



THE UNIVERSITY OF ZAMBIA
SCHOOL OF MEDICINE
DEPARTMENT OF OBSTETRICS AND GYNAECOLOGY

**THE USE OF ANTENATAL CORTICOSTEROIDS AND
OUTCOMES OF PREMATURE NEONATES AT THE
UNIVERSITY TEACHING HOSPITAL, LUSAKA, ZAMBIA.**

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DEDICATION

To my nuclear and extended family

DECLARATION

I HEREBY DECLARE THAT THIS DISSERTATION HEREIN PRESENTED FOR THE DEGREE OF MASTER OF MEDICINE IN OBSTETRICS AND GYNAECOLOGY HAS NOT BEEN PREVIOUSLY SUBMITTED EITHER WHOLLY OR IN PART FOR ANY OTHER DEGREE.

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APPROVAL

THIS DISSERTATION OF DR ANGEL MWICHE HAS BEEN APPROVED AS PARTIAL FULFILMENT OF THE REQUIREMENTS FOR THE AWARD OF MASTER OF MEDICINE IN OBSTETRICS AND GYNAECOLOGY BY THE UNIVERSITY OF ZAMBIA.

SIGNATURES:

STATEMENT

I HEREBY STATE THAT THIS DISSERTATION IS ENTIRELY A PRODUCT OF MY OWN WORK. THE CONTRIBUTORS HAVE CLEARLY BEEN MENTIONED IN ACKNOWLEDGEMENTS AND REFERENCES.

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Dr. A. Mwiche

ABSTRACT

Background: Following the administration of corticosteroids to pregnant women at risk of premature delivery, the occurrence of hyaline membrane disease and the related complications among neonates born of such women is significantly reduced. Despite this knowledge, the use of corticosteroids in developing countries remains low. This study aimed to determine the outcome of premature babies whose mothers were administered corticosteroids antenatally, and understand how health-staff used corticosteroids at the University Teaching Hospital (UTH).

Methods: The research had two components with two research designs: a prospective cohort to study outcomes of premature babies in intensive care unit (NICU) whose mothers were administered dexamethasone antenatally and a cross section study to evaluate the use of corticosteroids amongst staff in the maternity unit at UTH.

The prospective component measured clinical diagnosis of respiratory distress syndrome (RDS), necrotising enterocolitis (NEC), intra-ventricular haemorrhage (IVH) and sepsis in the neonate. The cross section component measured knowledge regarding antenatal corticosteroids, factors affecting use of dexamethasone and prescription trends.

Results: More than two-thirds (68%) of the enrolled neonates were delivered less than 24 hours after dexamethasone had been administered to the mother. The neonates that had birth weight less 2000 grams were 76%. Over half (58%) of enrolled neonates were delivered due to premature labour without an identifiable cause. The incidence of RDS was 25.9% (95% CI 20.03-31.77); sepsis was also 25.9% (95% CI 20.03 – 31.77). Almost half the neonates had no complications (47%; 95% CI 41.13 – 52.87). There was only one case of NEC and there was no occurrence of IVH recorded. The occurrence of complications among neonates whose mothers received the 6 mg regimen and those who received the 12 mg was 56.8% and 45.2% respectively. The occurrence of RDS was 29% among neonates whose mothers received regime 6mg and 12% among those who received 12mg. The maternal HIV-status (18%) was similar to the prevalence in the general population and HIV status was not associated with neonatal complications. Delivery by caesarean section seemed to have a higher occurrence of RDS (29.2%) than delivery by SVD (22.8%). The incidence of very low Apgar score for neonates delivered by SVD was 12.3% and 4% for babies born by caesarean section.

During the same period, 56 health-workers were interviewed. The three major factors affecting the non-use of dexamethasone were shortage of the drug (37.5%), patients coming in advanced labour (21.4%) and health workers forgetting to prescribe (10.7%). The prevalence of above average knowledge regarding the use of corticosteroids in pregnancy among health-workers was 93.6%.

Conclusions: The neonatal complication rate in neonates whose mothers had received antenatal corticosteroids was high, at 53%. However, the majority of deliveries occurred less than 24 hours before dexamethasone could take effect. Apart from the use of corticosteroids, several other factors affect the outcomes of babies born premature. Problems of the health system, compounded by either health-workers' forgetfulness or substandard-care, were the major factors affecting the non-use of antenatal corticosteroids.

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LIST OF ABBREVIATIONS AND ACRONYMS

HIV - Human Immune-deficiency Virus

IVH – Intra-ventricular Haemorrhage

ICU - Intensive Care Unit

NEC - Necrotising Entero-Colitis

NICU- Neonatal Intensive Care Unit

RDS - Respiratory Distress Syndrome

SPSS – Statistical Package for Social Scientists

UNZA – University of Zambia

UNZABREC – University of Zambia Biomedical Research Ethics Committee

UTH- University Teaching Hospital

WHO- World Health Organisation

1.0 INTRODUCTION

1.1 BACKGROUND

Neonatal mortality in most developing countries is as high as 30 per 1000 live births (UNICEF, 2010). One of the powerful interventions to reduce neonatal mortality is the administration of corticosteroids during the antenatal period for pregnant women at high risk of premature delivery (NIH consensus, 1994). Despite the evidence gathered from several studies, the utilisation of antenatal corticosteroids among mothers with preterm labour in developing countries is below 30% (WHO, 2010).

From 1972 onwards, when Liggins et al showed that corticosteroids prevent RDS, several other studies have been done in developed countries to study antenatal corticosteroids. Developing countries like Tunisia, Brazil and South Africa have also performed similar studies involving more than 4000 pregnant women at risk of preterm labour (Amorin et al, 1999; Fekih et al, 2002; Pattison et al, 1999; Qublan et al, 2001). The results showed relative reduction in respiratory distress syndrome (RDS), intraventricular haemorrhage (IVH) and neonatal mortality. In South Africa, it was found that low utilisation of corticosteroids was a major drawback and concluded that neonates in developing countries receive little or no care (Kambafwile et al, 2010).

The purpose of this research was to study how antenatal corticosteroids were used to prevent RDS and other related complications in premature babies at University Teaching Hospital. Further, the research covered the study of the outcomes of neonates whose mothers received corticosteroids during the antenatal period. The component evaluating the use of corticosteroids covered the type of corticosteroid that was being used at the time, the dosages being prescribed and the gestation ages for which it was being prescribed. In part, the study also investigated the knowledge of health-workers regarding the commonly used corticosteroid. The component of the research that studied outcomes of neonates involved following up neonates that were admitted to the neonatal intensive-care-unit. All neonates enrolled were followed up for, either to the first 28 days or to the date of discharge (for those discharged before the 28th day). The primary outcomes were respiratory distress syndrome, intraventricular haemorrhage and sepsis.

1.2. STATEMENT OF THE PROBLEM

Antenatal corticosteroids have been found effective in reducing respiratory distress syndrome for premature babies. Despite this fact, a preliminary survey conducted at UTH revealed that 25% of neonates admitted to NICU, whose mothers were eligible to receive antenatal corticosteroids, were not given dexamethasone. The World Health Organisation also reported that the rate of corticosteroid use in developing countries was below 30% (WHO, 2010). This is short of the WHO recommended coverage of 80% antenatal corticosteroids for premature labour.

1.3. STUDY JUSTIFICATION

Different studies show that corticosteroids have significant benefit in improving neonatal outcome. Knowing about neonatal outcomes at UTH could help improve health service delivery. Further, an understanding of the knowledge and attitudes of health-care providers towards preterm labour and the role of corticosteroids can help in designing interventions to improve perinatal management. Several studies of this nature have been done in other parts of the world but not in local setting of UTH.

2.0. LITERATURE REVIEW

Numerous studies investigating the effect of antenatal administration of corticosteroids on neonatal outcome have been carried out in different parts of the world; most of which have been in the developed countries. The outcomes of these studies summarised below suggest that antenatal administration of corticosteroids improve neonatal outcome in premature delivery by reducing the incidence of respiratory distress syndrome.

