CLINICAL ESTIMATION OF FETAL WEIGHT IN THE PRETERM POPULATION - AN ALTERNATIVE TO LEOPOLD`S METHOD VALIDATED BY BIRTH WEIGHT AT THE UNIVERSITY TEACHING HOSPITAL, LUSAKA

BY

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Dissertation submitted to the University of Zambia in partial fulfilment of the requirements for the award of degree of Master of Medicine in Obstetrics and Gynecology

THE UNIVERSITY OF ZAMBIA

LUSAKA

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DECLARATION

I, Dr. Swali Vusa Fundafunda, hereby declare that this dissertation presented for the award of degree of Master of Medicine in Obstetrics and Gynaecology has not been previously submitted wholly or in part for any other degree at this or any other university nor is it currently submitted for any other degree

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APPROVAL

The dissertation of Dr. Swali V. Fundafunda 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

Preterm birth is defined as childbirth occurring at less than 36 completed weeks or 259 days of gestation (World Health Organization, 2014). In most developing and resource limited countries such as Zambia, ultrasound estimation of fetal weight in most circumstances is not readily available for the health care professional to make decisions, a gap which can be filled by a cheaper and simpler clinical method of estimation fetal weight. One such method is the Dare's formula which relies on the product of the symphysio-fundal height and abdominal circumference to estimate the fetal weight. The study aimed at exploring this alternative clinical method to estimate fetal weight among women at highest risk of preterm birth in a low resource population and validate it with the actual birthweight.

This was a prospective study on mothers admitted to University Teaching Hospital (UTH) at risk of preterm delivery. Between 1st June and 31st October 2016, a structured questionnaire was used to collect pregnancy and outcome data on a sample size of 168 mothers that had a singleton pregnancy, longitudinal lie and known gestation <37 weeks about to deliver within one week. Maternal anthropometrics included height, weight, abdominal circumference and fundal height. The derived (estimated) fetal weight calculated using Dare's formula was compared to the actual birthweight. Paired t-test was used to compare the mean between derived and actual weights. Multivariate analysis was used to understand what maternal or pregnancy characteristics could have led to the variance (under and over-estimate beyond 300g or 10%).

Of the 168 women enrolled, over half were moderate to late preterm (32 to 37 weeks) with 134 (79.8%) were between 32-37 weeks with 54.2% between 34-<37 weeks. Very Preterm were 29 (17.3%) and only 5 (3%) were <28 weeks. Using Dare's formula. The derived birthweight was on average 553g greater than actual birthweight (SD = 641, 95% confidence interval 456– 651, p<0.0001). There was a 71.5% chance of variance beyond 300g. On multivariate analysis for every 1cm increase in fundal height measurement the odds for above 300g weight variance reduced on average by 14% (aOR =0.86, 95% CI = 0.76 - 0.98, P= 0.0249). Similarly, for every 1cm increase in maternal abdominal circumference measurement, the odds for above 300g weight difference increased on average by 7% [adjusted Odds Ratio (aOR) = 1.07, 95% Confidence Interval (CI) = 1.03 - 1.12, P= <0.001].

Based on this study population, this clinical method and using Dare's formula cannot be reliably used in estimation of fetal weight in preterm pregnancies. Ultrasonography remains the gold standard for determining fetal weight in preterm pregnancies and should therefore be availed as part of the tools to help in counselling mothers on perinatal prognosis.

Key words: Preterm birth, Fetal weight estimation

ACKNOWLEDGEMENTS

My supervisor, Prof Bellington Vwalika for the supervision, mentorship and encouragement.

Mr. Y. Ahmed, my co-supervisor, who dedicated a lot of his time in making sure this work is completed.

Staff in the department of Obstetrics and Gynaecology

All the women who participated in the study without whom this study wouldn`t been

Mr. John Banda for assisting with statistical analysis

God my creator for the privilege of life and carrying out this study to help improve neonatal and maternal life.

DEDICATION

This dissertation is dedicated to all the mothers who participated in the study, my wife Kalayire Saka Phiri, my sons Samuel and Nathaniel for their encouragement and allowing me spend time away from them while working on this study and lastly but not least, my mother Ms. Elizabeth Thandiwe Daka without whom I would not be here today.

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ABREVIATIONS

AG	Abdominal Girth
ID	Identity
LMP	Last Menstrual Period
SFH	Symphisio-Fundo-Height
SPSS	Statistical Package for Social Sciences
UNZA	University of Zambia
U/S	Ultrasound
UTH	University Teaching Hospital
WHO	World Health Organization

CHAPTER ONE: INTRODUCTION

1.1 Background

Preterm birth is defined as childbirth occurring at less than 36 completed weeks (i.e. <37 weeks) or 259 days of gestation (WHO, 2014). It further notes that preterm birth is a major determinant of neonatal mortality and morbidity and has long-term adverse consequences for health. There are sub-categories of preterm birth, based on gestational age ranging from extreme preterm which is less than 28 weeks, very preterm from 28 to 32 weeks and moderate preterm from 32 to 37 weeks (WHO, 2014).

In most developing and resource limited countries such as Zambia, ultrasonographic estimation of fetal weight is not readily available for the healthcare professional to make decisions, a gap which can be filled by a cheaper and simpler clinical method of estimation fetal weight. The University Teaching Hospital (UTH) delivers about 30% of its deliveries as preterm (UTH 2016 delivery records). With most of them being admitted without ultrasonic estimation of fetal weight in the preceding week, it is difficult for professional care providers to make decisions on mode of delivery and whether labour needs to be delayed.

In most of the developed countries and some developing countries, studies have been done to determine the validity of an ultrasound and clinical methods in estimating fetal weight, but no similar studies have been done on preterm deliveries (Colman, 2012).

A study on accuracy of clinical and ultrasound estimation of fetal weight in predicting actual birth weight in Enugu, Southeastern Nigeria concluded that the ultrasound method is generally a better predictor of the actual birth weight than the clinical method, and thus should be used in estimating the actual birth weight when accessible (Ugwu et al, 2014). This was validated by another study done at the University College London Hospitals, United Kingdom, on the clinical and ultrasound estimation of birth weight prior to induction of labor at term which concluded that although in general, clinical estimation of birth weight performed favorably compared with ultrasonic estimates, ultrasound done immediately prior to labor is more accurate at predicting the low or high birth weights (Peregrine et al, 2007). This was however

disputed by a study done at the Ambo Hospital, West Shoa, Ethiopia to estimate the accuracy of the Johnson`s formula (which states that for estimation of fetal weight in vertex presentation: Fetal weight (g) =fH H (cm) x n x 155. Where fH=fundal height and n=13 when presenting part not engaged n= 12 when presenting part at station 0 n= 11 when presenting part at station +1) and palpation methods of fetal weight estimation and their correlation which concluded that estimation of fetal weight by palpation appeared to be more accurate than the Johnson's method (Belete and Gaym, 2008). This was supported by a study done in Israel on comparison of clinical and ultrasonic estimation of fetal weight which concluded that clinical estimation of birth weight in early labour is as accurate as routine ultrasonic estimation obtained in the preceding week in the lower range of birth weight less than 2500g (Sherman et al, 2014).

A simplified version is the Dare's formula. Dare et al (1990) stated it as: 'the product of symphysiofundal height (Mc Donald's measurement) and abdominal girth at the level of umbilicus measured in centimetres and result expressed in grams to estimate foetal weight in uteru at term. They found that the estimation correlated well with birthweight. While many studies regarding accuracy and estimation of fetal weight have been done on term babies, none have been specifically done in the preterm pregnancies. This study endeavored to validate a clinical method of estimating fetal weight using the Dare's formula in preterm pregnancies.

1.2 Statement of the Problem

An estimated 12.9% of births in Zambia are estimated to be preterm (Blencowe et al, 2013). Preterm birth is associated with an increased risk of newborn complications during labor and the puerperium. Many survivors face a lifetime of disability, including learning disabilities and visual and hearing problems (Menon, 2012). Ultrasonography remains the gold standard for estimation of fetal weight. However, this is not readily available at UTH where 30% of deliveries are preterm (UTH delivery records 2016) and most times estimation of fetal weight is dependent on the experience of the frontline professional health care providers which may be variable.

1.3 Study Justification

Perinatal counselling on likelihood of survival, the intervention undertaken to postpone preterm delivery, optimal route of delivery, or the level of hospital where delivery should occur may be based wholly or in part dependent on the estimation of expected birth weight. Colman, (2012). However, there was no study which had been done on preterm pregnancies in Zambia to show the validity of clinical estimation of the fetal weight. This research endeavored to provide a more accurate clinical assessment of fetal weight using a simple formula including fundal height and abdominal circumference (Dare's formula) among women at risk of preterm delivery in low resource settings where obstetrical ultrasound is may not be available.

1.4 Research Question

Is clinical estimation of fetal weight using the Dare's formula accurate in preterm pregnancies within one week prior to delivery using abdominal girth and symphisio-fundal height measurements?

1.5 Objectives

1.5.1 General objective

To explore the clinical method (using Dare's formula) as opposed to ultrasound to estimate fetal weight among women at highest risk of preterm birth in a low-resource population

1.5.2 Specific objectives

1. To demonstrate the difference between the actual birthweight and the clinically estimated birthweight in preterm deliveries at UTH using abdominal girth and symphisio-fundal height (Dare's Formula).
2. To explore the extent of the variance between estimated and actual birthweights compared to typical tolerances (e.g. $\pm$ 300g, or $\pm$ 10%)
3. To determine the determinants of under and over-estimates in birthweights using in preterm pregnancy.

CHAPTER TWO: LITERATURE REVIEW

In lower-income countries, on average, 12% of babies are born prematurely compared with 9% in higher-income countries (Blencowe et al, 2013). These findings were in support of an earlier study to determine prevalence and determinants of preterm deliveries in the University of Ilorin Teaching Hospital, Ilorin, Nigeria which estimated preterm birth to be at 11.8% of all live births (Mokuolo et al, 2010) and data from national, regional and worldwide estimates of preterm birth rates in the year 2010 which estimated preterm births in Tanzania and Burundi to be at 11.4% while in Zambia was estimated to be at 12.9% (Blencowe et al, 2013).

Worldwide, there is a slight difference in the prevalence of preterm birth, and this is due to the difference in the population studied (Silwimba, 2014). Preterm birth affects about 9.6% of all live births and approximately 85% of the burden is concentrated in Africa and Asia (WHO, 2014).

Although in general, clinical estimates of birth weight perform favorably compared with ultrasonographic estimates, ultrasound immediately prior to labor is more accurate at predicting the low or high birthweight fetus (Peregrine et al,2007). A study to determine accuracy of clinical and ultrasound estimation of fetal weight in predicting actual birth weight in Enugu, Southeastern Nigeria concluded that the ultrasound method of fetal weight estimation is generally more accurate than the clinical method of fetal weight estimation (Ugwu et al, 2014). This was related to a study on accuracy of estimated fetal weight by ultrasonography compared with the Leopold maneuver. The maneuvers consist of four distinct actions, each helping to determine the position of the fetus. The maneuvers are important because they help determine the position and presentation of the fetus, which in conjunction with correct assessment of the shape of the maternal pelvis can indicate whether the delivery is going to be complicated, or whether a cesarean section is necessary. The effect of maternal obesity which concluded that both ultrasound assessment and clinical estimation of fetal weight are strongly associated with actual birthweight. Ultrasonography provides a more accurate assessment of fetal weight in the term patient than clinical estimation by residents (Horton et al, 2014).

This was however disputed by an Iranian hospital study which concluded that clinicians' estimates of birthweight in term pregnancy were as accurate as routine ultrasound estimation in the week before delivery (Ashrafganjooei et al, 2010).

A study to determine accuracy of prediction of birth weight by fetal ultrasound in Nepal concluded that there is a significant error in the estimation of the fetal weight when depending only on the fetal ultrasound (Bajracharya et al, 2010). They felt that estimation of fetal weight by ultrasound can lead to unnecessary obstetrical intervention and therefore requires correlation of the ultrasound findings with clinical examination.

This was further consolidated by findings in a study to determine the accuracy of fetal weight using ultrasound and clinical fetal weight estimations in Nigeria which concluded that clinical estimation of birthweight clearly has a role in management of labour and delivery in a term pregnancy (Njoku et al, 2014).

Abdulrazak et al, (2013) in Iraq in a study to evaluate how far clinical and sonographic fetal weight assessment done by obstetrician can correlate with the actual birth weight of the newborn concluded that clinical fetal weight estimation is proved to be a relatively accurate and comparable to ultrasound.

The advantages and superiority of ultrasonography is that it not only measures estimated fetal weight but also the gestational age, fetal maturity, biophysical profile and amniotic fluid index which play an important role in management of labor and reduction of perinatal morbidity and mortality. Chitra et al (2014) states that despite the superiority of ultrasonography, the simple clinical method of estimating fetal weight is of great value especially in a developing country

CHAPTER THREE: METHODOLOGY

3.1 Study design and site

This prospective cross-sectional comparative study was carried out at the University Teaching Hospital in the Department of Obstetrics and Gynecology**.**

3.1.1 Study duration

Study participants were enrolled between1st June 2016 and 31st October 2016.

