION

The undersigned certify that they have read and hereby recommend for acceptance by Muhimbili University of Health and Allied Sciences a dissertation entitled ***Use of antenatal corticosteroids prior to preterm delivery. The practice at Muhimbili National hospital Dar es Salaam, Tanzania***, in fulfillment of the requirements for the degree of Master of Medicine (Obstetrics and Gynaecology) of Muhimbili University of Health and Allied Sciences.

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Dr. C.D.S Kilewo

(Supervisor)

Date: _____

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Dr. A. Massawe

(Supervisor)

Date: _____

DECLARATION AND COPYRIGHT

I **Merin Mseeni Erick**, 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 ……..

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DEDICATION

This work is humbly dedicated to my lovely wife Martha Lazaro Tevely, my children Erica, Osiligi and Lengai and to my parents.

ABSTRACT

Background

Foetal lung maturity has been a challenge to obstetricians and pediatricians in managing neonates born prematurely. In preterm babies RDS is the main cause of neonatal death and therefore the solution to the immaturity of foetal lungs is a primary concern**.**

Several studies have shown the efficacy of antenatal corticosteroids prophylaxis in reducing RDS and intraventricular haemorrhage in preterm infants hence reducing neonatal death.

This life saving therapy is now widely used throughout the world however the coverage of its use and practice in Tanzania which is one of the developing countries is not adequately documented. The present study evaluated the use of antenatal corticosteroids prior to preterm delivery as practiced at MNH.

Methodology

Data was collected by using a questionnaire which was supplemented by maternal and neonatal data from the case notes. The questionnaire contained fifty items grouped into four sections for survey of the mother and neonate. The maternal survey included questions concerning sociodemographic characteristics, obstetric history, antenatal care and items related to the administration of antenatal corticosteroids and to events surrounding the delivery and the health of the newborn.

Eligible women were identified from the delivery book which contains the summary of ANC data, delivery data, maternal and neonatal outcome and destination of the mother after delivery and her premature neonate. Data was cleaned and analyzed by SPSS version 17 for windows. Chi-square test was used to find out the significant differences between variables.

Results

The prevalence of antenatal corticosteroids use in preterm deliveries at MNH was 31%. For neonates born between 28 and 34 weeks of gestation 34% of theirs mothers were given dexamethasone of whom 76% received a complete course. About 51% of those with PPROM received dexamethasone of whom 57% received a complete course.

Our study found that the use of dexamethasone was associated with a number of factors such as long time of stay in hospital, caesarian section delivery and seniority of the first doctor to attend the patient. Among the socio-demographic factors women with high level of education and those employed were more likely to be administered dexamethasone.

Conclusion

The use of antenatal corticosteroids among the pregnant mothers who had preterm delivery at MNH was low compared to other studies. However the prevalence was high for mothers directly admitted to MNH as compared to those referred from other hospitals for care of anticipated premature neonate. This observation necessitates education to the health workers on use of antenatal corticosteroids in anticipated preterm delivery especially in the peripheral hospitals.

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LIST OF ACRONYMS

ANCS	Antenatal Corticosteroids
ANC	Antenatal Care
DM	Diabetes Mellitus
CS	Caesarian Section
EDD	Expected date of delivery
GA	Gestation Age
IVH	Intraventricular Haemorrhage
LNMP	Last Normal Menstrual Period
MUHAS	Muhimbili University of Health and Allied Sciences
MNH	Muhimbili National Hospital
NIH	National Institute of Health
NBS	New Ballard Score
PIH	Pregnancy Induced Hypertension
PPROM	Preterm Rupture of Membranes
PROM	Premature Rupture of Membranes
PI	Principal Investigator
RA	Research Assistant
RDS	Respiratory Distress Syndrome
SPSS	Statistical Package for Social Science
SVD	Spontaneous Vaginal Delivery
SBF	Stillbirth Fresh
SBM	Stillbirth Macerated
WHO	World Health Organization

CHAPTER ONE

1. Introduction and literature review

1.1 Introduction

Foetal lung maturity has been a challenge to obstetricians and pediatricians in managing neonates born premature. In preterm babies respiratory distress syndrome (RDS) is the main cause of neonatal death and solution to the immaturity of foetal lungs is a primary concern**.**

Administration of antenatal corticosteroids (ANCS) therapy is indicated to all women at high risk of preterm delivery between 24 and 34 weeks of gestation. They are also indicated over 34 weeks of gestation when there is evidence of pulmonary immaturity. Antenatal corticosteroids are most effective in reducing RDS in pregnancies that deliver 24 hours after and up to 7 days after administration of the second dose of antenatal corticosteroids.[10, 11]

Antenatal corticosteroids are also beneficial in reduction of cerebroventricular haemorrhage, necrotizing enterocolitis, infectious morbidity, need for respiratory support and neonatal intensive care unit admission among the premature neonate. Antenatal corticosteroids use has not shown to increase the risk of death, chorioamnionitis and puerperal sepsis for the mother[10, 13] and not associated with increased infection in those with preterm rupture of membranes (PPROM) or rate of stillbirth in those with pregnancy related hypertension .[10]

The major barrier to implementation of antenatal corticosteroids therapy is the difficulty of identifying women at risk of preterm delivery in time to administer corticosteroids. Antenatal corticosteroids implementation at primary health care level is feasible and inexpensive provided skilled health care providers are available to identify women at risk of preterm delivery and administer intramuscular injections. Also there is no specific organizational and infrastructure changes needed [18] however the coverage of use has been low in developing countries unlike the developed world.

Respiratory distress syndrome occurs after the onset of breathing and is associated with an insufficiency of pulmonary surfactant. Neonates at greatest risk for RDS are premature and have low lecithin and sphyngomyelin ratio. Respiratory distress syndrome develops in 30% to 60% of infants between 28 and 32 weeks of gestation. Other risk factors include delivery of a previous preterm infant with RDS, maternal diabetes mellitus, hypothermia, foetal distress, asphyxia, male sex, white race, being the second born of twins and delivery by cesarean section without labour. [1]

Respiratory distress syndrome may develop immediately in the delivery room in extremely immature neonates at 26 to 30 weeks of gestation. Some more mature infants at 34 weeks gestation may not show signs of RDS until 3 to 4 hours after birth correlating with the initial release of stored surfactant at the onset of breathing accompanied by the ongoing inability to replace the surfactant owing to inadequate stores. Manifestations of RDS include cyanosis, tachypnea, nasal flaring, intercostals and sternal retractions and grunting.[1]

Foetal lung development has several stages. Development begins with the embryonic phase for the first 6 weeks of gestation in which the lung buds and bronchopulmonary segments form. The diaphragm also develops during this period which is essential for normal foetal lung development. Other stage is pseudo glandular phase from 7 to16 week's gestation were by conducting airways develop and the respiratory epithelium differentiates into early pneumocytes and ciliated cells. In the canalicular phase which lasts from 16 to 26 weeks airway branching is completed and capillary growth increases. At the end of this phase type I and type II pneumocytes can be found in the alveoli. [2, 3]

Two regimens of antenatal corticosteroid are effective in the promotion of foetal lung maturity. Betamethasone is administered as 2 doses of 12 mg intramuscularly 24 hours apart. Dexamethasone is administered as 4 doses of 6 mg intramuscularly 12 hours apart. These agents are structurally similar and both cross the placenta in their biologically active forms with foetal blood levels of approximately 30% of maternal levels achieved.[5]

In unavailability of both betamethasone and dexamethasone, hydrocortisone has been proposed as an alternative therapy but it is extensively metabolized in the placenta

and relatively little crosses into the foetal compartment and adequate foetal therapy can not be assured. [6]

The National standard treatment guidelines for mainland Tanzania recommend use of antenatal corticosteroids to prevent RDS in women with risk of premature delivery before 36 weeks. It recommends hydrocortisone as first line and dexamethasone as second line. [7] Muhimbili National Hospital (MNH) has adopted a corticosteroid regimen using dexamethasone given intramuscularly for women with anticipated preterm delivery.