In 1972, Liggins and Howie conducted a controlled trial to investigate the outcome of antepartum-glucocorticoid treatment for prevention of respiratory distress syndrome in premature infants. The research was conducted in New Zealand, University of Auckland. This study involved the use of betamethasone on 282 mothers in whom premature delivery was threatened or was planned before 37 weeks with the hope of reducing neonatal respiratory distress by accelerating functional maturation of the lung. Two hundred and thirteen mothers were in spontaneous premature labour. Whenever indicated, tocolytics that included salbutamol and ethanol were used to delay delivery while either corticosteroid or placebo was being administered. Delay for a minimum of 24 hours was achieved in 77% of the patients. In these unplanned deliveries neonatal group neonatal mortality was 3.2% in the treated group and 15.0% in the control group (p 0.01). There were no deaths with respiratory distress syndrome or intraventricular cerebral haemorrhage in infants of mothers who had received betamethasone at least 24 hours before delivery. The respiratory distress syndrome occurred less often in treated babies (9.0%) than in the controls (25.8%, p 0.003), but the difference was restricted to babies of below 32 weeks gestation who had been treated for at least 24 hours before delivery (11.8% of the treated babies compared with 69.9% of the control babies p 0.02). They concluded that preliminary evidence justified further trials

A study was conducted by Bronstein et al (1988) between 1983 and 1986 at University of Alabama, USA to assess the relationship between clinical demographic and site-of-care factors and the use of tocolysis and corticosteroid therapy in the treatment of premature labour. Of 4,625 episodes of labour occurring before 37 weeks gestation were identified from either preterm labour or preterm delivery records recorded for the 33,792 women enrolled in the trial. Logistic regression analysis was used in assessing the clinical, patient and care-site factors associated with the use of tocolysis and corticosteroid therapy during episodes of premature labour occurring to women enrolled in the trial. The findings were

that the use of tocolysis, an intervention that attempts to control premature labour contractions and that was widely used in high-risk obstetrics, varied almost exclusively by clinical factors. The use of corticosteroid therapy, a little used but effective intervention that reduces respiratory complications in premature infants, varied significantly by site of care and was used less frequently across sites and clinical conditions for minority group patients. The study concluded that practice variation based on non-clinical factors occurs more commonly for interventions where there is more uncertainty about clinical indications and effectiveness.

In 1990, Crowley et al summarised her evidence from overview of controlled trials. Data from 12 controlled trials, involving over 3000 women, showed that corticosteroids reduce occurrence of respiratory distress syndrome overall and all subgroups of trial participants that were examined. The reduction in respiratory distress syndrome was associated with reduction in the risk of intraventricular haemorrhage, necrotizing enterocolitis and neonatal death. There was no strong evidence suggesting adverse effects of corticosteroids. The risk of foetal and neonatal infection may be raised if corticosteroids are administered after prolonged rupture of membranes, though this possibility was not substantiated by the results of the available trials. The available data on the long-term follow-up suggested that the short-term beneficial effects of corticosteroids might be reflected in reduced neurological morbidity in the long term.

In 1995 in South Africa, at the Johannesburg Hospital, Ballot et al (1995) conducted a retrospective study involving 101 preterm infants delivered at this hospital. The aim of the study was to determine the use of antenatal corticosteroids. Out of the 38 opportunities to use antenatal corticosteroids, 18 (47%) opportunities were missed. Of the remaining mothers, 32 presented in advanced labour, 22 presented with obstetric emergencies and six were managed as inevitable abortions. A significant association was reported between lack of antenatal care and presenting in advanced labour. The researchers concluded that even though only 20% of the mothers received antenatal corticosteroids, there was no opportunity for their use in the majority of patients.

In 1998, Quinlivan et al conducted a survey in Australia that involved 1281 fellows, members and trainees of the Royal Australian College of Obstetricians and Gynaecologists resident in Australia. Each one received a questionnaire concerning their practice of prescribing corticosteroids. Out of the total number interviewed, 833 (65%) responded.

The key findings were that 97% of Australian obstetricians prescribe antenatal corticosteroids in the classical setting of uncomplicated early preterm labour and 85% prescribe repeated courses in those cases in which the risk of preterm labour persists or recur; 50% of obstetricians prescribe this agent weekly in cases with persisting risk of preterm birth. Some of prescribing practices were found to be related to the number of years since obtaining specialist qualification.

Another study was conducted in North America on 710 neonates born at 25-32 weeks of mothers enrolled in a study of multiple courses of antenatal corticosteroids and outcome of premature neonates (Banks et al, 1999). The study design was a post hoc non-randomised analysis on neonates who had received one, two, three or more doses of antenatal corticosteroids. Results showed that there was no detectable difference in the incidence of respiratory distress syndrome, chronic lung disease and intraventricular haemorrhage related to the antenatal corticosteroids. The outcomes were also similar for infants delivered at 7-14 days with those delivered at 1-6 days after receiving antenatal corticosteroid. Neonates who received two or more doses of antenatal corticosteroid had a lower birth weight than those who only received one dose (39g less, $p = 0.02$). Those neonates who received three or more doses had an increased risk of death (adjusted odds ratio, 2.8; 95% confidence interval 1.3-5.9, $p = 0.1$) and lower levels of plasma cortisol at age 2 hours. The authors concluded that multiple doses of antenatal corticosteroids did not improve neonatal outcome but was associated with increased risk of death, decreased foetal growth and prolonged suppression of adrenal glands.

In another review, the Reproductive Health Library (RHL) reported evidence concerning the effect of repeat antenatal corticosteroid doses in accelerating foetal lung maturity (WHO, 2009). This review included five trials involving 2028 women. In all the five trials, repeat corticosteroid was given to women who had earlier received the first dose seven or more days earlier. Four trials used two doses of betamethasone 12 mg intramuscularly while one trial used a single dose repeated weekly. One or more repeat doses of corticosteroids were associated with reduced severe lung disease (RR 0.60; 95 CI 0.48-0.75) serious infant morbidity (RR 0.79; 95 CI 0.67-0.93). In one trial, there was reduced birth weight (RR - 0.13; 95 CI 0.26-0.00) and in two trials there was an increased chance of being small for the gestation age at birth (RR 1.63; 95% CI 1.12-2.37). The authors concluded that while repeat doses were associated with short-term benefits of reduced respiratory distress there was insufficient evidence regarding potential risks.

The WHO Reproductive Health Library (RHL) reported evidence based on three Cochrane reviews that antenatal administration of corticosteroids has reduced neonatal complications such as respiratory distress syndrome, necrotising enterocolitis, cerebral haemorrhage, systemic infections, and childhood developmental and neonatal death (WHO, 2010). This Cochrane review included 21 studies involving 3885 women and 4269 infants. The article further reports that these benefits are found when treatment is commenced between 26 and 35 weeks gestation age, and for babies born 1-7 days after commencing treatment. Further, the regimens found to be effective included betamethasone 12mg intramuscularly two doses 24 hours apart; or dexamethasone 6mg given four doses that are 12 hours apart.

A study conducted by a team of Dutch researchers at Maastricht University Medical centre reported that results of a meta-analysis indicate that antenatal corticosteroids seem safe and reduce adverse outcomes in preterm infants when pregnancy is complicated with chorioamnionitis (Saunders, 2010). The authors report that even though it has become standard to give corticosteroids when premature labour is anticipated general concern exists regarding the administration of corticosteroids when intrauterine infection is suspected. Intrauterine infections range from 10 to 15%. In most clinical trials of maternal corticosteroids, these have been excluded due to fears of adverse outcomes resulting in lack of data. The researchers analysed data from seven relevant observational studies and randomised controlled trials that either excluded patients with chorioamnionitis or did not report a subgroup analysis for this group. A histological diagnosis of chorioamnionitis after birth and a clinical diagnosis before birth were available because of important diagnostic differences between the two. In histological chorioamnionitis corticosteroids administered during antenatal was associated with reduced mortality (odds ratio 0.45), respiratory distress syndrome (OR 0.53), patent ductus arteriosus (OR 0.56) and intraventricular haemorrhage (0.53). On the other hand, cases of clinical chorioamnionitis antenatal corticosteroids were associated with significant reduction in intraventricular haemorrhage (OR 0.29) and preriventricular leucomalacia (OR 0.35). The researchers concluded that antenatal corticosteroids were not associated with adverse outcomes in their setting but they recommended for further studies on the long term outcomes on both the mother and foetus.

Kambafwile et al reported in 2010 from South Africa in her systemic review of the role of antenatal corticosteroids in prevention of neonatal death in low, middle and high-income

countries that antenatal corticosteroids are very effective in reducing neonatal morbidity and mortality. The review further reported low coverage in the utilization of corticosteroids in premature labour as a major drawback in low and middle-income countries. This study identified 44 studies, including 18 randomised control trials (14 of these in high income countries) in a Cochrane meta-analysis, suggested that antenatal corticosteroids reduced neonatal mortality among preterm infants by 31% (RR 0.69; 95% CI 0.58- 0.81). A new meta-analysis of four randomised control trials from middle-income countries suggests a 53% reduction in mortality (RR 0.47; 95% CI 0.35-0.64) and 37% reduction in morbidity (RR = 0.63; 95% CI 0.49-0.81). Observational mortality data was consistent. The control group in these studies was standard care, which involved standard ventilation and surfactant in some cases. Results further showed that in low-income countries preterm babies receive little or no care.

At the University Teaching Hospital, dexamethasone is the drug used in high risk for preterm delivery. The eligible gestation-age range has changed from 28-34 weeks previously, to the current 24-36 weeks. A variety of dosages of dexamethasone given intramuscularly are prescribed and include; 12mg BD, 12.5mg BD, 25mg start and 6mg given four doses every twelve hours. However, the outcomes of babies whose mothers received dexamethasone are not known.

3.0 STUDY DEFINITIONS

3.1. Corticosteroid

A class of chemicals that include steroid hormones involved in a wide range of physiological processes including stress response, immune response and regulation of inflammation, carbohydrate metabolism, protein catabolism and blood electrolyte levels.