3.1.2 Target population

The study targeted mothers admitted to UTH with pregnancies less than 36 completed weeks (with sure known LMP) and at risk of preterm delivery.

3.1.3 Study population

The study population was mothers who met the eligibility criteria.

3.1.4 Eligibility Criteria

Inclusion Criteria

To be included in the study:

1. Pregnant women needed to have presented with a live singleton pregnancy
2. Known sure last menstrual period in labour,
3. Either in spontaneous labour or induced prior to 37 weeks gestation
4. Longitudinal lie
5. Provided informed consent

Exclusion Criteria

1. Multiple pregnancy
2. Maternal obesity>100kg,
3. Polyhydramnios
4. Transverse lie
5. Clinical or ultrasonic evidence of uterine fibroids
6. A woman that delivered later than one week of admission
6. Oligohydramnios
7. Does not provide informed consent

3.1.5 Participant Recruitment

Singleton pregnant mothers presenting to UTH labour ward for delivery between 24 and 37 gestational weeks and, likely to deliver within a week, were recruited into the study.

3.1.6 Sampling Methods

Purposeful sampling of singleton pregnant mothers presenting to UTH labour ward for delivery between 24 and 37 gestational weeks and, likely to deliver within a week.

3.1.7 Sample Size

The sample size calculated using a formula adopted from "The John Hopkins and IFRC Public Health Guide for Emergencies" by Abdallah & Burnman (undated) given below.

The degree of certainty (confidence) chosen for this study was 95% (with a cut off value of the appropriate probability distribution of 1.96) and margin of error at 5%.

$N=Z^2pq/ d^2$

Where N=sample required

Z=Level of statistical certainty chosen or confidence interval (at 95% Z = 1.96 at 90%) The value Z is usually rounded to 2.

d=the degree of accuracy desired which is half the confidence interval

p= estimated level/ Prevalence/ coverage rate being investigated and

q= 1-p

$N=1,96^2x0.129(1-0.129)/0,0025=172.655$

Sample size was =173

3.2 Procedures and Data Collection

When a pregnant woman in the preterm condition was admitted, the eligibility criteria were administered and if these were met, information was provided to her in the appropriate language (Appendices A, B, C) informing her of the study and whether

she wanted to participate. If she agreed to participate, written consent was obtained (Appendix D). For an antenatal woman below 18 years, assent was obtained from the guardian (Appendix E) .

Data was collected by means of interviews and clinical assessment using a pretested questionnaire (Appendices F and G).

A short training was conducted on the health personnel who were to be engaged in the study on the clinical method for estimation of fetal weight. Following an informed consent, the Dare's formula, (Weight in grams = Abdominal girth (in cms) x Symphysio-fundal height (in cms) (AG x SFH) was used. The numerical value of the product is in grams. Abdominal girth was measured at the level of the umbilicus.

Symphysio-fundal height measurement was done after correcting the dextro-rotation, from the upper border of symphysis to the height of fundus. (Ugwu et al, 2014). The clinical estimation was carried out to the nearest centimeter using a two surfaced non-stretchable tape; one surface was graduated in centimeters while the other was in inches. The symphysiofundal height was measured from the highest point on the uterine fundus to the midpoint of the upper border of the symphysis pubis using the reverse side (inch surface) of the tape to minimize measurement bias. Thereafter, the abdominal circumference was measured immediately at the level of the umbilicus. The fetal weight in grams was then calculated as described above and compared with the actual birth weight which was measured using a desktop baby scale weighing machine.

Vaginal examination was carried out by the admitting doctor to determine the fetal station and cervical dilatation as soon as a woman meeting the above criteria was admitted for vaginal or abdominal delivery.

Measuring exposure and outcome

Exposure: Various maternal, anthopometric and fetal (see summary overleaf)

Primary outcome: Birth weight

Secondary outcomes:

Summary of dependent and independent variables

Primary dependent (or outcome) variable	**Type**	**Notes**
Estimated Birth weight	Continuous variable	Measured in grams
Secondary dependent (outcome) variables		
Actual Birth Weight	Continuous Variable	Measured in grams
Independent (or exposure) variables	**Type (continuous or categorical**	**Notes**
Age of mother	Continuous	Subsequently categorised into discrete categories (e.g. <16, 17-19, 20-24 etc).
Birth weight Parity	Continuous Categorical (dichotomous)	Categorised into discrete categories (e.g.600g to 1000g, 1000g to 1500g, 1500 to 2500). Primiparas or multiparas
Abdominal girth	Continuous	To be reported in centimetres
Gestational age	Continuous	(24to 26, 27to 29, 30 to 32, 33 to 35, 36 to 37)
Height of fundus	Continuous	Reported in centimetres
Residential area	Categorical (dichotomous)	Categorised as Low or High density

3.3 Data Analysis

Data from structured questionnaires was entered and IBM SPSS version 21.0 was used for statistical analyses and to produce graphical output.

All statistical tests were at 5% significance level. Independent samples T-test was used to compare mean values between groups and the Pearson's chi-squared test was used for comparison of proportions between groups. The Fisher's exact test was used when one or more of the cells had an expected frequency of five or less. Some variable categories with less frequency were collapsed together accordingly.

Study variables were checked for evidence of collinearity based on a Spearman correlation coefficient >0.8.

The relationship between study variables and fetal birth weight estimation variance was examined using logistic regression. The backward elimination method was used and selection for entry into the logistic regression model was considered at level $p<0.20$ or known clinical significance.

3.4 Ethical Considerations

Permission was sought from the University Teaching Hospital management through the Head of Department in Obstetrics and Gynaecology to conduct the study at the institution and ethical approval was sought from ERES Converge IRB (Appendix H).

Confidentiality of the study participants was ensured by ID codes to conceal their identity. No patient names were used in the data collection process.

All data collection tools were kept in a locked filing cabinet and electronic data stored in a password protected file.

CHAPTER FOUR: RESULTS

4.1: Description of study participants and pregnancy outcome

There were total 173 women recruited for this study but complete data, specifically for actual birthweight (dependent variable) was only available for 168.

4.1.1 Sociodemographic characteristics

Table 1 shows summary descriptive statistics of the study subjects' sociodemographic characteristics.

Two (2) of the recruited women were aged < 18 years (1.2%), while the larger majority (92.3%) were aged between 18 and 35 years, and only 11 (6.5%) were aged above 35 years. A larger proportion of the study women were married (66.1%), while (33.9%) were unmarried.

A greater majority of the mothers had up to secondary level education (63.7%), and 28% had up to primary level education (Table 1). Over three quarters of the mothers were also not employed, (79.2%), while 16.1% were in informal employment and 4.7% were in formal employment. There were just under three quarters (73.8%) mothers from high density residential areas, 19.6% from medium density areas, and 1.8% from rural areas and 4.7% from low density areas.

Table 1: Socio-demographic characteristics of the study subjects

Variable	Frequency N=168	Percentage
Age		
Less than 18	2	1.2
18 - 35	155	92.3
Greater than 35	11	6.5
Marital status		
Single	51	30.4
Co-habiting	5	3.0
Married	111	66.1
Widowed	1	0.6
Education		
None	5	2.9
Primary	47	28.0
Secondary	107	63.7
Tertiary	9	5.4
Employment		
Formal	8	4.7
Informal	27	16.1
Not employed	133	79.2
Residence		
High density	124	73.8
Medium density	33	19.6
Low density	8	4.8
Rural	3	1.8
Alcohol		
Yes	7	4.2
No	161	95.8
Tobacco		
Yes	0	0
None	168	100

4.1.2 Past Medical and Surgical History Characteristics

Of the 168 study participants, 7 (4.2%) had a history of hypertension, 18 (10.7%) had history of malaria, 28 (16.7%) were positive for HIV, and two (1.2%) had history of syphilis (Table 1). Further, majority of the mothers had no past surgical history, (n=156, 92.9%), while eight (4.8%) had a previous caesarean operation (Table 2).

None of the mothers had past medical history of pre-gestational diabetes, sickle cell, heart disease, TB, or fibroids.

Table 2: Past medical and surgical history

Variable*	Frequency N=168	Percentage
HTN medical history		
Yes	7	4.2
No	161	95.8
Malaria medical history		
Yes	18	10.7
No	150	89.3
HIV medical history		
Yes	28	16.7
No	140	83.3
Syphilis medical history		
Yes	2	1.2
No	166	98.8
Past surgical history		
None	156	92.9
Caesarean section	8	4.8
Other surgical operation**	4	2.4

*None had history of gestational diabetes, sickle cell disease, cardiac disease

**The four other surgical operations included two for laparotomy, one had an appendectomy and one has a breast lump removal.

4.1.3 Complications in current pregnancy

There were 137 (81.5%) preterm mothers who had no complications during pregnancy and 31(18.5%) who had any complications during this pregnancy. They could have had more than one complication as follows: twelve (7.1%) that had gestational hypertension, 14 (8.3%) that had preeclampsia, 2 (1.2%) had eclampsia, 27 (16.1%) had a urinary tract infection, 7 (4.2%) had malaria. As previously noted, 28 of the 168 (16.7%) were HIV positive and were on combined antiretroviral therapy while two (1.2%) had received treatment of syphilis earlier in the pregnancy. None of the mothers had chlamydia, herpes, gonorrhea, trichomanias, or hepatitis infection.

Table 3: Complications in current pregnancy

Variable	Frequency N=168	Percentage
Had any clinical complication during pregnancy		
Yes	31	18.5
No	137	81.5
Had gestational hypertension during pregnancy		
Yes	12	7.1
No	166	98.8
Had Preeclampsia/HELLP during pregnancy		
Yes	14	8.3
No	154	91.7
Had Eclampsia during pregnancy		
Yes	2	1.2
No	166	98.8
Had UTI during pregnancy		
Yes	27	16.1
No	141	83.9
Had Malaria infection during pregnancy		
Yes	7	4.2
No	161	95.8
Was HIV positive		
Yes	28	16.7
No	140	83.3
Was Syphilis reactive		
Yes	2	1.2
No	166	98.8

4.1.4 Indications for preterm delivery

Of the 168 participants, 148 (88.1%) had PPROM which accounted for the major cause of preterm deliveries, while only 1 (0.6%) had for vaginal bleeding as an indication for preterm delivery (Table 4). Eight (4.8%) of the participants presented with preeclampsia or eclampsia and three (1.8%) presented with fetal distress and of all preterm deliveries under the study, none presented with chorioamnionitis despite 88.1% presenting with PPROM.

Table 4: Indications for preterm delivery

Variable	**Frequency N=168**	Percentage
Indication for preterm delivery		
PPROM		
Yes	20	11.9
No	148	88.1
Vaginal bleeding/placental abruption		
Yes	1	0.6
No	167	99.4
Gestational HTN		
Yes	4	2.4
No	164	97.6
Preeclampsia/eclampsia		
Yes	8	4.8
No	160	95.2
Chronic HTN (NO pre-eclampsia)		
Yes	3	1.8
No	165	98.2
Diabetes		
Yes	0	0.0
No	168	100.0
Fetal distress		
Yes	3	1.8
No	165	98.2
Ante-partum stillbirth		
Yes	2	1.2
No	166	98.8
Chorioamniotis		
Yes	0	0.0
No	168	100.0
Antibiotics given		
Yes	35	20.8
No	133	79.2

4.1.5 Maternal anthropometrics

The height, weight abdominal circumference (girth) and fundal height distributions are tabulated in Table 5. The abdominal circumference (girth) and fundal height are the parameters used to calculate the estimated fetal weight. The median for each parameter was: 166cm for height, 75.5kg weight, 89cm abdominal circumference and 34cm fundal height).

Table 5: Maternal anthropometrics

Variable	Frequency N=168	Percentage
Maternal height (cm)		
<150	3	1.8
150-159	44	26.2
160-169	79	47.0
170-179	41	24.4
180+	1	0.6
Mean 164.1cm; SD 7.6; median 166; (range 140-180cm)		
Maternal weight (kg)		
50-59	26	15.5
60-69	37	22.0
70-79	55	32.7
80-89	46	27.4
90+	4	2.4
Mean 73.0kg; SD 11.6; median 75.5; (range 50-96kg)		
Maternal abdominal circumference (cm)		
50-59	1	0.6
60-69	5	3.0
70-79	27	16.1
80-89	70	41.7
90-99	54	32.1
100-109	7	4.2
110+	4	2.4
Mean 87.3; SD 9.4; median 89; (range 55-117cm)		
Fundal Height (cm)		
20-24	3	1.8
25-29	17	10.1
30-34	78	46.4
34-39	70	41.7
Mean 33.5cm; SD 3.1; median 34; (range 21-38cm)		

4.1.6 Gestation at enrolment

Most of the participants 79.8% were in the moderate to late preterm period (32 to 37 weeks) with only 3% delivering extremely preterm (less than 28 weeks) and all delivered within one week of enrolment (Table 6). The mean gestation age was 33.2 weeks though the range was from 25 to under 36 completed weeks, i.e. <37 weeks).

