FETAL OUTCOME IN WOMEN PRESENTING WITH MECONIUM STAINED LIQUOR AT THE UNIVERSITY TEACHING HOSPITAL, LUSAKA.

BY

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DECLARATION

I, **Dr Chazya Sikambale,** hereby declare that this dissertation herein presented for the degree of **Master of Medicine (Obstetrics and Gynaecology)** is my original work and has not been previously submitted either in whole or in part for any other degree at this or any other university, nor being currently submitted for any other degree. The various sources to which I am indebted have been clearly indicated in the References and Acknowledgements sections.

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APPROVAL

The dissertation of **Dr Chazya Sikambale** is approved as fulfilling part of the requirements for the award of the degree of Master of Medicine in Obstetrics and Gynaecology by the University of Zambia.

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ABSTRACT

The detection of meconium stained liquor (MSL) during labour often causes anxiety in the delivery room because of its association with increased perinatal mortality and morbidity. Meconium is graded into grade 1, grade 2 and 3 according to thickness. The higher the grade, the poorer the outcome. Therefore, the presence of MSL calls for intensified fetal monitoring during labour usually electronically with cardiotography (CTG) or with use of scalp electrodes or scalp PH in order to ensure good fetal outcome. However, this is not possible in resource constrained centres like UTH which might lead to poor outcome or unnecessary intervention through Caesarean sections in order to avoid poor outcome. The fetal outcome in women with MSL at UTH is not known. Therefore, the aim of the study was to determine the fetal outcome, magnitude of MSL, and risk factors responsible for MSL at University Teaching Hospital in Lusaka, Zambia.

The study was a case control study conducted at University Teaching Hospital in Lusaka Zambia from May to August 2018. Information was collected from a calculated sample size of 186 women using a structured interview schedule of which 93 were cases and another 93 were controls. Patient files were also used to collect data. In order to ensure that the findings were valid, statistically significant was set at $p < 0.05$.

The study found that the burden for MSL during the period under study at UTH was 10.2%. It also demonstrated no significant difference in terms of good fetal outcome at 5 minutes in women with MSL compared with those without MSL. (Adjusted p value= 0.773). Most women (90.2%) with MSL also had good outcome of Apgar score 7 or more at 5minute though less when compared to those without MSL at 97.8%. Caesarean section rate was high (37.6%) among women with MSL versus 19.4 % among those without MSL. There was also a strong association between MSL and being delivered by C/S (Adjusted odd ratio = 4.579 and adjusted p value = 0.002) indicating that women with MSL are 4.5 times more likely to be delivered by Caesarean section (C/S) as compared to those without MSL. Electronic monitoring of patients with MSL was low with only 33 (35.5%) of women with MSL being monitored with CTG. During the period under study 30 (32%) of women with MSL had associated complications. However, there was no significant association between any demographic characteristic, and or investigated obstetrics risk factor and MSL.

In conclusion, the frequency of MSL at UTH was 10.2%. There was no significant difference in fetal outcome at 5 minutes in women with MSL compared with those without MSL. However caesarean rate was noted to be higher in those with MSL compared to those without MSL. No investigated complication was significantly associated MSL at UTH.

Key Words: meconium stained liquor, maternal risk factors, fetal outcome

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DEDICATION

This piece of work is dedicated to my dear wife Ngao Sichone Sikambale and my lovely kids, Ndanji, Suwilanji, Chipanta, Temwa and Chishimba, for their understanding and support during the time I was conducting this research.

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ABBREVIATIONS

APGAR	Appearance, Pulse, Grimace, Activity, Reflexes
CPD	Cephalo-Pelvic Disproportion
C/S	Caesarean Section
CTG	Cardiotocography
FHR	Fetal Heart Rate
GA	Gestational Age
HIE	Hypoxic Ischemic Encephalopathy
IUGR	Intrauterine Growth Restriction
IVD	Instrumental Vaginal Delivery
LMP	Last Menstrual Period
MAS	Meconium Aspiration Syndrome
MOH	Ministry of Health
MSAF	Meconium Stained Amniotic Fluid
MSL	Meconium Stained liquor
NICU	Neonatal Intensive Care Unit
PIH	Pregnancy Induced Hypertension
UTH	University Teaching Hospital
VBAC	Vaginal Birth After Caesarean Section
VD	Vaginal Delivery

CHAPTER ONE: INTRODUCTION

1.1 Background

The detection of meconium stained liquor (MSL) during labour often causes anxiety in the delivery room because of its association with increased perinatal mortality and morbidity. Meconium stained liquor has long been associated with fetal distress. Meconium is greenish –yellowish liquid composed of small dried amniotic fluid debris, bile pigments, lanugo, epithelial cells and the residue from intestinal secretions. Although meconium is sterile, its passage into amniotic fluid is important because of the risk of meconium aspiration syndrome (MAS) and its sequelae. Infants delivered through meconium-stained liquor are more likely to be depressed at birth and to require resuscitation and neonatal intensive care. Meconium is graded into grade 1, grade 2 and 3 according to thickness. The higher the grade the poorer the outcome (Deepak et al, 2014). Therefore, detection of meconium stained liquor after rupture of membrane demands urgent intervention in terms of either continuing with vaginal delivery but with close fetal monitoring if the fetal heart pattern is reassuring or emergency delivery by Caesarean section. However, in resource limited institutions like University Teaching Hospital (UTH), with inadequate staffing in labour ward, inadequate electronic fetal monitoring by cardiotocography (CTG) and lack of equipment for definitive diagnosis of fetal distress through fetal scalp sampling technique, it can be a challenge to adequately monitor these women and may result in poor outcome or unnecessary intervention through Caesarean sections.

Several studies globally have been done to determine the fetal outcome in MSL as well as to assess the risk factors. In Pakistan, Rekha et al (2012) found that MSL was a common occurrence during labour and that electronic fetal monitoring, timely obstetrical intervention and paediatric care can reduce associated complications and improve fetal outcome. Sheikh et al (2010) found that meconium stained liquor was associated with higher rate of Caesarean delivery, increased need for neonatal resuscitation and meconium aspiration syndrome. In India, Priyadharshini and Panicker (2012) found that meconium Stained liquor alone was not associated with an adverse neonatal outcome and that 86% of babies remained asymptomatic in spite of MSL and only required routine care. The study also found that increasing grade of MSL was associated with increased adverse outcome and that MSL with abnormal CTG was

associated with poor outcome, increased caesarean section rate and increased neonatal complications. Ashfaq and Shah (2004) also found that meconium by itself was not always associated with poor fetal outcome but that severe respiratory distress called meconium aspiration syndrome increased in cases of non-reassuring FHR.

Studies of this nature however, had not been done previously in Zambia. Therefore, this study endeavored to explore this gap. The aim of this study was to determine the magnitude of MSL, fetal outcome and risk factors responsible for MSL at UTH.

1.2 Statement of the problem

Meconium staining is common in labour with the prevalence of 12-16% (Biradar et al, 2018). It is usually a potential sign for fetal hypoxia as it gives a crude idea of fetal jeopardy associated with an increased perinatal mortality and morbidity. Therefore, the presence of MSL calls for intensified fetal monitoring during labour usually electronically with ECG or with use of scalp electrodes or scalp PH in order to ensure good fetal outcome. However, this is not possible in resource constrained centers like UTH which might lead to poor outcome or unnecessary intervention through cesarean sections in order to avoid poor outcome.

1.3 Study justification

MSL is common in labour at UTH. However, fetal outcome in labour with MSL was not known at UTH. Also, various studies worldwide have identified several risk factors associated with meconium stained liquor in labour in their respective settings. Despite this, there was no study done at UTH or anywhere in Zambia to determine the fetal outcome in labour with MSL or to assess associated risk factors for MSL in our setting. Therefore, the study analyzed the extent of the problem caused by MSL. It has also contributed to the epidemiological data of MSL at UTH and serves as a basis for future research. In addition, data that was collected would help in coming up with suitable management protocols for women with MSL at UTH and Zambia as a whole which will in turn contribute to the reduction of perinatal morbidity and mortality.

1.4 Research questions

What are the risk factors and fetal outcomes in women diagnosed with meconium stained liquor during labour at UTH, Lusaka Zambia?

1.5 Objectives

1.5.1 Main objective:

To study fetal outcomes in women with meconium stained liquor during labour at UTH, Lusaka.

1.5.2 Specific objectives:

1. To determine the magnitude of meconium stained liquor during labour at UTH Lusaka.
2. To determine the fetal outcomes in mothers with meconium stained liquor
3. To determine the common obstetrical complications (risk factors) associated with meconium stained liquor during labour at UTH Lusaka.

1.6 Organization of the Dissertation

The dissertation is organized as follows:

Chapter One is entitled Introduction provides the Background of the subject matter of MSL. It describes what MSL is and its importance in labour in terms of some already known risk factors and fetal outcome.

Chapter Two is the Literature Review which summarizes the relevant global, regional and the local literature around MSL. The literature is from previous studied done in Asia, Europe, America and Africa.

Chapter Three contains the Methodology. This describes the study design, the study site, the target and study population, the inclusion and exclusion criteria, sampling strategies and sample size, study procedures and data collection techniques, data analysis plan, ethical considerations and the study limitations.

Chapter Four describes the results of the study including demographic characteristics of the participants and some major study findings. Results are displayed in form of percentages, tables, and graphs.

Chapter Five is the Discussion that reviews the results and explains their significance in the local context and also with respect to previously published results from elsewhere.

In Chapter Six, the Conclusions based on the findings and Recommendations. The references and Appendices follow.

CHAPTER TWO: LITERATURE REVIEW

Meconium stained amniotic fluid (MSAF) is a major global public health problem. Meconium staining is common in labour with the prevalence of 12-16% (Biradar et al, 2018). Many studies have been conducted worldwide especially in Asia to determine the fetal outcome and risk factors in patients with MSAF. Kumar et al (2012) conducted descriptive case control study in the department of Obstetrics and Gynaecology, Koshi Zonal Hospital in India from March 2006 to July 2006. A total of 50 women with meconium stained amniotic fluid (MSAF) were studied to identify maternal and fetal outcome and was compared with women with clear amniotic fluid. In this study, it was found that normal delivery was significantly higher (58%) in clear liquor group as compared to MSAF group (22%). Low Apgar score of < 5 at one minute was seen in 48% of MSAF and 6% in babies born in clear liquor. Among the babies born with MSAF 34% were referred to higher center compared to 6% in clear liquor babies. The study concluded that mode of delivery and fetal outcome were adversely affected by the presence of thick meconium stained liquor as compared to clear liquor and that additional monitoring facilities e.g. cardiotocography (CTG) if available would reduce fetal distress and allow timely intervention in such cases.

