VALIDATION OF A LOCAL WEIGHT ESTIMATION FORMULA IN CHILDREN UNDERGOING SURGERY AT THE UNIVERSITY TEACHING HOSPITAL, LUSAKA, ZAMBIA

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A dissertation submitted to the University of Zambia in partial fulfillment of the requirements for the award of Master of Medicine degree in Anesthesia and Critical care.

University Of Zambia
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Lusaka

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DEDICATION

To my wonderful husband Edward for his love and encouragement. To my children, Khumbo Olivia and Nathaniel Chigomezyo, for the unending supply of smiles. To my mother who continues to encourage me to reach for the stars. To my best friend, Ngoza, and siblings for their support also to my late father who believed in me.

DECLARATION

I **Dr. Hope Phiri** declare that this dissertation herein presented for the Degree of Master of Medicine in Anaesthesia and Intensive Care has not been previously submitted either wholly or in part for any other Degree at this or any other University nor is it being currently submitted for any other Degree.

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APPROVAL

This dissertation of Dr. Hope Phiri is approved as fulfilling part of the requirements for the Award of the Degree of Master of Medicine in Anaesthesia and Critical Care by the University of Zambia.

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ABSTRACT

Accurate determination of weight is essential to avoid drug errors. Where weighing is not feasible, age or length based formulae are used to estimate weight. Formulae must be validated in the local population as most are derived from high income countries where childhood obesity is increasing.

The "Lusaka formula" was derived from a previously published data set. The study aimed to validate this formula in a new data set. Weights, heights and age of 330 children were measured before surgery. Accuracy was examined by comparing the (1) Mean Percentage Error and (2) the percentage of actual weights that fell between 10% and 20% of the estimated weight for the Lusaka formula and other existing formulae.

The Lusaka formula had a mean percentage error of 1.37% (95% limits of agreement 7.7,-6.8) and estimated weights to within 10% of actual weight 48.5% of the time. It had a slight tendency to underestimate weights. Its precision was comparable to the Broselow tape.

No significant difference was found between the sexes with regards to the mean age, measured weight and estimated weights differences but regression analysis showed that maternal education level significantly predicts weight for children above 1 year. Out of the 163 children aged 0-5 years, 17.8% had under nutrition of varying extents; 3.1% had extreme malnutrition, 3.1% had severe malnutrition and 11.7% had moderate malnutrition.

The study concluded that when actual weight is unknown, the Lusaka formula is superior to previously published age based weight estimating formulae in children presenting for surgery at the University Teaching Hospital (UTH) in Lusaka, Zambia. Newer formulae significantly overestimated weights of the children in this population.

Keywords: Paediatric, weight estimation, low middle-income countries.

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ABBREVIATIONS/ ACRONYMS

ALSG	-	Advanced Life Support Group
APLS	-	Advanced Paediatric Life Support
ARC	-	Australian Resuscitation Council
ASA	-	American Society of Anaesthesiologists classification
BMI	-	Body Mass Index
cm	-	centimetres
D Block	-	UTH Paediatric Surgery Operating Theatre/Wing
ERC	-	European Resuscitation Council
GDP	-	Gross Domestic Product
HDI	-	Human Development Index
LMICs	-	Low and Middle Income Countries
Mcg/mg/kg	-	Microgram/Milligram/ Kilogram
MMED	-	Master of Medicine
MUAC	-	Mid Upper Arm Circumference
OIML	-	Organisation International Meterologie Legale
PG	-	Postgraduate

UK	-	United Kingdom
UNICEF	-	United Nations International Children's Emergency Fund
US	-	United States of America
USD	-	United States Dollar
UNZA	-	University of Zambia
UTH	-	University Teaching Hospital
WHO	-	World Health Organisation
ZDHS	-	Zambia Demographic Health Survey

CHAPTER ONE: INTRODUCTION

1.1 Background

It is almost a sacrosanct statement in modern medicine that "children are not small adults." This is to highlight the specialized care and detail that clinicians should have when dealing with the child patient (Klassen et al, 2008). In prepubertal children, height, age and body weight represent anthropometrics which predict organ function including the liver and kidney and by inference, the function of physiological processes which collectively determine drug disposition (Abdel-Rahman et al., 2014).

From the announcement at birth up to the fifth birthday, body weight remains a strong reflector of organ system maturity and one of the major parameters used to measure and monitor growth during the Zambian Under 5 program. Throughout childhood, body weight remains a vital parameter and mainstay tool for drug dose calculations, choice and sizing of equipment, selection of assisted ventilation lung volumes and pressures, calculation of resuscitation and maintenance fluids, caloric intake and calculation of defibrillation energy dose during cardioversion and resuscitation.

In clinical practice, drugs are calculated according to a child's body weight as the majority of paediatric drugs are calculated on milligram/microgram per kilogram bodyweight basis making it essential to have an accurate determination of the child's weight (Abdel-Rahman et al, 2014). The most common paediatric drug errors are dose errors which are often based on weight estimate (Ferner, 2012).

In the operating theatre setting, the establishment of weight before the child enters the operating room is critical for correct pharmaceutical administration of the many anaesthetic drugs that will render the patient unconscious, pain-free and sometimes paralyzed and still make reversal possible. In an emergency situation, it may be impractical to weigh a surgical patient due to the concurrent administration of life saving resuscitative measures and ongoing history collection. In resource limited countries like Zambia, this problem is magnified by the unavailability of medical weighing scales, non-calibration or broken down scales.

Where weighing is not feasible several methods of weight estimation can be used including parental recall and clinician's guess. When 'guesstimation' is used, the accuracy is poor with variable results and significant errors can occur (Argall et al, 2002). Age or length based formulae can be used. The available formulae have been derived from populations from different locations, mostly in high-income countries. This has potential to overestimate or underestimate weight when applied to different locations, ethnic and socioeconomic groups especially when considering the global obesity epidemic in high income countries and ongoing prevalence of malnutrition in children of low income countries (Ali et al., 2012).

These formulae are rendered ineffectual in settings where the age of the child is unknown or undocumented hence other anthropometric surrogates such as stature (humeral length) and body habitus (mid upper arm circumference) have been designed (Abdel-Rahman et al., 2014). The Mercy Tape a tool incorporating both parameters has performed better than methods that rely on single variables but remains a patented tool. The most commonly used length based tool is the Broselow tape, and its reference value is the ideal body weight of US children. This tool performs poorly in non-US settings and even among overweight and obese children in the USA (Abdel-Rahman et al., 2014). The Mid-upper arm circumference (MUAC) which represents an anatomic site where the bone: muscle: fat ratio approximates that of the whole body, is an extension of the work in the field of nutrition where the relationship between MUAC and weight has been used to assess nutritional status in critically ill children and also for mass screening programs of severe malnutrition in children in developing countries. These methods are typically developed using normative data from single site studies and perform best in a relatively narrow range of ages.

Inaccurate estimation of weight may have serious consequences such as over-resuscitation in the presence of malnutrition. This has dangerous sequelae including fluid overload, cardiac failure and death (Pollock et al., 2007), (Guidelines for the inpatient treatment of severely malnourished children, WHO 2003). This necessitates validation of weight estimation formulae before adoption in a particular region or location and where feasible, formulating of a local 'best fit' formula.

1.2 Statement of the Problem

The nutritional status and weight normograms of children presenting for surgery at the University Teaching Hospital was not known. The various weight estimation formulae currently being used in Zambia were not validated against this population and actual statistical relationships were unknown.

1.3 Study Justification

This study aimed to contribute to the body of knowledge on nutritional status, applicability of existing weight estimation formulae and validation of a local weight estimation formula. It was anticipated that the de novo local formula could be extrapolated to similar hospitals in Zambia and the sub-Saharan region.