In deciding whether antenatal corticosteroids use is appropriate at a specific GA the number needed to treat must be balanced by the frequency of disease. Although the risk of RDS is higher under 34 weeks the absolute number of neonates delivering in the late preterm period and requiring admission to the neonatal unit for RDS is greater. At 34 weeks' gestation nearly 50% of neonates require intensive care and at 35 weeks this drops to 15% and at 36 weeks to 8%. [8]

1.2 Literature review

Preterm delivery is the leading cause of neonatal deaths worldwide, 99% of which occur in low and middle income countries.[9]The administration of antenatal corticosteroids to mothers at high risk of preterm delivery is a highly effective intervention that can reduce neonatal deaths between 25%-50%. However in low and middle income countries only 10% of preterm babies are currently receiving antenatal corticosteroids[9.] This figure contrasts sharply with the more than 70% of preterm babies that receive the intervention in high income countries. [9] The use of antenatal corticosteroids and their effectiveness in preventing neonatal morbidity is not in dispute. Due to its life saving it is now widely used throughout the world but the coverage of its use in Tanzania which is one of the developing countries remains unknown.

The evidence of benefit of antenatal corticosteroids prophylaxis on reduction of RDS is now clear that in high income countries litigation is likely if antenatal corticosteroids are not administered to women with anticipated preterm delivery when there is no any contraindication. In developed countries the coverage of use of antenatal corticosteroids remained low for several years even after clear evidence of their effectiveness was clear but the NIH Consensus Statement in 1994 has lead to almost universal uptake in developed countries especially Western Europe and North America .[12]

The Consensus also concluded that a single course of corticosteroids should be considered for women at risk of preterm delivery and that the optimal benefit of antenatal corticosteroids lasted for 7 days recommending further research to determine the possible benefit of repeat antenatal corticosteroids doses seven days after the initial course. [12]

Some clinicians urged about the benefit of antenatal corticosteroids use in the sub group of babies who were born more than 7 days after a single course of treatment but in 2000 the NIH again convened a consensus panel to address the issue of antenatal corticosteroid use for preterm women reaffirming the benefit of a single course of corticosteroids but concluding that current data did not support the routine

use of repeat courses recommending rescue course with caution in pregnancies where the initial course was given at less than 26 weeks of gestation.[13]

In a recent randomized controlled trial which recruited 437 pregnant women at less than 33 weeks of gestation who had completed a single course of antenatal corticosteroids before 30 weeks of gestation revealed a significant reduction in the primary outcome of neonatal morbidity at less than 34 weeks of gestation in the rescue steroid group than in the placebo group and significantly decreased RDS, ventilator support and surfactant use. [14]

A study done in France revealed high prevalence of antenatal corticosteroids among mothers who had preterm delivery, 73% of the neonates' mothers received ANCS but rates of treatment varied with gestation age . Among neonates born between 24 and 27 weeks of gestation 67% of them received ANCS of whom 74% received a complete course and 74% of those born between 28 and 32 weeks of gestation received ANCS of whom 79% received a complete course.[19]

A large study conducted in United State of America revealed a prevalence of 77% use of ANCS. Among premature neonates born in between 2005 and 2007, 23.1% of 15,343 neonates eligible for the study did not receive corticosteroids. Mothers with diagnosis foetal distress and vaginal delivery as compared with caesarian section delivery were less likely to receive antenatal corticosteroids. Rupture of membranes before delivery and multiple gestations were associated with higher likelihood of receiving antenatal corticosteroids. Between 24 to 30 weeks gestation ANCS administration ranged from 80% to 85% and decreasing steadily from 78% at 31 weeks to 39% at 34 weeks.[20]

In a multicentre prospective descriptive study conducted in three Latin American counties to determine the prevalence of the use of ANCS in women who delivered prematurely and their characteristics associated with the use of ANCS revealed a varied pattern of use of prenatal corticosteroids. Ecuador had the lowest use (35%) followed by El Salvador (55%) and Uruguay (71%). Among the factors associated with use of antenatal corticosteroids were gestational age at delivery, cause of preterm delivery and time from admission to delivery. [21]

Another study in four South East Asian countries within the SEA-ORCHID project found that administration of antenatal corticosteroids to women who gave birth

before 34 weeks gestation varied widely between countries and also between hospitals within countries. Antenatal corticosteroids were most commonly given when women were between 28 and 34 weeks gestation and dexamethasone was the only type of antenatal corticosteroid used. Most women who received antenatal corticosteroids were in preterm labour or had preterm prelabour rupture of the membranes or hypertension. Neonates exposed to antenatal corticosteroids compared with those not exposed were less likely to die. Live born exposed neonates were less likely to have Apgar scores of < 7 at five minutes and less likely to have lung disease. [22]

A study conducted in Thailand to determine the mortality and morbidity rates of very low birth weight infants reported a major cause of mortality was RDS. Eighty-five percent of mortalities occurred within 7 days of birth and nearly half of them died within the first 24 hours. In that study antenatal corticosteroids were provided in only 49% of infants. [23]

Another study done in Thailand on changing physician's practice on antenatal corticosteroids in preterm birth, almost all physicians considered a gestational age of 28-34 weeks as appropriate for corticosteroid and they all administered dexamethasone because no alternative choice of corticosteroid was available at the hospital.[24]

Administration of ANCS has been identified as an essential and feasible intervention that could be of public health benefit in low and middle income countries where preterm birth is more common and no adequate neonatal care facilities available. In a criteria based audit on management of eclampsia patients at MNH in Dar es Salaam; Tanzania in 2006 it was found that few preterm mothers received antenatal corticosteroids and the reason given was that most of them were referred and had spent considerable time at the referring hospital and therefore were delivered as soon as they were admitted to MNH. [25]

In a five month qualitative perinatal audit done in 2007 at MNH among the causes of early neonatal death, RDS contributed about 22 % of the deaths [26] and based on hospital annual maternity report in 2010 prematurity rate was 5 % [27] and other studies reported about 25% of total admission in the neonatal unit are due to prematurity complications. [28]

The primary entry point for neonatal morbidity and mortality among preterm infants is RDS hence a solution to the immaturity of foetal lungs is a primary concern**.** Maternal administration of antenatal corticosteroids has served as the primary intervention that reduces morbidity and mortality due to RDS. The prevalence of use of this life saving drug is not known at MNH and hence research is needed to explore the use of ANCS and identify the gaps and provide the best way to meet the solution.

1.3 Problem statement

The prevalence of preterm delivery at MNH is about 5% of all deliveries[27]and RDS which is the main cause of morbidity and mortality among preterm babies accounting to 25% of admissions in the neonatal unit.[26]The problem of preterm delivery in developing countries like Tanzania is compounded by a lack of neonatal health care facilities. Antenatal corticosteroids administration to women at risk of preterm delivery is even more important in developing countries where resources are scarce and often difficult to provide expensive treatments such as surfactant therapy.