Lubna et al (2011), also conducted a study to assess the frequency of meconium stained liquor and related factors at Karachi General Hospital, from April 2010 to March 2011. The study discovered that out of 908 deliveries, meconium stained amniotic fluid was found in 7.7% cases and more than 50% were of grade III type. Most of the women were multigravida and 67% were moderately anaemic. Grade I meconium was present in 15 (21%) cases, grade II in 19 (27%) and grade III in 36 (51%) cases. Obese multigravidas accounted for majority of cases as compared to Primigravidae. Gestational age and postdate pregnancies had no significant impact on meconium stained amniotic fluid (MSAF). Most of the women (64%) had spontaneous vaginal delivery.

Also in India, Priyadharshini and Panicker (2012) conducted a study to determine the fetal outcome and mode of delivery in patients with meconium stained liquor during labour. This was a retrospective study that was conducted from January 2012 to December 2012 on 250 clients with MSL out of 2124 patients admitted to Labour

ward. The study concluded that Meconium Stained Liquor alone was not associated with an adverse neonatal outcome, as 86% of babies remained asymptomatic. Increasing Grade of MSL was associated with increased adverse outcome. Meconium stained amniotic fluid with abnormal CTG was associated with poor outcome, increased caesarean section rate and increased neonatal complications.

Rasheed et al (2015) also conducted a cross section study to determine the neonatal outcome in meconium stained liquor in the Department of Obstetrics & Gynaecology in India. In this study, it was found that out of a total of 149 patients, 57 babies (38.3%) were admitted to NICU, 21 neonates (14.0%) died, satisfactory Apgar score was observed in 73 (49%) neonates and meconium aspiration syndrome was found in 26 cases (17.5%).It was therefore concluded that meconium staining of amniotic fluid was a commonly observed phenomenon in labour and was frequently associated with prolonged labour, increased incidence of poor APGAR score, neonatal nursery admission, meconium aspiration syndrome and neonatal death.

Deepak et al (2014) found that Meconium aspiration syndrome is associated with significant mortality i.e. 44 (26%) out of 170 patients with MSL died. Vijayasree et al (2014) also conducted a comparative descriptive case control study in which they compared fetal outcomes in women with MSL to those with clear liquor. The study found that both mode of delivery and fetal outcome were affected by the presence of thick meconium stained liquor as compared to clear liquor. Normal delivery was significantly higher (58%) in clear liquor group as compared to MSAF group (22%). Caesarean section was more common in MSAF group (66%) whereas it was (38%) in the clear liquor group ($p=0.005$). Low Apgar scores of < 5 at one minute was seen in 48% of MSAF and only 6% in clear liquor group ($p<0.2$). The study concluded that presence of thick meconium should be monitored closely and additional monitoring facilities such as CTG if available could guide obstetricians to decide the mode of delivery and any other necessary intervention on time. Thick MSAF in presence of low Apgar score was also found to be directly responsible for high neonatal morbidity and mortality and that amino infusion could be an alternative option in countries like India to improve maternal and fetal outcome.

Rajput et al (2016) conducted a study to determine risk factors and outcome in neonates born with meconium stained liquor. In this study, the incidence of MSAF

among admitted newborn neonates was 17.5%. High prevalence of MSAF was seen in male neonates with an incidence of 65.2% and 90% babies were term. Mode of delivery was also found to have been significantly affected by meconium staining of liquor as caesarean sections were performed twice as frequently in women presenting with MSAF and the incidence of caesarean section was 85%. Shaikh et al (2010) also observed similar results. Risk factors with high prevalence for MSL included, oligohydramnios, pregnancy induced hypertension and anaemia with an incidence of 30%, 26% and 19% respectively. Fetal distress was high in pregnancies with MSAF with an incidence of 30%.

Rajput and Yadav (2016) also showed a high incidence of fetal distress (11.8%). Risk factors identified for MSL included oligohydramnios, PIH, anaemia and fetal distress. Thick meconium was associated with more admissions to Neonatal Intensive Care Unit (NICU). The study also concluded that the knowledge of antenatal and intranatal factors associated with MSAF provide a way of early identification of high-risk cases in resource poor setup where facilities like electronic fetal monitoring are not available, which can be managed by optimal timely intervention in order to avoid severe asphyxia and meconium aspiration and its complications.

The Department of Obstetrics & Gynaecology in India also conducted a study to determine neonatal outcomes in meconium stained liquor. They found out that (38.3%) were admitted to NICU, 21 neonates (14.0%) died. Satisfactory Apgar score was observed in 73 (49%) neonates; meconium aspiration syndrome was found in 26 cases (17.5%). The study concluded that meconium staining of amniotic fluid was a commonly observed phenomenon in labour and that it was frequently associated with prolonged labour and with increased incidence of poor Apgar score, neonatal nursery admission, meconium aspiration syndrome and neonatal death.(Rasheed et al, 2015).
Rajput et al. (2016) also conducted a study to determine risk factors and outcome in neonates born with meconium stained liquor. They found that oligohydramnios, pregnancy induced hypertension (PIH), anaemia and fetal distress were common antenatal and intranatal factors which were associated with MSAF and that major morbidity and indication for NICU admission was birth asphyxia and meconium aspiration syndrome. Mortality rate was estimated at 17.5% and was commonly associated with thick meconium and severe hypoxic ischemic encephalopathy (HIE).

Rokade et al (2016) also conducted a study to determine the fetal outcome and mode of delivery in patients with meconium stained amniotic fluid. The findings were that Apgar score was > 7 for 82 % of babies and only 18 % had Apgar score <7. About 56% of the patients with MSL were delivered by caesarean section, whereas 49 patients (24%) had instrumental delivery (18% with forceps and 6% with vacuum) and 40 patients (20%) delivered normally. The study concluded that meconium stained amniotic fluid had importance both from obstetrician and paediatrician point of view as it increases the caesarean section rate due to birth asphyxia as well as increases NICU admission rate.

Shaikh et al (2010) conducted a study to determine the effect of clear liquor and meconium stained liquor on mode of delivery, and to evaluate neonatal outcome. The study was a cross sectional analytical, conducted in the department of Obstetrics and Gynaecology at Federal Postgraduate Medical Institute/Hospital, Lahore and Shaikh Zaid Women Hospital Larkana, from April 2006 to March 2007. The study found out and concluded that meconium stained amniotic fluid (MSAF), was associated with increased neonatal morbidity and mortality. Caesarean sections were performed twice as frequently in women presenting with MSAF.

Mortality among babies with meconium aspiration syndrome is very high. Deepak et al, (2014) found that out of 172 babies with meconium aspiration syndrome, 44 (26%) died. Unsworth and Vause, (2010) also showed that MAS was the major concern when meconium was floating about in the amniotic fluid and that around 2-5% of the 15-20% of babies with meconium stained liquor would develop MAS and that of the 2-5% of the 15-20%, 3-5% of babies will die.

In Europe, Lee et al (2011) conducted a study at Seoul National University Hospital and found that the frequency of MSAF in term pregnancies was 18.4%. Women who delivered by elective C/S had only 2.8% MSAF whereas those that delivered after onset of labour had MSAF of 23.1%. The study also found that the longer the duration of labour, the higher the risk of MSAF.

In America, Sriram et al (1999) conducted a study to determine the Racial Differences in the Risk of Meconium Aspiration Syndrome in relation to meconium stained amniotic fluid, fetal distress and labour. The study found that the prevalence of

meconium stained fluid was about 89 per 1000 live births and the risk for meconium stained fluid was 69% higher in African Americans as compared with whites (OR 1.69; CI, 1.68-1.71).The most important risk factor identified was fetal distress or prolonged labour for more than 20hrs.

Regionally here in Africa, about 15% of babies are born with meconium stained liquor (MAS). Risk factors that may cause stress on the baby before birth include placental aging if the pregnancy goes far past the due date, decreased oxygen to the infant while in the uterus, diabetes mellitus in the pregnant mother, difficult delivery or long labour, high blood pressure in the pregnant mother, smoking, direct pushing, lack of antenatal care, cord involvement, natural therapies and early rupture of membranes (Alliance of African midwives, 2010). In Nigeria, David et al (2006) conducted a study to determine the incidence of meconium staining of the amniotic fluid (MSAF) and its associated factors in a Nigerian teaching hospital. The study analyzed perinatal data on 80 consecutive live, singleton infants of booked mothers born through meconium-stained liquor and compared with babies born through clear liquor. The study found that the incidence of MSAF was 20.4% for 393 deliveries and that prime parity, prolonged rupture of fetal membranes and obstructed labour were more often associated with MSAF. In Ethiopia, Addisu et al (2018) found that the prevalence of MSAF was 17.8% which was similar as compared to the international standard. The risk factors identified included preeclampsia, maternal age, induced labour and prolonged labour.

In Zambia however, data about the fetal outcomes in mothers with meconium stained liquor is lacking as no study has so far been done. This study is therefore designed to address this information gap so that the findings can be used to formulate guidelines on the management of women with meconium stained liquor in labour so as to improve the fetal outcome.

CHAPTER THREE: METHODOLOGY

3.1 Study design:

This was a case control study.

3.2 Study site

The study was carried out at the labour ward of the University Teaching Hospital, in Lusaka, Zambia.

3.3 Target population.

Pregnant women admitted to UTH labour ward.

3.4 Study population

Women who were diagnosed with MSL as cases and another equal group of women with clear amniotic fluid as controls, that met eligibility criteria.

3.5 Inclusion criteria:

1. Admitted to UTH labour ward.
2. Women with singleton pregnancy, cephalic presentation and longitudinal lie and gestation age 37 weeks and above.
3. Able to provide informed consent to participate in the study. For those below 18 years of age, or unable to sign, guardian provided consent on their behalf.

3.6 Exclusion criteria

1. Documented intrauterine fetal death at the time of labour ward admission.
2. Documented congenital fetal anomaly.
3. Women with multiple gestation
4. Gestation age below 37 weeks
5. Malpresentation e.g. breech delivery

3.7 Study duration

The study, including recruitment, data entry, analysis and write up, took twelve months from commencement after approval by ERES ethics committee in April 2018 to March 2019.