Table 6: Gestation at enrolment

Variable	Frequency N=168	Percentage
extremely preterm (less than 28 weeks)	5	3.0
very preterm (28 to 32 weeks)	29	17.3
moderate to late preterm (32 to 37 weeks)	134	79.8
32 to <34 weeks	43	25.6
34 to <37 weeks	91	54.2
Mean 33.2 weeks; SD 2.6; median 34; (range 25-36 weeks)		

4.1.7 Method of estimating gestation

The given last menstrual period was used in most cases to estimate the participants` gestational age (98.2%) while only 1.8% had an early scan.

Table 7: Method of estimating gestation

Variable	Frequency N=168	Percentage
fundal height	0	0.0
LMP only	165	98.2
LMP/US	0	0.0
U/S only	3	1.8

4.1.8 Mode of delivery

Most of the participants had spontaneous vaginal deliveries (94.6%), 4.8% had a caesarean delivery and only 1 (0.6%) had an assisted vacuum delivery as most of them came in active phase of labor without indication for operative delivery.

Table 8: Mode of delivery

Variable	Frequency N=168	Percentage
Spontaneous vaginal	159	94.6
Vacuum assisted vaginal	1	0.6
Forceps assisted vaginal	0	0.0
Caesarean	8	4.8

4.1.9 Pregnancy Outcome

Most of the participants (95.2%) had good outcome (livebirth) while 3% had antepartum stillbirths (IUFD) and 1.8 % had intrapartum deaths (Table 9). A disproportionately high percentage were male (70.2%). Two neonates were <750g and 84 (50%) were over 2500g (though they were deemed premature before delivery. The median was 2450g.. Over three quarters (77.4%) of babies were born with good Apgar score at 1 minute and showed an improved Apgar score at 5 minutes of birth (94%).

Table 9: Pregnancy Outcome

Variable	Frequency N=168	Percentage
Fetal outcome		
Livebirth	160	95.2
Ante-partum stillbirth/IUFD	5	3.0
Intrapartum stillbirth	3	1.8
Gender of newborn		
Male	118	70.2
Female	50	29.8
Actual Birthweight		
500-749	2	1.2
750-999	1	0.6
1000-1499	21	12.5
1500-1999	27	16.1
2000-2499	33	19.6
2500-2999	43	25.6
3000-3499	31	18.5
3500-3999	10	6.0
Mean 2358g; SD 740.4; median 2450; (range 570-3900g)		
Apgar scores at 1 minute		
0	8	4.8
1-3	1	0.6
4,5,6	15	8.9
7,8,9,10	130	77.4
missing	14	8.3
Apgar scores at 5 minutes		
0	8	4.8
1-3	0	0.0
4,5,6	2	1.2
7,8,9,10	158	94.0
missing	0	0.0

4.1.10 Disposition after delivery

Just under three quarters (72.6%) of all live births were taken to their mothers in the newborn nursery while 22.6% were referred to the neonatal intensive care unit for various reasons. The other 8 (4.8%) were stillborn (to the mortuary).

Table 10: Disposition after delivery

Variable	Frequency	Percentage
Newborn Nursery	122	72.6
NICU	38	22.6
Mortuary	8	4.8

4.2 Determinants of actual birthweight with maternal anthropometrics

4.2.1 Correlation of birthweight with maternal anthropometrics

In this part of the results section, the determinants of the actual birthweight are correlated with maternal anthropometrics and tabulated in Table 11. Simple linear regression was used to determine correlation coefficients with a 'p-value' indicating whether it was significantly different from zero (i.e. no correlation). Birthweight was significantly correlated with maternal height, BMI and fundal height. The maternal abdominal circumference was slightly correlated and barely significant at p=0.0467. Birthweight was not significantly correlated with maternal height alone. The respective analysis and figures are summarised and presented in figures 4 to 8 in Appendix I.

Table 11: Correlation between actual birthweight and maternal anthropometrics

	Correlation coefficient (r)	**P value**	**Correlation coefficient significance from zero**
Birth weight vs. Maternal Height	0.15	0.0605	Not significant
Birth weight vs. Maternal Weight	0.24	0.002	significant
Birth weight vs. BMI	0.19	0.0143	significant
Birth weight vs. Maternal abdominal circumference	0.15	0.0467	Just significant
Birth weight vs. fundal height	0.63	< 0.0001	Highly significant

4.2.2 Maternal anthropometric determinants of birthweight

Though birthweight was significantly correlated with maternal height, BMI and fundal height, on multiple linear regression, only fundal height was independently correlated with birthweight (r=0.61, p<0.0001). (Table 12).

Table 12: Multiple linear regression: Determinants of birthweight

variable	**Correlation coefficient (r)**	**P value**
Maternal Height (cm)	0.101608	P = 0.1941
Maternal Weight (kg)	0.113359	P = 0.1471
Maternal abdominal circumference (cm):	0.143239	P = 0.0664
Fundal Height (cm):	0.611967	P < 0.0001

4.3 Estimated birthweight using Dare's formula compared to actual birthweight

4.3.1 Dare's formula compared to actual birthweight

Table 13 below illustrates that when derived birthweights (using Dare's formula) and actual birthweights were tabulated using categories, there were none derived using Dare's formula below 1500g though there were three newborns with birthweight below 1500g. In the categories of 1500-1999g and 2000-2499g, derived birthweights erroneously underestimated actual birthweights as noted by the proportions (percentages). Conversely, in the 2500-2999g and 3000-3499g categories, more derived birthweights were erroneously over-estimated using Dare's formula. There was little difference in the 3500-3999g category (11 vs 10 cases; 6.5% vs. 6.0%).

Table 13: Estimated birthweight: Dare's formula compared to actual birthweight

variable	**Dare's formula* derived birth weight**		**Actual birth weight**	
Birthweight category (g)	Frequency	Percentage	Frequency	Percentage
500-749	-	-	2	1.2
750-999	-	-	1	0.6
1000-1499	-	-	21	12.5
1500-1999	8	4.8	27	16.1
2000-2499	14	8.3	33	19.6
2500-2999	67	39.9	43	25.6
3000-3499	68	40.5	31	18.5
3500-3999	11	6.5	10	6.0
Any weight	**168**	**100.0**	**168**	**100.0**

***Dare's formula: Fundal height (in cm) multiplied by maternal abdominal circumference (in cm); product total in grams.**

4.3.2 Comparing derived and actual birthweights (descriptive and test statistic: 't'test)

Instead of categories of birthweight, the means of the Dare's formula derived birthweights were compared to the actual birthweights and summarised in Table 14. The derived birthweight using Dare's formula over-estimated birthweight. The mean derived birthweight was 2,925g vs 2,357.8g actual (see below for statistic in next paragraph). The minimum derived was 1,562g and the minimum actual was 570g. However, the maximum for the derived and actual did not differ much (3,861g compared to 3,900g).

Table 14: Descriptive statistics: Derived and Actual birthweights

Variables	**Dare's formula derived birth weight (g)**	**Actual Birth weight (g):**
Valid data	168	168
Mean	**2,925.0**	**2,357.8**
Standard deviation	425.4	740.4
Standard error of mean	32.8	57.1
Maximum	3,861	3900
Minimum	1,562	570
Range	2,299	3,330

Paired Samples T-test statistics showed a significant difference ($P<0.001$) between estimated birth weight using Dare's formula and actual birth weight. The estimated birth weight (2,925g) was on average 567.2g (95% confidence interval 469.6 - 664.8) greater than actual birth weight (2,357.8g). Dare's formula over-estimated birthweight in this population.

Nevertheless, there was a high correlation ($r=0.51$, $p<0.001$) between the derived and actual birthweights as illustrated in Figure 1 overleaf.
Similarly, Figures 2, 3, 4, 5 and 6 illustrate the correlations of the various maternal anthropometrics with birthweight.

4.3.3 Correlation of Actual Birthweight vs. Derived Birthweight (Dare's)

Correlation of actual birthweight compared to estimated birthweight using Dare's formula

Simple linear regression
Equation: Birth weight (grams): = 0.879531 Derived Bwt gms -214.827703
Standard Error of slope = 0.116552
95% CI for population value of slope = 0.649416 to 1.109647
Correlation coefficient (r) = 0.505395 (r_2 = 0.255424)
95% CI for r (Fisher's z transformed) = 0.383317 to 0.610118
Two-sided P < 0.0001
Power (for 5% significance) > 99.99%
Correlation coefficient is significantly different from zero

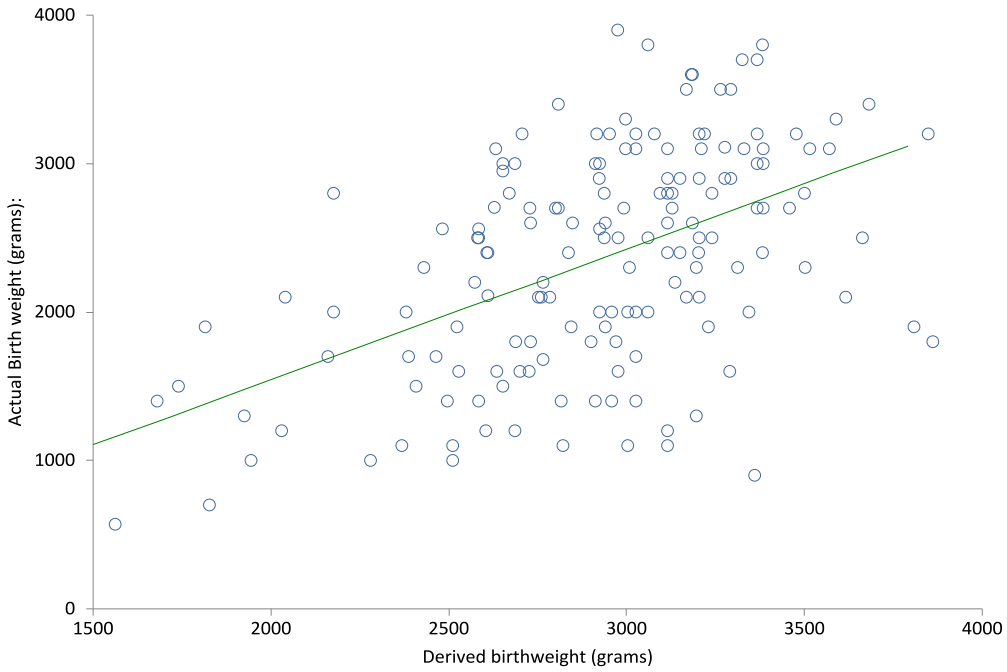

Figure 1: Actual Birthweight vs. Derived Birthweight (Dare's)

4.3.4 Correlation of Birth weight vs. Maternal Height

Simple linear regression

Equation: QB15000BIR Birth weight (grams): = 14.057342 Maternal Height (cm) + 50.439208

Standard Error of slope = 7.438621
95% CI for population value of slope = -0.629157 to 28.743842

Correlation coefficient (r) = 0.145122 (r_2 = 0.021061)

95% CI for r (Fisher's z transformed) = -0.006429 to 0.290157

t with 166 DF = 1.889778
Two-sided P = 0.0605
Power (for 5% significance) = 46.49%

Correlation coefficient is not significantly different from zero

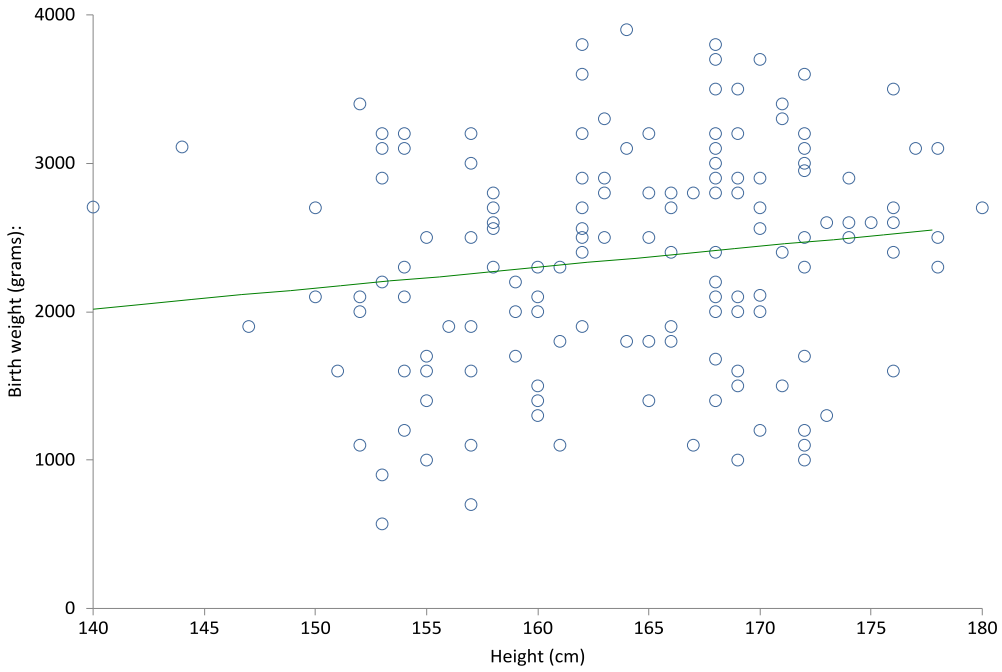

Figure 2: Birth weight vs. Maternal Height

4.3.5 Correlation of Birth weight vs. Maternal Weight

Simple linear regression

Equation: Birth weight (grams): = 15.101596 MaternalWeight (kg) + 1,255.890715

Standard Error of slope = 4.799909
95% CI for population value of slope = 5.624859 to 24.578332