After the evidence that antenatal corticosteroid are effective on prevention of RDS research should instead be directed towards methods of achieving effective implementation of the intervention such as education of health care providers regarding its effectiveness, identification of women at risk of preterm delivery in time to administer antenatal corticosteroids and introduction of protocols for its use.[18]Although at Muhimbili National Hospital women at risk of preterm delivery are prescribed antenatal corticosteroids there is no data that shows coverage of this intervention. There was a need to conduct a study to get a baseline data on practice of use of antenatal corticosteroids.

1.4 Rationale of the study

In preterm babies RDS is the main cause of neonatal death and this can be minimized by promoting correct use of antenatal corticosteroids. The study of the prevalence of use of the corticosteroids can inform us how well the coverage and uptake of the intervention is at MNH.

The study provided baseline data and came out with recommendations for possible measures to be taken for improvement of management of preterm delivery.Results obtained will also be used as the baseline for more researches regarding use of antenatal corticosteroids.

1.5 Research question

What is the prevalence and associated factors on use of antenatal corticosteroids prior to preterm delivery at MNH?

1.6 Objectives

1.6.1 Broad objectives

To assess antenatal corticosteroids use and its associated factors in preterm delivery at MNH, Dar es Salaam, Tanzania.

1.6.2 Specific objectives

1. To determine the proportion of women delivered between 28 and 36 completed weeks given antenatal corticosteroids and their neonatal health outcomes.
2. To determine the proportion of women with prelabour premature rupture of membranes given antenatal corticosteroids.
3. To determine the predictors of use antenatal corticosteroids at MNH.

CHAPTER TWO

2. Methodology

2.1 Study design

A prospective hospital based descriptive study.

2.2 Study duration

The study was conducted in five month period from 1st of July to 31st of November 2011

2.3 Study setting

The study was conducted at MNH maternity block. Muhimbili National Hospital is a tertiary referral institution and a teaching hospital for the Muhimbili University of Health and Allied Sciences (MUHAS). Muhimbili National Hospital offers specialized obstetrics services for Dar es Salaam city and its suburbs, through its department of obstetrics and gynecology. The city of Dar es Salaam is estimated to have a population of more than three million people (census 2002). Patients are referred from city municipal hospitals, nearby Coast region and from private maternity homes. Apart from the referred patients a substantial number of patients with or without obstetrics complications come directly from home.

Muhimbili National Hospital has a special neonatal care unit which provides neonatal care to premature newborns and sick babies born at MNH and surrounding hospitals. The neonatal unit has got three rooms and premature babies are admitted in one of the rooms. Baby delivered by CS is directly admitted at least for one day in neonatal unit for care or till their mothers become ambulant. Muhimbili National Hospital neonatal unit is the only public neonatal unit in Dar es Salaam. It has 130 baby cots and admits between 12-25 neonates per day whereby one third of them being premature born babies at MNH and referrals from other municipals hospitals within the city. The unit is overcrowded which necessitates sharing of baby cots. The unit has two neonatologists and four pediatricians. Other staffs are registrars, resident doctors, intern doctors and nurses.

All patients admitted to the MNH labour ward bring their antenatal cards which contain summaries of events during ANC. Information from the cards is supplemented by interviews of the patients and are recorded in the case note on admission. Delivery data, progress of labour, maternal and neonatal outcome are also recorded in the partogram and case notes. All these information are finally summarized in midwifery book before entering them into the obstetrics data base. In the neonatal unit the neonatal register keeps summaries of the case notes of each neonate.

2.4 Study population and sampling procedures

All women delivered at MNH labour ward during the study period fitting the criteria and accepting participation in the study together with their premature neonates were included in the study.

2.4.1 Inclusion Criteria

All women delivered preterm at MNH labour ward between 28 and 36 completed weeks and their neonates.

2.4.2 Exclusion Criteria

Women who had serious infections such as chorioamnionitis before delivery, intrauterine foetal death, congenital anomalies and neonates delivered at a gestation less than 28 weeks and late preterm not admitted in the neonatal unit.

2.4.3 Study sample

All women who had preterm birth delivered at MNH labour ward between 28 and 36 complete weeks admitted with foetal heart beat.

2.4.4 Sample size

Sample size was calculated using the following formula;

$$N=\frac{Z^2P\,(1-P)}{D^2}$$

Where:

N = The expected minimum sample.

Z = The standard value which correspond to 1.96 at a 95% confidence interval

P = Estimated prevalence (35%)

D = Margin of error taken as 5 %

With the proportion of mothers with anticipated preterm delivery given antenatal corticosteroids, 35% in a multicenter study done in Latin America (Ecuador) between July 2004 and June 2008, the calculated minimum sample size was found to be 182.Ten percent of the non-respondents was added to the sample size calculated above, hence a minimum sample size taken to be 200 mothers.

2.5 Training of Research assistants

Two nurses, one nurse midwife from the labour ward and one from neonatal unit were recruited and trained as research assistants (RA) for two days on the protocol and ethical issues concerning the study on the correct conduct of human subject in the research. The training included the study procedures such as identification of study participants, application of inclusion and exclusion criteria, administration of consent form and extraction of variables of interest from the patient files, registers and participants themselves. The principle investigator (PI) was trained by a consultant neonatologist on the assessment of gestation age after delivery using New Ballard Score method. The training was conducted in the neonatal unit in the maternity block.

2.6 Questionnaire pre - test

This was conducted for three days duration to assess the flow of variables in the questionnaire, difficulties of obtaining information and other important aspects.

2.7 Study variables

Foetal variables including Apgar score at 5 minutes, condition of the baby after 24 hours. The condition of the baby included development of RDS, need for resuscitation soon after delivery and death within 24 hours. Maternal variables included gestation age, sociodemographic characteristics, obstetric history and antenatal care.

2.8 Data collection

Data was collected by using a questionnaire which was supplemented by maternal and neonate data from the case notes. The questionnaire containing fifty items grouped into four sections was used for survey of the mother and and neonate. The maternal survey included questions concerning sociodemographic characteristics, antenatal, obstetrics history and clinical data .The clinical data part included items related to the administration of antenatal corticosteroids and to events surrounding the delivery and the health of the newborn. The clinical data was counter checked using case notes.

Eligible women were identified from the delivery book which contains the summary of ANC data, delivery data, maternal and neonatal outcome and destination of the mother after delivery and her premature neonate.

The RA and principle investigator PI extracted the data from the midwifery book and case notes. Mothers were interviewed in the respective admitting wards by research assistants and PI. Information extracted and enquired included age, pre-existing diseases, complications during pregnancy and gestational age at labour or delivery and time from admission to delivery. Information about the neonate included birth weight, Apgar score, resuscitation after delivery and admission in neonatal unit. The antenatal corticosteroid use, regimens and doctor who prescribed were checked. The information extracted from the delivery book and case notes were proved by mother's interview. The mothers were interviewed after transfer out from the labour ward to the admitting ward. Those who had elective caesarian were interviewed after ambulation.

Daily check up of midwifery book was done to make sure that all cases were identified. All premature neonates admitted to neonatal unit were traced daily. The identification of the room in which the baby was admitted was done through the admission book .The baby cot was identified and identification confirmed by the baby coin number. Birth outcomes for all neonates were collected including gestational age at birth, weight at birth and health outcomes. The accurate gestational age (GA) was checked by obstetric and postnatal assessment using the new Ballard score (NBS) (See Annex 7.3 pages 41 to 43). Gestation age at admission and

delivery was calculated by last menstrual period, extrapolation from the antenatal card records and early ultrasound. Basing on New Ballard method if the postnatal assessment differed from the obstetric assessment by more than two weeks, the gestational age was based on the new Ballard Score. If the difference was less than two weeks the gestational age was based on obstetric assessment.