1.4 Research Question

Is the Lusaka formula [weight (kg) = 2n+7 (where n is age in years) and; weight (kg)=(month age)*0.5+3.5, for children below 1 year] superior to previously published formulae for the estimation of weight in children presenting for surgery at the University Teaching Hospital (UTH) in Lusaka, Zambia?

1.5 Hypothesis

1.5.1 Null Hypothesis: A new locally derived formula overestimates weights of children presenting for surgery at the UTH, Lusaka, Zambia when compared to existing weight estimation formulae.

1.5.2 Alternate Hypothesis: Frequently used Weight estimation formulae overestimate weight of children presenting for surgery at the University Teaching Hospital, Lusaka, Zambia.

1.6 Objectives

1.6.1 General Objectives: To validate a locally derived age based weight estimation formula and compare it to existing formulae in all age groups of children presenting for surgery at the University Teaching Hospital.

1.6.2 Specific Objectives:

1. To check the adequacy of age based formulae and habitus (length) based formula against measured weight in children presenting for surgery at UTH.
2. To determine the nutritional status of children presenting for surgery at UTH by comparing with the WHO Growth standard charts.
3. To determine the incidence of malnutrition in children presenting for surgery at the University Teaching Hospital.
4. To determine whether the performance of weight estimation formulae is affected by gender and maternal level of education.

CHAPTER TWO: LITERATURE REVIEW

The first age-based weight estimation formulae include the European Resuscitation Council (E.R.C)/Advanced Life Support Group (ALSG) formula that was derived from the National Centre for Health Statistics (NCHS) in the US. They published percentile curves for assessing physical growth of children using data collected from 1963-1975. Many newer formulae have been developed to compensate for underestimation of weights in developed countries (Geduld et al., 2010) as the incidence of child obesity in high-income countries has been shown to be on the increase as illustrated in Table 1.

Table 1. Age and length based weight estimating formulae in current use
Data Source: Bowen et al., (2016)

Key:
Where n = age in years

Name of Formula	Method of Calculation	Applicability
Old APLS	([n+4] x 2	Age: 1-10years
New APLS	0.5(month age)+4 2n+8 3n +7	Age:Infants(0-12 months) Age:1-5 years Age: 6-12 years
Nelson	0.5(month age +9) 2n+8 0.5(7n-5)	Age:Infants(0-12 months) Age:1-6 years Age: 7-12 years
Argall	(*n* + 2) x 3	Age: 1-10years
Luscombe	3(n)+7)	Age: 1-10years
ARC Formula	2(n+4) 3.3n	Age: 1-9years Age: >10
Best Guess	(month age+9)/2 (2n) +10 4(n)	Age:infants(0-12 months Age:1-4years Age: 5-14
Michigan	3(n)+10	Age: 1-9years
Broselow tape	(50th centiles)	length range 46-143cm weight: under 36kg
Leffler	0.5(month age) +4 2(n) +10	Age:infants(0-12 months Age:1-10 years
Theron	exp [2.20+0.175(n)]	Age: 1-14years
Shann	2(n)+9 3(n)	Age: 1-9 years Age: >9 years
Garwood-McEwen	(month age/4) +6	Age: 1-14years
Park Formula	(month age+9)/2 (2n) +9 4(n)	Age:Infants(0-12months) Age:1-5 years Age:6-12 years
Tintinalli	(2n)+10	Age: 1-12 years
Chinese Age Weight Rule	(3n) +5	Age: 1-10years

2.1 Local Data

Economically, Zambia is a lower middle income country (World Bank Classification) estimated to have 15% of the under-five population as undernourished, and ranks 52nd worldwide in this regard (UNICEF, Progress for children, 2006). Undernutrition is defined as being underweight for age, short for age, wasted and deficient in vitamins and minerals. This is termed severe malnutrition when the weight for height is below -3 Z scores of the median WHO growth standards, there is visible severe wasting, or by the presence of nutritional oedema.

The preliminary 2013-14 Zambia Demographics Health Survey (ZDHS) estimates that 40% of this under five population is stunted (low height for age) with a further 6% being wasted (underweight for height). It therefore remains one the 22 African countries with the highest burden of under nutrition in the under-fives (UNICEF, 2006).

With 68% of the Zambian population living below USD $1.25/day (World Bank. 2013; http://data.worldbank.org/country/zambia), factors such as access to food and quality health care which are fundamental to good nutritional status are compromised necessitating the need to validate weight estimation formulae derived from high income countries where these factors are not compromised.

A previous study at the UTH (Bowen et al., 2016) showed that most children presenting for surgery were under 5 years old and linear regression analysis of this data showed that their weights were better estimated by a novel formula, weight = 2n+7 (where n is age in years) for children above 1 year and weight = (month age)*0.5 for children below 1 year. This "Lusaka formula" must be validated against a new cohort of children before it can be used clinically with confidence.

2.2 Global Data

Several studies comparing validity of different age based weight estimation formulae, MUAC and the Broselow tape have been done around the world post the original APLS formulae with conflicting results and no single fit formula suits all locations.

New formulae have been developed in different affluent countries and seem to overestimate age based weight estimation when compared with the traditional APLS.
A study in the United Kingdom in 2011 of children from 1 month to 12 years found that the APLS formula underestimated weight by progressing amounts with advancing age while de

novo formula like the Luscombe & Owens performed best in their 1 year to 10 year group (Seddon et al., 2011) and similarly an Australian study of four hundred and ten children with a median age of 4 years, found that the Luscombe formula (a new formula) is among the more accurate age-based weight estimation formulae when measured weight is not available with a mean weight difference of 0.66kg representing a minimum error from measured weight (Kelly et al., 2010).

A study of a national dataset of 124,094 children in Korea found that existing weight-estimating methods of APLS, Nelson formula, Best Guess formula and Broselow tape had a tendency to underestimate the weights of Korean children. One of the possible reason advanced by the authors for this observation is that other methods of weight-estimation are outdated and do not reflect the increasing growth tendency of Korean children where body mass index (BMI) of Korean children showed a dramatic increase from 1998 to 2005. A new formula (Park formula) was then derived and validated for the local population (Park et al., 2012).

Similarly, a USA study of preoperative anthropometrics and clinical data on 13,933 children aged 2 to 12 years to comparing the Luscombe, APLS and Theron formula found that in their population, accuracies of current weight estimation formulae varied greatly. A new formulae was derived (Michigan formula) that demonstrated high accuracy when compared with existing formulae and may be more applicable for estimating the weight of contemporary American children (Ackwerh et al., 2014).

These studies are from developed countries do not correlate well with similar studies in developing countries like Kenya, Nigeria, Malawi and South Africa. Several studies have been done with conflicting results from those in developed countries.

A South African study validating 4 weight estimation tools in Western Cape found that the APLS and Broselow Tape showed the best correlation with measured weights though a small tendency to underestimate was noted. The APLS underestimated weight by 3.3%. The Luscombe formula significantly overestimated weight in all age groups (Geduld et al., 2010). South Africa is however an upper middle income country with a mixture of ethnicities and different socioeconomic levels and is regarded as a rapidly developing country. Its GDP at USD$349.8 billion surpasses Zambia and its Human Development Index is higher that Zambia.

http://siteresources.worldbank.org/NUTRITION/Resources/281846-1271963823772/southafrica.pdf

A prospective study of 114 children aged 1-14 years in southern Nigeria found that the Luscombe formula overestimated weight in all age groups just as the South African study found. It was noted that the APLS formula significantly underestimated weights in the 6-10years group by 12.3% and by 20.86% in the 11-14 year group rendering it an inaccurate estimation tool for children above 5 years. The Argall formula performed better in this 6-14 year group. In the 1-5 year group, the APLS underestimated weights by 2.43% while the Argall formula overestimated by 3.64% (Ilori et al., 2015). Economically, Nigeria is a developing country with a bigger economy than Zambia (GDP of USD$568 Billion) and a higher Human Development Index (HDI).

