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Umbilical Cord Blood Hematological Parameters Reference Interval for Newborns in Ambo University Referral Hospital, Ambo, Ethiopia.

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This is to certify that the thesis prepared by **Barecha Soboka**, entitled:“ **Umbilical Cord Blood Hematological Parameters Reference Intervals for Newborns in Ambo University Referral Hospital Ambo, Ethiopia** and also submitted to partial fulfillment of the requirements for Master of Science degree in Clinical Laboratory Sciences (Hematology and Immunohematology) complies with the regulations of the University and meets the accepted standards with respect to originality and quality.

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Contents

List of table

Abbreviations

AAU ……..Addis Ababa University

AURH ……...Ambo University Referral Hospital

CBC ……Complete blood count

CBNC ……Community-based newborn care

CI …… Confidence Interval

CS……...Cesarean section

EDTA……..Ethylene diamine tetra acetic acid

HCT ……..Hematocrit

HGB ……..Hemoglobin

LYM……. Lymphocyte

MCH…….Mean cell Hemoglobin

MCHC…….. Mean cell Hemoglobin Concentration

MCV…….Mean Cell Volume

MPV……. Mean Platelet Volume

MXD……Mixed population of Monocytes Eosinophil and Basophils

NEU……..Neutrophils

PDW……..Platelet Distribution Width

PLT……Platelet

RBC……....Red Blood Cell

RI …….Reference interval

SOPs……. Standard Operating Procedures

SPSS…….Statistical Package for Social Sciences

SVD…….....Spontaneous Vaginal Delivery

UCB…….Umbilical Cord Blood

WBC…….....White Blood Cell

WHO …….. World Health Organization

Abstract

Background: Hematology RIs in newborns are a good informative for the evaluation of newborn's health condition. The values may possibly indicate difference within some factors such as Birth weight, Sex, and other factors. However, Published information/data on Reference Intervals of hematological parameter of newborns from UBC for Ambo and the surroundings of AURH is lacking.

Objective: To determine RIs for umbilical cord blood hematological parameters of newborns In Ambo, Ethiopia.

Methods: A cross-sectional study was conducted from April 1 to June 30, 2024GC on Newborns with normal birth weight (2.5-4Kg) by using convenient non-probability sampling technique in Ambo town. About 2-3ml UBC was collected according to standard operating procedure from cord by using EDTA tube. Sample analysis was performed by using Sysmex XN-550. Finally, the data was entered and then data analysis was performed by using the SPSS version 25. Reference Intervals of 2.5th and 97.5th was established by using non parametric method.

Result: 200 umbilical cord samples were collected from newborns and out of these 57% were female. Mean ± SD WBC (14.4±5.08), RBC (4.13±0.49), HGB (15.9±2.88), HCT (47.2±8.28), MCV (127.2±9.97), MCH (35.1±1.97), MCHC (40.5±4.17), RDW-CV (14.4±3.60), PLT(207.1±55.29), LYM(37.2±6.96), NEU%(58.3±9.04), MPV (11.2±8.60), PDW-CV (13.6±2.57). RBC counts are similar between sexes, with males at a median of 4.2 and females at 4.18. From our Results of Complete blood count (CBC), HGB and HCT, show no significant. Platelet counts are consistent across genders (P=0.057) whereas WBC indicate no significant sex-related differences.

Conclusion and Recommendation: This study highlights the needs for region-specific hematological RIs for umbilical cord blood within newborns from Ambo, due to significant differences from other populations. Broader studies are recommended to improve clinical assessments and public health strategies tailored to local contexts.

Keywords: Complete Blood Count, neonates, hematological RIs, Umbilical cord blood

1. Introduction

1.1. Background

Hematological profile is a common Blood test which analyzes a sample for various fundamental blood cell measures and provides a count of each type of blood cell in the sample. Hematological parameters of Newborn mostly represented as area of study focusing in study of umbilical cord blood. Establishment of Hematological parameters specially Uses as a baseline data to facilitate screening and detection if there is disorders present at the time of birth. Hematological parameters in Umbilical cord blood of New born may influenced by Gender, Race, nutritional status and time of umbilical cord blood collection(1).

In the recent years, there have been many studies in the cord blood parameters and their applicability to assess the health status of the newborn. Several works had been done in the developed countries on the cord blood stem cells and their applications for curing certain disorders and for research purpose. The cellular components of Umbilical cord blood include stem cells which includes; Mesenchyme stem cells, Hematopoietic stem cells and Multipotent non-hematopoietic stem cells and mature cells of hematopoietic stem cells namely RBC, WBC and platelets(2).