After delivery the neonate was observed for the first 24 hours during which information on assessment of gestation age and condition of the neonate was done by the PI. Assessment of gestation age was done within the first 24 hours and follow up for the condition done after 24 hours which involved a total of two visits to the baby. RDS was diagnosed by clinical findings consistent such as cyanosis, tachypnea, nasal flaring, intercostals and sternal retractions and grunting in premature infant without fever and also diagnosis based on doctor's records in the case notes. The causes of early neonatal deaths based on clinical diagnosis were traced from the neonatal unit records.

Causes of preterm birth were classified into three categories. Preterm associated with preterm premature rupture of membranes, medically indicated preterm birth and spontaneous preterm birth.

2.9 Data analysis

Data was coded and entered into SPSS for window version 17, cleaned and analyzed using proportions and frequency tables. Tables of relevant variables were constructed and Chi square test was used to compare and assess the statistical association of the variable investigated. Binary logistic regression analysis was done on variables that were significantly associated with administration of ANCS.

2.10 Ethical consideration

Ethical clearance was granted from MUHAS research and publication committee as well as permission to conduct the study from the Executive Director of MNH. The participants were explained about the study. Assurance to participants concerning their decision to join the study or not was given and that it had nothing to do with the effect of medical care and no risk are associated with the study. The participants were treated with respect and their information was kept confidential.

2.11 Definition of terms

Apgar score: A system of assessing the general physical condition of a newborn based on a rating of 0, 1, or 2 for five criteria: heart rate, respiration, muscle tone, skin colour, and response to stimuli. The five scores are added together, with a perfect score being 10. Low Apgar score = final score <7.

Preterm birth refers to a birth that occurs before 37 completed weeks of gestation.

Preterm Premature Rupture of Membranes (PPROM) is defined as rupture of the foetal membranes before the onset of labor at less than 37 weeks gestation.

Term Premature Rupture of Membranes (PROM) is defined as rupture of the foetal membranes when gestation age is at 37 weeks or more before onset of labour.

Single course of corticosteroids: Dexamethasone two doses of 12 mg given intramuscularly 12 hours apart.

Respiratory distress syndrome is condition manifesting with cyanosis, tachypnea, nasal flaring, intercostals and sternal retractions and grunting in premature infant without fever.

CHAPTER THREE

3. Results

A total of four thousand and ten (4010) women delivered at MNH during the study period whereby 19 had preterm delivery at a gestation below 28 weeks and 328 were preterm deliveries at a gestation age between 28 to 36 weeks. Nineteen women who delivered at a gestation less than 28 weeks and one hundred and five (105) women who delivered between 28 and 36 weeks were excluded from the analysis due to various reasons (forty five had late preterm delivery and their babies were not admitted in the neonatal unit because they did not need admission after being assessed, twenty three had fresh stillbirths and thirty seven had macerated stillbirths). None of the excluded mothers was given antenatal corticosteroids. A total of 223 women were included in the study for analysis and only 70 (31.4%) of them were given dexamethasone which was the only antenatal corticosteroids used.

During the study period a total of 292 premature babies were born by women delivered at MNH labour ward and were admitted in the neonatal unit. One hundred ninety eight (198) neonates were singleton, forty four (44) pairs of twins and two births of triplets. Thirty three (33) neonates were excluded in data analysis due to various reasons including two births of triplets, three pairs of twins and sixteen singletons who were born at gestation age less than 28 weeks and five babies who had gross congenital anomalies.

For the remaining 259 neonates, the range of birth weight was between 600 gm and 2800 gm and the mean of birth weight was 1579 gm and the mean gestation age was 32 weeks (See table 2, page 20 for details).

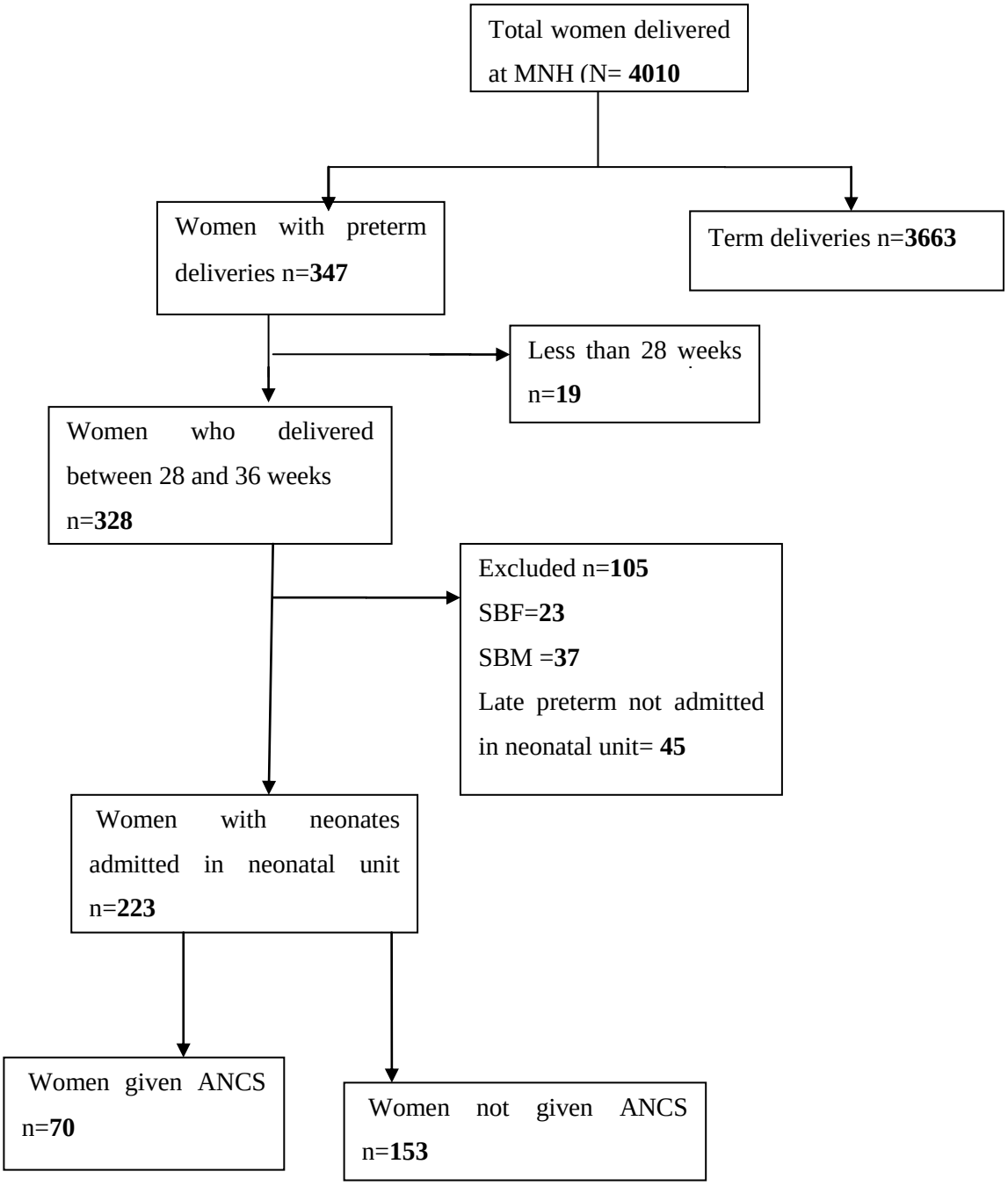


Figure 1. Summary of the women delivered at MNH labour ward during the study period.