3.2. Respiratory Distress Syndrome

A condition that affects prematurely born infants characterised by rapid breathing rate, intercostals recession, blood gas reflecting oxygen deficiency, excessive blood carbon dioxide and acidosis and could be due immature lungs.

3.3. Intra-ventricular haemorrhage

This is bleeding inside or around small fluid-filled chambers in the brain called ventricles.

3.4. Necrotising Entero-Colitis

This is a condition seen in premature infants where portions of bowel undergo necrosis and characterised by feeding intolerance, increased gastric residuals, abdominal distension, bloody stools, abdominal discolouration, intestinal perforation, peritonitis and systemic hypotension.

3.5. Neonatal Sepsis

This is the presence in a neonate of bacterial stream infection (meningitis, pneumonia, pyelonephritis or gastroenteritis) in the setting of fever.

3.6. Ante-partum haemorrhage

This is defined as bleeding from the birth canal after the 24th week of pregnancy. It can occur at any time until the second stage of labour is complete.

3.7. Apgar score

This a score that rates a baby's physical condition soon after delivery. It assesses physical activity, pulse, grimace, appearance and respiration at one and five minutes.

3.8. Gestation age

Relates to the age of an embryo or foetus (often calculated from last menstrual period)

4.0. RESEARCH QUESTIONS AND STUDY HYPOTHESES

4.1 Research Question

4.1.1. How are antenatal corticosteroids used at UTH?

4.1.2. What are the outcomes for the babies whose mothers received antenatal corticosteroids?

4.2 Study hypotheses

4.2.1 **A. Null hypothesis:** The use of antenatal corticosteroids for women at risk of premature delivery to prevent respiratory distress syndrome is **good**.

4.2.1 **B. Alternate hypothesis:** The use of antenatal corticosteroids for women at risk of premature delivery to prevent respiratory distress syndrome is **poor**.

4.2.2 **A. Null hypothesis:** The incidence of neonatal complications among neonates born of mothers who **do not receive** antenatal corticosteroids to prevent respiratory distress syndrome is high.

4.2.2 **B. Alternate hypothesis:** The incidence of neonatal complications among neonates born of mothers **who receive** antenatal corticosteroids to prevent respiratory distress syndrome is low.

5.0. OBJECTIVES

5.1. General Objectives

To study the use of antenatal corticosteroids and outcomes at University Teaching Hospital of neonates born to mothers who received antenatal corticosteroids for premature labour.

5.2. Specific Objectives

The following were investigated:

1. Factors influencing corticosteroid use in impending premature delivery.
2. The outcome of neonates whose mothers received antenatal corticosteroids due to premature delivery.
3. The knowledge of healthcare providers regarding steroid use for premature delivery.

6.0. METHODOLOGY

Target population

1. All pregnant women, ones seeking antenatal services and those presenting to the labour ward for delivery services or Obstetrical/Gynaecological ward for management of complications.
2. Health workers designated in maternity unit formed part of the target population.

Study population

1. Antenatal mothers who had received dexamethasone and their neonates.
2. Skilled health workers designated to maternity unit.

Study Design

This research had two components - a prospective cohort and a cross section study. The follow up component of the study involved women identified as at high risk for premature delivery and had received dexamethasone. These were asked to participate after being given information about the study. Those who accepted to participate were followed to delivery and the babies that were admitted to neonatal ICU were enrolled into the study. These babies were followed to discharge-day, day of death or up to 28th day. Diagnosis of neonatal complications was done by the attending neonatologist and this was taken as an outcome. At any of the three exit points above, an interviewer administered questionnaire was completed. Regarding the cross sectional component, a self-administered questionnaire was distributed to four gynaecological wards and six obstetric wards. Each ward received eight questionnaires that were distributed through a focal point person. Receipt of the completed questionnaire remained open until the last month of data collection, 1st December 2012.

ELIGIBILITY CRITERIA

Inclusion Criteria for neonates

1. Mother received at least one dose of dexamethasone antenatally at UTH.
2. Maternal age 16 years and above. If below 18 years, required consent to be given by an adult relative.
3. Less than 36 weeks gestation
4. Labour together with delivery occurred within UTH.
5. At delivery, there was a live birth.
6. Birth weight between 500 and 2500g.
7. The neonate was admitted to NICU at UTH.
8. Neonate was less than 28 days old.

Exclusion Criteria for neonates

1. Babies born with a life-threatening congenital abnormality.
2. Neonate delivered with a birth-weight of < 500 grams or > 2500 grams.
3. No signs of life on arrival at NICU.
4. Neonates delivered outside UTH.

Inclusion Criteria for health workers

1. Skilled health-worker working in the Department of Obstetrics and Gynaecology at UTH.

Exclusion Criteria for health workers

1. Skilled health-worker not working in the Department of Obstetrics and Gynaecology at UTH.
2. Non-Skilled health-worker.

SAMPLE SIZE CALCULATION FOR NEONATES

The prevalence formula was used to calculate the sample size of the neonates to be followed in NICU. The prevalence of prematurity was taken from the literature to be 0.06, which was used to estimate the sample size to be 84.3, rounded off to 85 neonates. Systematic method was used to enrol every other woman presenting with preterm labour. The number of mothers to be enrolled in the study was not certain at the beginning of the study because babies who were going to be admitted to neonatal ICU were only known after delivery. To enrol 85 neonates, more than 130 pregnant women with high risk for premature delivery were followed until delivery.

Sample size calculation for health workers

The number of health-workers invited for participation in the study was estimated at half of the total number of skilled health workers designated in maternity unit. At the time, the register had 150 health workers on it. The calculation of 50% translated into 75 health workers. A total of 80 questionnaires were printed. Purposeful sampling was used, initially having distributed an equal number of questionnaires among the eight wards. The health workers volunteered to complete the questionnaires. In some wards, the response rate was 100% where as in other wards it was much less than 50%. The questionnaires that were not completed in some wards were redistributed to other wards.

Sampling neonates

Systematic method was used to select every other woman, among those who presented with high risk for preterm-delivery, who were followed to delivery and enrolled babies who were admitted to NICU. The neonates that did not get admitted to NICU had no further follow up and nothing was documented on these babies and their mothers. Neonates whose mothers did not consent to their enrolment were excluded.

Outcome measures

The primary outcome measure of the study was the presence or absence of complications (RDS, IVH, NEC, sepsis) for each neonate admitted to ICU. This was a clinical diagnosis, with or without radiological backup, made by the neonatologists.

The secondary outcome measure was the occurrence of neonatal death.

Statistical analysis

Prior to collection of data the questionnaires were tested on ten pregnant women that went on to deliver. Wherever flaws were identified, they were corrected. Upon completion of data collection, each data form was checked for completeness and. In case of incomplete data, either file number on the antenatal record or file number on neonatal record was used to retrieve the data item. Collected data was entered into Statistical Package for Social Scientists (SPSS) version 17.0 and analysed by the investigator. The general characteristics were subjected to descriptive and analytical assessment. Initially, the numbers and prevalence of neonatal complications and respective confidence intervals were tabulated. Then, neonatal complication was treated as a dependent variable and its relationship with eleven other variables studied by chi-square for categorical variables.

Data collected from the corticosteroid use was tabulated and descriptive analysis done. The factors affecting the use of dexamethasone was tabulated in a table and percentages calculated. Trends of dexamethasone prescription were stratified according to health-workers' level of qualification and the ability to prescribe the correct dosage of dexamethasone was also stratified according to the length of time worked in maternity unit. This was then presented in a table. Health workers' knowledge about dexamethasone was graded into four categories: very good, good, fair and poor. This was then tabulated in a table and plotted in a bar chart.

Ethical considerations

Ethical approval was sought and obtained from the University of Zambia Biomedical Research Ethics Committee. This was done before commencing enrolment of participants and data collection. Consent was sought from eligible participants before they were enrolled. Client confidentiality was maintained throughout the study and the identities of the participants were only known by core study staff. Members of UNZABREC also have access to participant identity.

The main ethical issue in this observational study was confidentiality, which was well maintained. Customs in local communities associate prematurity with problems of development. Some women did not want it to be known that their baby was admitted in neonatal ICU.

7.0. RESULTS - PART 1: NEONATAL OUTCOME

A total of 85 neonates were enrolled during the antenatal period and were followed for the first 28 days of their life or to either date of discharge or death. All these babies were born of mothers who had received dexamethasone injection during the antenatal period. Only mothers who had agreed to have their babies participate in the study were followed up to the time of delivery. No further follow up was made on the mothers after delivery and there was no further documentation. The women whose babies were not admitted to neonatal ICU fall off completely and no record was kept on them and their babies. The period of enrolment was from March 2012 to December 2012.

Of the 85 neonates, 40 (47%) did not have complications, 22 (25.9%) had sepsis and the other 22 (25.9%) had respiratory distress. Only one baby had necrotising enterocolitis (Table 1). There was no neonate diagnosed with intra-ventricular haemorrhage.