Correlation coefficient (r) = 0.237224 (r_2 = 0.056275)

95% CI for r (Fisher's z transformed) = 0.089011 to 0.375159

t with 166 DF = 3.146226
Two-sided P = 0.002
Power (for 5% significance) = 87.23%

Correlation coefficient is significantly different from zero

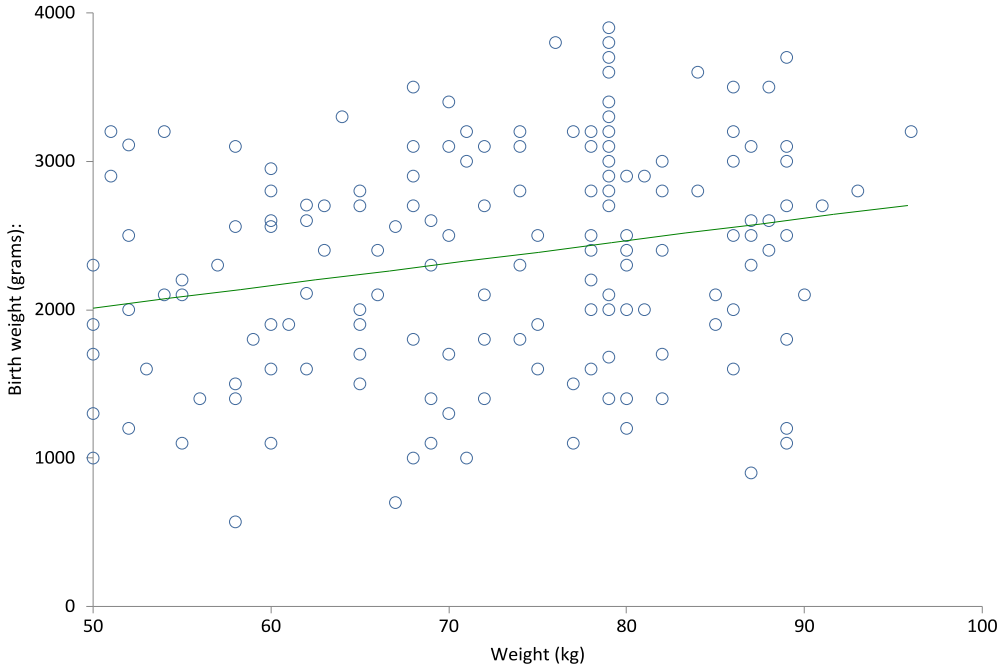

Figure 3: Birth weight vs. Maternal Weight

4.3.6 Correlation of Birth weight vs. BMI

Simple linear regression

Equation: Birth weight (grams): = 38.956709 BMI + 1,305.150089

Standard Error of slope = 15.735908
95% CI for population value of slope = 7.888396 to 70.025022

Correlation coefficient (r) = 0.188696 (r_2 = 0.035606)

95% CI for r (Fisher's z transformed) = 0.038383 to 0.330659

t with 166 DF = 2.475657
Two-sided P = 0.0143
Power (for 5% significance) = 68.66%

Correlation coefficient is significantly different from zero

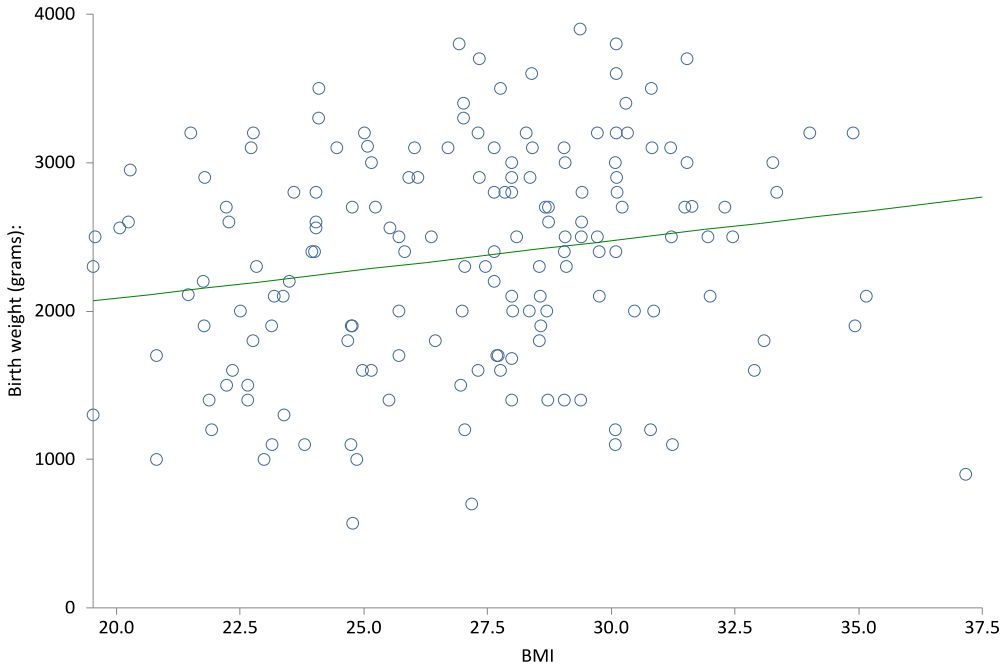

Figure 4: Birth weight vs. BMI

4.3.7 Correlation of Birth weight vs. Maternal abdominal circumference

Simple linear regression

Equation: QB15000BIR Birth weight (grams): = 12.145516 Maternal abdominal circumference (cm): + 1,297.420969

Standard Error of slope = 6.059689
95% CI for population value of slope = 0.181521 to 24.10951

Correlation coefficient (r) = 0.153716 (r_2 = 0.023629)

95% CI for r (Fisher's z transformed) = 0.002361 to 0.298186

t with 166 DF = 2.004313
Two-sided P = 0.0467
Power (for 5% significance) = 50.98%

Correlation coefficient is significantly different from zero

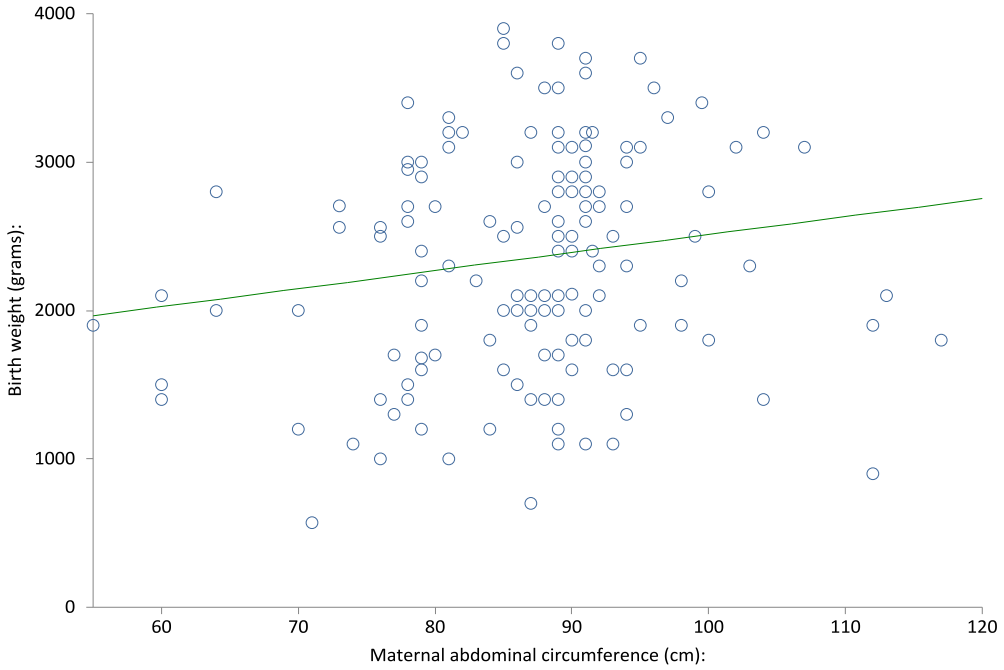

Figure 5: Birth weight vs. Maternal abdominal circumference

4.3.8 Birth weight vs. Fundal Height

Simple linear regression

Equation: QB15000BIR Birth weight (grams): = 150.113662 Fundal Height (cm): -2,666.572148

Standard Error of slope = 14.335906
95% CI for population value of slope = 121.809454 to 178.41787

Correlation coefficient (r) = 0.630696 (r_2 = 0.397777)

95% CI for r (Fisher's z transformed) = 0.529886 to 0.71393

t with 166 DF = 10.471166
Two-sided P < 0.0001
Power (for 5% significance) > 99.99%

Correlation coefficient is significantly different from zero

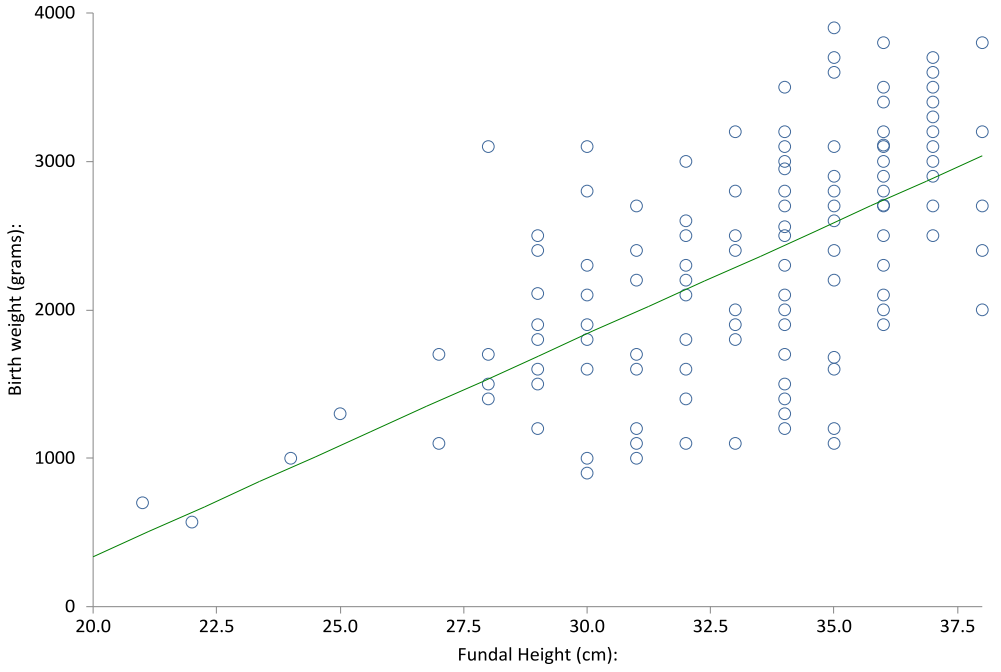

Figure 6: Birth weight vs. Fundal Height

4.4 Exploring variance between estimated and derived birthweights

In this part, the variance between derived and actual birthweights is presented in grams and as also a 10% percentage variance of actual birthweight.

4.4.1: Variance between derived and actual birthweights

All 168 ranked by weight variance (derived birthweight subtracted from actual in grams). A positive value indicates that the derived birthweight is an over-estimate. Figure 2 shows that a higher proportion (81%) were over-estimates (136/168) and this overestimate extended up to and over 2000g. A much smaller proportion (19%) (32/18) were under-estimates and extended up to just over 900g.

Typically, a 300g variance is noted on ultrasound. In this series, there were 136 overestimates beyond 300g (± 300g). However, of these 105 over-estimates by more than 300g. Similarly, of the 32 under-estimates only 15 were under-estimates by more than 300g.

Over-estimates more than 300g=105. This is 62.5% of all cases (105/168).

Under-estimates more than 300g=15. This is 9% of all cases (15/168).

Hence, the Dare's Formula method had an estimation more than ± 300g in 120 out of 168 (71.4%) cases.