Table 1: Socio-demographic characteristics of women enrolled in the study (N=223

Characteristic	Number	(%)
Age (years)		
Between 15 to 25	81	36.3
Between 26 to 34	108	48.4
Greater than 34	34	15.2
Level of education		
No formal education	2	0.9
Primary education	146	65.5
Secondary education	48	21.5
College/University	27	12.1
Marital status		
Single	20	9
Married	203	91
Occupation		
Not employed	77	34.5
Self employed	111	49.8
Employed	35	15.7
Parity		
Primeparous	102	45.7
1 - 4 children	102	45.7
Grater than 4	19	8.5
GA at delivery		
Between 28 and 34	154	69.1
Between 35 and 36	69	30.9

The median age of the participants was 27 years with a range of 15 - 40 years. Majority were married (91%). About forty six percent of the women in the study population were primepara with only 8.5% having delivered more than four times in

their lifetime. The median parity was 2. Majority had primary education (65.5%) and 0.9% had no formal education.

Table 2: Characteristics of premature neonates enrolled in the study (N=259)

Characteristic	**Number**	**(%)**
Gestation age at delivery by LNMP		
Between 28 - 34	178	68.7
Between 35 - ≤ 37	81	31.3
Gestation age post delivery by NBS		
Between 28 - 34	183	70.7
Between 35 - ≤ 37	76	29.3
Sex		
Female	135	52.1
Males	124	47.9
Birth weight		
≤ 1000 mg	20	7.7
≤ 2000 mg	194	74.9
>2000 mg	45	17.4
Number of fetuses		
Singleton	177	68.3
Twins	82	31.7

Most of the premature deliveries occurred at a gestation between 28 and 34 weeks and about 75 of the neonate had birth weight between 1000 gm and 2000 gm.

Table 3: Proportion of women who delivered preterm who received dexamethasone therapy

Characteristic	Gestation age in weeks		
	Between 28 to 34	Greater than 34	Total
Corticosteroids use			
Given	53 (33.5%)	17 (26.2%)	70 (31.4%)
Not given	105 (66.5%)	48 (73.8%)	153 (68.6%)
Total	158	65	223
Dose of corticosteroids			
Incomplete course	13 (24.5%)	6 (35.3%)	19 (27.1%)
Complete course	40 (75.5%)	11 (64.7%)	51 (72.9%)
Total	53	17	70

Of the women with preterm delivery at gestation age between 28 to 34 weeks, 33.5% were given antenatal corticosteroids of which 75.5% received a complete course. In women who delivered preterm at a gestation more than 34 weeks 26.2% were given antenatal corticosteroids and 64.7% received a complete course.

Table 4. Health outcomes for neonates exposed to dexamethasone versus those not exposed delivered a gestation between 28 and 36 weeks

Health outcome		Given	Not given	
	N	n (%)	n (%)	P value
Condition of infant after 24 hours				
No RDS	203	71 (34.9%)	132 (65.1%)	
RDS	56	19 (33.9%)	37 (66.1%)	0.02
Apgar score at five minutes				
≥7	195	73 (37.4%)	122 (62.8%)	
<7	64	17 (26.2%)	47 (73.8%)	0.1130
Need for resuscitation				
Yes	92	27 (28.4%)	65 (71.6%)	0.1756
No	167	63 (37.9%)	104 (62.1%)	

Respiratory distress syndrome was high among infants not exposed to antenatal corticosteroids (P value 0.02).Apgar score less than 7 at five minutes and need for resuscitation were common among those neonates not exposed to dexamethasone compared the exposed but the differences were not statistically significant.

Table 5. Health outcomes for neonates exposed to dexamethasone versus those not exposed delivered a gestation between 28 and 34 weeks excluding late preterm neonates (N=186).

Health outcome	Number N	Given n (%)	Not given n (%)	P value
Condition of neonate after 24 hours				
No RDS	133	50 (37.6%)	83 (62.4%)	
RDS	53	15 (28.3%)	38 (71.7%)	0.231
Apgar score at five minutes				
≥ 7	135	53 (39.3%)	82 (60.7%)	
< 7	51	12 (23.5%)	39 (76.5%)	0.044
Need for resuscitation				
Yes	70	17 (24.3%)	53 (75.7%)	0.017
No	116	48 (41.4%)	68 (58.6%)	

Apgar score less than 7 at five minutes and need for resuscitation were significantly high among those neonates not exposed to dexamethasone compared the exposed (p value less than 0.05)

Table 6: Cause of preterm birth and dexamethasone administration

Characteristic	Cause of preterm delivery			
	Spontaneous	PPROM	Medical indication	Total
Corticosteroids use				
Given	16 (17.4%)	30 (50.8%)	24 (33.3%)	70 (31.4%)
Not given	76 (82.6%)	29 (49.2%)	48 (66.7%)	153 (68.6%)
Total	92	59	72	223
Dose of corticosteroids				
Incomplete course	3 (18.8%)	13 (43.3%)	2 (8.3%)	18 (25.7%)
Complete course	13 (81.2%)	17 (56.7%)	22 (91.7%)	52 (74.3%)
Total	16	30	24	70

Among the women with PPROM 50.8% were given dexamethasone and of these 56.7% received a complete course. About 33% of those delivered premature due to medical indications received antenatal corticosteroids and about 92% of them received complete course.

Table 7: Association between administration of dexamethasone and different characteristics (N=223)

Maternal characteristic		Administration of dexamethasone		
		Given	Not given	P value
	N (%)	n (%)	n (%)	
Level of education				
Primary education	148	39 (26.4%)	109 (73.6%)	
Secondary/College/University	75	31 (41.3%)	44 (58.7%)	0.022
Occupation				
No employment	77	23 (29.9%)	54 (70.1%)	
Self employed	111	29 (26.1%)	82 (73.9%)	
Employed	35	18 (51.4%)	17 (48.6%)	0.018
Age				
15 – 25	81	20 (24.7%)	61 (75.3%)	
26 – 34	108	35 (32.4%)	73 (67.6%)	
>34	34	15 (44.1%)	19 (55.9%)	0.117
Marital status				
Single	20	5 (25%)	15 (75%)	
Married	203	65 (32%)	138 (68%)	0.519
Parity				
Primeparous	102	26 (25.5%)	76 (74.5%)	
1 - 4 children	102	37 (36.3 %)	65 (63.7%)	
5 and more children	19	7 (36.8%)	12 (63.2%)	0.129
Gestation age				
28 – 34	158	53 (33.5%)	105 (66.5%)	
>34	65	17 (26.2%)	48 (73.8%)	0.146
Type of antenatal care				
Normal tract	190	54 (28.4%)	136 (71.6%)	
Fast tract	33	16 (48.5%)	17 (51.5%)	0.02

The administration of dexamethasone in preterm birth was associated with level of education, employment status and type of antenatal care the woman received

Table 8. Administration of dexamethasone and associated factors (N=223)