3.8 Participant recruitment

Women were recruited from the labour ward at the UTH after meeting the eligibility criteria. One group of women was recruited from those with MSL and another group from those with clear amniotic fluid at UTH. The study was an observational study and therefore the decision on the mode of deliver after diagnosis of MSL was made by the unit doctors and was in no way influenced by the researcher.

For those who qualified to be included in the study, information was explained to them on what was involved in the study (Appendix A, B and C – depending on language preference). Written or oral informed consent was obtained from participants. Data was obtained both verbally from the women and from the case files.

3.9 Sampling methods

Purposeful sampling method was used to select 93 pregnant women with meconium stained liquor as cases while another 93 pregnant women with clear liquor were selected using systematic random sampling method as a control group. Purposeful sampling method was used to select the cases because meconium stained liquor is a rare occurrence. On the other hand, systematic random sampling was used to select controls and a sampling interval was calculated as below:
Average deliveries per month = 900 deliveries, and women with MSL per day is 3 women. Therefore, the calculated sampling interval = 900 divided by 30 days= 30 then divided by 3 = 10

Therefore, for every case of MSL the tenth woman without MSL was selected to be included in the study.

3.10 Sample size (Unmatched case-control study)

- calculated using openepi version 3 at **10%** prevalence of meconium stained liquor
- Using Kelsey method for unmatched sample size,
- Two-sided confidence level (1-alpha) = 80%
- Power (% chance of detecting) = 80%
- Ratio of control to cases = 1
- Hypothetical proportion of control with exposure = 0
- Hypothetical proportion of cases with exposure = 10%
- Least extreme Odds ratio to be detected = 0.00

Therefore, total sample size was **150** pregnant women

Then 10% was considered for handling loses and this translated into 170.

- Therefore, calculated women with MSL (cases) = **85**
- Therefore, calculated women with clear liquor(controls) = **85**

However, the actual study participants included in the study were 93 for cases and another 93 for controls.

3.11 Measuring exposure and outcome

Exposure: Those in labour diagnosed with MSL and those with clear liquor.

Primary outcome: Apgar score.

Secondary outcomes: vaginal delivery or caesarean delivery. Refer to Table 1.

Table 1: Dependent and independent variables

Independent variables (in alphabetical order)	**Type (continuous or categorical; if categorical – nominal or ordinal)**	**Notes**
Age of the woman	Continuous	Categorized into discrete categories (e.g. <16, 17-19, 20-24 etc.)
Parity	Continuous	Categorized into discrete categorise (e.g., 1,2,3, 4, 5, etc.)
Gestation age	Continuous (nominal)	Categorized into discrete categories (e.g. 37 to 38, 39 to 40).
Presence of MSL	Categorical (dichotomous)	Categorized as yes or no.
Meconium grade	Categorical (ordinal)	Categorized into discrete categories (e.g. 1, 2 and 3)
Associated complication or risk factor	Categorical (nominal)	E.g., anaemia, PIH, Oligohydramnios, Prolonged labour etc.
Birth weight	Continuous	Categorized into discrete categories (e.g.2000g to 2400g, 2500g to 2900g).
Sex of baby	Categorical	Male or female

Primary dependent variables	**Type**	**Notes**
Apgar score at 5min	Continuous variable	<7 or >7 at 5min
Secondary dependable variables		
Eventual mode of delivery	Categorical (ordered)	Vaginal or caesarean. (Vaginal will include Spontaneous vaginal delivery and instrumental).

3.12 Data collection

Data was collected using a structured questionnaire and information from the patient's files from May to August 2018. A pilot study was conducted at Shangombo District Hospital during the last week of April 2018 in order to test the questionnaire as well as to make necessary amendments on the document before the actual study.

Trained research assistants who were also midwives were provided with a structured questionnaire to collect the data (Appendix D). Also, total number of deliveries as well as total number of women with MSL was recorded on each particular day of data collection.

3.13 Follow up

Enrolled clients were only followed up from the time of diagnosis until they delivered.

3.14 Data Analysis

In order to minimize errors, double data entry method was used. Cleaned data was analyzed using Epi-info. Descriptive results were presented as percentages and means (with 95% confidence intervals). Data entry, validation was done using SPSS 25.0. Bivariate analysis using the chi-square test was used to assess women who had good outcome to those who did not with respect to various independent variables. For continuous variables, t-student test was used. A multivariate logistical regression and backward logistic regression analysis were used to determine effects of independent variables on the fetal outcome (e.g. grade of meconium, age, parity, birth weight, presence of obstetric condition, etc.). In all cases significance was set at 0.05.

Odds ratio was used to determine risk factors associated with meconium stained liquor (MSL) as well as to determine the association between MSL and fetal outcome.

3.15 Ethical considerations

It was made clear to the patients that their participation in the study was purely voluntary and that they would be allowed to withdraw from the study at any time without any prejudice to further medical care if they wish to. Participants were also informed that there were no monetary or material benefits in being part of the study.
Approvals were obtained from Head of Department of Obstetrics and Gynaecology to carry out the research at the institution, the Graduate Proposal Presentation Forum approval and the research ethics approval was obtained from the ERES Converge Research Ethics Committee, approval No. 2018-Jan-017 (Appendix E).

Patient confidentiality was assured as no names were used. There were also no personal identifiers on data collection instruments. Publication and scientific presentations of the research findings has been presented in aggregates and without the identities of individual participants. Research assistants were also trained on how to maintain confidentiality on the data collected. The questionnaires were designed in English and then translated in Bemba and Nyanja which are the main languages spoken in Lusaka.

3.16 Study Limitations

Some of the limitations of this study include:

1. Apgar scoring and grading of meconium as these variables are subjective with inter and intra observer variations. Therefore, some babies could have been given a wrong Apgar score which could have affected the results. Equally meconium could also have been graded wrongly, hence affecting results.
2. Possibilities of incorrect gestation age as a considerable number of women were not sure of their LMP and hence could have led to wrong calculation of the gestational age. To mitigate this, gestational age of the pregnancy was estimated using early trimester scan in women that presented with first trimester scan as it is more reliable and accurate than LMP.

CHAPTER FOUR: RESULTS

4.1: Introduction

The data and findings presented were obtained from 186 women participants from UTH labour ward of which 93 had MSL and another 93 did not have. Data was collected over a period of three months (May 2018 to July 2018) During the period under study the total number of deliveries were 953 of which vaginal deliveries were 526 (55.2%) and caesarean sections were 427 (44.8%).

4.1.1 Socio-demographic characteristics

Most participants on both the cases and control groups were aged between 20 to 29 years 49 (52.7%) and 51 (54.8 %) respectively. Majority of them were of single parity (para 1) 49(52.7%) among cases and 43(46.2%) among control (Table 2).

Table 2: Socio-demographic characteristics of women with and without MSL

	Presented with Meconium			
	Yes		**No**	
	n	**%**	**n**	**%**
Age				
Less than 20	12	12.9%	18	19.4%
20 - 29	49	52.7%	51	54.8%
30 - 39	30	32.3%	18	19.4%
40 and above	2	2.2%	6	6.5%
Parity				
Para 1	49	52.7%	43	46.2%
2 - 4	36	38.7%	37	39.8%
≥ 5	8	8.6%	13	14.0%
Gestation age				
37 - 40	66	81.5%	74	86.0%
41 - 44	15	18.5%	12	14.0%
Marital status				
Single	22	23.7%	19	20.4%
Married	71	76.3%	74	79.6%
Education				
Primary	48	51.6%	49	52.7%
Secondary	32	34.4%	33	35.5%
Tertiary	13	14.0%	11	11.8%
Occupation				
Unemployed	66	71.0%	66	71.0%
Formal Employment	11	11.8%	12	12.9%
Informal Sector	16	17.2%	15	16.1%
Residence				
High Density	76	81.7%	80	86.0%
Medium Density	10	10.8%	7	7.5%
Low Density	7	7.5%	6	6.5%

4.2: Burden (frequency) of meconium stained liquor at UTH

During the period under study, the total number of deliveries was 953. The total number of women with meconium stained liquor during the same period was 97 giving meconium burden rates of 10.2%. Women with grade 1 MSAF were 53(57 %), while 32(34.4 %) had grade 2 and 8(8.6 %) had grade 3 as shown in Figure 1.

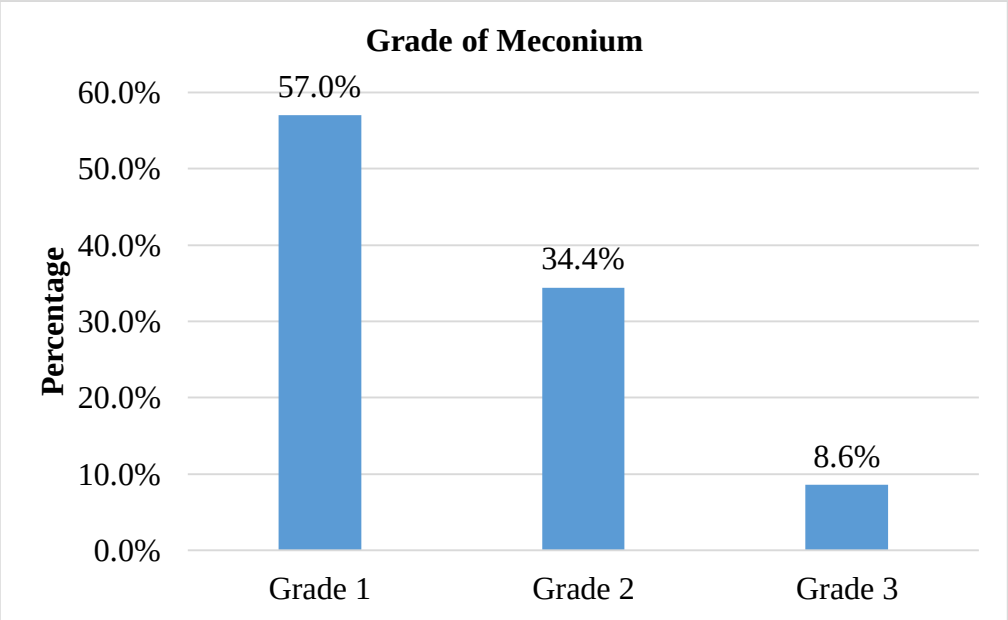

Figure 1: Burden of meconium stained liquor according to the grade

4.3: Fetal outcome

4.3.1: Fetal outcome in MSL Vs Non MSL at one- and five-minutes Apgar score

There was no significant difference in fetal outcome at 1 minute in women with MSL verses women without MSL (Adjusted P value = 0.062). However, more women without MSL had good outcome with Apgar score of 7 or more at 96.4% compared to those with MSL at 81.5%.