In sub Saharan region, studies at Eldoret, Kenya showed that the old APLS and Broselow tape better predicted weights of children in western Kenya under 10 years old even though the percentage underestimation of 5.6% was found with the APLS formula. The study further showed that the Broselow tape (height for age) outperformed mathematical formula (House et al., 2013). Like Zambia, Kenya is a sub-Saharan African country, rated lower middle income by the IMF. Its GDP of USD$60.9 Billion is significantly more than that of Zambia which is at USD$27 Billion and 43% of Kenya's population is estimated to live below USD$1.25 mark. However Zambia has a higher Human Development Index (HDI) than Kenya, and validation is needed in Zambia before extrapolating this data.

A retrospective Malawian Study at Queen Elizabeth Central Hospital showed that 95% of Malawian children were weight appropriate for height and that the Broselow tape would be a better guide than age derived weight estimation formula. It also showed that the Luscombe and Owens formula overestimated weight by a mean of 10.6% and this was even greater in older children. This was attributed to the cumulative effect of age on stunting. The old APLS formula and Broselow tape were better estimators than de novo formulae. The Malawi study compared the Old APLS, Luscombe and Broselow tape (Pollock et al., 2007).

Despite the variability of results, it is evident that even amongst developing countries in Africa, the old APLS formula has a tendency to underestimate weight by different margins while the newly derived formulae from affluent countries overestimate weights in African children. The evidence from these various studies has prompted the Advanced Life Support

Group (ALSG) to advise health professionals decide locally what method provides the easiest and best method of weight estimation in children for their own use (Ilori et al., 2015).

CHAPTER THREE: RESEARCH METHODS

3.1 Setting

The University Teaching Hospital, Zambia's tertiary referral center for paediatric surgery.

3.2 Study Site

The study was conducted in Paediatric Surgery Operating Theatre at D block.

3.3 Target Population

All children up to the age of 14 scheduled for surgery.

3.4 Study Population

All children that met the inclusion criteria.

3.5 Study Design

The study was a prospective cross sectional study.

3.6 Inclusion Criteria

All children from birth up to the age of 14 years with a documented date of birth who presented for surgery and underwent anaesthesia (general, regional or local) with heights/ lengths and weights measured.

3.7 Exclusion Criteria

Children with unknown or undocumented dates of birth and children with external orthopaedic devices or prostheses.

3.8 Duration of Study

Data was collected for a five (5) month period from September 2016 to January 2017.

3.9 Data Collection

Data was collected by myself and two trained research assistants (for the purpose of the study) in paediatric operating theatre and ward and entered into a pro forma for each patient and assigned identification numbers for data collection and entry purposes.

3.10 Procedure

Measurement of weight, height/length and mid upper arm circumference was done as part of the routine preoperative assessment on the day of surgery. Weight was measured using Medical Grade III scales (as per Organisation International Meterologie Legale:OIML) and rounded off to the nearest 0.1kg. The stand on scale HCS-200-RT (Sainty International Group, Shanghai, China) was used to measure weight and length. It can measure up to 200kg weight in graduations of 100g and heights of 70-190cm in graduations of 0.5cm. The infant ACS-20B-YE scale (Lencen Medical Co. Shanghai, China) was used for infants. It measures from 200g to 20kg with 10g graduations. Research assistants were trained to use and regularly calibrate the scales, and to accurately measure the length of the children.

The Mid Upper Arm Circumference (MUAC) was measured by a measuring tape/MUAC Tape on the left upper arm at the mid-point of the tip of the shoulder and the tip of the elbow while head to toe lengths/heights were measured and rounded off to the nearest 1cm and compared to the Broselow Paediatric Emergency Tape by trained anaesthetists.

For children below the age of one year, month age was analysed while age at last birthday was used for children above one year with WHO weight-for-height Z score charts was being used for the detection of malnutrition.

Additional data included in the data set include gender, surgical procedure performed and parents level of education.

3.11 Primary Outcome

Agreement between estimated weight using the proposed new formula [weight = (2n +7), where n is age in years for children above 1 year and weight= (0.5n+3.5), where n is month age for children below 1 year] and the measured weight.

3.12 Secondary Outcome

Comparison of performance of the new local formula against existing weight estimation formulae. The performance of age based mathematical formulae was also compared to length based estimators.

3.13 Sampling Method

Consecutive series of all children presenting for surgery and undergoing anaesthetic procedures who meet the inclusion criteria will be enrolled from Monday-Friday during normal working hours.

3.14 Sample Size

The sample size was based on analysis of the 95% limits of agreement of bias. According to Bland and Altman the standard error of the 95% limit of agreement is approximately $\sqrt{(3s^2/n)}$ where s is the standard deviation of the differences between measurements by the two methods

n is the sample size (Bland et al., 1986).

The 95% confidence interval is the estimate of the limit +/-1.96 standard errors or +/-1.96$\sqrt{(3s^2/n)}$. A sample size of 300 gives 95% confidence intervals of approximately 0.2 standard deviations.

3.15 Statistical Analysis

Data entry was checked for completeness and consistency using double entry check by the two research assistants. Data that passed was then stored on a data capture sheet in SPSS software. Analysis of the data was performed using SPSS version 19 (IBM, Armonk, US).

Method agreement analysis of normally distributed data was performed using the paired t test and Bland Altman analysis while the Wilcoxon signed rank test was used for data that was not normally distributed. The Bland Altman method was used to examine the mean bias and 95% limits of agreement in keeping with previous literature on this subject.

The precision of different formulae was then examined by calculating median percentage error [100 x (actual weight – estimated weight / actual weight] and the percentage of actual weights that fall between 10% or 20% of the estimated weight to correspond to other studies.

One sample's t tests were conducted to establish whether there were statistically significant differences between the actual measured weight and the weights estimated using various formulae while the paired t-test was used for pair-wise comparison of the mean bias of the Lusaka formula with the mean bias of all the age-based formulae. An independent samples t test was used to compare the actual weights measured of male and female participants while a multivariable linear regression analysis was carried out to look at the effect of maternal education on a child's body weight.

A Bonferroni adjustment was made for multiple comparisons, requiring a $p < 0.00357$ for significance (equivalent to $p<0.05$ for a single comparison). A Fisher's exact test was used to compare the proportion of children within 10% and 20% of estimated weight for the Lusaka formula with the proportion of children within 10% of estimated weight for all the age-based formulae.

3.16 Ethical Considerations

Ethical approval was obtained from the Excellence in Research (ERES) research ethics committee. Permission from the University Teaching Hospital management to carry out a study in the institution was also obtained.

Participation in this study was voluntary and participants were not remunerated. No harm was rendered to the participants as all interventions were part of routine preoperative assessments and weighing them optimized the quality of care rendered. Assent was obtained from children between 7-14 years in addition to written parental permission for all the participants. Data was then entered into a coded pro forma which only the research assistants and myself had access to.

CHAPTER FOUR: RESULTS

4.1 Demographic Characteristics of the Patients

Three hundred and thirty patients were recruited in this study. Two hundred and thirty-three (70.6%) patients were undergoing general surgery, 33 (10.0%) for neurosurgery procedures, 29 (8.8%) were ENT cases, 25 (7.6%) were bronchoscopy cases, 9 (2.7%) were plastic surgery and 1 (0.3%) was a central line insertion.