Associated factors	Number	Given	Not given	P value
	N	n (%)	n (%)	
Time of admission to delivery (hours)				
≤13	146	25 (17.1%)	121 (82.9 %)	
>13	77	45 (58.4%)	32 (41.6%)	0.0001
First doctor to see				
Junior doctors	106	25 (23.6%)	81 (76.4%)	
Senior doctors	117	45 (38.5%)	72 (61.5%)	0.017
Type of preterm				
Spontaneous	92	16 (17.4%)	76 (82.6%)	
PPROM	59	30 (50.8%)	29 (49.2%)	0.001
Medical indication	72	24 (33.3%)	48 (66.7%)	
Where from				
Home	127	51 (40.2%)	76 (59.8%)	0.001
Referral hospital	96	19 (19.8%)	77 (80.2%)	
Type of delivery				
Vaginal delivery	138	31(22.5%)	107(78.1%)	
Caesarian section	85	39(45.9%)	46(54.1%)	0.001
Reason for referral				
Spontaneous labor	51	8 (15.7%)	43 (84.3%)	
Preeclampsia/PIH	27	10 (37%)	17 (63%)	
Eclampsia	20	2 (10.5%)	18 (90%)	
PPROM	11	1 (9.1%)	10 (90.9%)	
Placenta praevia	17	9 (52.9%)	8 (47%)	0.001

The administration of dexamethasone in preterm birth increased with increase in time from admission to delivery. It was commonly administrated to women delivered by caesarian section and those from home and those with preterm premature rupture of membranes. Senior doctors prescribed more than junior doctors.

CHAPTER FOUR

4. Discussion

The present study was designed to describe use of corticosteroids prenatally in preterm deliveries which took place at MNH labour ward in July to November 2011.More than half of the mothers were referrals from municipal hospitals because MNH neonatal unit is the only public health neonatal unit in the city and intrauterine transfer is a preferred mode of transfer of foetuses expected to be born prematurely. It was found that almost all pregnant mothers with anticipated preterm deliveries were referred to MNH for care of preterm babies but antenatal corticosteroids were not administered at the referring hospital.

In this study dexamethasone was the only antenatal corticosteroids used and was given to 31.4% of mothers enrolled in the study. Of those given 73% were directly admitted to Muhimbili National hospital from home. The prevalence of use of antenatal corticosteroids was low compared to studies done worldwide where by antenatal corticosteroids use ranged between 40% - 70% [21, 22, 24] in developing countries and 70% - 80% in developed countries. [19, 20] The difference in the prevalence of use of antenatal corticosteroids in our study as compared to studies done in other developing countries could be due to several factors such as lack of clear standard protocol, short time of stay between admission to delivery and first contact by junior doctors especially interns who are less experienced.

Our study also found that among mothers who gave birth between 28 and 34 weeks gestation only 33.5% were given dexamethasone in which 75.5% of them received a complete course. This was lower compared to a study done in France whereby 74% of mothers who delivered preterm between 28 and 34 weeks of gestation received ANCS of whom 79% received a complete course. [19] The low use of antenatal corticosteroids in our study as compared to developed countries could be due to difference in standard of medical care between developing countries and the

developed ones in terms of interventions and dissemination of evidence based information.

It was also found that low Apgar scores at 5 minutes, need for resuscitation and respiratory distress syndrome were low in the exposed neonates to dexamethasone compared with neonates who were not exposed. The same findings were reported in a study done on use of antenatal corticosteroids prior to preterm birth in four South East Asian countries within the SEA-ORCHID project.[22]

Women who delivered at a gestational age more than 34 weeks had a lower chance of receiving antenatal corticosteroids. This was similar to findings from a study done in Thailand which aimed to monitor the change of practice in antenatal corticosteroids use in preterm delivery assessing how physicians would prescribe and identify factors associated with such a prescription. In that study almost all physicians considered a gestational age of 28-34 weeks as appropriate for antenatal corticosteroid use. [24]

Preterm births associated with PPROM were more likely to use dexamethasone .The same observation was noted in a study done in California in which rupture of membranes before delivery and multiple gestations were associated with higher likelihood of receiving antenatal corticosteroids.[19] Of the preterm birth associated with PPROM (56.7%) had a complete course of antenatal steroids. Although more than fifty percent of patients with PPROM were exposed to antenatal corticosteroids a significant number were not exposed which might be due to delay from home or referring hospital.

Among the referred mothers only 17.8% were given antenatal corticosteroids at MNH.Those with preeclampsia and non proteinuric hypertensive disorders were more likely to receive dexamethasone as compared to eclampsia.The reason for not receiving antenatal corticosteroids at MNH might be arrival to hospital with advanced labour. The same observation was reported in criteria based audit on management of eclampsia patients at MNH where few preterm mothers received corticosteroids due to spending considerable time at the referring hospital and therefore were delivered as soon as they were admitted at MNH.[25]

It was found that the use of antenatal corticosteroids at MNH was associated with several factors. There was a very strong significant association between use of

antenatal corticosteroids and time from admission to delivery. Women with long stay in hospital were more likely to receive antenatal corticosteroids compared with short stay. There was a positive trend in the use of prenatal corticosteroids as time from admission to delivery increased. This finding is similar to findings in a study done in Latin America where those women with long stay in hospital were likely to receive corticosteroids [21] because of sufficient time for identication and administration of the corticosteroids.

Women who had preterm delivery with prior admission in the antenatal wards during pregnancy were more likely to receive antenatal corticosteroids. The same finding was observed in a study done in France [19] and Latin America [21]. Better identification of the potential risk for preterm birth by healthcare providers may have contributed to the increased use of antenatal corticosteroids.

Depending on mode of delivery those delivered by elective caesarian section were likely to receive corticosteroids as compared to vaginal delivery. The explanation for this is adequate time to administer antenatal corticosteroids. The same findings were reported in a study done in the United States of America whereby mothers delivered preterm with diagnosis foetal distress and vaginal delivery as compared with elective caesarian section delivery were less likely to receive antenatal corticosteroids.[19]

This study revealed that hypertensive disorders of pregnancy, multiple pregnancies and prolonged rupture of membranes were common problems leading to preterm delivery, which seems to be common according to other studies on preterm delivery worldwide. [19, 20, 21, 22, 23, 24] Among the referred patient delivered due to medical indications, dexamethasone was more likely to be administered to neonates' mothers with preeclampsia and gestational hypertension and less likely in patients with eclampsia.

This study found high significant association between the use of dexamethasone and both education level and occupation. The number of women given antenatal corticosteroids increased with increasing level of education. Although there are many other factors influencing the use of antenatal corticosteroids, educating women helps them make correct decisions such as early seeking of medical care. Also educated women will make relevant consultation when they experience pregnancy complications.

CHAPTER FIVE

5. Conclusion

The use of antenatal corticosteroids among the pregnant mothers who had preterm delivery at MNH was low compared to other studies. However the prevalence was high for mothers directly admitted to MNH as compared to those referred from other hospitals for care of anticipated premature neonate. This observation necessitates education to the health workers on use of antenatal corticosteroids in anticipated preterm delivery especially in the peripheral hospitals.

5.1 Recommendations

Health care workers should be empowered with knowledge and skills on the importance and use of antenatal corticosteroids in anticipated preterm delivery in the country.