Table1. Number and percentage of outcomes among neonates.

Neonatal outcome	Number	Percentage	Confidence interval
RDS	22	25.9	20.03-31.77
Sepsis	22	25.9	20.03-31.77
NEC	1	1.2	0-7.07
No complication	40	47	41.13-52.87
Total	85	100	

A total number of 32 neonates (37.6%) died before 28 days. Out of those who died, 26 had complications and six did not have complications. However, the six neonates who did not have a complication but ended up dying may have been born with congenital problems that were not identified.

Table 2 below shows how complications occurred among neonates delivered by different methods of delivery. Of the 85 babies that were enrolled in the study, 57 (67%) were delivered by spontaneous vaginal delivery (SVD), 3 by assisted breech, 1 by instrumental delivery and 24 (28.2%) were delivered by caesarean section. The incidence of respiratory RDS among babies delivered by caesarean section, 29.2% (7), was higher than that of babies delivered by spontaneous vaginal delivery 22.8% (13). There were more babies delivered by SVD who did not have any complications, 28 (49%), compared with those delivered by caesarean section 11 (45.8%). The occurrence of sepsis among SVDs 26.3% (15) was slightly higher than those delivered by caesarean section 25% (6). Only one baby delivered by SVD suffered from the rare necrotising enterocolitis.

Table 2. Neonatal complications and mode of delivery

	NEONATAL COMPLICATIONS				Total n (column%) (row %)
	RDS n (column%) (row %)	NEC n (column%) (row %)	Sepsis n (column%) (row %)	No Complication n (column%) (row %)	
Mode Of Delivery Spontaneous Vaginal delivery	13 (59.1) (22.8)	1 (100) (1.8)	15 (68.2) (26.3)	28 (70) (49.1)	57 (67) (100)
Caesarean section	7 (31.8) (29.2)	0 (0) (0)	6 (27.3) (25.0)	11 (27.5) (45.8)	24 (28.2) (100)
Assisted Breech delivery	2 (9.1) (66.7)	0 (0) (0)	1 (4.5) (33.3)	0 (0) (0)	3 (3.5) (100)
Instrumental delivery	0 (0) (0)	0 (0) (0)	0 (0) (0)	1 (2.5) (100)	1 (1.2) (100)
Total	22 (100) (25.9)	1 (100) (1.2)	22 (100) (25.9)	40 (100) (47.1)	85 (100) (100)

	died	alive	total
Not caesarean	25	36	61
caesarean	7	17	24
all	32	53	85

Odds ratio of baby that did not have a caesarean dying = 1.69 (i.e. not having caesarean birth was 1.69 times more detrimental). Approximate 95% confidence interval = 0.61 to 4.66, non-significant (p=0.455).

Table 3 below shows how neonatal complications were distributed among the different Apgar scores at 5 minutes. The scores were divided into three blocks: very low, low and normal. Very low Apgar score had a prevalence of respiratory distress syndrome 55.6% (5) compared with good apgar 15.4%. The occurrence of respiratory distress syndrome among babies with low apgar was also low 37.5% (9). A low apgar score was associated a higher occurrence of sepsis 33.3% (8) compared with a good apgar score 25% (13). There were more babies born with no complications in the good apgar score-group 30 (57.9%) compared with low apgar score-group 7(29%). The only case of necrotising entero-colitis occurred among the category with good Apgar score.

Table 3. Apgar scores at five minutes and neonatal complications.

	NEONATAL COMPLICATIONS				Total N (column%) (row %)
	RDS n (column%) (row %)	NEC n (column%) (row %)	Sepsis n (column%) (row %)	No Complication n (column%) (row %)	
Apgar score very low apgar at 5 minutes score (up to 4)	5 (22.7) (55.6)	0 (0) (0)	1 (4.5) (11.1)	3 (7.5) (33.3)	9 (10.6) (100)
low apgar score (5,6,7)	9 (40.9) (37.5)	0 (0) (0)	8 (36.4) (33.3)	7 (17.5) (29.2)	24 (28.2) (100)
good apgar sore (8,9,10)	8 (36.4) (15.4)	1 (100) (1.9)	13 (59.1) (25)	30 (75) (57.7)	52 (61.2) (100)
Total	22 (100) (25.9)	1 (100) (1.2)	22 (100) (25.9)	40 (100) (47.1)	85 (100) (100)

	died	alive	total
Apgar score 7 or less	15	18	33
Good Apgar score	17	35	52
all	32	53	85

Odds ratio of baby that had Apgar score 7 or less dying = 1.72 (i.e. having a poor Apgar score at 5 minutes is detrimental). Approximate 95% confidence interval = 0.7 to 4.21, non-significant (p=0.34)

Table 4 below shows the distribution of neonatal complications among the different groups of gestation ages at which neonates were born. Respiratory distress syndrome among neonates born less 29 weeks was 53% (8) compared with babies born between 29 weeks and 36 weeks 21% (14). The number of neonates who developed sepsis for those delivered between 29 and 36 weeks was 17, 2 for those delivered below 29 weeks and three for those delivered at unknown gestation age. The incidence of having no-complications for neonates delivered between 29 and 36 weeks gestation was 51% (33).

Table 4. Neonatal complications and gestation age

	NEONATAL COMPLICATIONS				Total n (column%) (row %)
	RDS n (column%) (row %)	NEC n (column%) (row %)	Sepsis n (column%) (row %)	No Complication n (column%) (row %)	
GESTATION AGE					
24 -28 weeks	8 (36.4) (53.3)	0 (0) (0)	2 (9.1) (13.3)	5 (12.5) (33.3)	15 (17.6) (100)
29 - 36 weeks	14 (63.6) (21.5)	1 (100) (1.5)	17 (77.3) (26.2)	33 (82.5) (50.8)	65 (76.5) (100)
Unknown	0 (0) (0)	0 (0) (0)	3 (13.6) (60)	2 (5) (40)	5 (5.6) (100)
Total	22 (100) (25.9)	1 (100) (1.2)	22 (100) (25.9)	40 (100) (47.1)	85 (100) (100)

	died	alive	total
Gestation 24-28wks	13	2	15
Gestation >28wks	18	47	65
all	31	49	80

Note, in 5 cases the gestation was not known

Odds ratio of baby that had a gestation 24-28 (compared to >28 weeks) dying = 16.97 (i.e. gestation 24-28 weeks is 17 fold detrimental compared to >28 weeks). Approximate 95% confidence interval = 3.48 to 82.79, significant (p<0.001).

Table 5 below shows the occurrence of neonatal complications among neonates born at different times of the day. Most of the babies were born in the morning 30 (35.3%), followed by nighttime 29 (34.1%) and the least number 26 (30.6%) were born in the morning. Among those born in the morning, 5 (16.7%) had RDS, 6 (20%) had sepsis, 18 (60%) had no complication and one had NEC. Among babies born in the afternoon, 6 (23%) had RDS, 7 (26.9%) had sepsis and 13 (50%) had no complication. The neonates delivered at night had the following complications; 11 (37.9%) had RDS, 9 (31%) had sepsis and the other 9 had no complication

Table 5. Time of day at which delivery occurred and neonatal complications.

		NEONATAL COMPLICATIONS				Total N (column%) (row %)
		RDS n (column%) (row %)	NEC n (column%) (row %)	Sepsis n (column%) (row %)	No Complication n (column%) (row %)	
Time of delivery	Morning	5 (22.7) (16.7)	1 (100) (3.3)	6 (27.3) (20)	18 (43.9) (60)	30 (35.3) (100)
	afternoon	6 (27.3) (23.1)	0 (0) (0)	7 (31.8) (26.9)	13 (32.5) (50)	26 (30.6) (100)
	Night	11 (50) (37.9)	0 (0) (0)	9 (40.9) (31)	9 (22.5) (31)	29 (34.1) (100)
Total		22 (100) (25.9)	1 (100) (1.2)	22 (100) (25.9)	40 (100) (47.1)	85 (100) (100)

	died	alive	total
After regular hours	24	35	59
Regular hours	8	18	26
all	32	53	85

Regular hours = 08:30-16:30 hrs. Out of regular hours = rest of day
Odds ratio of baby dying if born after regular hours = 1.54. Approximate 95% confidence interval = 0.58 to 4.12, non-significant (p=0.531).

Table 6 below shows how neonatal complications occurred among the different weight categories. The occurrence of RDS was highest among the extremely low-birth-weight category 69.2% (9) followed by the low birth weight group 25% (13). No neonate among the normal weight group had respiratory distress syndrome (Table 6). The prevalence of sepsis among normal-weight category was 45% (9) and 23% (12) among the low-birth weight category. The extremely low-birth-weight category had three (23%) with no complications while normal-weight group and low-birth-weight category had 11(55%) and 26 (50%) respectively.