Analyzing the CBC of umbilical cord blood and comparing with the biological reference interval is essential for clinical interventions and further investigations. Neonates exhibit profound quantitative as well as qualitative hematologic differences compared to older children and adults (3). At birth, hematological parameters of New-borns are significantly higher than those of older children and adults (4). Thus, it is inappropriate to use adult reference ranges for the assessment of pediatrics blood (5). There is a need for precise and dependable hematological parameter Reference Intervals due to the difficulties and physiological changes that are seen in pregnant women (6) that can affect the baby.

According to World Health Organization, hematology profile is the main indicator of General health status of an individual (7). On the other hand , applying a reference interval obtained from somewhere else to a population of interest could potentially proceed to wrong patient management and wastage of resources(8). Umbilical Cord blood hematological parameters reference intervals are vital in Newborns care and also in transplantation medicine (9).

Many influences play a vital roles in stable Status of UBC indices, Such as Pregnancy condition, nutritional status and other antenatal complications like iron deficiency anemia, and growth retardations (10). Umbilical Cord blood is a blood collected from placenta, which connects mother and fetus for purposes of nutritional and other substance's exchange (11). Complete blood count (CBC) provides several important information and supports diagnoses. When used in conjunction with a careful review of the peripheral smear and a limited number of other tests, the CBC is more effective diagnostic tool (12).

It is well recognized that hematological profiles can be used to interpret a person's status by contrasting the blood data of the individual and facilitate the interpretation of numerical clinical pathology with reference data (13). Maternal status factors like smoking habit (14), Habit of drinking alcohol too much content of alcohol (15), Medical problems and complications like Hypertension, Diabetic mellitus and others.(16) and Also Mode of delivery and frequency of pregnancy affects the hematological profile of Newborns (17). Hematocrit levels of Umbilical Cord blood are affected by the time of umbilical cord blood clamping, delay of cord blood clamp leading to increases hematocrit levels (18). Generally, delay cord blood clamping and umbilical cord blood milking also affects the values of hematological parameters (19).

Hematological parameters reflect the health status of an individual, hence Umbilical cord blood, the health status of newborn. Knowledge of normal hematological profile of newborns is very important for proper interpretation of test results and understanding of the dynamic changes occurring during that period. In the neonatal period, the CBC correlates highly with gestational age, birth weight, blood sampling site, therapy, mode of delivery and other factors (3). Hematopoietic regulation in the human fetus differs markedly from that in adult. In adult, homeostatic maintenance is a prime function of hematopoietic regulation, whereas in the embryo and fetus, constant changes characterize all phases of hematopoiesis (20).

Umbilical cord blood (UCB) is a source of hematopoietic stem cells and the lifeline between the fetus and placenta. UCB is also an acceptable sample to assess neonatal sepsis. It is formed by the fifth week of development and it functions throughout pregnancy to protect the vessels that travel between the fetus and the placenta (11). The cord blood is composed of all the elements found in whole blood ,It contains red blood cells, white blood cells, plasma, platelets and is also rich in hematopoietic stem cells, which have immense potential to cure malignant and genetic disorders(21).

Umbilical cord blood count at birth show that there is an increased in hemoglobin, hematocrit, mean corpuscular volume (MCV), leukocyte count, reticulocytes count and nucleated red blood cells with presence of occasional immature white blood cells or left-shifted in peripheral blood of healthy infants, with variable degree of count in immature sick newborns (22). Compromise of the fetal blood flow through the umbilical cord vessels can have serious deleterious effects on the health of the fetus and newborn. The umbilical cord protects the fetal vessels that connect the placenta and fetus (23).

1.2. Statement of the Problem

There are few published reference interval for hematological parameters in cord blood of Ethiopians (24, 25). In 2013, the Ethiopian government launched community-based newborn care (CBNC), through which community health workers are trained, supplied with essential commodities, and supported to provide care for newborns that have infections(24). For this reason, the aim of this study is to provide information/data on Reference Intervals of hematological parameter of newborns from Umbilical cord blood In AURH. So that as the hematological parameters vary according to gestational age, gender difference and to certain geographical factors, it is essential that biological reference interval should be established before undergoing studies on health related conditions and interventions (22).