Two hundred and twenty (66.7%) were males while 110 (33.3%) were females. Seventy-one patients were aged ≤ 11 months and 262 were aged 1 to 14 years. This is depicted in Table 2.

Table 2: Distribution by Specialty

	Frequency	Percent (%)	Cumulative Percent (%)
General surgery	233	70.6	70.6
Neurosurgery	33	10.0	80.6
ENT	29	8.8	89.4
Bronchoscopy	25	7.6	97.0
Plastic surgery	9	2.7	99.7
Central line insertion	1	0.3	100.0
Total	330	100.0	

The age range and actual weights and height distribution of the study population was analysed for normal distribution. The median and mean values were tabulated in Table 3 to show the interquartile range and standard deviation.

The histogram in Figure 1 shows a slight skew to the left in the distribution of weights in the study population while Figure 2 shows a normal distribution curve for the heights.

Table 3. Age range of the 330 children recruited, with height and weight distribution. Values are median (IQR [range]) or mean (SD)

Age	N	Height; cm	Weight; kg
Months			
0	7	42 (39-47 [39-53]	2.5 (0.4)
1	4	47.5 (44.3-56.8 [44-59])	3.6(1.3)
2	5	54 (54 [49.5-56.5])	4.5(1.4)
3	6	59.5 ([55.8-62.5])	6(1.2)
4	4	51.5 (50-57.5 [50-59])	6.25(2.0)
5	8	60 (59-63 [56-73])	6.7(1.8)
6	5	60 (55-84 [52-95])	8.1(5.9)
7	8	68.5 (66-69.8 [65-68.5])	7.2(2.1)
8	4	67.5 (64.5-69.8[64-70])	7.5(2.0)
9	6	69.5 (63.5-70.5[56-72])	8.4(1.1)
10	5	70 (70-82.5 [70-83])	8.2(2.7)
11	9	72 (67-77[59-83])	8(2.1)
Years			
1	47	75 (72-80 [62-98])	9.8(3)
2	31	85 (82-88 [72-109])	11.3(1.6)
3	38	94 (90-99 [76-109])	13.4(1.9)
4	19	104 (100-109 [85-114])	15.7(2.9)
5	22	106.5 (101.5-115[71-123])	16.4(3.1)
6	27	114 (108-116 [97-130])	18(3.6)
7	17	121 (116-124.5 [105-127])	21.2(3.4)
8	15	125 (120-129 [110-150])	23(3.3)
9	6	135.5 (127.3-140[110-140])	25.9(3.7)
10	15	131 (126-141 [116-152])	28(5.7)
11	6	129 (117-136 [108-137])	23.9(6.8)
12	4	148.5 (138.8-154.5 [136-156])	35.2(12.5)
13	6	144.5 (135.3-151.8 [130-157])	29.5(15.4)
14	6	156 (136.8-164 [115-164])	32.3(15.5)

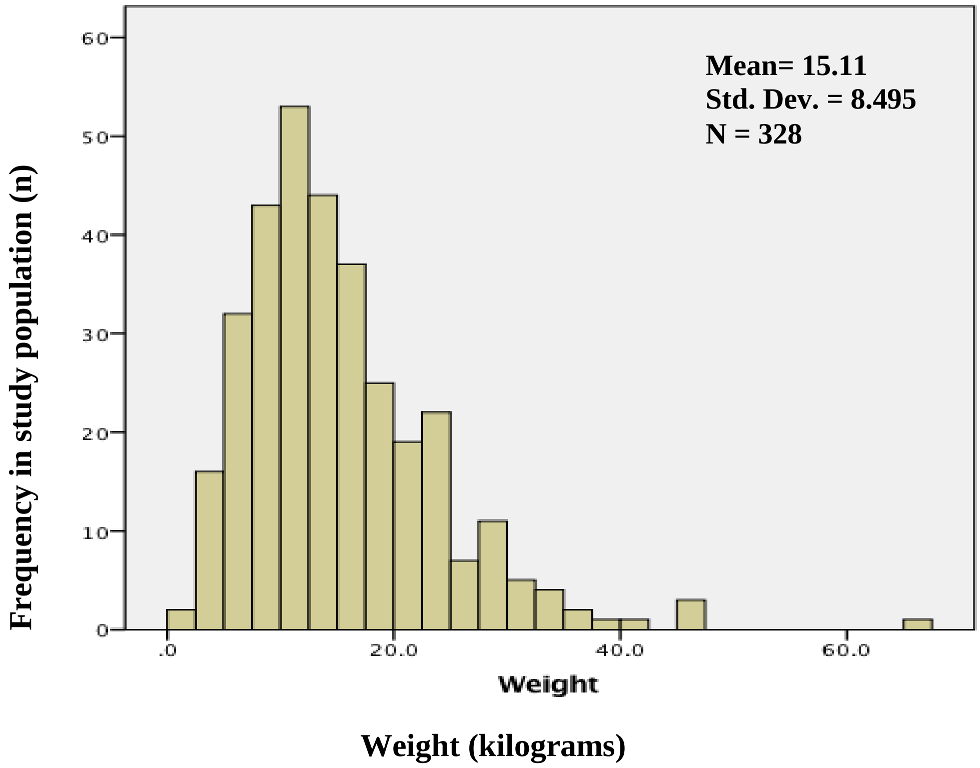

Figure 1. Distribution of Weights of Study population

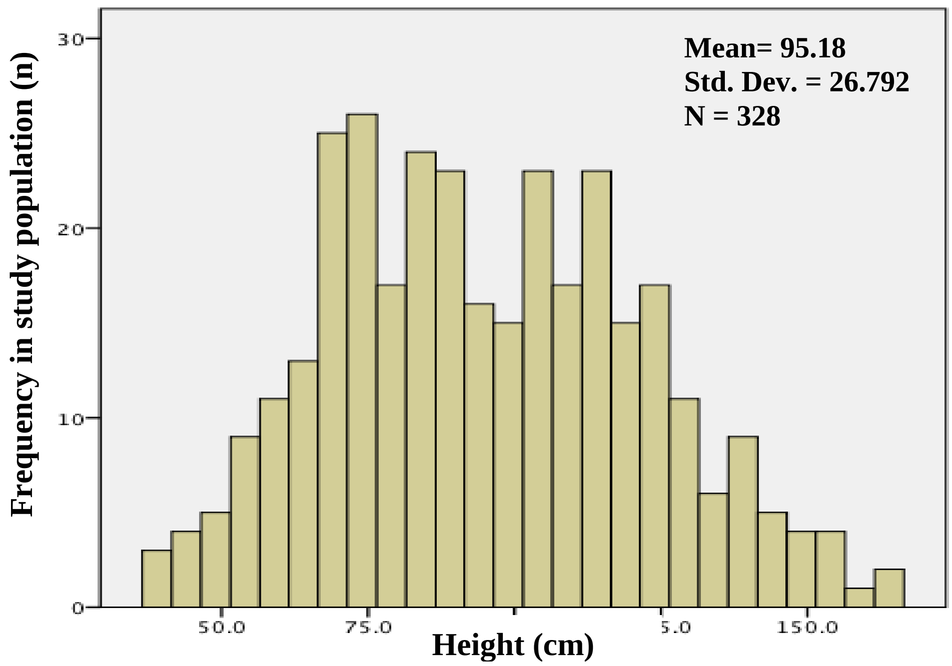

Figure 2. Distribution of Heights of Study population

4.2 Adequacy of various Age Based and Length Based Formulae

Table 4 illustrates the number (proportion) of children in the study sample in whom actual weight fell within 10% and 20% from the estimated weight.

Table 4. Median percentage difference between actual measured weight and estimated weight.