Table 6. Categories of birth weight and neonatal complications

		NEONATAL COMPLICATIONS				Total n (column%) (row %)
		RDS n (column%) (row %)	NEC n (column%) (row %)	Sepsis n (column%) (row %)	No Complication n (column%) (row %)	
weight category	Extremely low birth weight <1000g	9 (40.9) (69.2)	0 (0) (0)	1 (4.5) (7.7)	3 (7.5) (23.1)	13 (15.3) (100)
	low birth weight <2000g	13 (2.9) (25)	1 (100) (1.9)	12 (54.5) (23)	26 (65) (50)	52 (61.2) (100)
	Normal birth weight >2000g	0 (0) (0)	0 (0) (0)	9 (40.9) (45)	11 (27.5) (55)	20 (23.5) (100)
Total		22 (100) (25.9)	1 (100) (1.2)	22 (100) (25.9)	40 (100) (47.1)	85 (100) (100)

	died	alive	total
<2000g	29	36	65
>2000g	3	17	20
all	32	53	85

Odds ratio of baby that had a birth weight <2000g (compared to birth weight > 2000) dying = 4.56. Approximate 95% confidence interval = 1.22 to 17.11, significant (p=0.033).

Table 7 below depicts how neonatal complications occurred among neonates in relation to the dosing regimen of dexamethasone received during the antenatal period. The number of neonates who developed RDS among those who received 12 mg twice per day was 4, and 11 (29.7%) for those who received 6 mg every 12 hours. Among the neonates who received 25 mg single dose, the number of those who developed RDS was two and five for those who received 12.5 mg twice per day. The number of neonates with sepsis was 10 (32.3%) among neonates receiving 12 mg twice per day and nine (24.3%) for those who received 6 mg every 12 hours. The prevalence of no-complication among neonates who received 6 mg every 12 hours was 43.2% (16) and 54.8% (17) among those who received 12 mg twice per day. The number of no-complication among neonates who received the single dose 25 mg was three and four among neonates who received 12.5 mg twice per day.

Table 7. Neonatal complications and dexamethasone dosage

	NEONATAL COMPLICATIONS				Total n (column%) (row %)
	RDS n (column%) (row %)	NEC n (column%) (row %)	Sepsis n (column%) (row %)	No Complication n (column%) (row %)	
Dexamethasone 12 mg BD Dosage	4 (18.2) (12.9)	0 (0) (0)	10 (45.4) (32.3)	17 (42.5) (54.8)	31 (36.5) (100)
25 MG Stat	2 (9.1) (28.6)	0 (0) (0)	2 (9.1) (28.6)	3 (7.5) (42.9)	7(8.2) (100)
12.5mg BD	5 (22.7) (50)	0 (0) (0)	1 (4.5) (10)	4 (10) (40)	10 (11.8) (100)
6 mg 12 hourly, 4 doses	11 (50) (29.7)	1 (100) (2.7)	9 (40.9) (24.3)	16 (40) (43.2)	37 (43.5) (100)
Total	22 (100) (25.9)	1 (100) (1.2)	22 (100) (25.9)	40 (100) (47.1)	85 (100) (100)

	died	alive	total
25mg in other combinations	18	30	48
6mg bd 4 doses	14	23	37
all	32	53	85

Odds ratio of baby that had 4 doses of 6mg given 12 hours apart (compared with baby that had 12mg BD, 25 mg start or 12.5 mg BD) dying = 0.99. Approximate 95% confidence interval = 0.41 to 2.39, non-significant (p>0.999).

Table 8 below shows the distribution of neonatal complications in relation to the three categories of duration of action of dexamethasone. The number of neonates with duration of action less than 24 hours was 58 (68%) and 21 (24.7%) for neonates with duration of one week. Only six neonates had duration of more than one week. Among neonates with duration less than 24 hours, the prevalence of RDS was 24% (14), sepsis 22.4% (13) and 51.7% (30) no complication. Duration of action of one week had an equal distribution of seven neonates who developed RDS, sepsis and no-complication. In the category of duration of action greater than one week, there were six babies with one developing RDS, two had sepsis and three had no complication.

Table 8. Duration of action of dexamethasone and neonatal complications.

		NEONATAL COMPLICATIONS				Total n (column%) (row %)
		RDS n (column%) (row %)	NEC n (column%) (row %)	Sepsis n (column%) (row %)	No Complication n (column%) (row %)	
Duration of action of Dexamethasone	Less than 24 hrs	14 (63.6) (24.1)	1 (100) (1.7)	13 (59.1) (22.4)	30 (75) (51.7)	58 (68.2) (100)
	Between 1 and 7 days	7 (31.8) (33.3)	0 (0) (0)	7 (31.8) (33.3)	7 (17.5) (33.3)	21 (24.7) (100)
	More than 7 days	1 (4.5) (16.7)	0 (0) (0)	2 (9.1) (33.3)	3 (7.5) (50)	6 (7.1) (100)
Total		22 (100) (25.9)	1 (100) (1.2)	22 (100) (25.9)	40 (100) (47.1)	85 (100) (100)

	died	alive	total
Dexamethasone less than 24 hrs	26	32	58
>24 hours	6	21	27
all	32	53	85

Odds ratio of baby that had dexamethasone less than 24 hours before delivery (Compared with baby delivered more than 24 hours of dexamethasone injection) dying = 2.84. Approximate 95% confidence interval = 1.00 to 8.08, not significant (p=.078).

Table 9 below depicts the distribution of complications in relation to maternal HIV status. The prevalence of maternal HIV was 18.8% (16). Out of the 16 neonates born of reactive mothers, 6 (37.5%) had RDS, 4 (25%) had sepsis and six (37.5%) had no complication. Of the 67 neonates born of non-reactive mothers, 15 (22.4%) had RDS, 1 (1.5%), 18 (26.9%) had sepsis and 33 (49%) had no complication. 2 neonates were born of mothers with unknown HIV status; one developed RDS and one had no complication.

Table 9. Neonatal complications and maternal HIV status

	NEONATAL COMPLICATIONS				Total n(column %) (row %)
	RDS n (column %) (row %)	NEC n(column %) (row %)	Sepsis n (column %) (row %)	No Complication n (column %) (row %)	
HIV STATUS Reactive	6 (27.3) (37.5)	0 (0) (0)	4 (18.2) (25)	6 (15) (37.5)	16 (18.8) (100)
Non-reactive	15 (68.2) (22.4)	1 (100) (1.5)	18 (81.8) (26.9)	33 (82.5) (49.2)	67 (78.8) (100)
Unknown	1 (4.5) (50)	0 (0) (0)	0 (0) (0)	1 (2.5) (50)	2 (2.3) (100)
Total	22 (100) (25.9)	1 (100) (1.2)	22 (100) (25.9)	40 (100) (47.1)	85 (100) (100)

	died	alive	total
HIV Positive	6	10	16
HIV negative	25	42	67
all	31	52	83

Odds ratio of baby whose mother was HIV positive (compared with baby whose mother was HIV negative) dying = 1.01. Approximate 95% confidence interval = 0.33 to 3.11, not significant ($p>0.999$).

Table 10 below shows graph of neonatal complications distributed according to either presence or absence of chronic maternal disease. Out of the 85 neonates enrolled in the study, five were born of mothers with a pre-existing chronic disease (including chronic hypertension, asthma, and diabetes mellitus), two of the five neonates developed sepsis, 1 had RDS and two had no complication. On the other hand, 38 (47.5%) neonates born of mothers with no pre-existing disease had no complication, 20 (25%) had sepsis, 21 (26.2%) had RDS and one had NEC.

Table 10. Neonatal complications and maternal chronic disease

	NEONATAL COMPLICATIONS				Total N (column %) (Row %)
	RDS N (column %) (Row %)	NEC N (column %) (Row %)	Sepsis N (column %) (Row %)	No Complication N (column %) (Row %)	
Maternal No Disease	21 (95.4)	1 (100)	20 (90.9)	38 (95)	80 (94.1)
Chronic Disease	(26.2)	(1.25)	(25)	(47.5)	(100)
With Disease*	1 (4.5)	0 (0)	2 (9.1)	2 (5)	5 (5.9)
	(20)	(0)	(40)	(40)	(100)
Total	22 (100) (25.9)	1 (100) (1.2)	22 (100) (25.9)	40 (100) (47.1)	85 (100) (100)

*Chronic hypertension, asthma, diabetes mellitus

	died	alive	total
Maternal Chronic Disease	2	3	5
No Maternal Chronic Disease	30	50	80
all	32	53	85

Odds ratio of baby whose mother had chronic disease (compared with baby whose mother had no chronic disease) dying = 1.11. (Using Fischer's Exact Test) Approximate 95% confidence interval = 0.13 to 7.86, not significant (p=.45).

Table 11 below shows the distribution of neonatal complications among four different causes of birth. Out of the 50 (58.8%) neonates born due to premature labour, 16 (18%) had RDS, 10 (11.8%) had sepsis, 1 (1.2%) had NEC and 23 (27%) had no complication. A total of 28 (32.9%) neonates were born due to hypertensive disorders, 5 (17.9%) of these had RDS, 9 (32.1%) had sepsis and 14 (50%) had no complication. Neonates delivered due to ante-partum haemorrhage were only seven, out of which one (1.2%) had RDS, 3 (42.9%) had sepsis and the other three (42.9%) had no complication. No neonate was delivered due to chorioamnionitis.