6. References

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7. Annexes

7.1 Data collection tool

Identification			
Name of the mother			Registration number
Date _____/_____/2011			Questionnaire number [ ]
1. DERMOGRAHIC CHARACTERISTICS			
1.1	Age [ ]	1.2	Gravidity
1.3	Parity [ ]	1.4	**LNMP/____/_____/201_____/**
1.5	**EDD** _____/_____/_201_/	1.6	Date of admission to hospital[ ] Time of admission [Hrs][Check case notes]
1.7	Gestation age at admission [Weeks]	1.8	Marital status1.Married 2.Single 3.Cohabiting 4.Divorced
1.9	Highest level of education attained 1.No formal education 2.Primary school 3.Secondary 4.College/University	1.20	What is your occupation 1.No employment 2.Self employment 3.Employed
2. DELIVERY CHARACTERISTICS			
2.1	Gestation age at delivery [wks]	2.2	Date of delivery [____/_____/201_] Time of delivery [Hours]
2.3	**Sex** Singleton 1.Female 2.Male Twins 1st — 2nd ____	2.4	First doctor to see the patient 1. Intern 2.Registar 3.Resident 4.Specialist 5.Not seen by doctor

	3.Triplet 1st___ 2nd___ 3rd_____		
2.5	Mode of delivery 1.Vaginal] 2.Caesarian section	2.6	Types of preterm 1.Spontaneous 2.PPROM 3.Medically indicated condition (Mention) _____
2.7	Was ANCS planned to be given 1.Yes 2.No [Look at clinical notes]	2.8	Any intramuscular injection given recently 1. Yes 2.No (If yes which drug)_____
2.9	Were you given corticosteroids injection in this pregnancy? 1.Yes 2.No (**Case notes)**	2.10	Who prescribed 1? Intern 2.Registar 3 .Resident 4.Specialist [Case notes]
2.11	Given 1.Yes 2.No (Check treatment chart)	2.12	If given name of ANC[ ]
2.13	Course 1. Single 2.Repeat	2.14	Was she given at referring hospital 1.Yes 2.No
2.15	Period from admission to delivery	2.16	Period from starting antenatal corticosteroids to delivery[ ]
3. **FETAL OUTCOME**			
3.1	Resuscitations done 1. Yes 2. No	3.2	Apgar score
3.3	Birth weigh	3.4	GA by modified Ballard method [Weeks]
3.5	Admission at neonatal unit 1.Yes 2. No	3.6	Reason for admission(Check case notes) _____
3.7	Condition of the baby/Babies after 24 hours		

	1.Well 2.RDS 3.Dead		
4. ANTENATAL CHARACTERISTICS			
4.1	Did you attend antenatal clinic? 1.Yes 2.No	4.2	Category of care 1. Normal tract 2. Fast tract
4.3	Where did you attend ANC? 1. MNH 2.Municipal hospital 3.Private hospital 4.Dispensary 5.Health center	4.4	Where is the mother from 1.Home 2.Referal 3? ANC
		4.5	If referral why [see referral letter]
4.6	Did you know that you are at risk of preterm birth 1.Yes 2.No	4.7	Who told you 1.Doctor 2.Nurse 3.Others
4.8	Any pre existing condition (Mention) 1.No 2.Pre eclampsia/PIH 3. Eclampsia 4.DM 5. Anemia 6.Placenta praevia 7. Abruptio placenta		

7.2 Swahili version of data collection tool

Utambulisho			
Jina la mama			Namba ya jalada
Tarehe ya usaili _____/_____/2011			Namba ya dodoso [ ]
1. DEMOGRAPHIA YA JAMII			
1.1	Umri [ ]	1.2	Mimba ya ngapi
1.3	Umezaa mara ngapi [ ]	1.4	Tarehe ya mwisho kuona hedhi/____/_____/201_____/
1.5	Tarehe ya matazamio _____/_____/_201__	1.6	Tarehe ya kulazwa [ ] Muda wa kulazwa [Saa][Angalia jalada]
1.7	Umri wa mimba alipolazwa [Wiki]	1.8	Hali ya ndoa1.Kaolewa 2.Hajaolewa 3.Kaachika
1.9	Kiwango cha elimu 1.Hajasoma kabisa 2.Elimu ya msingi 3.Elimu ya sekondari 4.Chuo	1.20	Kazi yako 1.Hana ajira 2.Kajiajiri 3.Kaajiriwa
2. MAELEZO YA UZAZI			
2.1	Umri wa mimba alipojifungua [wiki]	2.2	Tarehe ya kujifungua [____/_____/2011] Muda alipojifungua [Masaa]
2.3	Jinsi 1.Kike 2.Kiume Mapacha 1.___ 2.___	2.4	Daktari wa kwanza kumwona 1.Daktari chini ya usimamizi 2.Daktari aliyeajiriwa/Si

	Watatu 1__ 2.__ 3.____		bigwa 3.Daktari mkazi 4.Daktari bingwa 5.Hajaonwa na dakari
2.5	Njia ya kujifungua 1.Kawaida 2.Upasuaji	2.6	Aina ya uchungu 1.Ulianza wenyewe 2 Chupa kupasuka bila uchungu 3.Ushauri wa daktari (Fafanua) _____
2.7	Je kulikuwa na mpango wa kupewa dawa ya kukomaza mapafu ya mtoto 1.Ndio 2.Hapana [Angalia jalada]	2.8	Kuna sindano umechomwa kwenye msuli hivi karibuni 1. Ndio 2.Hapana (Kama ndiyo kwanini)_____
2.9	Ulipewa dawa ya kukomaza mapafu ya mtoto ujauzito huu 1.Ndiyo 2.Hapana (**Angalia jalada)**	2.10	Nani kakuandikia 1. Daktasri chini ya usimamizi 2.Daktari aliyeajiriwa/si bingwa 3 .Daktari mwanafunzi/Uzamili 4.Daktari bingwa [Jalada]
2.11	Kapewa 1.Ndiyo 2.Hapana (Angalia chati ya matibabu)	2.12	Kama kapewa ni ipi [ ]
2.13	Mara ngapi 1. Moja 2. Marudio	2.14	Je kapewa hospitali iliyompa rufaa 1.Ndiyo 2.Hapana
2.15	Muda aliyolazwa hadi kujifungua	2.16	Muda aliyopewa dawa hadi kuifungua [Masaa]
3. MAELEZO YA MTOTO			
3.1	Kusaidiwa kuweza kupumua mwenyewe 1. Ndiyo 2. Hapana	3.2	Apgar score
3.3	Uzito alipozaliwa	3.4	Umri wa mimba kwa njia Ballard [Wiki]

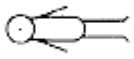
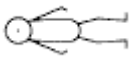
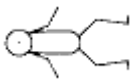
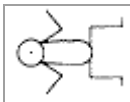
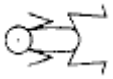
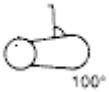
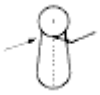
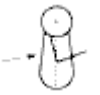
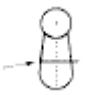
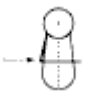
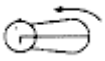
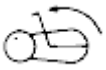
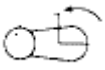
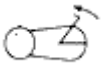
3.5	Kulazwa wodi maalum ya watoto 1.Ndio 2. Hapana	3.6	Sababu ya kulazwa(Angalia jalada
3.7	Hali ya mtoto/Watoto baada ya mass 24 1. Mzima 2. Shida ya kupumua. Kafariki		
4. MAELEZO YA UJAUZITO			
4.1	Ulihudhuria kliniki ya mama na mtoto? 1.Ndiyo 2.Hapana	4.2	Aina ya huduma 1. Kwaida 2. Maalum
4.3	Ulihudhuria kliniki ya mama na mtoto wapi? 1. MNH 2.Hospitali ya wilaya 3.Hospitali binafsi4.Dispensari 5.Kituo cha afya	4.4	Mama katokea wapi 1.Nyumbani 2.Rufaa 3.Kliniki ya mama na mtoto
		4.5	Kama rufaa kwani nini [Angalia jalada] _____
4.6	Ulijua uko kwenye hatari ya kujifungua kabla ya wakati 1.Ndiyo 2.Hapana	4.7	Nani kakuambia 1.Daktari 2.Nesi
4.8	Ulikuwa na tatizo linguine la kiafya (Taja) 1.Hapana 2. Pressure kupanda 3.Kifafa cha mimba 4.Kisukari 5.Upungufu wa damu 6. Kando kutangulia 7.Kondo kuachia		