Also at 5 minutes, more women without MSL had good outcome of 97.8% compared to those with MSL at 90.2%%, but there was no significant difference in outcome in those with MSL versus non MSL (adjusted p value =0.773) (Figure 2).

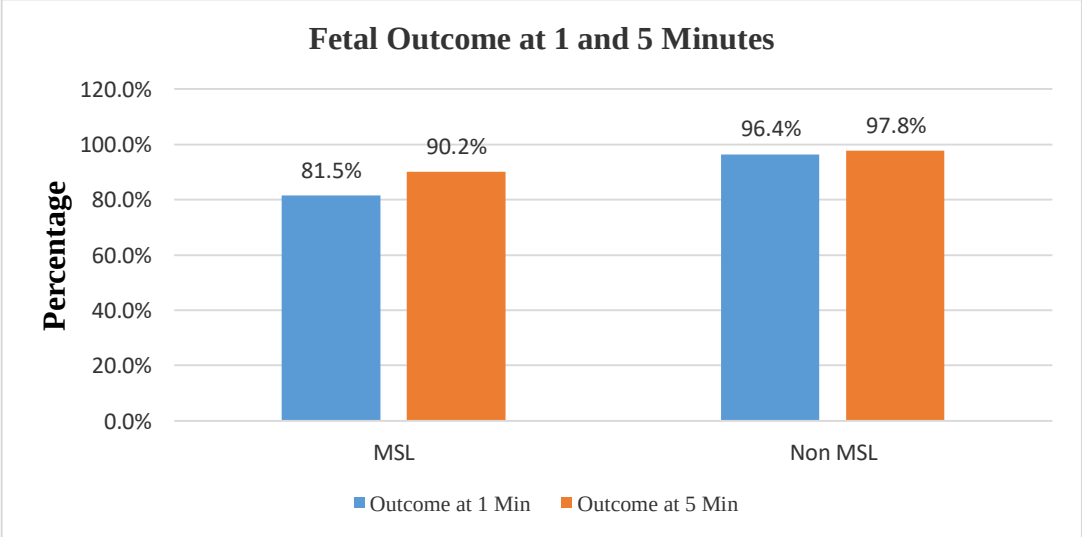

Figure 2: Fetal outcome in MSL and non MSL at 1 and 5minutes

4.3.2: Fetal outcome by grade of meconium

At 1 minute, more women with poor outcome were from those with grade 3 followed by grade 2 at 50% and 37% respectively, with the least among those with grade 1 at 1.9%.

At 5 minutes, most women with good outcome were from those with grade 1, 53 (100%) followed by grade 2, 27(84.4%) with the least among grade 3, 4 (50%). (Figures 3 and 4).

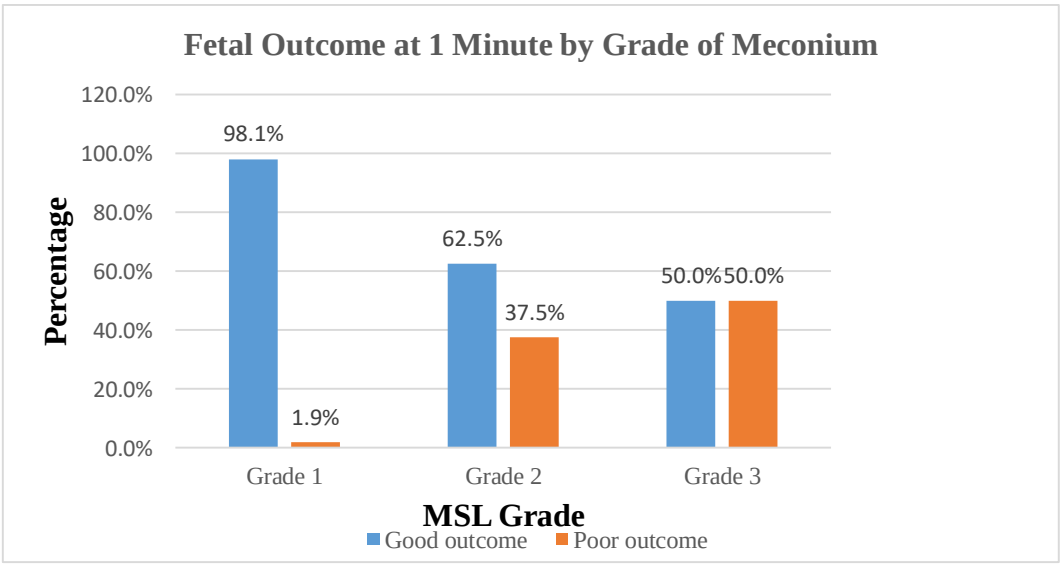

Figure 3: Fetal outcome according to grade of meconium at 1 minute

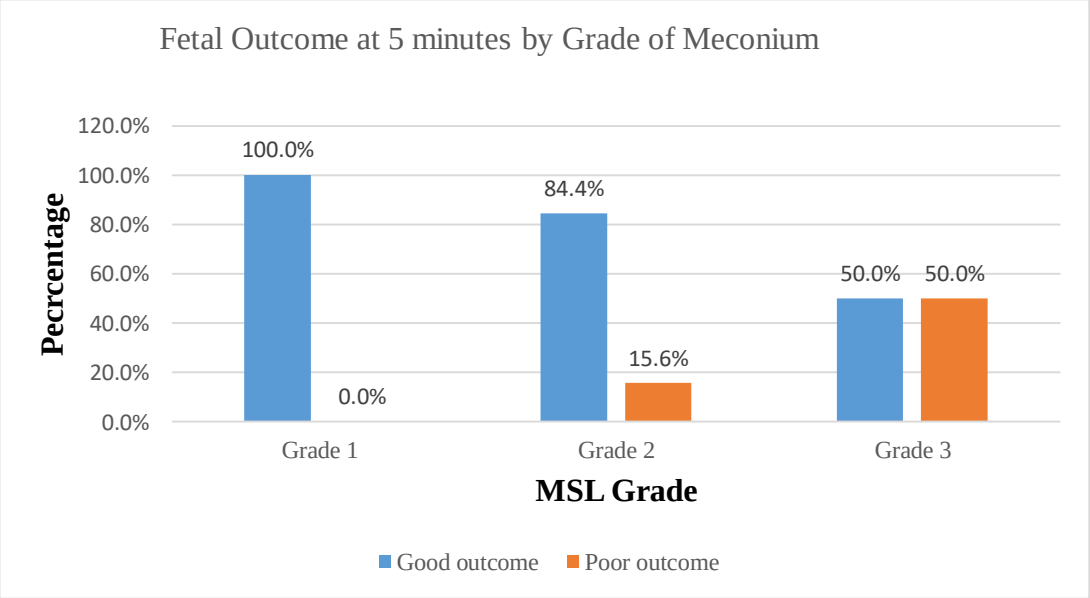

Figure 4: Fetal outcome according to grade of meconium stained liquor (MSL)

4.3.3: Admission to Neonatal Intensive Unity (NICU)

More admissions were seen in babies with MSL 24 (26.1%) versus those without MSL (20.4%). The reasons for admission included: low A/S (41.4%), meconium aspiration (27.6%), poor breathing (22.7%) & low birth weight (13.8%). (Figure 5).

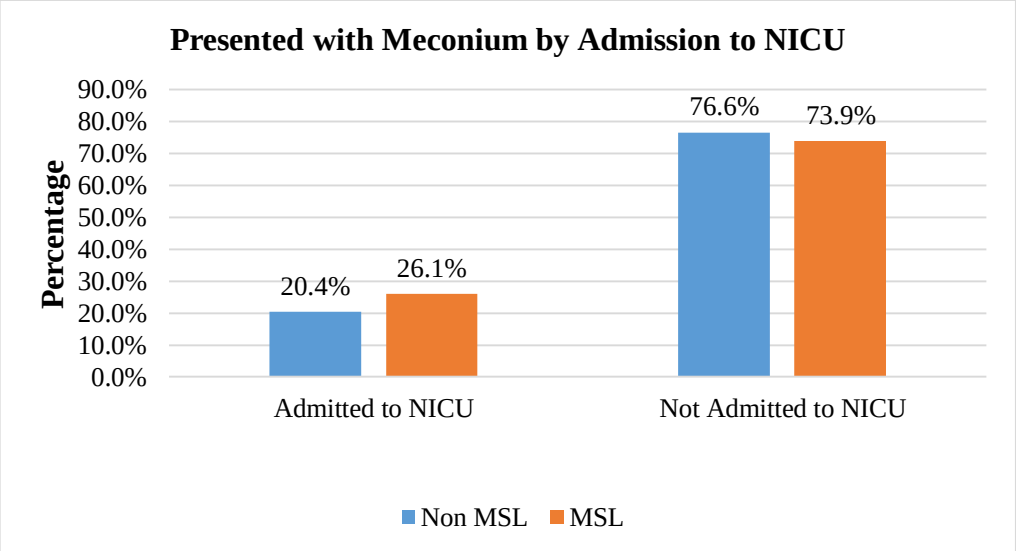

Figure 5: Admission to NICU

4.3.4: Monitoring of labour in MSL with CTG

Only 33/93 (36.6%) of women with MSL were monitored by CTG as shown in Figure 6.