Table 11. Cause of premature birth and neonatal complications.

	NEONATAL COMPLICATIONS				Total N (column %) (Row %)
	RDS N (column %) (Row %)	NEC N (column %) (Row %)	Sepsis N (column %) (Row %)	No Complication N (column %) (Row %)	
Condition Antepartum	1 (4.5)	0 (0)	3 (13.6)	3 (7.5)	7 (8.2)
Leading Haemorrhage	(14.3)	(0)	(42.9)	(42.9)	(100)
To Hypertensive	5 (22.7)	0 (0)	9 (40.9)	14 (35)	28 (32.9)
Delivery Disorder	(17.9)	(0)	(32.1)	(50)	(100)
Unknown	16 (72.7)	1 (100)	10 (45.4)	23 (57.5)	50 (58.8)
trigger	(32)	(2)	(20)	(46)	(100)
Total	22 (100) (25.9)	1 (100) (1.2)	22 (100) (25.9)	40 (100) (47.1)	85 (100) (100)

	died	alive	total
APH	3	4	7
No APH	29	49	78
all	35	53	85

Odds ratio of baby dying whose mother had APH = 1.27. (Using Fisher's exact test) 95% confidence interval = 0.17 to 8.05, not significant (p=.532).

	died	alive	total
Hypertensive Disorder	8	20	28
No Hypertensive Disorder	24	33	57
all	32	53	85

Odds ratio of baby dying whose mother had hypertensive disorder = 0.55. Approximate 95% confidence interval = 0.21 to 1.46, not significant (p=.331).

Table 12 above shows neonatal complications as related to status of neonate at exit from the study. A total of 48 (56.5%) babies were discharged from the study by the 28th day of life. Out of those discharged, five (10.4%) had been treated for RDS, 12 (25%) had sepsis, and 31 (64.6%) had no complication. A total of 32 (37.6%) neonates died and of those 16 (50%) had RDS, 9 (28.1%) had sepsis. Six of the neonates that died (19.8% of all that died) had no complication though 16 (50%) had RDS, 1 (3.1%) had NEC, and nine (28.1%) had sepsis. Only five neonates remained in the hospital at 28th day of their life; 1 (20) had RDS, 1 (20) had sepsis and three (60) had no complication.

Table 12. Neonatal complications and status at exit from the study

		NEONATAL COMPLICATIONS				Total n (column%) (row %)
		RDS n (column%) (row %)	NEC n (column%) (row %)	Sepsis n (column%) (row %)	No Complication n (column%) (row %)	
EXIT STATUS	Discharged	5 (22.7) (10.4)	0 (0) (0)	12 (54.5) (25)	31 (77.5) (64.6)	48 (56.5) (100)
	Still in the Hospital	1 (4.5) (20)	0 (0) (0)	1 (4.5) (20)	3 (7.5) (60)	5 (5.9) (100)
	Died	16 (72.7) (50)	1 (100) (3.1)	9 (40.9) (28.1)	6 (15) (19.8)	32 (37.6) (100)
Total		22 (100) (25.9)	1 (100) (1.2)	22 (100) (25.9)	40 (100) (47.1)	85 (100) (100)

	died	alive	total
Any neonatal complication	26	19	45
No neonatal complication	6	34	40
all	32	53	85

Odds ratio of baby dying if had any neonatal complication = 7.75 (baby with neonatal complication had 7.75 times more chances of dying than baby with no neonatal complication). Approximate 95% confidence interval = 2.71 to 22.17, (p<0.001).

Despite the fact that mothers of all babies in this cohort admitted to neonatal unit had received corticosteroids, there was still 37.6% mortality by 28 days. The odds ratios of the variables related to death (as presented in the 2 x 2 contingency tables) are listed below:

Table 14: Summary table of unadjusted odds ratios of factors related to neonatal death

	unadjusted Odds Ratio	95% CI	
Mother HIV positive	1.01	0.33 to 3.11	ns
chronic disease	1.11	0.13 to 7.86	ns
APH	1.27	0.17 to 8.05	ns
Hypertensive Disorder	0.55	0.21 to 1.46	ns
25mg in combination (other than 6mg BD qid)	0.99	0.41 to 2.39	ns
dexamethasone less than 24 hours before delivery	2.84	1.00 to 8.08	p=.078, ns
gestation 24-28	16.97	3.48 to 82.79	<0.001
did not have a caesarean	1.69	0.61 to 4.66	ns
after regular hours	1.54	0.58 to 4.12	ns
Apgar score 7 or less	1.72	0.7 to 4.21	ns
birth weight <2000g	4.56	1.22 to 17.11	0.033
any neonatal complication	7.75	2.71 to 22.17	<0.001

The results suggest that once admitted to NICU, having only received a dose of corticosteroids less than 24 hours previously (as opposed to more than 24 hours), a gestation less than 28 weeks, and having any of the listed neonatal complications were associated with mortality by 28 days.

The regression model was not done to determine which factors were independently associated with risk of death by 28 days in NICU despite antenatal corticosteroids. The study was not powered for such an undertaking and this could be done in the future in a larger study.

Results- Part 2 –Antenatal corticosteroid use at UTH

Table 15 below shows different reasons given by health workers for not administering dexamethasone. A total of 65 questionnaires were sent out to labour ward, obstetric wards and gynaecological wards. Out of these, only 56 were returned after their completion. Among the factors cited by health workers affecting the use of corticosteroids included non availability of the drug (37.5%), patients presenting in advanced labour (21.4%) and health-workers forgetting to prescribe the drug 6 (10.7%).

Table 15. Reasons health-workers gave for not using dexamethasone at UTH maternity unit.

Factor	Number of Respondents	Percent
Shortage of the Drug	21	37.5
Advanced Labour	12	21.4
Forgetting	6	10.7
No Reason	5	8.9
Too busy	4	7.1
Drug not prescribed	2	3.6
Never encountered eligible patient	2	3.6
Not sure of dates	4	7.1
Total	56	100

The health workers represented among the 56 respondents included nurses, Junior Resident Medical Officers and post-graduate doctors in Obstetrics and Gynaecology.

Table 16 below shows the pattern of prescription among and between categories of health workers and experience gained through working. All the registrars prescribed the correct dosage of dexamethasone where as nurses were more likely to prescribe other dosages.

Table 16. Trends in dexamethasone prescription among junior doctors and nurses at UTH

Staff Type	Correct dosage	Other dosage	Total
	n (column%) (row %)	n (column%) (row %)	n (column%) (row %)
Nurse	30 (65.2) (76.9)	9(90) (23.1)	39 (69.6) (100)
JRMO	9(19.6) (90)	1(10) (10)	10(17.9) (100)
Registrar	7(15.2) (100)	0(0) (0)	7(12.5) (100)
Total	46 (100)	10 (100)	56 (100)

Table 17 below shows how experience gained through working influenced prescription of dexamethasone. The nurses who had been in service longer were more likely to prescribe other doses than the correct dosage. All the postgraduate student doctors prescribed the correct dosage and only one Junior Resident Medical Officer prescribed the wrong dosage.

Table 17. Number of years worked in the department of Obstetrics and Gynaecology and prescription of dexamethasone by nurses and junior doctors at UTH.

Years worked	Correct dosage	Other dosages	Total
	n (%)	n (%)	N (%)
Less than 2 years	21	3	24
More than 2 years	25	7	32
Total	46	10	56

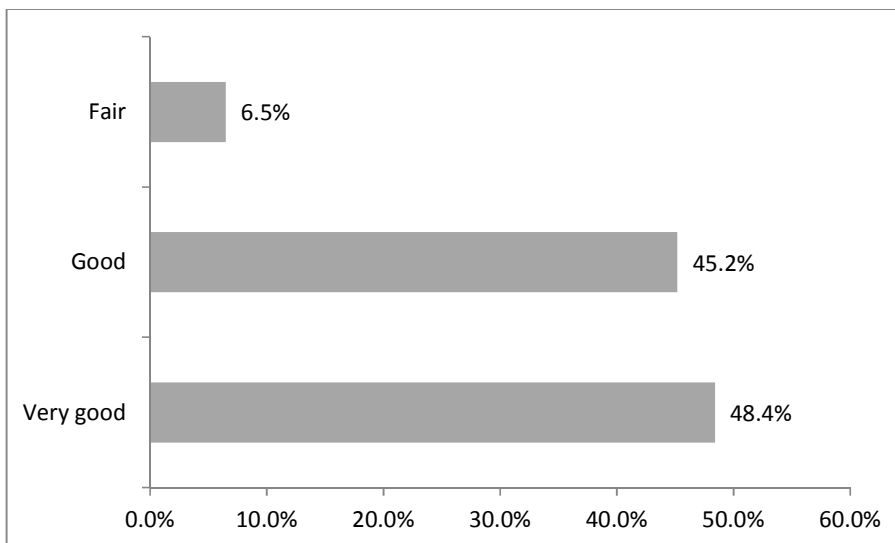
The odds ratio for a health worker who had worked less than 2 years prescribing the correct dosage (compared with more 2 years of working) = 1.96. Approximate 95% confidence interval 0.144 to 1.66, non-significant ($p > 0.75$).