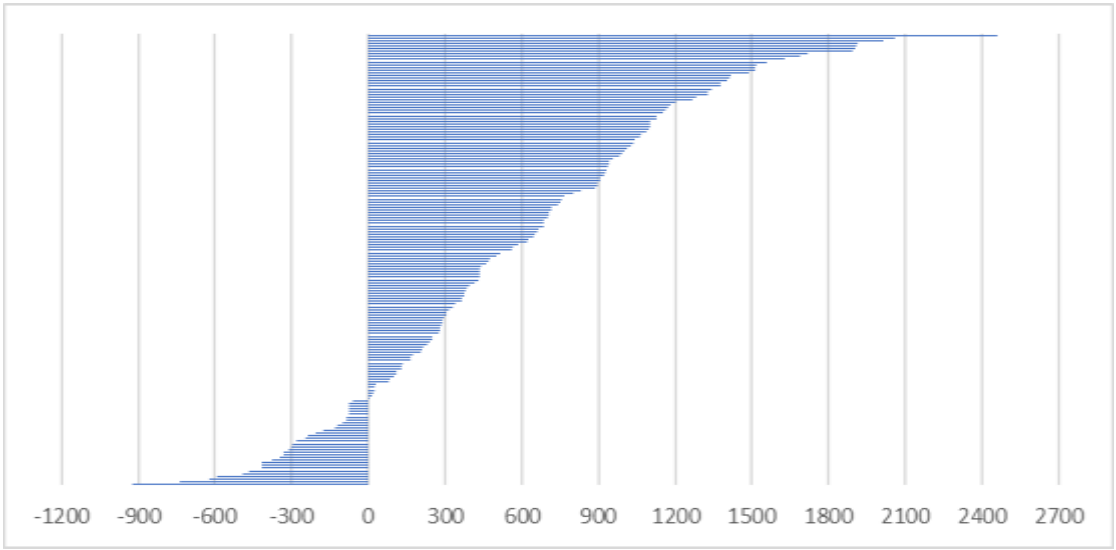

Figure 7: Weight variance between derived and actual birthweight (grams)

(All 168 variances in grams are stacked)

Similarly, Figure 3 shows all 168 ranked by weight variance **(derived subtracted from actual)** as a **percentage of actual**. A positive value indicates that the derived birthweight is an over-estimate. The numbers of over and under-estimates are the same as in the previous paragraph. They extended over 200% overestimate and to 24% underestimate.

Taking a 10% variance as a cut-off, in this series, there were 136 estimates beyond ±10%. Of these there were 109 **over-estimates** by more than 10%. This is 64.9% of all cases (109/168).

Similarly, there were 32 **under-estimates** but only 13 were under-estimates by more than 10%. This is 7.7% of all cases (13/168).

Hence, the Dare's Formula method had an estimation more than ± 10% in 136 (72.5%) cases.

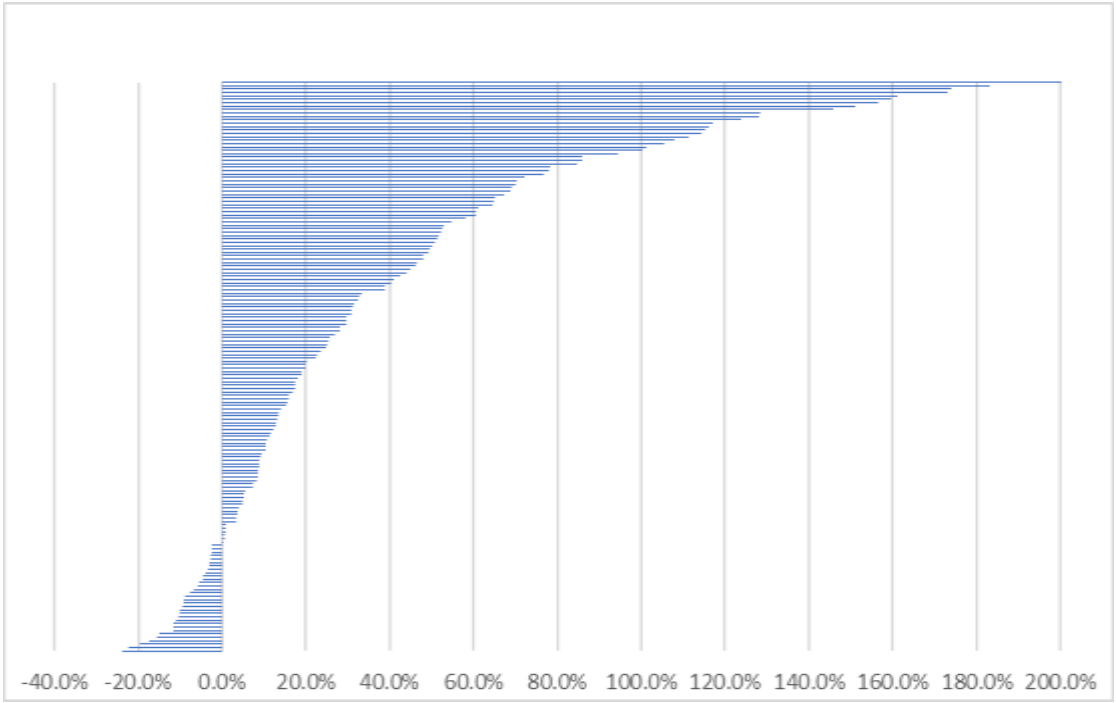

Figure 8: Percent variance between derived and actual birthweight

4.5 Bivariate and Multivariate Analysis

Analysis to evaluate determinants of under and over-estimates beyond 300g

4.5.1 Bivariate Analysis

The clinically acceptable/recommended birth weight estimate margin of difference (difference between estimate using Dare's Formula and actual birthweight) is ±300g. For this study there were 48 (28.6%) estimated within the ± 300g envelope, whereas over 120 (71.4%) were beyond 300g margin as previously illustrated (Figs 2 and 3).

Tables 15 and 16 shows bivariate analysis for association with weight estimate difference (stratification less than 300g and more then 300g). Table 15 tabulates the maternal characteristics. Table 16 tabulates the fetal neonatal outcomes. In both tables, the stratification is by weight difference less than or more than 300g. Variables were dichotomized, and the unadjusted odds ratio and p value listed. A p value <0.05 indicated that the odds ratio was significantly different from 1. None were significant.

Table 15: Bivariate analysis – characteristics with weight estimate difference

For association of maternal sociodemographic and characteristics (categorical variables) with weight estimate difference.

Table 15 Variable	Less than 300g Difference (n=48)		Above 300g Difference (n=120)		Unadjusted Odds ratio	P-value
	n	%	n	%		
Age						
Above 35 years	2	4.2	9	7.5	0.536232	0.4682*
Less than 35 years	46	95.8	111	92.5		
Marital status						
Unmarried	16	33.3	35	29.2	1.214286	0.5972
Married	32	66.7	85	70.8		
Education						
Up to Primary	13	27.1	39	32.5	0.771429	0.5037
Secondary or better	35	72.9	81	67.5		
Employment						
Formal/informal employment	10	20.8	25	20.8	1	> 0.9999
Unemployed	38	79.2	95	79.2		
Residence						
High density	34	70.8	90	75.0	0.809524	0.5802
Other	14	29.2	30	25.0		

Table 15 Variable	Less than 300g Difference (n=48)		Above 300g Difference (n=120)		Unadjusted Odds ratio	P-value
	n	%	n	%		
HTN medical history						
Yes	0	0.0	7	5.8	-	-
No	48	100.0	113	94.2		
Malaria medical history						
Yes	4	8.3	14	11.7	0.688312	0.5565*
No	44	91.7	106	88.3		
HIV medical history						
Yes	8	16.7	20	16.7	1	> 0.9999
No	40	83.3	100	83.3		
Past surgical history						
Caesarean section or other operation	5	10.4	7	5.8	1.877076	0.3213*
None	43	89.6	113	94.2		
Alcohol during pregnancy						
Yes	1	2.1	6	5.0	0.404255	0.4457*
None	47	97.9	114	95.0		
Had clinical complication during pregnancy						
Yes	9	18.8	22	18.3	1.03	0.9362
No	39	81.3	98	81.7		
Gestational hypertension						
Yes	3	6.3	9	7.5	0.82	0.8149*
No	45	93.8	111	92.5		
Pre-eclampsia						
Yes	5	10.4	9	7.5	1.434109	0.5417*
No	43	89.6	111	92.5		
Eclampsia						
Yes	1	2.1	1	0.8	2.531915	0.5714*
No	47	97.9	119	99.2		
Gestational diabetes						
Yes	0	0.0	0	0.0	-	-
No	48	100.0	48	40.0		
No infection during pregnancy						
Yes	36	75.0	77	64.2	1.675325	0.1809
No	12	25.0	43	35.8		
UTI during pregnancy						
Yes	5	10.4	22	18.3	0.51797	0.2139
No	43	89.6	98	81.7		

*Fisher exact test

Table 16: Bivariate analysis- fetal characteristics with weight estimate difference

For association of fetal/neonatal characteristics with weight estimate difference (categorical variable).

Variable	Less than 300g Diff (n=48)		Above 300g Diff (n=120)		P-value
	n	%	n	%	
Sex					
Male	33	68.8	85	70.8	0.7859
Female	15	31.3	35	29.2	
livebirth					
Yes	47	97.9	113	94.2	0.3413
No	1	2.1	7	5.8	
Neonatal care					
Nursery	40	83.3	82	68.3	0.1614
NICU	7	14.6	31	25.8	
stillbirth	1	2.1	7	5.8	

Stillbirths: 7 (4 MSB, 3FSB)

Comparison of gestation, maternal abdominal circumference and fundal height with weight estimate difference (continuous variables)

Table 17 is a summary showing the means of gestation, maternal abdominal circumference and fundal height in the two groups (<300g and >300g difference in estimate from actual birthweight). Whereas the gestation was statistically similar, maternal abdominal circumference was less in the group where there was a <300g difference from actual (83.8 vs. 88.7cm, p=0.0019). The fundal height appeared to be greater in the <300g group but this was not statistically significant (34.2 vs. 33.2cm, p=0.0663).

Table 17: Comparison of anthropometrics with weight estimate difference
Gestation, maternal abdominal circumference and fundal height with weight estimate difference (continuous variable)

Variables	Less than 300g Difference	Above 300g Difference	P-value
Gestation at delivery (weeks)			
(n, mean, SD)	48, **33.7**, 2.40	118, **33.0**, 2.66	0.1535
Maternal abdominal circumference (cm)			
(n, mean, SD)	48, **83.8**, 10.73	118, **88.7**, 8.41	0.0019
Fundal Height			
(n, mean, SD)	48, **34.2**, 2.59	118, **33.2**, 3.27	0.0663

4.5.2: Multivariate Regression Analysis

Table 18 shows what led to the predicting a weight estimate more than 300g difference margin (positive or negative) after considering all other characteristics apart from maternal abdominal circumference and fundal height (which are the constituents of the Dare's Formula).

For each one (1) cm increase in maternal abdominal circumference measurement, the odds for beyond 300g weight difference estimate increased on average by 7% [adjusted Odds Ratio (aOR) = 1.07, 95% Confidence Interval (CI) = 1.03 - 1.12, P= <0.001].

For every 1cm increase in fundal height measurement the odds for above 300g weight difference estimate reduced on average by 14% (aOR =0.86, 95% CI = 0.76 - 0.98, P= 0.0249).

Table 18: Logistic regression predicting above 300g difference weight estimate

Variable	**Unadjusted Odds Ratio (95% CI)**	**Adjusted Odds Ratio (95% CI)**	**P-value**
Maternal abdominal circumference	1.06 (1.02 to 1.10)	1.07 (1.03 - 1.12)	0.0013
Fundal Height	0.89 (0.79 to 1.01)	0.86 (0.76 - 0.98)	0.0249

CHAPTER FIVE: DISCUSSION

An important feature of this study on preterm pregnancies was that a substantial number of women delivered babies greater than 2500g. Although two neonates were <750g, 84 (50%) were over 2500g (though they were deemed premature before delivery based on the gestation) (table 9). This would have affected the study in that it may not have exclusively dealt with preterm pregnancy. All women were less than 36 completed weeks (<37 weeks) and the gestation was assessed using the last menstrual period in most cases (table 7). A more accurate assessment could be made in future using an early scan to date the pregnancy.

In part 2 of the results, it was shown that fundal height was independently associated with actual birthweight though it does not necessarily give a measure of the estimated fetal weight. However, together with abdominal circumference, it is an important part of Dare's formula to estimate the weight.

There was marked variance in the estimated fetal weight (and hence estimate weight within a week) compared to the actual birthweight. On the whole use of Dare's formula in this supposed preterm group grossly over-estimated in a majority of cases. Whether a variance from $\pm$300g of actual or $\pm$ 10% of actual was used, in most cases there was estimation beyond that envelope. In some cases, this was very marked. Although the study controlled for not including multiple pregnancy, polyhydramnios or abnormal lie that can affect both fundal height and abdominal circumference, there are other confounders that may have played a part. This could include measurement technique (though training was done to standardize), maternal weight, variations in adiposity and liquor volume amongst others.

The multivariate analysis showed that no antenatal, labour, gestation, outcome, or other characteristics were independently associated with explaining the variance. Only maternal abdominal circumference and fundal height. From this study, for every 1cm increase in maternal abdominal circumference measurement, the odds for beyond $\pm$300g weight difference estimate increased on average by 7% [adjusted Odds Ratio (aOR) = 1.07, 95% Confidence Interval (CI) = 1.03 - 1.12, P= <0.001]. This meant that for larger girths (with increasing gestation) there was a substantial increase in this large variance.