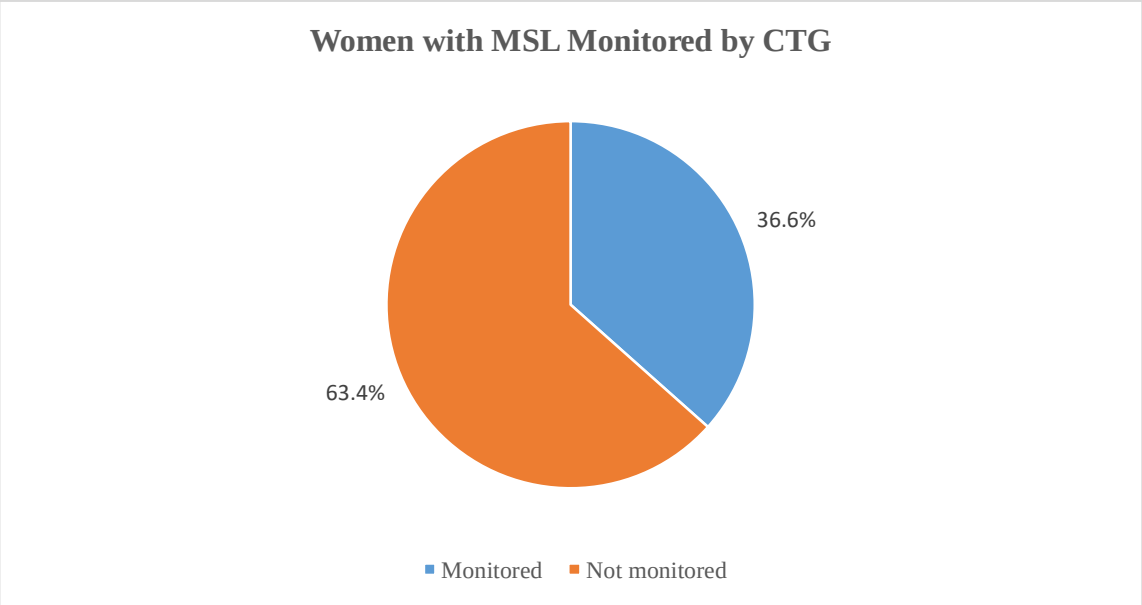

Figure 6: Cardiotography (CTG) in women with meconium stained liquor (MSL)

4.3.5: Mode of delivery in women with MSL

More 34 (37.6%) women with MSL were delivered by caesarean section versus 18 (19.4%) women without MSL, while 2(2.2%) of women among those with MSL were delivered through instrumental vaginal delivery (Figure 7). There was also a significant association between MSL and being delivered by C/S (odds ratio 4.579, p value = 0.002, 95% CI 1.727 - 12.137).

In women with MSL, 60.2 % delivered by spontaneous vaginal delivery while 37.6% delivered by caesarean section and 2.2% were delivered through instrument vaginal delivery.

More C/S were observed in those with grade 3 (62.5%) followed by those with grade 2 (58%) with the least in those with grade 1 (19.4%).

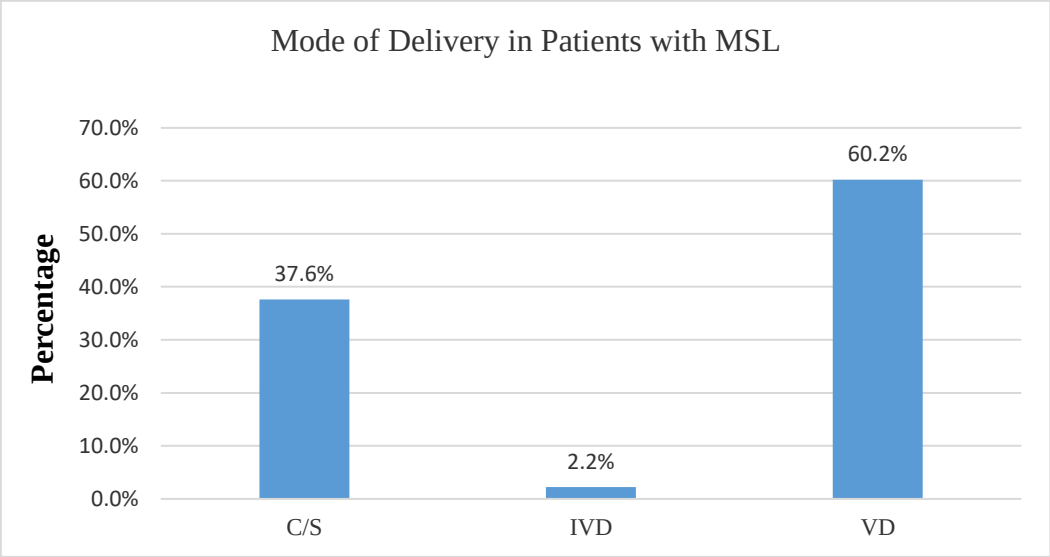

Figure 7: Mode of delivery in patients with meconium stained liquor (MSL)

4.4: Complications (risks) for MSAF

Out of 93 women with MSL, 29 (31%) had associated investigated complications. Among the first five common risk factors, PIH/ Preeclampsia was the leading risk factor at 15%, followed by prolonged labour (8.6%), anaemia (5.4%), VBAC (4.3%), and chronic hypertension (3.2%), (Table 3).

Table 3: Frequency of complications (risk factors) in women with MSL

		Presented with Meconium			
		Yes		No	
Investigated complication or risk factor	**Total**	**n**	**%**	**n**	**%**
Anaemia	7	5	5.4%	2	2.2%
Hypertension	9	3	3.2%	6	6.5%
PIH/Eclampsia	24	14	15.1%	10	10.8%
Gestational Diabetes	0				
Fever	1	1	1.1%	0	0.0%
Respiratory Problems	4	2	2.2%	2	2.2%
Prolonged Labour	8	8	8.6%	0	0.0%
Augmentation of labour with Oxytocin	5	3	3.2%	2	2.2%
Cardiac Problems	3	1	1.1%	2	2.2%
IUGR	2	1	1.1%	1	1.1%
Polyhydramnios	0				
Oligohydramnios	0				
Uterine Hyperstimulation	0				
Sickle Cell	0				
Vaginal Birth After Cesarean Section	9	4	4.3%	5	5.4%
Obstruction of Labour	3	2	2.2%	1	1.1%

4.5: Bivariate analysis

No investigated complication (summarized in Table 3) was significantly associated with MSL. There was no significant association between any demographic factors and risk of MSL as shown in Table 4. Birth weight less than 2.5kg was associated with MSL (p value =0.042). Sex of the baby was significantly associated with MSL (p value 0.018). Mode of delivery was also significantly associated with MSL (p value =0.008). Apgar score at 1 minute was also significantly associated with MSL, whereas Apgar score at 5minutes was not (p values at 0.012 and 0.062 respectively). PIH/Eclampsia was not significantly associated with MSL (P value =0.51). Refer to Table 4 below.

Table 4: Bivariate analysis for demographic factors

(age, parity, gestation age, marital status, education status, occupation, residence), PIH/Eclampsia, mode of delivery, birth weight, Apgar score at 1 and 5 minutes and sex of the baby.

	Presented with Meconium				
	Yes		**No**		**Statistics**
Variable	**n**	**%**	**n**	**%**	**p**
Age					0.100
Less than 20	12	12.9%	18	19.4%	
20 - 29	49	52.7%	51	54.8%	
30 - 39	30	32.3%	18	19.4%	
40 and above	2	2.2%	6	6.5%	
Parity					0.450
Para 1	49	52.7%	43	46.2%	
2 - 4	36	38.7%	37	39.8%	
≥ 5	8	8.6%	13	14.0%	
Gestation age					0.555
37 - 40	66	81.5%	74	86.0%	
41 - 44	15	18.5%	12	14.0%	
Marital status					0.724
Single	22	23.7%	19	20.4%	
Married	71	76.3%	74	79.6%	
Education					0.908
Primary	48	51.6%	49	52.7%	
Secondary	32	34.4%	33	35.5%	
Tertiary	13	14.0%	11	11.8%	

(continued next page)

Table 4 continues

Variable	Presented with Meconium				Statistics
	Yes		No		
	n	%	n	%	p
Occupation					0.963
Unemployed	66	71.0%	66	71.0%	
Formal Employment	11	11.8%	12	12.9%	
Informal Sector	16	17.2%	15	16.1%	
Residence					0.702
High Density	76	81.7%	80	86.0%	
Medium Density	10	10.8%	7	7.5%	
Low Density	7	7.5%	6	6.5%	
PIH/Eclampsia					0.512
Yes	14	15.1%	10	10.8%	
No	79	84.9%	83	89.2%	
Mode of delivery					0.008
Vaginal Delivery	56	61.5%			
Caesarean Section	35	36.5%			
Birth weight					0.042
Less than 2.5kg	11		22	24.2%	
2.51 - 3.5Kg	61		58	63.7%	
Greater than 3.5Kg	20		11	12.1%	
Apgar score at 1 minute					0.012
Good outcome	75	81.5%	88	94.6%	
Poor outcome	17	18.5%	5	5.4%	
Apgar score at 5 minutes					0.062
Good outcome	83	90.2%	90	97.8%	
Poor outcome	9	9.8%	2	2.2%	
Sex of child					0.018
Male	44	48.4%	62	66.7%	
Female	47	51.6%	31	33.3%	

4.5: Multivariate analysis

No demographic factor was significantly associated with MSL on multivariate analysis (Table 5). The adjusted p value for parity in para 1 to 3 was 0.309 and 0.375 in parity 4 to 6 (non-significant). Gestation age was also not significantly associated with MSL with adjusted p value was 0.542.

There was however significant association between MSL and risk of being delivered by C/S, adjusted odds ratio 4.579, p value 0.002. Apgar score at one minute (adjusted p value 0.006) showed significant association in terms of good outcome and no significant association at five minutes (adjusted p value 0.788). Sex of the baby also showed significant association with MSL with male babies being at less risk (adjusted odds ratio 0.309, adjusted p value 0.003). PIH/ Preeclampsia and birth weight did not show significant association with MSL with adjusted p values of 0.125 and 0.108 respectively.