Formula	Mean %error	Within 10% of estimated weight	Within +-20% of estimated weight	Mean difference	SD difference	n	95% CI mean bias	95% limit of agreement
BROSELOW	-4.76	51.6	79.5	-0.85	2.49	307	[-0.6, -1.1]	[4.0,-5.7]
LUSAKA	1.376	48.5	73.0	0.46	3.68	330	[0.9,0.1]	[7.7,-6.8]
OLD APLS	-4.4	47.3	74.1	-0.59	4.04	259	[-0.1, -1.1]	[7.4,-8.5]
ARC	-7.383	43.8	71	-1.58	4.73	259	[-1.0, -2.2]	[7.7,-10.9]
NELSON	-7.692	42.5	72.2	-1.19	3.40	302	[-0.8, -1.6]	[5.5,-7.9]
SHANN	-11.940	34.5	63.3	-1.95	4.14	259	[-1.4,-2.5]	[6.4,-10.1]
CAWR	-8.280	32.9	57.8	-1.88	4.18	237	[-1.3,-2.4]	[6.4,-10.1]
LEFFLER	-15.702	28.8	54.8	-2.07	2.94	308	[-1.7,-2.4]	[3.7,-7.9]
NEW APLS	-10.429	36.4	56.9	-2.55	4.58	311	[-2.0, -3.1]	[6.5,-11.6]
ARGALL	-15.942	26.1	52.7	-2.88	4.18	237	[-2.3,-3.4]	[5.4,-11.1]
TINTINALLI	-19.403	26.0	51.4	-2.63	3.30	247	[-2.2,-3.0]	[3.9,-9.1]
GARWOOD	-17.391	24.6	49.8	-3.57	5.36	259	[-2.9,-4.2]	[7.0,-14.1]
PARK	-17.949	24.1	52.3	-3.70	5.74	323	[-3.1,-4.3]	[7.6,-15.0]
THERON	-25.536	22.8	43.5	-5.62	7.10	237	[-4.7,-6.5]	[8.4,-19.6]
LUSCOMBE	-23.077	21.5	40.5	-3.88	4.18	237	[-3.3,-4.4]	[4.4,-12.1]
BEST GUESS	-27.27	14.3	35.9	-5.45	6.14	259	[-4.7,-6.2]	[6.6,-17.5]
MICHIGAN	-45.09	2.5	10.5	-8.14	4.44	200	[-7.5,-8.8]	[0.6,-16.9

Key:
SD: Standard deviation
CI: Confidence Interval
Negative numbers represent a measured weight that is lower than estimated and positive numbers a measured weight higher than estimated. Values are number (proportion) or mean (95% CI)

formulae. The results were not significant in only four situations: Lusaka formula estimated mean weight for children aged less than 1 year, Lusaka formula estimated weight for children aged more than 1 year, New APLS for children aged 0-12 months, and Broselow formula for children weighing 3-36 kg.

Figure 3 was used to graphically depict the difference between the weights estimated using the Lusaka formula and the actual measured weights.

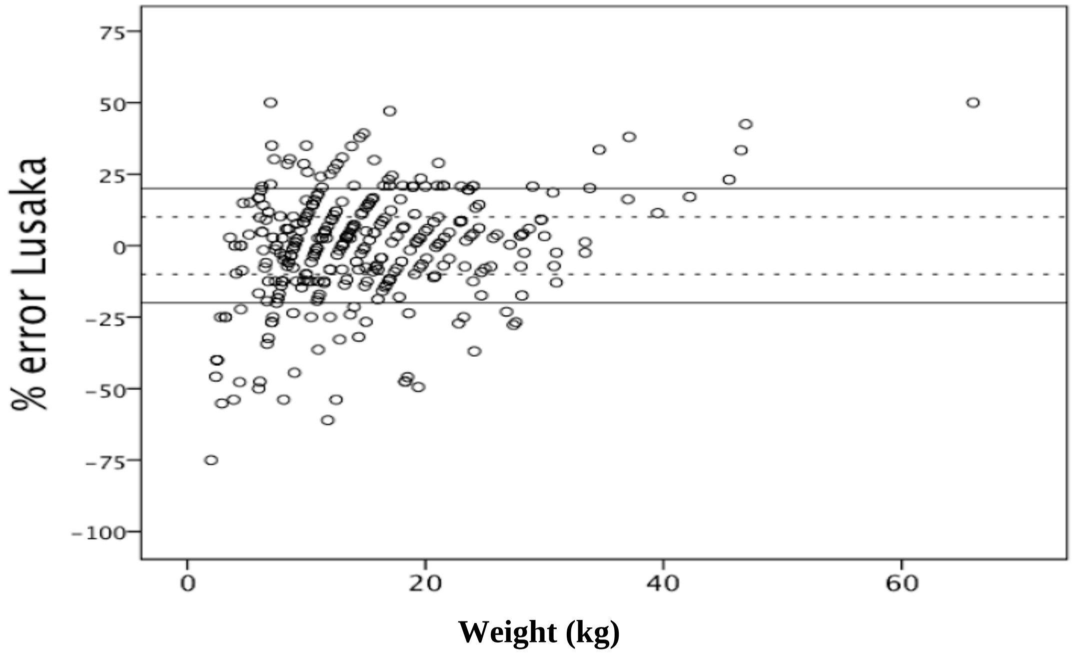

Figure 3. Scatter plot of Lusaka formula percentage error against actual weights

4.3 The Nutritional Status Compared to the WHO Growth Standard Charts

The WHO Global Database on Child Growth and Malnutrition which uses a Z-score cut-off point of <-2 SD to classify low weight-for-height as moderate and <-3 SD to define severe undernutrition was used to determine the nutritional status. http://www.who.int/nutgrowthdb/about/introduction/en/index5.html. Out of the 163 children who were aged 0-5 years, 17.8% (29) had under nutrition of varying extents; 3.1% had extreme malnutrition, 3.1% had severe malnutrition and 11.7% had moderate malnutrition. 37.4% of these children were below the median. One hundred thirty four (82.2%) of the children had normal nutrition status as depicted in Table 5.

Table 5. Assessment of nutritional status by WHO weight for height Growth Charts

Weight (Standard deviation)					
Standard Deviation		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	-4 (extreme malnutrition)	5	1.5	3.1	3.1
	-3 (severe malnutrition)	5	1.5	3.1	6.1
	-2 (moderate malnutrition)	19	5.7	11.7	17.8
	-1 (normal)	61	18.3	37.4	55.2
	0 (normal)	73	21.9	44.8	100.0
	Total	163	49.4	100.0	
Missing	not applicable	167	50.6		
Total		330	100.0		

The Mid Upper Circumference was also used to assess nutritional status. Table 6 shows that out of the 194 children aged 6 months to 5 years, only 1 child had a mid-upper arm circumference of less than 115cm which is the criteria for severe acute malnutrition or wasting by this tool. Screening by BMI found that 8.06% of the population had severe thinness, 12.1% had thinness while 3.23% of the population were obese with 6.45% being overweight.

Table 6. Screening of Nutritional status by BMI

BMI (Standard deviation)					
Standard Deviation		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	-3 (severe thinness)	10	3.04	8.06	8.06
	-2 (thinness)	15	4.55	12.1	20.6
	0 to -1(normal)	87	26.36	70.16	90.32
	+1 (overweight)	8	2.42	6.45	96.77
	+2 (obesity)	4	1.21	3.23	100.0
	Total	124	37.58	100.0	
Missing	not applicable	206	62.42		
Total		330	100.0		

4.4 The Performance of Weight Estimation Formulae By Gender Of Child

Table 7 shows that the mean actual weight of male children was 15.019 kg while the mean actual weight of female children was 15.702 kg.