Table 18 below shows the knowledge about dosage of dexamethasone, alternative to dexamethasone and correct storage temperature. These three parameters were used to grade knowledge into four categories - very good, good, fair and poor. The grading was done as follows; three questions answered correctly was graded as very good, two questions correctly answered was graded as good, only one question answered correctly was graded as fair and no question answered correctly was graded as poor. Out of the total number, 27 (48.4%) health-workers had very good knowledge, 25 (45.2%) had good knowledge and four (6.5%) had fair amount of knowledge.

Table18. Dexamethasone knowledge and number of health workers

Classification of Dexamethasone Knowledge	Number of health-workers	Percentage
Very good	27	48.4
Good	25	45.2
Fair	4	6.5
Poor	0	0
All	56	100

Graph 1. Distribution of basic knowledge of health-workers regarding dexamethasone.



8.0. Discussion

In this study, the occurrence of RDS in neonates of mothers that received dexamethasone was 25.9%, which was much lower than reported in literature. This together with the non-occurrence of IVH could be attributed to dexamethasone. The incidence of one case of NEC may be acceptable since this condition is not common. Sepsis, which is an infective process, was very high at 25.9%. This might imply that there could be something going on in the environment that may be contributing to this level of infection. This finding is not consistent with the results of a research that found that a single course of antenatal corticosteroid was not significantly associated with neonatal infectious complications (Vermillion et al, 1999). In this study, the main objective was to determine the effect of antenatal betamethasone exposure on the incidence of early onset sepsis in patients with preterm premature rupture of membranes. The researcher concluded that single course of antenatal corticosteroids, compared with multiple courses, was not significantly associated with maternal and neonatal infectious complications.

Babies delivered by caesarean section had a higher prevalence of RDS. This finding is consistent with what is expected because neonates delivered by caesarean section do not undergo decompression of the chest to squeeze fluid from the lungs. A population based case-control study conducted to determine if caesarean section is a risk factor for RDS and if this risk is modified by labour before caesarean section, had similar results (Gerten et al, 2005). The study found that caesarean section was an independent risk factor for RDS. Their concluding remark stated that the risk of RDS was reduced with labour before caesarean section, but still elevated.

The finding of more babies delivered by SVD with no complications than those delivered by caesarean section may be consistent with the fact that caesarean section may be performed for a compromised baby. Hearing et al (1986) in their case-control study found that caesarean delivery was associated with low one-minute Apgar scores and a greater incidence and severity of hyaline membrane disease. This study did not support caesarean delivery of all neonates with weight below 1000 grams.

There were very few neonates born with very low Apgar score but the proportion of those who developed complications among this group was higher than in the category of low-apgar score. The highest complication developed was RDS. In contrast, the largest numbers of neonates were delivered with a good apgar score. The larger proportion of

these had no complication. This finding is consistent with what was expected, as these babies were deemed healthy. Further, neonates delivered, less than 29 weeks had a higher occurrence of RDS compared with neonates born at later gestation ages. Accordingly, there were fewer complications with neonates delivered between 29 and 36 weeks. All these findings were similar to what was found in a population based study that was intended to assess apgar scores in preterm infants (Hegyl et al, 1998). The researchers found that less mature infants were significantly smaller, had lower one and five minute's apgar scores with a higher risk of dying.

The babies born at different times of the day were almost equally distributed, with slightly more babies being born in the morning. Among the babies born in the morning, the proportion of neonates that developed complications was much less compared with that with no complications. In comparison, among the neonates delivered at night, a larger proportion of these neonates had complications. Among the babies delivered in the afternoon there was an equal distribution of babies between those who developed complications and those who did not. These findings are consistent with findings of a prospective cohort study aimed at investigating the relationship between the time of birth and the mortality and morbidity of infants admitted to neonatal ICU (Badr et al, 2007). The mortality and morbidity were both higher for infants born at night. A contributing factor may be because most of the extremely low birth-weight neonates were born at night.

The relationship between birth weight, Apgar score and gestation age at birth was such that extremely low birth weight, birth below 29 weeks and low Apgar score was associated with a high occurrence of RDS. At extremely low birth weight, neonates who had complications were three times the number of those with no complications. Among neonates with low birth weight, there was an equal distribution of neonates between those with complications and those who did not have. Neonates born with weight above 2000 grams had no occurrence of RDS.

Out of the four ways of prescribing dexamethasone by health workers, the least prescribed was 25 mg followed by 12.5 mg. The two regimens, 6mg and 12 mg, were the most prescribed. The 12 mg regimen was associated with higher prevalence of no-complications and lower occurrence of neonatal complications compared with 6mg. Lee et al (2006) recommended the use of dexamethasone 6mg every four hours, given intramuscularly.

The duration from injection of dexamethasone to delivery for 68% of neonates enrolled into the study was less than 24 hours. Only 24% of neonates had duration lasting up to one week. Duration of action more than 24 hours is associated with better outcomes (Riley and Boozer, 2011). Gene transcription starts at 24 hours and messenger RNA peaks at 48 hours.

The prevalence of HIV among the mothers who agreed to participate in the study was similar to that in the general population (18%). In terms of occurrence of complications, the proportion of neonates who developed complications among reactive mothers was higher than the proportion of complications among neonates born of non-reactive mothers. Rollins et al (2007) conducted a prospective cohort on pregnant women to investigate pregnancy outcome in HIV infected and uninfected women. They found that HIV infected women were at significantly increased risk of adverse outcome, a result similar to what we found in this study.

Maternal chronic disease was uncommon, with 94% of the mothers to the neonates not having a chronic disease. Only five neonates were born of mothers with chronic disease, three of which had complications and two had no complications. Accordingly, the majority of neonates were born of mothers with no known chronic disease.

The majority of enrolled neonates were delivered due to premature labour with an unidentifiable trigger (58%). Neonates who were delivered due either premature labour or APH had a higher proportion of neonates with complications compared with those delivered due to hypertensive disorder. It is not clear whether the unidentifiable reason leading to premature labour may also have something with to do with the observed neonatal morbidity.

The study subjects that were discharged were 56% and the proportion of neonates with complications among the discharged neonates was smaller than that of neonates who had no complications. Among the neonates who died, the proportion of complications was much higher than that with no complications. Early neonatal deaths were 97% and only one death was a late neonatal death.

The major factor affecting the use of dexamethasone is the shortage of the drug. Eligible patients presenting in advanced labour was second commonest factor affecting the use of corticosteroids and was consistent with the earlier finding that 68% of the neonates had a

duration of action of dexamethasone less than 24 hours. This finding is consistent with what Kambafwile et al (2010) found in South Africa, that majority of patients with high risk for preterm birth missed the opportunity to receive corticosteroids because they presented in advanced labour.

Although the dexamethasone-knowledge variable explained important variations at an individual level, there remain important differences in factors affecting the use of dexamethasone. Further work is needed to explain factors such as having no reason for not injecting the drug, forgetting or being too busy to inject. On the other hand, an explanation such as being unsure of dates may occur at the upper and lower limits of the eligible gestation and this is acceptable in the absence of objective assessment of gestation age.

The finding that nurses who had worked longer were likely to prescribe other doses might be due to lack of updates.

9.0. CONCLUSIONS

Even though more than half of the neonates suffered complications, over two thirds of the subjects were delivered before dexamethasone could take effect. Several other factors, apart from dexamethasone, influenced the outcome of neonates.

The main factors affecting the use of dexamethasone were mainly due problems of the health system and forgetfulness by the health workers.

10.0. STUDY LIMITATIONS

The neonatal outcome was as entered in the neonates case file and could have been made by any of the neonatal medical staff regardless of seniority.

The sample size was also small and therefore, logistic regression could not be performed. This analysis would have showed how the different independent variables interacted to lead to neonatal complications despite maternal antenatal corticosteroids.

The study was performed in only one public institution (UTH) and one town only (Lusaka), and is not representative of the country's population. However, this was appropriate for the purpose of this study, which had set out to find answers to the research question specific for UTH.

Neonates whose mothers did not receive dexamethasone were not followed to see if they would have had different outcomes. The comparison, for example through a case-control study, would have allowed to determine the magnitude and associated factors of morbidity and mortality due to various factors, not only reduction in those with corticosteroid use.

Only dexamethasone was available for use as a corticosteroid as opposed to betamethasone, which has a different dosing regimen.