Table 5: Logistic regression model

(Variables: Age, Gestation Age, Parity, Marital Status, Education, Occupation, Residence, Labour type, PIH/Eclampsia, Mode of Delivery, Birth weight, Apgar score at 1 minute and 5 minutes and Sex of Baby by Presence of Meconium)

	OR	**95%CI**		**p**	**AOR**	**95%CI**		**p.Adjust**
Variable		**Lower**	**Upper**			**Lower**	**Upper**	
Age								
<20	2.000	0.344	11.615	0.440	1.321	0.133	13.165	0.812
20 - 29	2.882	0.555	14.973	0.208	2.027	0.262	15.688	0.499
30 - 39	5.000	0.910	27.470	0.064	3.416	0.491	23.780	0.215
≥40 (Ref)								
Parity								
Para 1	0.540	0.204	1.426	0.214	0.455	0.085	2.435	0.358
2 - 4	0.632	0.234	1.707	0.366	0.505	0.107	2.387	0.389
≥ 5 (Ref)								
Gestation Age								
37 - 40 Months	0.714	0.312	1.634	0.425	0.755	0.264	2.159	0.600
41 - 44 Months (Ref)								

(Continued on next page)

Table 5 continues:

Variable	OR	95%CI		p	AOR	95%CI		p. Adjust
		Lower	Upper			Lower	Upper	
Marital Status								
Single	1.207	0.602	2.418	0.596	1.690	0.611	4.676	0.312
Married (Ref)								
Education								
Primary	0.829	0.338	2.031	0.681	1.056	0.224	4.971	0.945
Secondary	0.821	0.321	2.098	0.680	0.846	0.206	3.475	0.817
Tertiary (Ref)								
Occupation								
Unemployed	0.938	0.429	2.051	0.872	0.832	0.238	2.910	0.773
Formal	0.859	0.292	2.530	0.783	0.427	0.076	2.401	0.334
Informal (Ref)								
Residence								
Low Density	0.814	0.262	2.533	0.723	0.294	0.049	1.753	0.179
High Density	1.224	0.285	5.255	0.785	0.374	0.053	2.652	0.325
Low Density (Ref)								
PIH/Eclampsia								
Yes	1.471	0.617	3.504	0.384	3.338	0.635	17.531	0.154
No (Ref)								
Mode of Delivery								
Cesarean section	2.569	1.320	5.002	0.005	4.579	1.727	12.137	0.002
Vaginal (Ref)								
Birth Weight								
<2.5	0.275	0.098	0.772	0.014	0.332	0.072	1.518	0.155
2.5 - 3.5	0.578	0.255	1.312	0.190	1.052	0.328	3.379	0.932
>3.5 (Ref)								
Apgar Score at 1m								
Good Outcome	0.251	0.088	0.712	0.009	0.164	0.025	1.094	0.062
Poor Outcome (Ref)								
Apgar Score at 5m								
Good Outcome	0.205	0.043	0.976	0.047	1.477	0.104	20.953	0.773
Poor Outcome (Ref)								
Sex of Baby								
Male	0.468	0.258	0.849	0.013	0.324	0.149	0.703	0.004
Female (Ref)								

CHAPTER FIVE: DISCUSSION

The study found that the burden of MSL was 10.2% and most of the patients (57%) had grade 1 meconium with the least being grade 3 at 8.6%. There was no significant difference in fetal outcome at 1 minute in women with MSL verses women without MSL. (Adjusted P value = 0.062.) However, more women without MSL had good outcome with Apgar score of 7 or more at 96.4% compared to those with MSL at 81.5%. Also at 5 minutes, more women without MSL had good fetal outcome of 97.8% compared to those with MSL at 90.2%%, but there was no significant difference in fetal outcome in those with MSL versus non MSL (adjusted p value =0.773) More admissions to NICU were among those with MSL at 26.1% compared to those without MSAF at 25.4%. Only 35.5% of women with MSL were monitored using CTG. Caesarean section rate was more among women with MSL at 37.2% compared to those without MSL at 19.4%. Patients with MSL were about 4.5 times more likely to be delivered by Cesarean compared with those without meconium (Adjusted odds ratio 4.579, p value = 0.002, 95% CI 1.727 – 12.137). About 31% of women with MSL also had at least one risk factor. However, there was no association between MSL and the investigated risk factors. Among the first five common top risk factors, PIH/ Preeclampsia was the leading risk factor at 15%, followed by prolonged labor (8.6%), then anemia (5.4%), VBAC (4.3%), and then chronic hypertension (3.2%).

5.1. Burden (frequency) of MSL

The result showed that the frequency of MSL in labour at UTH is 10.2 %. This finding though slightly higher is similar with the study, which was conducted at Karachi General Hospital, in which it was found that out of 908 deliveries, meconium stained amniotic fluid was found in 7.7% cases (Lubna et al., 2011). The finding however does not agree with the study conducted to determine the incidence of meconium staining of the amniotic fluid (MSL) and its associated factors in a Nigerian teaching hospital in which it was found that MSL was as high as 20.4%. (David et al, 2006). The differences in the frequencies of MSL in different areas could be due to various factors prevailing in different hospitals and also due to the different clinical practices as well as the level of hospital care and different demographic characteristic of women being attended to by various hospitals.

Majority (57%) of women with MSL were of grade one followed by those with grade 2 at 34.4% with the least being grade 3 at 8.6 %.

5.2. Fetal outcome

At 1 minute, more women without MSL had good fetal outcome with Apgar score of 7 or more at 96.4% compared to those with MSL at 81.5% and there was no significant difference in fetal outcome in women with MSL verse women without MSL(Adjusted P value = 0.062.) . At 5 minutes, more women without MSL had good outcome of 97.8% compared to those with MSL at 90.2%%, but there was no significant difference in outcome in those with MSL versus non MSL (adjusted p value =0.773). The outcome at 5 minutes could be attributed to additional effective neonatal resuscitative measures leading to improved Apgar score. The findings above agree with Priyadharshini and Panicker (2012) and Rokade et al. (2016) who conducted a study to determine the fetal outcome and mode of delivery in patients with meconium stained liquor during labour and found that meconium stained Liquor alone was not associated with an adverse neonatal outcome but good outcome of 86% and 82 % respectively.

In this study it was demonstrated that the higher the grade of MSL the poorer the fetal outcome at both one and five minutes Apgar's scores. For example, at 5 minutes Apgar score, the meconium grade with best outcome was grade one with 52 (100%) followed by those with grade 2 MSL at 27(84.4 %), with the least outcome of 4 (50%) among those with grade three. Best outcome was seen in those with grade one MSL at 100% as compared to those with grade two at 84.4 % and grade three at 50%. Deepak et al (2014) also found that the higher the grade of MSL, the poorer the fetal outcome.

The high percentage in terms of good fetal outcome in patients with MSL observed at UTH in comparison to other previous studies on MSL could be attributed to the good clinical practice that follows effective hospital treatment protocols in patients presenting with MSL as well as effective neonatal resuscitative skills resulting in good outcome especially at 5 minutes Apgar's score. Good outcome could also be attributed to increased use of emergency C/S rather than spontaneous vaginal delivery as a mode of delivery in most women presenting with MSL.

There was more admission to NICU among babies born from women with MSL (26.1%) as compared to babies born from women without MSL at 20.4%. This shows that more adverse outcomes were among those with MSL as compared to those without MSL.

This study shows less admission to NICU among babies born to women with MSL compared to the study conducted in India in which it was found out that about (38.3%) of babies born to women with MSL were admitted to NICU (Rasheed, et al, 2015). This could be attributed to a comparable good outcome as seen in this study.

5.3. Monitoring of patients with MSL with CTG and fetal outcome

The study found out that 33 (35.5 %) patient with MSL were monitored with CTG and that there was no association between being monitored with CTG and outcome (i.e. 94 % in CTG monitored versus 87 % in non CTG monitored (p value = 0.594). However, more women 31 (94%) who were monitored with CTG had good outcome compared with 52 (86.6%) without CTG monitoring though not statistically significant.

5.4. Mode of delivery

About 56(60.2%) of women with MSL delivered via spontaneous vaginal delivery while (34)37.2% delivered by Caesarean and 2 (2.2%) by vaginal instrument delivery**.** Caesarean section rate was twice as high among those with MSL at 37.2% compared with those without MSL at 19.4% respectively. The risk for C/S was also more in those with grade three at 62.5 % followed by those with grade two at 58.1% and least Caesarean sections were seen in those with grade one at 19.3%. The findings are in line with the studies conducted by Deepak et al. (2014) and by Rajput et al. (2016) who found that mode of delivery was significantly associated with MSL and that C/S was seen in 66%, and 85% respectively among women with MSL. In this study, C/S rate was 37.2%. The C/S rates among patients with MSL is likely to be high especially in institutions that lack resources for effective fetal monitoring like shortage of midwifes, CTG machines and lack of definitive diagnosis of fetal distress in MSL such as scalp sampling for PH etc. Therefore, high C/S observed in this study could be attributed to lack of resources for effectively monitoring of women with MSL such as CTGs and other equipment for definitive diagnosis of fetal distress

hence subjecting most of the patients with MSL especially those with grade 2 and 3 to C/S in order to avoid poor outcomes.

5.5. Risk factors for MSL

The study investigated various demographic and some common obstetric factors and risks for MSL. Some obstetric factors investigated included: PIH/preeclampsia and eclampsia, prolonged labour, oligohydramnios, anaemia, VBAC, IUGR etc. About 29 (31%) of those with MSL had the associated investigated complications. The study however did not demonstrate any significant association between either demographic characteristic or any investigated obstetrics complications and MSL. Both bivariate and Logistic regression did not show any factor that was significantly associated with MSL. The study also showed no significant statistical association between the level of parity and MSL. (p value = 0.450). Gestation age of pregnancy and postdates were also not significantly associated with MSL with adjusted p value = 0.600. Pregnancy induced hypertension (PIH) and Preeclampsia also did not show a significant association with MSL (adjusted p value = 0.154). There was however an association between birth weight and MSL (odds ratio 0.218, CI 0.058 - 0.822 and p value 0.024) indicating that babies with birth weight of less than 2.5kg had reduced risk of MSL of about 78.2%. The reason could be because those that had reduced weight were also of the lower gestational age in which risk of MSL is low.

Sex of the baby was also significantly associated with MSL. Women carrying male babies were less at risk of MSL by about 67.8% (adjusted odds ratio 0.322, CI 0.156 to 0.665 and p value 0.002). This is in contrast to the study conducted by Rajput et al. (2016), who found high prevalence of MSL in male neonates with an incidence of 65.2%.

In this study, obstetrics risk factors like gestation age and postdate did not show significant association with MSL (adjusted p value 0.600). These findings are similar with the study conducted by Lubna et al (2011) in which it was found that there was no association between gestation age or postdates with MSL.

Other risk factors observed in some previous studies such as PIH, Pre-eclampsia, oligohydramnios, prolonged labour etc., were also not associated with MSL in this study. However, the five common frequent risk factors noted in this study though not statistically significant included PIH/ Preeclampsia at 15%, followed by prolonged labour (8.6%), then anaemia (5.4%), VBAC (4.3%), and chronic hypertension (3.2%).

CHAPTER SIX: CONCLUSION AND RECOMMENDATIONS

6.1 Conclusions

The prevalence (frequency) of MSL in labour at UTH is 10.2%. There is no significant difference in fetal outcome at 5 minutes in women with MSL compared with those without MSL. However, caesarean rates were noted to be higher in those with MSL as compared to those without MSL. No obstetric complication was significantly associated with MSL.

6.2 Recommendations

UTH administration to provide equipment for definitive diagnosis of fetal distress to labour ward such as fetal scalp PH, fetal scalp electrodes, etc. to be used especially in grade 2 and 3 MSL in order to avoid possibility of unnecessary C/Ss.