In fact, it is worse for fundal height. For every 1cm increase in fundal height measurement the odds for divergence beyond ±300g weight difference estimate **reduced** on average by 14% (aOR =0.86, 95% CI = 0.76 - 0.98, P= 0.0249).

Clinical estimation of fetal weight has been found to play a significant role in management of preterm laboring mother and having a validated method to use, the obstetrician managing a mother in preterm labor would make the best decision and give sound advice to the mother especially on mode of delivery, place of delivery and prognosis on survival for the new born. However, this study casts doubt on the use of the Dare's formula to reasonably accurate predict birthweight. There were too few extreme preterm pregnancies and table 6 shows that most were between 34 and 37 weeks. A future study may need to include larger numbers in the other gestation categories. It appeared from the data presented in table 13 (comparing estimated birthweight to actual in birthweight categories) that Dare's formula underestimated in the very low birthweight, and low birthweight (<2500) but over-estimated in the higher birthweight categories (>2500g). The reasons for this is unclear but numbers were small in the lowest birthweight categories.

Paired Samples T-test statistics showed significant difference (P<0.001) between estimated birth weight and actual birth weight. The estimated birth weight was on average 553g greater than actual birth weight (SD = 640.9), with a 95% confidence interval = (455.73– 650.97). The accuracy within ±300grams of the actual birth weight was about 30% while clinically estimated birth weight in preterm pregnancies was over estimated by a mean of 553 grams in 70 % of the patients subjected to the test.

This finding was consistent with findings of one study which concluded that there was an apparent superiority of sonographic EFW over clinical EFW applies principally to preterm pregnancies (Chauhan et al, 1998). This study included 1034 mother of which 373 were preterm, 460 were term and 201 were post-term. It concluded that when the population was partitioned by gestational age, it was found that sonographic EFW was more accurate than clinical EFW in preterm (n = 373) but not in term (n = 460) or post-term (n = 201) pregnancies.

This was not consistent with a study on determination of accuracy of fetal weight using ultrasound and clinical fetal weight estimation in Nigeria on term pregnancies

(Njoku et al, 2014) which concluded that there was no significant difference between the mean weight obtained through clinical methods and actual birthweight. This UTH study does not appear to support that.

Other studies have also supported the use of ultrasound as being superior in predicting birthweight (Peregrine et al, 2007). The Johnson's formula though, as used by Belete and Gaym (2008) appeared to dispute this. Evidence remains contradictory with Horton et al (2014) showing ultrasounds superiority; Ashrafganjooei et al (2010) concluding that clinicians' estimates of birthweight in term pregnancy were as accurate as routine ultrasound estimation in the week before delivery; Bajracharya et al (2010) concluded that there is a significant error in the estimation of the fetal weight when depending only on the fetal ultrasound; Abdulrazak et al, (2013) showed clinical fetal weight estimation to be a relatively accurate and comparable to ultrasound. However, as earlier pointed out, none looked specifically at the preterm alone.

CHAPTER SIX: CONCLUSIONS

6.1 Conclusions

This is the first study specifically to examine clinical estimation of fetal weight in the preterm pregnancies at risk of delivery within one week of admission.

The analysis showed that using Dare's formula, there was a 71.5% chance of variance (under and overestimation of birthweight) by more than 300grams and lends more support to the accuracy of ultrasound estimation of fetal weight in predicting actual birth weight which should be used in estimating the actual birth weight when accessible. Based on this study population, this clinical method and using Dare's formula cannot be reliably used in estimation of preterm pregnancies.

Though ultrasound remains a better choice for predicting birthweight, it non-availability should mean that clinical method should still be used.

6.2 Limitations

An important limitation is that the gestation of pregnancy was not accurately determined, e.g. by early dating ultrasound scan.

Instead of using study participants that had come in preterm labour, a different population, not in preterm labour (but gestation <37 weeks) could have been used.

Balancing of different gestations may have assisted in having suitable numbers in extreme prematurity up to 37 weeks.

6.3 Recommendations

Ultrasonography remains the gold standard for determining fetal weight in preterm pregnancies. Therefore, it should be availed as part of the tools to help in counselling mothers on perinatal prognosis because clinical estimation is associated with unacceptable error of margin.

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APPENDICES

Appendix A: Participant information sheet

TITLE: A prospective observational study on the clinical estimation of fetal weight in the Preterm population to be validated by actual birth weight at The University Teaching hospital, Lusaka.

My name is Dr. Swali Vusa Fundafunda a postgraduate student at the University of Zambia School of Medicine. I am conducting a research on the above subject at the University Teaching Hospital (UTH), Obstetrics and Gynaecology department, as part of the requirement for the award of a Master's Degree in Medicine. As such, I am here by inviting you to take part in this study.

PURPOSE: At the end of this study, I would like to come up with a validated, simple and cheap clinical method for estimation of fetal weight in the preterm population. Furthermore, the information collected will help us manage cases of this nature adequately at UTH and in areas where ultrasonography may not be practically available.

EXPLANATION OF THE PROCEDURE:

You have been invited to this study because you are likely to deliver before 37 completed weeks of gestational age and your baby will be born premature. If you agree to take part in the study, you will be asked some questions to help us know you better while some other information concerning you, will be extracted from your medical records. The doctor will perform a full examination and to estimate your baby`s weight, they will use a measuring tape around your abdomen at the level of your umbilicus in centimetres then multiply that with the length of your abdomen from above the bone below your bladder to where your abdomen reaches above the umbilicus Ultrasonography scan of the baby will be done were necessary to help us manage you accordingly. I wish to state that there is nothing new that will be done to you, everything that will be done is the standard of care for the condition that you have. In addition, participation is voluntary, and you are free not to answer questions that may seem personal or otherwise, and if you decide to withdraw from this study at any time, you will still receive the standard medical care. Moreover, the information obtained from you will not be shared with anyone not involved in the study.

BENEFITS: There is no direct benefit to the participant by virtue of participating in this study because everything done is part of standard care for early preterm labour. We hope that the information gathered at the end of this study will help in managing such cases adequately at UTH and beyond.

RISKS: The risk to participants in this study will most likely be due to emotional stress from some sensitive questions otherwise all the procedures that will be done are part of the standard of care and will be done under clean conditions. Also, nothing new will be administered to participants.

If you agree to take part, please sign the consent form which will allow us to enroll you in this study. If you have any questions, please contact us on the addresses below.

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Dr. Swali Vusa Fundafunda
Cell: +260977310305
email: swali_v@yahoo.com
University Teaching Hospital
Department of OBGY
P/Bag RW1X, Lusaka.

The Secretary,
ERES CONVERGE IRB
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Rhodes Park, Lusaka
Tel: +260955-155633/4
email: eresconverge@yahoo.com

Appendix B: Participant Chewa consent form

Mutu wa Maphunziro: Clinical Estimation of fetal weight in preterm

Ofufuza Akulu: Dr. Swali V. Fundafunda, University Teaching Hospital (UTH)

Kochoka Ndalama ndi/kapena Opasa Ndalama: kulibe

Dzina ya Okamba Nao Mu Maphunziro: Swali V. Fundafunda

Namba ya Foni ya Okamba Nao mu Maphunziro: +260977310305

Kodi ndi zinthu zina zotani zimene mufunika kuziwa pa za maphunziro yakufufuza?

Mukupemphedwa kuti mutengeko mbali mu maphunziro yakufufuza. Kungena mu maphunziro ndikozifunira. Mwina mungakane kungena, kapena mwina mungachose chivomerezo chanu chakukhala mu maphunziro, pa nthawi ili yonse, pa chifukwa chili chonse.

Maphunziro yakufufuza yamapangidwa kuti yatenge nzeru zasopano zimene mwina zingathandize anthu ena musogolo. Mwina simungalandireko phindu ili yonse yoloza kwa inu pa kukhala mu maphunziro yakufufuza. Mwina kungakhalenso ziopyezo za kukhala mu maphunziro yakufufuza.

Zoonjezera pali aya maphunziro zakambidwa pansi apa. Nichofunikila kuti mumvesese nkhani iyi kotero kuti mungapange chosankha choziwisidwa pa za kukhala muli aya maphunziro yakufufuza. Kusankha kusangena mu maphunziro kapena kuchoka mu maphunziro yakalibe kusila sikuzakhuza ubwenzi wanu ndi opasa chisamaliro cha umoyo wanu. Simufunikila kuti mukhale mu maphunziro yakufufuza kuti mulandire chisamaliro cha umoyo.

Ichi ndi chipepala cha chivomerezo. Chikupasani nkhani pa za maphunziro aya. Anchito za maphunziro azakambisana ndi inu pa za iyi nkhani. Muli aufulu wofunsa mafunso pa za maphunziro aya pa nthawi ili yonse. Ngati mwasankha kuti mungakonde kutengako mbali muli aya maphunziro, tizakupemphani kusaina kapena kusindikiza ndi chala pali ichi chipepala cha chivomerezo.

Muzapasidwa kope ya chipepala ichi cha chivomerezo. Mufunika kufunsa ofufuza amene achulidwa pamwamba apa, kapena mamembala ya maphunziro amene

akuwathandiza, pa mafunso ali onse amene muli nao pa za aya maphunziro pa nthawi ili yonse.

Kodi cholinga cha aya maphunziro nichani?

Ana ena amabadwa milungu kapena myezi pamene tsiku yao kapena yoelekezera kubadwilapo (EDD) ikalibe kukwana. Amabadwa m'sanga, ndipo ichi chimachedwa kuti kubereka nthawi ikalibe kukwana (preterm delivery). Ana ena amafunika kubadwa m'sanga chifukwa niodwala kapena muzimai amene ali ndi mimba niwodwala. Ana ena amabadwa milungu kapena myezi yambiri pamene tsiku yao yoelekezera kubadwilapo (EDD) ikalibe kukwana chifukwa mimba ya mai imauka m'sanga, chochedwa kuti kuuka m'sanga kwa mimba (pre-term labor), kapena chifukwa manzi ake amapwanyika, chochedwa kuti premature preterm rupture of membranes. Mwamene mwana wobadwa nthawi ikalibe kukwana amalemela nikofunika kwambiri ku mupata wakuti uyo mwana angadwale kapena kufa. Cholinga chonse cha aya maphunziro nikuthandiza kuona ngati kupima pamala mai mu njira ziwiri kungasewenzesedwe kunyelekeza kulema kwa mwana akalibe kubadwa. Kuyelekeza kulema kwa mwana molondola kwambiri kungatithandize kuyesa kuziwa mupata wa mwana wakukhala wodwala. Tizatenganso nkhani pa za umoyo wonse ndi khalidwe (overall health and wellbeing) wa amai ndi ana obadwa nthawi ikalibe kukwana ali mu maphunziro.

Mukupemphedwa kuti mutengeko mbali muli aya maphunziro yakufufuza chifukwa muli ndi mimba ndipo mwina mungabereke nthawi ikalibe kukwana mukati mwa m'lungu umodzi.

Kodi kuli zifukwa zili zonse simufunikira kukhala muli aya maphunziro?

Tizafuna kungenesa azimai amene Tikhulupilira kuti ali ndi mupata ukulu wakubereka nthawi ikalibe kukwana (milungu 37 ikalibe kufika) mukati mwa m'lungu umodzi wa kungena mu maphunziro. Simufunikira kukhala muli aya maphunziro ngati muli ndi mimba yochepekera pa milungu ili 24 lero kapena ngati muli ndi mimba ili ndi ana opitilira pa mwana umodzi (amphundu, anayi . Simufunikiranso kungena muli aya maphunziro ngati muli ndi zaka zakubadwa zochepekera pa 18.

Kodi ndi anthu angati amene azatengako mbali muli aya maphunziro?

Azimai ama mimba onse pamodzi ali 173 azatengako mbali muli aya maphunziro. Maphunziro akuchitidwa pa University Teaching Hospital.

Kodi ndi utali bwanji mbali yanu izatenga muli aya maphunziro?

Ngati mwasankha kungena muli aya maphunziro, chizatenga pafupi-fupi ma mineti 20 kuti tisilize kupima ndi chipepala cha mafunso.

Kodi nichani chizachitika ngati mwatengako mbali muli aya maphunziro?

- Anchito za mu maphunziro azakufunsani mafunso pa za malo a nyumba yanu ndi ya pa nchito, mbiri yanu ya mankhwala, ndi mbiri yanu ya ma mimba. Muli aufulu kusayankha mafunso amene simufuna kuti muyankhe.
- Pa mala panu pazapimidwa ndi tepu yopimilako mu njira ziwiri, kamodzi kuzunguluka pa batani ya pa mala ndipo kamodzi kuchoka pa fupa ya pa chinena chanu mpaka pamwamba pa chibaliro chanu (uterus).

Kodi ni maphindu otheka otani ochoka mukukhala mu maphunziro?

Maphunziro yakufufuza yamapangidwa kuti yaphindulise komyuniti mwa kutenga nzeru zasopano. Simuzalandira phindu ili yonse yoloza kwa inu kuchoka muli aya maphunziro koma tiyembekezera kuti zotulukamo kuchoka muli aya maphunziro mwina zingathandize kukonza chisamaliro cha azimai ali ndi mimba amene ali pa chiopyezo cha kubereka m'sanga. Zotulukamo mwina zingathandize kukonza chisamaliro cha ana amene amabadwa m'sanga.