Table 7. Actual weights by gender

	Gender	N	Mean	Std. Deviation	Std. Error Mean
Actual weight (kg)	male	220	15.019	8.3260	.5563
	female	110	15.702	9.7394	.9286

An Independent samples' t test was conducted to establish whether there was any significant difference between actual weight and gender; a null hypothesis being that there was no difference. The test was conducted at a significance level of 0.05. The results were not significant ($t = -0.666$ (df=332), $p = 0.506$). There was no difference in actual weights of males and females in this study population.

4.5 The Actual Weights Compared To Parental Level Of Education

4.5.1 Paternal Educational Level

Twenty six fathers (7.8%) had attained primary education, eighty (24.0%) had attained secondary education, and one (0.3%) had attained tertiary education. The education level of 223 fathers could not be ascertained. No further analysis was conducted.

4.5.2 Actual Weight Vs. Mother's Educational Level

To look at the effect of the maternal education, a multivariable linear regression analysis was carried out. Table 8 shows that seventy eight (78) of the mothers had attained primary education while one hundred forty two (142) had attained secondary school. Only 1 mother attained tertiary education and was not included in this test.

Table 8. Maternal Education level in study population

		N
Mother's educational level	Primary	78
	Secondary	142

The analysis was split into two as the Lusaka formula is different for children less than a year, reflecting the rapid growth in the first 12 months. The regression analysis in Table 9 is for the children 1 year or over. It shows that mother's education level significantly predicts weight in children over a year ($p<0.001$).

Table 9. Tests of Between-Subjects Effects for Children >1 year

Dependent Variable: Weight					
Source	Type III Sum of Squares	Df	Mean Square	F	Sig.
Corrected Model	11379.7[a]	2	5689.9	332.5	.000
Intercept	3356.86	1	3356.9	196.1	.000
mother_education	260.5	1	260.5	15.2	.000
Age	11318.9	1	11318.9	661.3	.000
Error	3713.9	217	17.1		
Total	83392.6	220			
Corrected Total	15093.6	219			

a. R Squared = .754 (Adjusted R Squared = .752)

Table 10 shows the B values for age and mother's education and illustrates that weight goes up by 2kg for each year of age, which is in keeping with the Lusaka formula. It also shows that if the mother only finished primary school her child is on average around 2kg lighter. So the effect of maternal education on weight is similar to that of a year's age, (n-1, on the Lusaka formula).

Table 10. Parameter Estimates in children >1 year

Dependent Variable: Weight

Parameter	B	Std. Error	T	Sig.	95% Confidence Interval	
					Lower Bound	Upper Bound
Intercept	8.1	.5	15.8	.000	7.1	9.2
[mother_education=1.0]	-2.3	.6	-3.9	.000	-3.4	-1.1
[mother_education=2.0]	0[a]	.	.	.	.	.
Age	2.0	.08	25.7	.000	1.9	2.2

a.This parameter is set to zero because it is redundant.

Figure 4 plots the residuals for weight (actual –estimated weight) against age. It shows good correlation between the ages of 1 year and 7 years but there is a lot of variance when children reach 8 or 9 years, in keeping with a growth spurt in some children at that age as they approach adolescence.

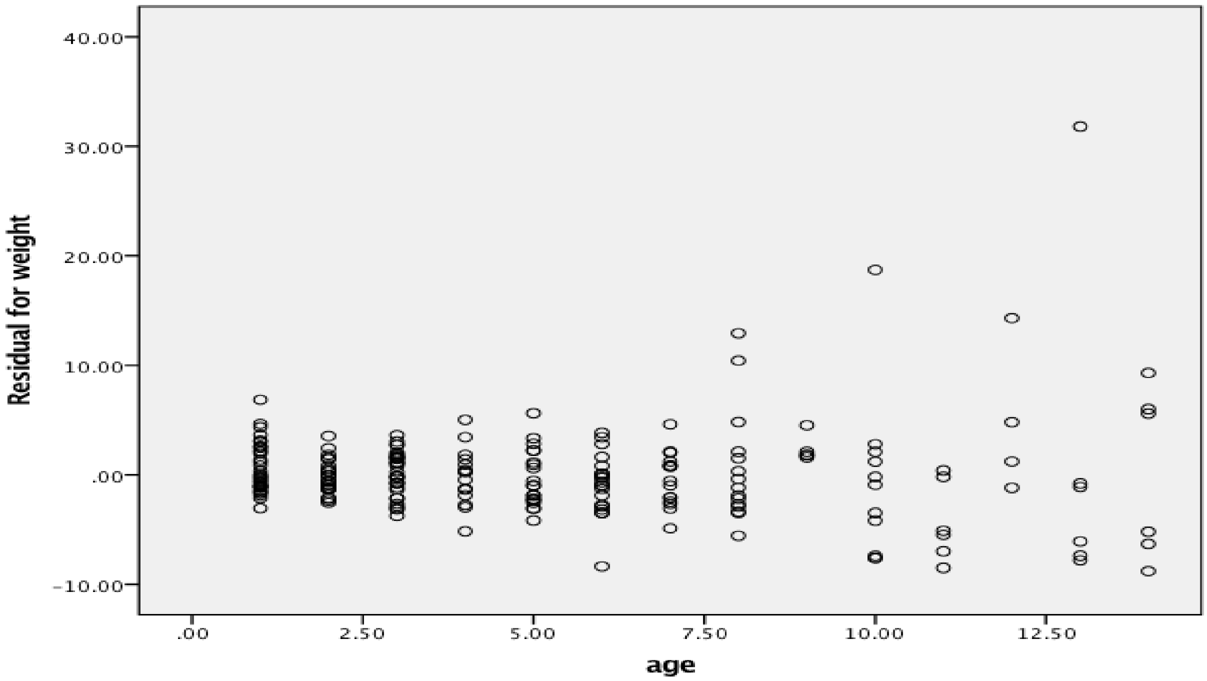

Figure 4. Plot of Residual Weight (actual- estimated weight) vs Age

Table 11 illustrates the effect of maternal education on weight, at an average age of 5 years for the children above 1 year in our study population. The average weight was 16.1kg if the mother finished primary school but 18.4kg if the mother finished secondary school.

Table 11. Effect of maternal education on weight at an average of 5 years in study population

Mother's educational level	Mean	Std. Error	95% Confidence Interval	
			Lower Bound	Upper Bound
1.0	16.147[a]	.469	15.222	17.072
2.0	18.429[a]	.348	17.744	19.114

Dependent Variable: Weight

a. Covariates appearing in the model are evaluated at the following values: age = 5.1318.

4.6 Effect of Maternal Education on Weight in Children below 1 Year

In our study, 22 mothers with children under 1 year had attained primary level education while 41 had attained secondary education. Multivariable linear regression was done for this subpopulation as illustrated in Table 12. It was found that the effect of maternal education was not significant in this patient group. It can be speculated to be due to breastfeeding maintaining the weight of the baby.

Table 12. Tests of Between-Subjects Effects in Children < 1 year

Source	Type III Sum of Squares	df	Mean Square	F	Sig.
Corrected Model	211.2[a]	2	105.6	46.7	0.0
Intercept	209.3	1	209.3	92.5	0.0
mother_education	.01	1	.01	.004	0.1
Agemo	203.8	1	203.7	90.05	0.0
Error	135.8	60	2.3		
Total	3145.6	63			
Corrected Total	347	62			

a. R Squared = .609 (Adjusted R Squared = .596)

a. This parameter is set to zero because it is redundant.

Table 13 depicts an example of the effect of maternal age on weight, at an average age of 6 months in the under 1 year study population. It shows no statistical difference in weights at age 6 months between children whose mothers had attained primary and those whose mother's had attained secondary education.