Women with meconium grade 2 and 3 in labour should be monitored closely possibly with continuous electronic fetal monitoring or fetal scalp PH in order to avoid poor outcome.

UTH to make policy recommendation for the whole country on management of MSL using the available UTH treatment protocols to MOH as management of the woman with MSL is the same whether at tertiary or lower level.

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APPENDICES

Appendix A: Participant Information Sheet

"Fetal outcome in women presenting with Meconium stained Amniotic fluid"

Principal Investigator: Dr Chazya Sikambale.
Sponsor: GRZ.

Dear Participant,
I invite you to participate in this study being conducted by Dr Chazya Sikambale as part of the requirement for the award of a Master's Degree in Medicine.
The study is looking at factors associated with meconium stained liquor (MSL) and the fetal outcomes at UTH for term pregnancies. You have been chosen in this study because you meet the criteria for inclusion. Research assistants will interview you and will get other information from your medical records and files as well. The findings of this study will help us determine factors associated with MSL and fetal outcomes at UTH. This will enable us plan better for our future patients. The study will not in any way affect the plan of management of your condition.

There are no known risks associated with this study. Also there will not be any monetary gain to you by participating in this study. Nevertheless, the information you will honestly provide will help identify gaps on the management of women with meconium stained liquor.

Be informed also that your participation in this study is purely voluntary and as such you are free to withdraw if you are not interested at any time and your action will not disadvantage your acquisition of health services in the district.
Please feel free to seek clarification when in doubt and also note that the information you will provide will be strictly confidential. The study information will be disseminated to the relevant authorities who will have no direct link to you since anonymity will strictly be observed.

We will ask you a few questions and note some information from your file. If you agree to take part, please sign this consent form.

Informed Consent form

The purpose of the study has adequately been explained to me and I understand the aim, benefits, risks and confidentiality of the study. I further understand that; if I agree to take part in this study, I can withdraw at any time without having to give an explanation and taking part in this study is purely voluntary.

I----------

(Names)

Consent to participate in this study

Signed; ----------date :----------

(Participant)

Participants signature or thumb print

Signed; ----------date :----------

(Witness)

Name of the interviewer: ----------

Signed----------date; ----------

PERSONS TO CONTACT FOR PROBLEMS

1. Chazya Sikambale. University of Zambia, School of Medicine, Department of Obstetrics and Gynaecology, P.O. Box 50110, Lusaka, Zambia. Cell: 0976577356
2. The Chairperson, Eres Converge, Research Ethics Committee, Joseph Mwila Road, Rhodes Park Lusaka, Zambia. Tel 0955155633; Email eresconverge@yahoo.com

Appendix B: Participant Information Sheet (Bemba)

“Amafya yatumbuka muli banamayo abo abasangwa ukutila umwana anyela mumala lyo talati afyalwe”

Kepusha mukalamba: Dr Chazya Sikambale.

Bakafwa: ubuteko bwa mu Zambia.

Mwebatemwikwa

Namilomba ukutila musendemo ulubali mumasambililo ayelechita shing’anga Chazya Sikambale pamo ngo bufwayo bwepepala ilikalamba mufyabumi.

Amasambililo aya yalelolesha pafintu ifikuma kukulufyanya (kunya) Kwa mwana mumala (mwifumo) elyo namafya yesa pamulandu WA icho pa chipatala chikalamba icha UTH.mwasalwa ukutimusende ulubali pamulandu wakutila mwasangwa palibamo abengasendamo ulubali.

Bakafwa Amasambililo aya balamwipusha amepusho elyo yambi amasuko balasenda muli bakadi benu abakuchipatala.

Ifyalafuma mumasambililo aya fyalayafwako ukwishiba nangula ukusanga amafya ayakuma kukulufyanya kwa mwana mwifumo namafya yatumbukamo pachipatala cha UTH. Ifi fikatwafwa ukuitenya mumafwa yonse eyo twingasangwa nayo pa chipatala, amasambililo aya tayali munshila iiliyonse nokulolesha pabundamishi bwenu.

Takuli amafya nangula yamo ayakuma kuli ayamasabililo, elyo takwabe ubunonshi bwandala pakusendamo ulubali mumasambililo aya.namukulundapo, amasuko mwalapela mulibuchishinka yali nokulangisha ichipunda mubundapo ubu banamayo bapokelela nabwafwa bwamwana ukulufyanya Kwa mwifumo.

Ishibeni ukutila ukusenda kwalubali kwalutubiicho muli abantungwa ukuleka ukusendamo ulubali panshita iyo mulefwaya elyo nemichitile yenu tayakwate ukuleta ubwafwa nangu bumo mumipokele yafya bumi bwenu.muli abantungwa ukwipusha tantu tamumfwikishe elyo mwishibe ukutila amasuko yenu yali ukusungwafye pakati kenu Na ine.

Amasambililo aya yali nokuya kubakalamba balolesha pafya bumi abo abatabamwishiba.

Twalamwipusha amepusho elyo yamo amasuko twalasenda muli bakadi benu.Ngamwasumina ukusenda ulubali fwatikeni panshi yachipepala.

Bemba Informed Consent form

Inchito yamasambililo aya yalondololwa bwino eicho naumfwa nokwishiba ubusuma, nobubi, kabili nenkama yamasambililo. Nokulundapo naishiba ukutila nganasumina ukusendemo ulubali, kuti na leka inshita iyo ndefwaya ukwabula ukupela ubulondoloshi nangu bumo nakabili ukusendamo ulubabi kwakuipeleshafye.

Ine---------- (Ishina)

Ukwishiba kwa usendelemo ulubali

Saineni; ----------ubushiku :----------

(kasendawalubali) fwatikeni apa

Saineni; ----------ubushiku :----------

(kamboni)

Ishina lyakwa kepusha : ----------

Saineni----------ubushiku; ----------

PERSONS TO CONTACT FOR PROBLEMS

1**.** Chazya Sikambale. University of Zambia, School of Medicine, Department of Obstetrics and Gynaecology, P.O. Box 50110, Lusaka, Zambia. Cell: 0976577356

2. The Chairperson, Eres Converge, Research Ethics Committee, Joseph Mwila Road, Rhodes Park Lusaka, Zambia. Tel 0955155633; Email eresconverge@yahoo.com

Appendix C: Nyanja Information Sheet

“Mabvuto opezeka mu amai ndikudzionongela kwamwana mmala”

Wamkulu ofufuza: **Dr Chazya Sikambale**.
Opereka thandizo: Boma la Zambia.

Mwalandilidwa kutenga nawo mbali mumaphunzilo la Dotolo Chazya Sikambale yofunikila kuti apatsiwe pepala ikula yau Dotolo wa mankwala.
Maphunzilo alangana pa dzinthu dzogwilizana ndimwana akalimmimba mwa amai ake pamene akadzionongela. Phunzilo lamenei izankhalila pa chipatala cha UTH. Mwasankidwa kuli phunzilo iyi chifukwa mukwanisa zofunikila zamapunzilo.

Chidzachitika ndi chani mukatenga nawo mbali pa kafukufuku ameneyu?
Pambuyo pa kusayina nkhalata la chilolezo chanu, Ofunafuna okonkapo adzakufunsani mafunso ndikutenga nkhani zofotokoza za mbiri ya ochembele wanu wose. Sipazakhala kutengedwa zoyeza za nthupi lanu zilizonse.

Chidzachitike ndi chiani pa zotsatila za kafukufuku ameneyu?
Zotsatila za kafukufukufuku ameneyu dzizathandidza kuonesa zomwe zimalengesa zogwilizana ndikuzionongela mumimba mwamai ake ndimavuto amene amaoneka. Idzi dzidzatandidzila kupheza njila dzotandidzila amayi oyembekezera ndi makanda awo amene adzakhale ndi vuto lotelo kusogolo.

Pali kusintha kwachithandizo mukatenga nawo mbali mukafuku ameneyu?

Mukavomela kutenganawo mbali pa kafukufuku ameneyu sizasokoneza chilanganizo chilichose chokhuza chithandizo chanu kapenaso mwana wanu pa chipatala.

Nanga ndi mabvuto anji adzakhalepo mukatenga nawo mbali?
Kulibe vuto limenelizapezeke logwilizana kafukuyu, madzafusidwa mafuso okhuzana ndi ochembere wanu kumaso za nkhanda lanu opanda kukuyezani kulikonse kapena mwana wanu.

Nanga pali malipilo aliwonse pambuyo pa kafukufukuyu

Mukatenga nawo pakafukufukuyu palibe malipilo amtundu uliwonse kapena tandizo la ndalama lamene lidzaphasidwa. Khoma nkani mwachilungamo la mmene

mudzapatsa izatandiza kuziwa mphata lamene lilipo kwa amai ndi kuzionongela kwamwana mumimba mwamai ake.

Dziwani kuti kutenga nawo mbali kuphunzilo iyi ndikodzipeleka, mwaichi ndinu amatsuka kuzipatulula kuli phunzilo iyi nthawi ili yonse ndipontso dzichitidwe izi sizizasokoneza umoyo wanu ndi tandizo la chipatala mu boma. Nkhalani omasuka kufunsa ngati muli ndi nkhawa mukatenga nawo mbali pa kafukufukuyu. Mayankho anu azasungidwa mwachinsisi.

Nkhani ya phunzilo iyi idza gawika kuofunikila oziwankhani iyi amene Sali pafupi ndinu, ndiponso nkhope yanu izabisidwa muma buku anu. Ngati mwavomela kutenga mbali kuphunzilo iyi, fwatikani papepa lamalamulo.

PERSONS TO CONTACT FOR PROBLEMS

1. Chazya Sikambale. University of Zambia, School of Medicine, Department of Obstetrics and Gynaecology, P.O. Box 50110, Lusaka, Zambia. Cell: 0976577356

2. The Chairperson, Eres Converge, Research Ethics Committee, Joseph Mwila Road, Rhodes Park Lusaka, Zambia. Tel 0955155633; Email eresconverge@yahoo.com

Appendix D: Questionnaire

Fetal outcome in women presenting with meconium stained liquor at UTH Lusaka

"Amafya yatumbuka muli banamayo abo abasangwa ukutila umwana anyela mumala lyo talati afyalwe pachipatala cha UTH"
"Mabvuto yopezeka mu adzimai ndikudzionongela kwamwana mumala pa chipatala cha UTH."