Kodi ni ziopyezo zotani zotheka kapena zomvesa kuipa zimene zili mukukhala muli aya maphunziro?

Mwina kungakhale kumvera kuipa kwina kung'ono, kwa ka nthawi kochepa pamene tipima pamala panu.

Ngati mwasankha kusakhala mu maphunziro, kodi ndizosankha zina za bwanji za kuchirisa zimene muli nazo?

Simukakamizidwa kuti mutengeko mbali. Muzalandira chisamaliro chimodzi-modzi cha ama mimba pa malo ano aza umoyo.

Nanga bwanji ngati taphunzira pa zopezeka zasopano kapena nkhani pa nthawi ya maphunziro?

Muzapasidwa nkhani ili yonse yasopano yophunziridwa pa nthawi yakuchita maphunziro imene mwina ingakhuze kufunisisa kwanu kupitiliza kutengako mbali kwanu mu maphunziro.

Kodi chisinsi chanu chizachingilizidwa bwanji?

Tizachita ndi mphamvu zonse kusunga nkhani zanu-zanu mu chisinsi. Chizakhala kusankha kwanu ngati mufuna kugawana zili zonse zotulukamo zanu za zipimo ndi ena mu nyumba mwanu kapena mu komyuniti yanu. Ife sitizachita zimenezo. Nkhani zanu za mu maphunziro zizaziwika ndi nambala kuti tichingilize chisinsi chanu. Kufalisa kuli konse kwa zotulukamo sikuzasewenzesa dzina lanu kapena kukuziwikisani mwa inu nokha.

Zolembedwa zanu mwina zingapitiwemo ndi oimilako AKalembela(secretary),ERES CONVERGE IRB

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chi chili ndi cholinga cha kukonza ubwino ndi chitetezo cha maphunziro (quality control and safety).

Kodi nichani chizachitika ngati mwazichita ndi kufufuza uku?

Chiopyezo cha kuzichita kuchoka muli aya maphunziro ni ching'ono kwambiri. Simukutaya ufulu wanu uli onse wa lamulo mwa kusaina kapena kusindikiza ndi chala chanu pa Chipepala cha Chivomerezo.

Nanga bwanji ngati mufuna kuleka pamene mbali yanu mu maphunziro ikalibe kusila?

Kulibe chilango ngati simunapase chivomerezo cha kungena mu maphunziro kapena ngati simusiliza maphunziro. Kulibenso chilango ngati mwachoka kapena kuleka maphunziro pa nthawi ili yonse.

Kodi muzalandirako chili chonse chifukwa cha kukhala muli aya maphunziro?

Muzalandira chitenge monga chizindikiro cha kuyamikira pa nthawi yanu ndi kutengako mbali kwanu.

Kodi muzalipirako zili zonse chifukwa cha kukhala muli aya maphunziro?

Sikuzakhala mutengo uli onse kwa imwe chifukwa cha kutengako mbali muli aya maphunziro.

Kodi ndi andani amene apasa ndalama aya maphunziro?

Uku kufufuza sikupasidwa ndalama. Gulu la kufufuza sizaphindulapo chili chonse cha ndalama kuchoka mu maphunziro aya kapena zotulukamo za maphunziro.

Nanga bwanji ngati muli ndi mafunso pa za aya maphunziro?

Muli ndi ufulu wakufunsa, ndi kukhala ndi mayankho, pa mafunso ali onse amene mwina mungakhale nao pa za uku kufufuza. Ngati muli ndi mafunso, madandaulo, zokukhuzani, kapena ngati kuzichita kokhuzana ndi kufufuza kwachitika, muyenera kukamba ndi a:

Dr. Swali Fundafunda, Investigator
University Teaching Hospital
Department of Obstetrics and Gynaecology
PO Box 50110, Lusaka, Zambia
Tel: 0977310305
Email:swali_v@yahoo.com

Nanga bwanji ngati muli ndi mafunso pa za ufulu wanu monga wotengamo mbali mu kufufuza?

Konse kufufuza kwa pa ozipereka aumuntu kumapitiwamo ndi a kabungwe kamene kasebenzera pakuchingiliza ufulu wanu ndi kakhalidwe. Ngati muli ndi mafunso kapena zokukhuzani pa za ufulu wanu monga wotengako mbali mu kufufuza, kapena ngati mungakonde kutenga nkhani kapena kutipasa nkhani, mwina mungakambe ndi a:

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Appendix C: Participant consent form Bemba

Umutwe wa Masambililo: Estimation of fetal weight in preterm
Bakafwailisha Bakalamba: Dr Swali Fundafunda, University Teaching Hospital (UTH)

Ukufuma Indalama elyo/nangu Abapeela Indalama: takuli

Ishina Iya Abo Mwingalanda Nabo mu Masambililo: Swali Fundafunda

Namba iya Foni Iyakutuminapo ku Masambililo: +260 0977310305

Bushe fintu nshi fimo ifyo mufwile ukwishiba pa lwa masambililo ayakufwailisha?

Mulelombwa ukubulamo ulubali mu masambililo ayakufwailisha. Ukwingila muli aya amasambililo kwa kuitemenwa. Kuti limbi mwakana ukwingila, nangu kuti limbi mwafumya icisuminisho cenu icakuba mu masambililo, panshita ili yonse, pa mulandu uli onse.

Amasambililo ayakufwailisha yapangwa ukusenda amano ayapya ayo limbi ayengafwilisha abantu bambi kuntanshi. Kuti limbi teti mukwate ukunonkelamo ukuli konse ukwalosha kuli imwe pakuba mu masambililo ayakufwailisha. Kuti limbi nakabili kwaba amafya ayakuba mu masambililo ayakufwailisha.

Ifingi ifya palwa aya amasambililo fyalanshiwa panshi apa. Cikankala ukuti mumfwikishe ili ilyashi pakuti mupange ukusala ukwaishibishiwa palwa kuba muli aya amasambililo ayakufwailisha.

Ukusala ukukanaingila mu masambililo nangu ukufuma mu masambililo ilyo tayalapwa takwakakume bucibusa bwenu na bamipeela ukutangata kwa bumi bwenu. Tamufwile ukuba mu masambililo ayakufwailisha pakuti mupoke ukutangatwa kwa bumi.

Ici cipepala ica cisuminisho. Cilemupeela ilyashi ilya palwa aya amasambililo. Ababomfi bamasambililo balalanda na imwe palwa ili ilyashi. Muli abakakuka ukwipusha amepusho palwa aya amasambililo pa nshita ili yonse. Nga cakuti mwasala ukuti kuti mwatemwa ukubulamo ulubali muli aya amasambililo, twalamilomba ukusaina nangu ukufwatika pali ici icipepala ica cisuminisho.

Mwalapeelwa kope iya ici icipepala ica cisuminisho. Mufwile ukwipusha bakafwailisha abalumbwilwe pamulu apa, nangu amamembala yababomfi abalebafwilisha, pa mepusho ayali yonse ayo mukwete aya palwa aya amasambililo pa nshita ili yonse.

Bushe bufwayo nshi ubwa aya amasambililo?

Bamo abana balafyalwa imilungu nangu imyeshi ilyo ubushiku bwabo ubwakufyalilwapo ubwakwelenganya tabulakwana (nangu EDD). Balafyalwa bwangu, elyo ici citwa ukuti **ukufyalwa inshita tailakwana** (preterm delivery). Bamo abana bafwaikwa ukufyalwa bwangu pantu balaba abalwala nangu namayo uli pabukulu ali uwalwala. Bamo abana balafyalwa imilungu nangu imyeshi iyingi ilyo EDD tailakwana pantu ifumo ilya banyinabo lilabuka bwangu, icitwa ukuti ukubuka bwangu ukwe fumo (pre-term labor), nangu pantu amenshi yabo yatobeka, icitwa ukuti premature preterm rupture of membranes. Ifyo umwana uwafyalwa inshita ilyo tailakwana afina cikankala sana ku macansi ayakuti umwana uyo kuti alwala nangu ukufwa. Ubufwayo ubwa aya amasambililo bwakwafwilisha ukumona nga cakuti ukupima pa mala apa kwa nyina mu nshila shibili kuti kwabomfiwa mukutunganya ukufina ukwa mwana ilyo talafyalwa. Ukutunganya ukufina ukwa mwana ukwalungama sana kuti kwatwafwilisha ukutunganya ukwelenganya cansi iya mwana iya kulwala. Tukasenda nakabili ilyashi iya palwa bumi bonse elyo nobwikalo ubwa kwa nyina elyo nabana abafyalwa inshita ilyo tailakwana mu masambililo.

Mulelombwa ukuti mubulemo ulubali muli aya amasambililo ayakufwailisha pantu muli pabukulu elyo kuti limbi apaapa inshita ilyo tailakwana mukati ka mulungu umo.

Bushe kuliko imilandu ishili shonse isho tamufwile ukubela muli aya amasambililo?

Twalafwaya ukwingisha banamayo abo abacetekela ukuti balikwata cansi icikalamba ica kupaapa inshita ilyo tailakwana (ilyo imilungu 37 tailakwana) mukati ka mulungu umo ubwakwingila mu masambililo. Tamufwile ukuba muli aya amasambililo nga cakutila muli ne fumo ilili ne milungu ukucepela pa milungu 24 ilelo nangu nga cakuti muli ne fumo ilyakwata abana ukucila pali umo (ba mpundu, bane). Tamufwile nakabili ukwingila muli aya amasambililo nga cakutila muli ne myaka iyakufyalwa iyacepela pali 18.

Bushe nibaga abantu abakabulamo ulubali muli aya amasambililo?

Banamayo abali pabukulu bonse pamo 173 bakabulamo ulubali muli aya amasambililo. Amasambililo yalecitilwa ku University Teaching Hospital.

Bushe butali shani ubo ulubali lwenu lukasenda muli aya amasambililo?

Nga cakuti mwasala ukwingila muli aya amasambililo, kwalasenda mupepi na mamineti 20 ukupwisha ukupima elyo ne cipepala ica mepusho.

Bushe cinshi cikacitika nga cakutila mwabulamo ulubali muli aya amasambililo?

- Ababomfi bamu masambililo balamwipusha amepusho palwa ncende iya ng'anda yenu elyo na pa ncito yenu, ilyashi ilya muti wenu, elyo nelyashi ilyefumo lyenu. Muli abakakuka ukukanaasuka amepusho ayo tamulefwaya ukwasuka.
- Pamala penu palapimwa na tepu iyakupiminako mu nshila shibili; umuku umo ukushinguluka pebatani iya pefumo yenu elyo nomuku umo ukufuma pefupa iya pa cinena cenu mpaka pamulu wa cisa cenu (uterus).

Bushe kunonkelamo nshi ukwingabako ukufuma mukuba muli aya amasambililo?

Ukufwailisha kupangwa pakuti kunonkeshe icintubwingi pakukwata amano ayapya. Tamwakakwate ukunonkelamo ukuli konse ukwalosha kuli imwe ukufuma muli aya amasambililo lelo tulesubila ukuti ifitumbukamo ifya aya amasambililo limbi kuti fyayafwilisha ukuwamya ukutangata ukwa banamayo abamafumo ababa pa bwafya (risk) ubwa kupaapa inshita bwangu. Ifikatumbukamo limbi kuti nakabili fyayafwilisha ukuwamya ukutangata ukwa bana abo abafyalwa bwangu.

Bushe mafya nshi ayengacitika nangu ifyumfwisha ububi ifisangwa mukuba muli aya amasambililo?

Limbi kuti kwaba ukumfwa ububi ukunono, pa kashita akanono lintu balapima pa mala penu.

Nga cakutila mwasala ukukanaingila mu masambililo, bushe kusala nshi kumbi ukwakundapwa uko mukwete?

Nga cakutila mwasala ukukanabulamo ulubali, mukakwata ukutangatwa kumo kwine ukwa pefumo (antenatal care) pali ino ncende iya bumi.

Nga nga cakutila twasambilila palwa ifyasangwa ifipya nangu ilyashi pa nshita iya masambililo?

Mukapeelwa ilyashi ilili lyonse ilipya ilyasambililwa panshita iyakucita amasambililo iyo limbi ilingakuma ku kufwaishisha kwenu ukutwalilila ukubulamo ulubali kwenu.

Bushe inkama yenu ikacingililwa shani?

Tukesha na maka yonse ukusunga ilyashi ilya palwenu mu nkama. Cikaba kusala kwenu nga cakuti mulefwaya ukwakana ifili fyonse ifyatumbukamo ifya fipimo fyenu nabambi mu ng'anda mu mwenu nangu mu komyuniti. Ifwe tatwakacitefyo. Ilyashi lyenu ilya mu masambililo likeshibikwa ne nambala pakuti tukacingilile inkama yenu. Ukusabankanya ukuli konse ukwa ifitumbukamo takwakabomfye ishina lyenu nangu ukumwishibikisha palwenu.