Table 13. Effect of Mother's educational level on Weight at an average of 6 months

Mother's educational level	Mean	Std. Error	95% Confidence Interval	
			Lower Bound	Upper Bound
Primary [1.0]	6.649[a]	.324	6.001	7.298
Secondary [2.0]	6.674[a]	.236	6.201	7.146

a. Covariates appearing in the model are evaluated at the following values: age in months = 5.9683.

CHAPTER FIVE: DISCUSSION

The need to know the true weight in children undergoing anaesthesia and surgery or critical care is cardinal as interventions are formulated depending on the child's weight. Medication doses, ventilator settings and equipment choice are weight dependent. Weight underestimation can result in poor outcome during resuscitation as a result of inadequate therapy (Luscombe, 2007) or overestimation could lead to over-resuscitation where the child is malnourished and lead to fluid overload, cardiac failure and death (Pollock et al, 2007).

A simple, precise yet reliable tool for rapid estimation in the setting where weighing scales are unavailable or actual weighing is not feasible becomes important. The choice of the tool or formula in a low to middle income country like Zambia is important as most formulae are derived from high income countries where factors determining nutritional status are not compromised.

This study was undertaken to validate a locally derived weight estimation formula that is clinically useful for paediatric surgical patients at the University Teaching Hospital in Zambia. The agreement between the new Lusaka formula and fourteen preexisting formula from different parts of the world was compared to the actual measured weights. The study also sought to determine the nutritional status of children presenting for surgery at UTH and the incidence of malnutrition by comparing with the WHO Growth standard charts.

5.1 Demography

A total number of 330 participants were enrolled for this study. Two hundred and twenty (66.7%) were males while 110 (33.3%) were females. Seventy-one patients (21.5%) were aged ≤ 11 months while 258 (78.2%) were aged 1 to 14 years. The majority of patients (70.6%) were undergoing general surgery procedures. There was no significant difference between the sexes in regards to their mean age, measured weight and estimated weights differences

To look at the effects of maternal education level on weight, a multivariable linear regression analysis was carried out and this was split for children below 1 year and those above 1 year.

In children above 1 year, regression analysis shows that mother's education level significantly predicts weight ($p<0.001$). The B values for age and mother's education show that weight goes up by 2kg for each year of age, which is in keeping with the Lusaka formula. It also shows that if the mother only finished primary school her child is on average around 2kg lighter. So the effect of maternal education on weight is similar to that of a year's age. There is however a lot of variance as a child approaches adolescence. This finding is in keeping with previous studies which have demonstrated that parental education has a significant positive impact on child health. Maternal education has been shown to affect a child's nutrition by information processing effects, income augmenting effects and interactive effects with community services (Thomas et al, 1991).

A sub analysis of the performance of the various weight estimation formulae by gender found no statistical difference in actual weights of males and females in this study population.

5.2 Performance of Weight Estimation Formulae

In this study, tool accuracy of a measurement (the degree of nearness of estimate to the true value) was measured using the mean percentage difference between actual measured weight and estimated weight, estimates accurate to within ± 10% and ± 20% of actual weight, and Bland-Altman bias (i.e. the mean of actual-estimated weight). The 10% level was used to determine the significance of divergence of the estimated from measured weight as described in other studies. At this level, a potential clinically significant risk of toxicity with a low-therapeutic index drugs like aminophylline or dopamine exists and more so in younger, lighter and less nourished children. (Ali et al, 2012).

The Lusaka formula had the best prediction accuracy of all the formulae. It estimated weights with a mean percentage error of 1.38% (95% limits of agreement 7.7,-6.8) and had a slight tendency to underestimate weights. The Old APLS formula had the second best prediction accuracy with a mean percentage error of -4.4% (95% limits of agreement 7.4,-8.5) and a slight tendency to overestimate weights. The performance of these two formulae was comparable to the length based Broselow tape which had a mean percentage error of -4.76% (95% limits of agreement 4.0,-5.7) and a slight tendency to overestimate weights.

The precision of the different formulae was determined by calculating the percentage of patients whose estimated weights were within 10% and 20% of the actual measured weight. The Lusaka formula accurately estimated weights to within 10% of actual measured weight

48.5% of the time while the Old APLS formula accurately estimated weights to within 10% of actual measured weight 47.3% of the time. The Old APLS predicted weights to within 20% of the actual measured weight 74.1% of the time while the Lusaka formula did so 73.0% of the time.

The Broselow tape accurately predicted weights within 10% more than 50% of the time and over three quarters of estimates (79.5%) fell within 20% of actual weights.

Concordance between the Lusaka formula mean bias and the other formulae mean bias by the Wilcoxon test showed that the Broselow tape had the most ties (43) with the Lusaka formula. Overall every pairwise comparison of the mean bias of the Lusaka formula with the mean bias of the existing formulae achieved statistical significance ($p < 0.001$).

One sample t test in the under 1 year population showed no significant difference between actual weight and estimated weights using the Lusaka formula, the New APLS, Broselow tape and Leffler formula. In the above 1 year population, no significant difference between actual and estimated weights was noted using the Lusaka formula and Broselow tape.

Studies in high income countries like the USA have showed that newer weight estimation formula such as Luscombe, APLS and Theron do not accurately estimate their children's' weight and led to the development of the even newer Michigan formula (ackwerh et al, 2014) which when compared to our study population significantly the overestimate weight of Zambian children. The Median Percentage Error for the aforementioned formulae being -23.01%, -10.429%, -25.536% and -45.09% respectively. The new Michigan formula had less than 2.5% of the estimates falling within 10% of the actual weight.

This trend is similar to those noted in the UK by Seddon et al and in Australia by Kelly et al and has led to adoption of newer formulae to accurately estimate the weight of contemporary children. This has been attributed to the increasing growth tendency of children in high income countries. (Park et al, 2012)

In South Africa, an upper middle income country, The Broselow tape (mean error 0.9%) and APLS formula (mean error 3.3%) showed the best correlation to measured weights but there was a notable tendency to underestimate weights with these tools. This was not observed in our study as all the exiting formulae tended to overestimate weight to varying extents (see Table 4). In the South African study, the Luscombe and Best Guess formula tended to overestimate weights significantly (Geduld et al, 2010) and this was also noted in our study. It can be speculated that this is because the two tiered South African economy, ranked as a Very high GDP (USD$ 315 Billion) economy and number 34 in the world, with a GINI index of 63.38, reflects high income inequality when compared to Zambia. This economic disparity could explain the discrepancy with findings in our study as Zambia has a smaller GDP of USD$ 21.2 Billion and a GINI Index of 55.62.

Our study's findings were however similar to Kenya where the existing weight estimating formula studied overestimated the weights of the local children with the Broselow tape, APLS and Nelson's formula having mean percentage differences of -2.2%. -5.2% and -10.4% respectively (House, 2013). The Broselow tape outperformed the mathematical formulae in the Kenya study. This is notable as Kenya is a bigger economy than Zambia (GDP USD$63.4 Billion) with a better income equality (GINI Index 48.51) than Zambia.

The results of this study coupled with other studies in Malawi, Nigeria, Kenya and South Africa are in agreement with assertions for LMICS to employ weight estimation methods that use data from the 1970s as opposed to those developed more recently using data that may be affected by rising obesity trends (Pollock et al, 2007). These results are also in agreement with the Advanced Life Support Group recommendations for health professionals to locally decide what method provides the easiest and best method of weight estimation in their children (Ilori et al, 2015).