Participant ID_____ Date: _____

Please tick or enter in the appropriate space.

Part 1 (Socio-Demographic and baseline health information

1. Age (years) _____

2. Parity_____

3. Gestation age of the pregnancy in weeks_____

4. Marital Status

Single 1.Nshaupwa 1.osakwatiwa	Married 2.Nalyupwa 2. Wapabanja	3. Widowed 3.Nine mukamfwilwa 3. Namfedwa	4.Divorced 4.Ifupwa fyalipwa 4. Osudzulidwa	5. Other (Specify) 5.Fimbi 5.Zina

5. Education Level

Primary 1.Amasambililo yanono 1.pulayimale	2. Secondary 2.ku secondary 2.sekondale	3. Tertiary 3. Amasambililo yakalamba 3.koleji	4. Never been to school 4. Nshatalaya ku sukulu 4.osasoma

6. Occupation Type

Unemployed 1.Nshibomba 1.Sinimasebenza	2.Formal Employment 2.Ndabomba 2.Nimasebenza	3. Informal Sector 3. Ndaibombela 3.Nimaisebenzela	4.Other (Specify) 4. Fimbi 4.zinangu

7. Religion

Christian 1.Umwina kiristu 1.Wa chikhilisitu	2Muslim 2.Umu Mosilemu 2. Msilamu	3Hindu 3.Umu Hindu 3.Mu hindu	4.Other (Specify) 4.Yambi 4.zinangu

8. Residential Address _____ (write name of compound)

1.High Density 1.Mukomboni	2.Medium Density	3. Low Density 3. Kumayadi

---

Part 2 (Presence of meconium)

9. **Tick where applicable (as indicated in the patient file)**

Yes	No

10. Grade of meconium as indicated in the patient file (tick)

1. Grade one	2. Grade two	3. Grade three

11. If the answer to question 9 and 10 is yes, was the patient monitored using a cardiotocography (CTG)

1. Yes	2. No

12. Sign of abnormal fetal heart rate as indicated in patient file.....

1.Yes	2.No

13. Labour spontaneous or Induced (Tick)

1.spontaneous 1.nfumo lyabukile iline 1.monachembeza bwino	2.induced 2.mumala ukukalipa bakutampishe ku chipatala 2.munayambisidwa matenda

14. Associated obstetric complication if any. From history or patient file (Tick)

1. Anaemia; 1.Ukubulwa umulopa; 1. Kusila magazi	
2.Hypertension; 2.Umulopa ukubutuka; 2. Magazi kutamanga	
3.PIH/ Eclampsia; 3.Umulopa ukubutuka pabukulu nungu uku samfula; 3. Magazi kutamanga pa mimba olo kukunyuka	
4.Diabetes; 4.Ubulwele bwa sugar; 4. Matenda ya sugar	
5.Fever during pregnancy 5.Umubili ukukaba mwifumo 5. Tupi kupya pamimba	
6.Respiratory problem 6.Ichifuba nangu ukushipema bwino 6.Kukosomola olo kukuta befu	
7.Prolonged labour 7.Ukutantalila kwanshita yakupapa ilyo ifumo lyabuka 7. Kubeleka kwamene kuchedwa	
8.Augumentation of labour with oxytocin (check file)	
9.Cardiac problem; 9.Ubulwele bwamutima; 9.Matenda amutima	
10.IUGR (check file)	
11.Polyhydramnious; 11.Amenshi ukufulisha pefumo 11.Manzi kupakisa pamimba	
12.Oligohydramnious; 12.Amenshi ukuchepa mwifumo 13. Manzi kusapaka pa mimba	
13.Uterine hyperstimulation as per plot on the partograph in the patient file (check file)	
14.Sickle cell; 14.Ukulwalila kwakuchepelwa umulopa 14. Matenda yosila magazi	

15. Mode of delivery as indicated in the file (tick)

1.Vaginal delivery	2.Instrumental vaginal delivery	3.Caesarean section

16. If delivery by caesarean section, indication as indicated in the file:

1.Failed induction of labour	2. Fetal distress	3.Cephalopelvic Disproportion	4.Malpresentation	5.Failed VBAC	6.Others indicate

17. Birth weight in grams as indicated in the file.....

Less than 2.5kg	2.2.5 -3.5 kg	3.Greater than 3.5kg

18 a. Apgar score at 1min_____

1.Less than 7	2. 7 or more

18b. Apgar score at 5 min as indicated in the file_____

1.Less than 7	2. 7 or more

19. Sex of baby as indicated in the file?

1. Male	2. Female

20. Admission to NICU after delivery

1. Yes	2. No

21. If answer to question 20 is yes, reason for admission to NICU (mention).....

Low APGARS score	2.Low Birth weight	3.Meconium Aspiration	4.Poor breathing

22. Did the baby die?

22. Bushe umwana alifwa?

Yes Aye	No Awe

THANK YOU
TWATOTELA
ZIKOMO KWAMBILI

Appendix E: Approvals

UNIVERSITY OF ZAMBIA

SCHOOL OF MEDICINE

Telephone : +260211252641
Telegram: UNZA, Lusaka
Telex: UNZALU ZA 44370
Email: assistantdeanpgmedicine@unza.zm

P.O Box 50110
Lusaka, Zambia

20 April 2017

Dr. Chazya Sikambale
Department of Obstetrics & Gynaecology
School of Medicine
University of Zambia
LUSAKA

Dear Dr. Sikambale,

RE: GRADUATE PROPOSAL PRESENTATION FORUM

Following the presentation of your proposal entitled **"Fetal Outcome in Women Presenting with Mecogium Stained Liquor at the Women and Newborn (University Teaching Hospital) – Lusaka Zambia"** your supervisor has confirmed that the necessary corrections to your research proposal have been done.

You can proceed and present to the Research Ethics.

Yours faithfully,

Dr. L. Prashar
Assistant Dean, Postgraduate
SCHOOL OF MEDICINE

UNIVERSITY OF ZAMBIA
SCHOOL OF MEDICINE
21 APR 2017
P.O. BOX 50110, LUSAKA

cc: Head, Department of Obstetrics and Gynaecology

Dept of Obstetrics & Gynecology,
University of Zambia School of Medicine,
P.O Box 50110,
LUSAKA.

10 August 2017

The Senior Medical Superintendant,
Women and Newborn Hospital,
UTH,
LUSAKA

Approved 14/8/17

Dear Sir/Madam

Ref: REQUEST TO CONDUCT A STUDY AT WOMEN AND NEWBORN HOSPITAL.

Refer to the above subject matter.

I'm an MMED student in the Department of Obstetrics and Gynecology at UNZA school of Medicine.

I wish to request for permission to conduct a study in your hospital entitled "**Fetal outcome in women presenting with meconium stained liquor at UTH**". The study will help analyze the extent of the problem caused by meconium stained liquor (MSL). It will also facilitate the formulation of suitable treatment protocols for MSL at UTH and Zambia as a whole which will in turn contribute towards the reduction of perinatal morbidity and mortality.

The study is a partial fulfillment of the requirements of the degree of masters of science in Obstetrics and gynecology by the university of Zambia

I thank you in advance,

Yours faithfully,

Dr Chazya Sikambale.
Phone: 0976577356

33 Joseph Mwilwa Road
Rhodes Park, Lusaka
Tel: +260 955 155 633
+260 955 155 634
Cell: +260 966 765 503
Email: eresconverge@yahoo.co.uk

I.R.B. No. 00005948
F.W.A. No. 00011697

4th April, 2018

Ref. No. 2018-Jan-017

The Principal Investigator
Dr. Chazya Sikambale
University Teaching Hospital
Dept. of Obstetrics & Gynaecology
Private Bag RW1X Ridgeway,
LUSAKA.

Dear Dr. Sikambale,

RE: FETAL OUTCOME IN WOMEN PRESENTING WITH MECONIUM STAINED LIQUOR AT UNIVERSITY TEACHING HOSPITAL, LUSAKA.

Reference is made to the above subject matter. The IRB resolved to approve this study and your participation as Principal Investigator for a period of one year.

Review Type	**Ordinary**	Approval No. **2018-Jan-017**
Approval and Expiry Date	Approval Date: 4th April, 2018	Expiry Date: 3rd April, 2019
Protocol Version and Date	Version - Nil	3rd April, 2019
Information Sheet, Consent Forms and Dates	• English, Nyanja, Bemba.	3rd April, 2019
Consent form ID and Date	Version - Nil	3rd April, 2019
Recruitment Materials	Nil	3rd April, 2019
Other Study Documents Questionnaires,	Questionnaires.	3rd April, 2019
Number of participants approved for study	170	3rd April, 2019

Specific conditions will apply to this approval. As Principal Investigator it is your responsibility to ensure that the contents of this letter are adhered to. If these are not adhered to, the approval may be suspended. Should the study be suspended, study sponsors and other regulatory authorities will be informed.

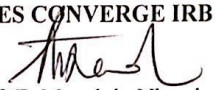
Conditions of Approval

- No participant may be involved in any study procedure prior to the study approval or after the expiration date.
- All unanticipated or Serious Adverse Events (SAEs) must be reported to the IRB within 5 days.
- All protocol modifications must be IRB approved prior to implementation unless they are intended to reduce risk (but must still be reported for approval). Modifications will include any change of investigator/s or site address.
- All protocol deviations must be reported to the IRB within 5 working days.
- All recruitment materials must be approved by the IRB prior to being used.
- Principal investigators are responsible for initiating Continuing Review proceedings. Documents must be received by the IRB at least 30 days before the expiry date. This is for the purpose of facilitating the review process. Any documents received less than 30 days before expiry will be labelled "late submissions" and will incur a penalty.
- Every 6 (six) months a progress report form supplied by ERES IRB must be filled in and submitted to us.
- ERES Converge IRB does not "stamp" approval letters, consent forms or study documents unless requested for in writing. This is because the approval letter clearly indicates the documents approved by the IRB as well as other elements and conditions of approval.
- Every 6 (six) months a progress report form supplied by ERES IRB must be filled in and submitted to us. Late submission of these will attract a penalty.

Should you have any questions regarding anything indicated in this letter, please do not hesitate to get in touch with us at the above indicated address.

On behalf of ERES Converge IRB, we would like to wish you all the success as you carry out your study.

Yours faithfully,
ERES CONVERGE IRB



Prof. E. Munalula-Nkandu
BSc (Hons), MSc, MA Bioethics, PgD R/Ethics, PhD
CHAIRPERSON