Ifyalembwa fyenu limbi kuti fyapitulukwamo nabemininako ERES, nangu ba Ministry of Health mu Zambia. Ici ciba ku bufwayo ubwa mibombele isuma elyo nokucingilila (quality control and safety).

Bushe cinshi cikacitika nga cakutila mwaicena noku ukufwailisha?

Ubwafya ubwa kucenwa ukuli konse ukufuma muli aya amasambililo bunono sana. Tamulelufya insambu ishili shonse ishe funde pakusaina nangu ukufwatika necikumo pali ici Icipepala ica Cisuminisho.

Nga nga cakutila mulefwaya ukuleka ilyo ulubali lwenu mu masambililo talulapwa?

Takuli icilango nga cakuti tamupeele ulusa ulwa kwingila muli aya amasambililo nangu nga cakuti tamupwishishe amasambililo. Takuli nakabili icilango nga cakuti mwafuma nangu mwaleka amasambililopanshita ili yonse.

Bushe mukapokapo icili conse pakuba muli aya amasambililo?

Mukapoka icitenge pamo nge cishibilo icakutotela kwesu pa nshita yenu elyo nokubulamo ulubali kwenu.

Bushe cikaba no mutengo uli onse kuli imwe pakuba muli aya amasambililo?

Takwakabe umutengo kuli imwe pakubulamo ulubali muli aya amasambililo.

Bushe nibani abapeela indalama aya amasambililo?

Uku ukufwailisha takulepeelwa indalama. Ibumba ilya masambililo talyakakwate ukunonkelamo ukuli konse ukwa ndalama ukufuma muli aya amasambililo nangu ifitumbukamo ifya masambililo.

Nga nga cakuti namukwata amepusho palwa aya amasambililo?

Namukwata insambu ishakwipusha, elyo nokukwata amasuko, pa mepusho ayali yonse ayo mukwete palwa uku ukufwailisha. Nga cakutila namukwata amepusho, ukuilishanya, ifimikumine, nangu nga cakutila ukuicena ukwakuma ku kufwailisha kwacitika, mufwile ukulanda na ba:

Dr. Swali Fundafunda, Investigator
University Teaching Hospital
Department of Obstetrics and Gynaecology
PO Box 50110, Lusaka, Zambia
Tel: 0977310305
Email:swali_v@yahoo.com

Nga nga cakuti namukwata amepusho palwa nsambu shenu pamo ngo ulebulamo ulubali mukufwailisha?

Konse ukufwailisha ukwa pa bantu abaipeela kulapitulukwamo nakabungwe akabombela pakucingilila insambu elyo nobwikalo bwenu. Nga cakutila namukwata amepusho nangu ifimikumine palwa nsambu shenu pamo ngo ulebulamo ulubali mu kufwailisha, nangu nga cakuti mulefwaya ukusenda ilyashi nangu ukutupeela ilyashi, limbi kuti mwalanda na ba:

The Secretary,
ERES CONVERGE IRB
33 Joseph Mwilwa Road
Rhodes Park, Lusaka
Tel:+260955-155633/4
email: eresconverge@yahoo.com

IBULA IYA KUSAINA ICIPEPALA ICA CISUMINISHO ICA BIOMEDICAL

Umutwe wa Masambililo: Estimating fetal weight by maternal biometry in preterm deliveries

Bakafwailisha Bakalamba: Dr Swali V. Fundafunda

Ukusuminisha ukwa Ulebulamo ulubali:

Nabelenga ilyashi ilyapeelwa pamulu apa. Naipusha yonse amepusho ayo nkwete pali ino nshita. Nasumina mukuipeela ukubulamo ulubali muli aya amasambililo ayakufwailisha.

Ukusaina nangu ukufwatika ukwa Ulebulamo ulubali Ubushiku mu Kufwailisha

Ishina Ilyalembwa bwino ilya Ulebulamo Ulubali mu Kufwailisha

Ukusaina ukwa kwa Membala Webumba Lyakufwailisha Ubushiku Ulepoka Icisuminisho

Ishina Ilyalembwa bwino ilya kwa Membala Webumba Lyakufwailisha Ulepoka Icisuminisho

Ukusaina ukwa kwa Kamboni Ubushiku

_____

Ishina Ilyalembwa bwino ilya kwa Kamboni

***Note: Witness name, signature and date are required on this consent form only when the Consenting volunteer is not able to read (illiterate)**

Appendix D: Participant consent form

TITLE: A prospective observational study on the clinical estimation of fetal weight in the Preterm population to be validated by birth weight at The University Teaching hospital, Lusaka

I wish to inform you that there is no direct benefit by virtue of participating and the risk involved is less than minimal risk, because everything done is part of standard of care for Preterm labour and nothing new is going to be administered to you. Participation is voluntary, and you are free to withdraw from the study at any time. We hope the information gathered will help us manage Preterm labour adequately in circumstances where ultrasonography is not available.

I have read and understood all the information concerning Preterm labour and what this study is all about is clear to me. I therefore voluntarily consent to take part in this study.

Name: _____

Signature: _____ Date: _____

Right Thumb Print: _____ Date: _____

Witness /Parent/Guardian

Name: _____

Signature: _____ Date: _____

Right Thumb Print: _____ Date: _____

Name of person taking consent: _____

Signature: _____ Date: _____

Appendix E: Assent form for participants under 18 years

My name is Dr Swali Vusa Fundafunda and I am from the University of Zambia School of Medicine. I am conducting a study entitled A prospective observational study on the clinical estimation of fetal weight in the Preterm population which will be validated by birth weight at The University Teaching hospital, Lusaka. I am asking you to take part in this research because I am trying to learn more about clinical estimation of fetal weight in the Preterm population.

If you agree to be in this study, you will be asked to complete a survey. Some of the questions ask on sensitive issues and may make you feel upset. You are free not to answer questions you are not comfortable with. Furthermore, no one will be able to know how you responded to the questions.

Please talk about this study with your parents before you decide whether to participate. I will also ask your parents to give their permission for you to participate. Even if your parents give consent, you can still decide not to participate. You may also change your mind before or during the survey. No one will be upset with you if you don't want to participate or if you change your mind later and want to stop.

You may ask me any questions about this study and feel free to call me at any time on 0977310305 or talk to me the next time you see me.

By signing below, you are agreeing to participate with the understanding that your parents have given permission for you to take part in this study. You are participating in this study because you want to. You and your parents will be given a copy of this form after you have signed it.

Name:

_____

Signature: _____ Date: _____

Right Thumb Print:_____ Date:_____

Appendix F: Questionnaire

TITLE: A prospective observational study on the clinical estimation of fetal weight in the Preterm population to be validated by birth weight at The University Teaching hospital, Lusaka.

Study ID# Name:

File #:_____ Firm: ____ Ward: _____

1.Age: _____years

2.Marital Status:

1. Single
2. Lives with partner
3. Married
4. Divorced/Separated
5. Widowed

3.Date of enrolment(weeks):

4.Date of delivery (weeks):

5.Age at enrolment (weeks):

6.Age at delivery (weeks):

7.EDD:____(day)_____(month)_____(year)

8.EDD determined by (circle one):

1.fundal height

2.LMP only

3.LMP/US

4.U/S

Please tick or enter in the appropriate space.

SOCIO-DEMOGRAPHICS

9. Education Level

0. None ( )

1. Primary ( )

2. Secondary ( )

3. Tertiary ( )

10. EMPLOYMENT

0. Formal ( )

1. Informal ( )

2. Not employed ( )

11. Residence (write name of place of stay) _____

0. High density ( )

1. Medium density ( )

2. Low density ( )

3. Rural ( )

12. Past Medical history YES (circle all that apply)

1.Pre-gestational diabetes

2.Chronic HTN

3.Sickle cell disease

4.Maternal heart disease

5.Tuberculosis

6.Malaria

7.HIV/AIDS

8.Syphilis

9.Fibroids

10.Other _____ (please specify)

13. Past surgical history YES (circle all that apply)

1.NONE

2.Caesarean section (if yes, # _____)

3.Other: _____ (please specify)

14. Tobacco during pregnancy

1.YES (if yes, number cigarettes/day in past 7 days____)

2.NONE

15. Alcohol during pregnancy

1.YES

2.NONE

16. Pregnancy complication YES (circle all that apply)

1.NONE

2.Gestational hypertension

3.Preeclampsia/HELLP

4.Eclampsia

5.Gestational diabetes

6.Rh negative

7.Other _____ (please specify)

Appendix G: Clinical Assessment

TITLE: A prospective observational study on the clinical estimation of fetal weight in the Preterm population to be validated by birth weight at The University Teaching hospital, Lusaka.

Study ID# Name:_____

File #:_____ Firm: ____ Ward: _____

1. Infection during current pregnancy YES (circle all that apply)

1.NONE
2.Chlamydia
3.Gonorrhoea
4.Syphilis
5.Herpes
6.Trichomonas
7.Hepatitis
8.UTI
9.Pyelonephritis
10.Malaria
11.Pneumonia
12.Influenza
13.HIV
14.Bacterial Vaginosis
15.Other _____ (please specify)

2. Measurement:

1.Height (cm) _____

2.Weight (kg): _____

3.Leopold's: _____ gram

4.Maternal abdominal circumference (cm): _____

5.Fundal Height (cm): _____

6.Ultrasound EFW (only if within one week of measurement): _____ gram

7.Date of Ultrasound ____ ____/_____ _____/_____ _____

3. Labour & Delivery Outcome Type of labour (circle one)

1.No labour

2.Spontaneous (including augmentation Induced)

4. Indication for preterm delivery (circle all that apply)

1.Preterm labour

2.PPROM

3.Vaginal bleeding/placental abruption

4.Gestational HTN

5.Preeclampsia/eclampsia

6.Chronic HTN (NO pre-eclampsia)

7.Diabetes

8.Fetal distress

9.Ante-partum stillbirth

10.Chorioamniotis

11.Other _____ (please specify)

5. Mode of delivery (circle one)

1.Spontaneous vaginal

2.Vacuum assisted vaginal

3.Forceps assisted vaginal

4. Caesarean

6. Antibiotics during labour

1.YES(if so, please specify type: _____)

2.NONE

7. If operative vaginal; indication (circle one):

1.CPD

2.Labour dystocia

3.Shortened 2nd stage

4.Maternal exhaustion

5.Other _____ (specify

8. If C-section, skin incision (circle one)

1.Pfannensteil

2.Vertical

3.Other _____(please specify)

9. If C-section, uterine incision (circle one)

1.Low transverse

2.Classical

3.Other _____ (please specify)

10. If C-section, pre-op antibiotics

1.YES (if so, please specify type: _____)

2.NONE

11. If C-section, indication (circle one)

1.CPD

2.Labour dystocia

3.Failed induction

4.Fetal distress

5.Preeclampsia/hypertension

6.Suspected macrosomia

7.Suspected IUGR

8.Suspected nuchal cord

9.Failed vacuum/forceps

10.Herpes

11.Vaginal bleeding(Placental abruption/Placenta Previa)

12.Abnormal presentation

13.Cord prolapse

14.Prior myomectomy

15.Prior Classical/T or J incision CS

16.Other _____ (please specify)

12. Anaesthesia (circle all that apply)

1.NONE

2.Intr-venous medications

3.Spinal

4.Epidural

5.General

13. Postpartum antibiotics:

1.Yes(If yes please specify)): _____

2.NONE

14. Neonatal outcomes (circle one)

1.Live birth

2.Ante-partum stillbirth/IUFD

3.Intrapartum stillbirth

15. Birth weight (grams): _____

16. Sex:

1.M

2. F

17. APGAR scores

1 minute: _____

5 minute: _____

10 minute:_____

18. Disposition:

1. Newborn Nursery

2. NICU

3.Morgue..... If morgue, cause of death: _____

4.Other_____

Appendix H: Ethics Approval Letter

ERES CONVERGE

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

10th February, 2016

Ref. No. 2015-Nov-013

The Principal Investigator
Dr. Swali V. Fundafunda
The University of Zambia
School of Medicine
Dept. of Obstetrics and Gynaecology
P/Bag RW1X,
LUSAKA.

Dear Dr. Fundafunda,

RE: CLINICAL ESTIMATION OF FETAL WEIGHT IN PRETERM PREGNANCIES: AN ALTERNATIVE TO LEOPOLD'S METHOD TO BE VALIDATED BY ACTUAL BIRTH WEIGHT AT UTH.

Reference is made to your corrections dated 25th January, 2016. The IRB resolved to approve this study and your participation as Principal Investigator for a period of one year.

Review Type	**Ordinary**	Approval No. **2015-Nov-013**
Approval and Expiry Date	Approval Date: 10th February, 2016	Expiry Date: 9th February, 2017
Protocol Version and Date	Version – Nil	9th February, 2017
Information Sheet, Consent Forms and Dates	• English.	9th February, 2017
Consent form ID and Date	Version-Nil	9th February, 2017
Recruitment Materials	Nil	9th February, 2017
Other Study Documents	Questionnaire.	9th February, 2017
Number of participants approved for study	173	9th February, 2017

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.

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

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