5.3 Determination of Nutritional Status

The WHO Growth standard charts for height and weight where used to determine the nutrition status of children between 6 months and 5 years. Of the 163 children in this subpopulation, 55.2% where undernourished (low weight for height) with 3.1% having extreme malnutrition, another 3.1% having severe malnutrition and 11.7% having moderate malnutrition. The study found that 17.8% of the children were below the -2SD Weight for height score. This is significantly higher than the WHO global estimate of 8% in the general population and the ZDHS 6% estimate. This finding is not surprising in a LMIC like Zambia where determinants of nutrition such as access to household resources, quality care and medical services, as well as water and sanitation facilities are compromised. Other international and national forces that impact the level of undernutrition in LMIC include climate change, trade, the rate and pattern of economic growth, food and energy prices and volatility, and land-use policies (Georgiadis, 2014)

For patients above 5 years old, BMI was used to ascertain the nutritional status. The BMI was found to be less than –2 SD and -3 SD in 12.1% and 8.06% corresponding to thinness and severe thinness respectively. About 2.42% of this subpopulation was overweight while 1.21% was obese. 70.16% had normal BMI. These findings correlate with previous studies that show that the distribution of childhood nutritional disease is shifting from a predominance of undernutrition to a dual burden of under- and overnutrition (Tzioumis et al., 2014)

The Mid Upper Arm Circumference which is body habitus based was also used to screen for severe malnutrition in the 6 months to 5 years age group. Using this tool, only 1 child was found to have severe malnutrition requiring rehabilitation.

5.4 Strengths and Limitations

The strengths of this study are that it is the first study that has determined the nutritional status of the paediatric surgical population at the UTH. It also paves the way for development of nutrition risk screening tools and interventional studies in this population. It also builds up on previous studies that have helped to establish a clinically useful weight estimating tool.

Another strength is that this study compared 15 different formulae unlike studies comparing selective formulae. The study site, UTH, is the national tertiary referral hospital for paediatric surgery and has an eclectic patient population from all over Zambia and therefore is representative of the national picture.

A limitation was that the data on the paternal level of education was not collected as only one caregiver was allowed to accompany the patients into the theatre suite. Availability of this information would have helped further determine the socioeconomic position of the household.

Incorrect reporting of a child's age is a potential limitation, which would affect the assessment of age-based formulas but not the Broselow tape. This provides one reason to consider use of the Broselow tape over age-based formulas.

Another limitation was the unavailability of information on confounding factors such as parental stature, household income bracket, gestational age at birth, birth weight, preexisting chronic illness and any special health care needs of the child that might have had an impact on a child’s growth pattern.

CHAPTER SIX: CONCLUSION AND RECOMMENDATIONS

6.1 Conclusion

The Lusaka formula [weight (kg) = 2n+7 (where n is age in years) and weight (kg) = (month age)*0.5, where n is month age for children below 1 year] is superior to previously published weight estimating formulae in children presenting for surgery at the University Teaching Hospital (UTH) in Lusaka, Zambia. Its accuracy and precision is comparable to the Old APLS formula and the Broselow tape. It can be used with clinical confidence where actual weight is unknown.

6.2 Recommendations

The following are the recommendations to the various stakeholders:

i. To the UTH departments of anaesthesia & surgery (paediatrics): The Lusaka formula must be adopted for standardised estimation of weights in children undergoing surgery.

ii. To the UTH management and Ministry of Health: The Lusaka formula must be explored for use in other clinical areas and other district and rural hospitals where weighing scales are unavailable.

iii. To the UTH, Ministry of Health and Directorate of Research and Graduate studies: A follow up study to be undertaken in other paediatric patient groups and a patient pathway algorithm to nutritionist to be formulated for undernourished children.

iv. To the UTH department of anaesthesia & UNZA Directorate of Research and Graduate studies: A large study specifically powered to look at perioperative complications and outcomes in undernourished children presenting for surgery at UTH is needed to improve quality of care.

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APPENDICES

APPENDIX A: DATA COLLECTION SHEET

VALIDATION OF A LOCAL WEIGHT ESTIMATION FORMULA IN CHILDREN UNDERGOING SURGERY AT THE UNIVERSITY TEACHING HOSPITAL (UTH), LUSAKA, ZAMBIA.

PATIENT PARTICULARS:

DATE OF OPERATION..

NAME OF OPERATION...

AGE (Years)............................... **(Months**).........................

GENDER...

ETHNICITY...

WEIGHT (kg)..

LENGTH (cm)..

MUAC (cm)..

ID CODE...

A MOTHER'S LEVEL OF EDUCATION (TICK)

1. **PRIMARY**
2. **SECONDARY**
3. **TERTIARY**

B FATHER'S LEVEL OF EDUCATION (TICK)

1. **PRIMARY**
1. **SECONDARY**
2. **TERTIARY**

APPENDIX B: PATIENT INFORMATION SHEET

VALIDATION OF A LOCAL WEIGHT ESTIMATION FORMULA IN CHILDREN UNDERGOING SURGERY AT THE UNIVERSITY TEACHING HOSPITAL (UTH), LUSAKA, ZAMBIA.

Introduction

I, Hope Phiri, a student of Master of Medicine (MMED) in Anaesthesia and Critical Care in the School of Medicine at the University of Zambia, hereby request your child's participation in the above mentioned study. This study is in partial fulfilment for the award of a Master of Medicine in Anaesthesia and Critical Care.

Request is hereby made that you carefully read this document and ask me whatever you are not clear on. Kindly understand the purpose of the study and what is expected of you. Be informed also that participation in this study is absolutely voluntary. If you agree that your child can be enrolled in this study, you will be asked to sign the consent form in the presence of a witness.

The aim of the study

The main objective of the study is to see whether a new locally derived formula for estimating weights of children based on their age works better than existing formulae derived from children in other parts of the world when compared with their measured weights in children presenting for surgery at the University Teaching Hospital.

Procedure of the study

Only if you agree to participate in the study, shall I obtain the following information from you; child's age, gender, ethnicity, and surgical procedure to be performed. I will then weigh the child on a measuring scale, measure the height/length and score the child's fitness.

I will enter this information on a pro forma and assign a code for data entry purposes but will not record the name of your child

Possible risks and discomforts

No possible discomforts and risks have been identified.

Benefits

You will benefit by knowing your child's weight and height and your child will have a thorough preoperative assessment before undergoing their surgery. Your child will be an ambassador in helping formulate a local weight estimation formula.

Confidentiality

All the information will be kept confidential. Data collected and analysed will not bear your child's name and cannot be traced to her/him.

Consent

Your child's participation is absolutely voluntary therefore you are free to withdraw him/her at any time for whatever reason without affecting the standard treatment and care provided by the hospital.

I am humbled by your consideration of your child's participation in this study. If you have any concerns or clarifications, please contact Dr. Hope Phiri or the Research Ethics Committee on the following addresses:

Dr. Hope Phiri

University Teaching Hospital

Department of Anaesthesia and Critical Care

Private Bag RX1,

Lusaka

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APPENDIX C: CONSENT FORM

I, ______________________________________ hereby confirm that the nature of this clinical study has been sufficiently explained to me. I am aware that my child's details will be kept confidential and I understand that I may voluntarily, at any point, withdraw his/her participation without suffering any consequences. I have been given sufficient time to ask questions and seek clarifications, and of my own free will consent to participation in this research.

I have received a signed copy of this agreement

______________________ ______________________ ______________

Name of Participant (Print) Participant (Signature/thumbprint) Date

_____________________ ______________________ ______________

Witness (Print Name) Witness (Signature) Date

VERBAL CONSENT COMPLETION

I have fully explained the research study described by this form. I have answered the participant and/or parent/guardians questions and will answer any future questions to the best of my ability. I will tell the guardians and/or the participant in this research of any changes in the procedures or in the possible harms/possible benefits of the study that may affect their health or their willingness to stay in the study.

____________________________ ________________________

Name of Research Assistant Signature of Research Assistant