11.0. RECOMMENDATIONS

1. In view of the finding that 68% of the women who received corticosteroids in this study delivered less than 24 hours after corticosteroid injection, there is urgent need for sensitization of the public to encourage pregnant women to seek health care services early whenever they are unwell.
2. It is imperative that managers work on the health systems to improve health-care delivery. In particular, dexamethasone should be made readily available in all health-institutions and included in the rural-health-centre drug-kits. There should also be enough well-trained health-workers in public institutions trained to administer it.
3. A bigger and multicentre study (involving private and public institutions) should be done in all the provinces to evaluate use of corticosteroids and study neonatal outcomes for babies treated with antenatal corticosteroid. This is not to test efficacy, but effectiveness to make the intervention work in practice.
4. The Department of Obstetrics and Gynaecology should set up guidelines on the appropriate management of premature delivery. These should be displayed in the wards and must be reviewed regularly and updated if necessary. Regular audits for identifying weaknesses and taking appropriate steps to improve practice must be held.

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13.0. APPENDIX

13.1. Appendix A- information for patients

Title of the study – The use of corticosteroids and outcomes of premature babies at University Teaching Hospital, Lusaka, Zambia.

Dear Patient

I am Dr Angel Mwiche studying for a postgraduate degree in Obstetrics and Gynaecology at the University of Zambia. I am doing a study to see how corticosteroids are used in pregnant women with a risk of premature delivery. Proof already exist that steroids accelerate the maturity of the lungs in premature babies. This means that premature babies of mothers who received antenatal steroids rarely develop breathing problems as compared to babies of mothers who did not receive antenatal corticosteroids. I am also going to look at the different outcomes of babies whose mothers had received this type of treatment before delivery. These other outcomes include bleeding in the brain and bacterial infections both of which tend to be reduced in babies who received antenatal steroids. I am doing this in order to improve our care for pregnant women and their unborn babies. You have been chosen because you qualify to participate in this type of research. Should you agree to participate in the study, I will ask you some questions and some more information may be extracted from your medical records. This information will be kept strictly confidential and our study will not affect the treatment of eligible candidates.

Procedures: In this study, patients will not be subjected to any experimental procedures. There will be no blood samples, biopsy or surgery done for the purpose of this study. The study will only involve collecting information from the files of the patient and asking patients some questions.

Confidentiality: The information collected will be kept strictly confidential and there will no names associated with the information collected.

Risks and benefits: This research has no risks associated with it. The benefit is that your participation in the study will contribute to the body of knowledge that may be used in improving the care of our pregnant women and the un-born babies. Your participation in the research is purely voluntary and you have the right to withdraw or seek clarification at any stage of the research. Patients participating in the study will receive standard treatment like the rest of the patients.

If you have questions contact:

Dr Mwiche Angel, University Teaching Hospital, Department of Obstetrics and Gynaecology, Private Bag RW 1X, Lusaka.

Phone: 0976045959.

or

The Chairperson: UNZA Biomedical Research and Ethics Committee, Ridgeway Campus, P.O. Box 50110, Lusaka, Zambia.

Phone: 256067, e-mail unzarec@zamtel.zm, Fax 260-1-250753

13.2 Appendix B- information Sheet for Health workers

Dear colleagues,

My name is Dr Angel Mwiche, a postgraduate student in Obstetrics and Gynaecology. I am conducting a research as part of the requirements for the award of Master of Medicine at the University of Zambia. The title of the research is, “The use of corticosteroids and outcomes of premature babies at University Teaching Hospital, Lusaka, Zambia”. As a health worker, the first part, regarding how corticosteroids are used, concerns you where as the second part, focused on outcomes, will involve the newborn and the mother. Use of corticosteroids component will study aspects such as; frequency of dexamethasone prescription, dexamethasone regimens being used, reasons for not prescribing the drug and alternatives to dexamethasone. All this information will be collected in form of a questionnaire, which will be a self-administered and returned upon completion. I must mention that this questionnaire is not intended to test you but entirely to collect information on how we care for our patients. Apart from satisfying the requirements of the University for the Award of the master’s degree, it is my sincere hope that this research brings out facts that might help us improve our care for the patients. If you agree to participate in the study, you will be required to sign consent in presence of a witness. You have every right to decline participation or withdraw from the study at any point. There is no cost to your participation and you will not receive any payment or incentive for participating in the study.

If you need any further clarification contact:

Dr Mwiche Angel, University Teaching Hospital, Department of Obstetrics and Gynaecology, Private Bag RW 1X, Lusaka.

Phone: 0976045959.

or

The Chairperson: UNZA Biomedical Research and Ethics Committee, Ridgeway Campus, P.O. Box 50110, Lusaka, Zambia.

Phone: 256067, e-mail unzarec@zamtel.zm, Fax 260-1-250753

13.3. APPENDIX C – INFORMED CONSENT

Evaluation of steroid use and outcomes of babies treated with antenatal steroids at University Teaching Hospital, Lusaka, Zambia.

I have read and understand all that has been explained to me what this study is all about.

Name..... Date.....

Signature..... Thumb Print.....

Witness Name..... Sign.....

Date..... Thumb Print.....

Dr Mwiche Angel, University Teaching Hospital, Department of Obstetrics and Gynaecology, Private Bag RW 1X, Lusaka.

Phone: 0976045959.

or

The Chairperson: UNZA Biomedical Research and Ethics Committee, Ridgeway Campus, P.O. Box 50110, Lusaka, Zambia.

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13.4. APPENDIX D – QUESTIONNAIRE

QUESTIONNAIRE- EVALUATION OF STEROID USE

EVALUATION OF STEROID USE AND OUTCOMES OF BABIES TREATED WITH ANTENATAL STEROIDS AT UNIVERSITY TEACHING HOSPITAL, LUSAKA, ZAMBIA

1. Initials of health-care-giver.....
2. Job title **CO/NURSE/DR**
3. Gender **M/F**
4. Approximate number of years working in maternity department
 - 0. less than 2 years**
 - 1. more than 2 years**

5. In what circumstance do you prescribe dexamethasone for a pregnant woman?.....
.....
.....
.....
6. In general, how would you describe your frequency of prescribing/administration of dexamethasone?
 - 0. often**
 - 1. occasional**
 - 2. rare**

7. In the instances you have missed the opportunity to use this drug (dexamethasone), what were the reasons?
.....
.....
.....

8. What is the correct dosage of dexamethasone?
 - 0. 12 mg bd**
 - 1. 12.5 mg bd**
 - 2. 6 mg 12 hourly, four doses**
 - 3. 25 mg start**

9. What is generally acceptable as an alternative to dexamethasone?
 - 0. hydrocortisone**
 - 1. betamethasone**
 - 2. prednisolone**

10. what is the appropriate temperature for storage of dexamethasone
 - 0. room temperature (15-30 degrees Celsius)**
 - 1. 4 degrees Celsius**
 - 2. Other (specify).....**

QUESTIONNAIRE- NEONATAL OUTCOME AND MATERNAL SERO-STATUS

EVALUATION OF STEROID USE AND OUTCOMES OF BABIES TREATED WITH ANTENATAL STEROIDS AT UNIVERSITY TEACHING HOSPITAL, LUSAKA, ZAMBIA.

1. Date of Birth...../...../.....
2. Time of birth.....
3. Mode of delivery
 0. spontaneous vaginal delivery
 1. caesarian section
 2. assisted breach delivery
 3. instrumental delivery
4. APGAR score **1min**..... **5min**..... **10min**.....
5. What was the gestational age at birth?
 0. between 24 and 28 weeks
 1. between 28 and 36 weeks
 2. unknown gestational age
6. What was the weight at birth? (actual weight) then categorise
 0. less than 2000 grams
 1. more than 2000 grams
 2. unknown weight at birth
7. What was the predisposing factor to premature birth?
 0. antepaturm heamorrhage
 1. hypertensive disorder
 2. chorioamnionitis
 3. premature labour
8. Dosage of dexamethasone received
 0. 12mg bd
 1. 25mg start
 2. 12.5mg bd
 3. 6mg 12 hourly, 4 doses
9. Time from commencement of steroids to birth
 0. less than 24 hours
 1. between 1 and 7 days
 2. more than 7days

10. Did this baby suffer from any of the following?

- 0. respiratory distress syndrome**
- 1. enterocolitis**
- 2. intraventricular haemorrhage**
- 3. sepsis**
- 4. non of the above**

11. Condition of the baby at 28 days.

- 0. Discharged**
- 1. Still in the hospital**
- 2. Dead**

(If the answer to the above is 0 or 1, skip to Question 13)

12. In case of a dead baby, at what age did the baby die?

- 0. Within 7 days of birth**
- 1. Between 7 days and 28 days of birth**

13. Maternal HIV status

- 0. Reactive**
- 1. Non-reactive**
- 2. Unknown**

(if the answer is 1 and 2, skip to question 16)

14. For this HIV reactive mother, what was the CD4 count done within last six months?

- 0. more than 350**
- 1. less than 350**
- 2. unknown**

15. Which one of the following treatment modalities is the patient receiving?

- 0. PMTCT**
- 1. HAART**
- 2. no treatment**
- 3. unknown**

16. Is there any other chronic disease?

- 0. No**
- 1. YES (Please Specify).....**