7.3 Summary of Postnatal assessment of gestational age using NBS

The Ballard system was modified as the new Ballard score to improve assessment of infants as premature as 20 weeks. This method expands the description of physical and neurologic features and was tested in infants from 20 to 44 weeks gestation. New Ballard Method for assessment of gestational age uses various physical signs and neuromuscular characteristics that vary according to foetal age and maturity. Physical criteria are features that mature with advancing foetal age, including increasing firmness of the pinna of the ear, increasing size of the breast tissue, decreasing fine immature lanugo hair over the back and decreasing opacity of the skin. Neurologic criteria are features that mature with gestational age, including increasing flexion of the legs, hips, and arms, increasing tone of the flexor muscles of the neck and decreasing laxity of the joints. These signs were determined during the first day of life and were assigned scores. The cumulative score is correlated with a gestational age which is usually accurate to within 2 weeks [29].

7.3.1 Score Sheet

NEUROMUSCULAR MATURITY

SIGN	SCORE							SIGN SCORE
	-1	0	1	2	3	4	5	
Posture								
Square Window								
Arm Recoil								
Popliteal Angle								
Scarf Sign								
Heel To Ear								
							TOTAL NEUROMASCULAR SCORE	

7.3.2 Physical maturity

SIGN	SCORE							SIGN SCORE
	-1	0	1	2	3	4	5	
Skin	Sticky, friable, transparent	Gelatinous, red, translucent	Smooth pink, visible veins	Superficial peeling &/or rash, few veins	Cracking, pale areas, rare veins	Parchment, deep cracking, no vessels	Leathery, cracked, wrinkled	
Lanugo	none	Sparse	Abundant	Thinning	Bald areas	Mostly bald		
Plantar Surface	heel-toe 40-50mm: -1 <40mm: -2	>50 mm no crease	faint red marks	Anterior transverse crease only	Creases ant. 2/3	Creases over entire sole		
Breast	imperceptable	Barely perceptable	Flat areola no bud	Stippled areola 1-2 mm bud	Raised areola 3-4 mm bud	Full areola 5-10 mm bud		
Eye / Ear	lids fused loosely: -1 tightly: -2	Lids open pinna flat stays folded	Less curved pinna; soft; slow recoil	Well-curved pinna; soft but ready recoil	Formed & firm instant recoil	Thick cartilage ear stiff		
Genitals (Male)	scrotum flat, smooth	Scrotum empty, faint rugae	Testes in upper canal, rare rugae	Testes descending, few rugae	Testes down, good rugae	Testes pendulous, deep rugae		
Genitals (Female)	clitoris prominent & labia flat	Prominent clitoris & small labia minora	Prominent clitoris & enlarging minora	Majora & minora equally prominent	Majora large, minora small	Majora cover clitoris & minora		

7.3.3 Maturity rating

TOTAL SCORE (NEUROMUSCULAR + PHYSICAL)	WEEKS
-10	20
-5	22
0	24
5	26
10	28
15	30
20	32
25	34
30	36
35	38
40	40
45	42
50	44

New Ballard Score expanded to include extremely premature infants. J Pediatr 1991; 119:417

7.4 Informed consent form

ID no _____

Consent to participate in the study assessing the use of antenatal corticosteroids prior to preterm delivery; practice at Muhimbili National Hospital.
Greetings! My name is Dr. Merin Mseeni Erick, a postgraduate student at Muhimbili University of Health and Allied Sciences.

The purpose of the study

To assess the use of antenatal corticosteroids prior to preterm delivery; the practice at Muhimbili National Hospital.

What participation involves

If you agree to participate in the study you will be requested to answer the questions on the questionnaire.

Confidentiality

All information collected on questionnaires will be entered into computer with identification number. The questionnaires will be handled with great secrecy in order to maintain confidentiality throughout the study.

Risks

There is no direct risk associated with this study.

Right to withdraw and alternatives

Taking part in this study is completely voluntary. If you choose not to participate in the study, you will continue to receive all services that you would normally get from the hospital.

Benefits

If you agree to take part in this study, you will benefit from knowing fine details about use antenatal corticosteroids.

In case of any injury

Apart from you providing time we do not expect any harm from your participation.

Whom to contact

If you have any question about the study you should contact Dr.Merin. M.E on +255715 69 9387.If you have any questions/concerns about your rights as a participant; you may contact Prof M. Aboud, Chairman of MUHAS Research and Publications Committee. P.O.BOX 65001 Dar es Salaam. Tel 2150302-6

Signature

I …… have read the content of this form .My questions have been answered. I agree to participate in this study.

Signature of participant …….

Signature of witness ……..

Date of signed consent …/…/ 2011

Participant agrees /___/ Participant does not agree /____/

7.5 Swahili version of informed consent form

ID no _____

Hati ya ukubali wa kushiriki kwenye utafiti unaoangalia matumizi ya dawa kwa ajili ya kukomaza mapafu ya mtoto kwa akina mama wajawazito waliojifungua kabla ya mimba kutimia waliojifungulia hospital ya taifa muhimbili.

Salaam!

Naitwa Daktari Merin Mseeni Erick, mwanafunzi wa uzamili katika chuo kikuu cha Tiba za Afya cha Muhimbili.

Lengo la utafiti

Kuangalia matumizi ya dawa za kukomaza mapafu ya mtoto kwa akina mama wajawazito waliojifungua kabla mimba kutimia hospitali ya Taifa Muhimbili.

Ushiriki wako ni wa namna gani?

Ukikubali kushiriki utaombwa kujibu maswali yaliyopo kwenye dodoso.

Usiri

Taarifa zote zilizochukuliwa kupitia dodoso letu vitatambulika kwa namba na siyo jina ili kuongeza usiri. Usiri huo utalindwa hata baada ya kukamilika kwa utafiti huu.

Madhara

Mbali na muda utakaotumika kwa mahojiano, hatutegemei kwamba utapata madhara yoyote.

Faida

Kama ulikuwa haujui undani juu ya dawa hizo utapata bahati ya kufahamu

Haki ya kujitoa

Ushiriki wako ni wa hiari, unaweza kujitoa wakati wowote katika utafiti huu. Ukiamua kutokushiriki, utaendelea kupatiwa huduma kama kawaida.

Mawasiliano

Ukiwa na maswali kuhusu utafiti huu wasiliana nami, Daktari Merin.M.E kwa nambari ya simu +255715699387

Ukiwa na maswali kuhusu haki yako kama mshiriki, wasiliana na Prof. Muhsin Aboud, mwenyekiti wa Kitengo cha Utafiti cha Chuo Kikuu cha Afya ya Tiba Muhimbili S.L.P 65001 Dar es Salaam. Tel 2150302-6

Mimi _____nimekubali kushiriki utafiti huu baada ya maswali yangu yote kujibiwa.

Sahihi ya mshiriki _____

Sahihi ya shahidi _____ Tarehe __/___/2011

Mshiriki amekubali /___/ Amekataa /___/