Nowadays, very little is known about hematological parameters of UCB in Ethiopia and there is a gap to describe the real representative reference intervals for Ethiopians. Moreover, information about the relationship of hematological parameters with Gestational age, Mode of delivery, maternal health, Nutritional status, Birth weight, socioeconomic status, and lifestyle is scanty. Furthermore, to establish local reference values for hematological parameters from Umbilical cord blood and uses as baseline information for other similar researches, Because of all clinical and related health related issues uses Reference intervals. Reference hematological values in newborns are informative in evaluation of newborns to determine state of health or disease. The hematological profile of an individual to a large extent reflects his or her general health condition(25).

A reference interval plays an important role in guiding the assessment of Hematological changes in newborn's result if it is determined by considering different influencing factors. Despite these, there are a few published reference intervals for hematological parameters in Umbilical Cord Blood of Ethiopians, Specifically in western part a gap which this study tries to address. Using a random reference interval which represents other populations could cause a wrong management and judgments to other population of interest, and also wastage of resources (8). In addition, there is a great deal of heterogeneity in previous studies founding and their application in clinical practice is limited.

1.3. Significance of the study

The establishment of Reference interval is useful to guide Neonatologists, Pediatricians, Hematologists, all those who manage neonates and also for future analysis in health and health related interventions. Moreover this study will show whether there are variations on results from Ethiopia. On the other hand several sources of information will be revealed by the study of Umbilical cord blood hematological parameters reference interval for newborns from Ambo and its surroundings in AURH. The results of this study will help in support the information available so far and will serve as base line data for future health related interventions and researchers in the area.

2. Literatures review

The literature which is relevant to Reference Intervals for umbilical cord blood hematological parameters of newborns were gathered and discussed, by searching different literature from different sources Google scholar, Pub Med, and other sites. A wealth of published studies demonstrated the age related changes in hematological parameters. Newborn's hematological parameters are different from those of infants or adults including differences according to the blood samples utilized (umbilical cord blood, venous blood, and capillary blood) as well as drawing time and nutritional fetal conditions (26).

The study done in Iraq shows that statistically significant difference in RDW, WBC count, neutrophil count and platelet count and difference in neutrophils percentage alone. However, the study shows lower neutrophil percentage in males when compared to females. This may be due to dilution of cell components when blood is collected in UCB bags in their study (27).

The study undertaken to establish reference range for Nepal neonates also showed there were no significant differences in the value of HGB(15.16 ± 1.95 and 15.31 ± 1.96g/dL), RBC (4.28 ± 0.64 and 4.30 ± 0.62x1012/L), WBC (14.68 ± 4.29 and 14.99 ±4.59 x109 /L) and PLT (229.38 ± 59.56 and 224.6 ± 62.98 x109 /L) for Male and Female respectively.. The study enrolled 210 full term healthy neonates from Jan 2014 to Feb 2015 and analyzed on automated hematology analyzer. They finalized the study by successfully establishing the required reference range; however, they indicated it was not adequate and should be recommended for confirming the result with more diverse population samples (28).

Indian study from Chandigarh found higher values for Hemoglobin and lymphocyte percentage. However, the study was done manually (34). When compared with Indian text book reference range at birth, the Hemoglobin value and RBC counts are lower than western text book reference range (35). Another relatively recent descriptive study was conducted on 316 full term normal neonates from rural Sindh, Pakistan analyzed by Sysmex KX-21 and found nearly HGB of (15.4±1.9g/dL) and WBC (13.7±4.0x109 /L), while the PLT is (285±62x109 /L) (29).

Other Study from Nigeria shows that there is no statistically significance difference of all hematological parameters between male and female newborns, which is consistent with a study reported in Sokoto, Northern Nigeria and Lagos, Nigeria. Mode of delivery have no influence of

hematological parameters of the newborns which agrees to a study done by Fady M, et al. reported that there was no significant difference in the MCV, MCH, MCHC, RDW, lymphocytes, and monocytes(30).

Other study from our continent also done on Cord Blood Hematological Profile of Sudanese Neonates at Birth in Khartoum concludes that hemoglobin and red cell indices mean values of healthy Sudanese cord blood at birth with normal reference ranges, but slightly lower than other studies because of ethnological and life style differences. Hemoglobin levels of healthy Sudanese cord blood at birth 14.35±1.55gm/dl, mean hematocrit level is 0.44.1 L/L±5.14, MCV, MCH, and MCHC counts 105.5fl ±5.14, 33.5pg±1.99 and 33.1gm/dl ±1.19, respectively. Fetal Hemoglobin, nRBCs, leukocyte, and platelet counts as described in other population and compatible with normal cord blood reference values (31).

The reference range for neonates in Greece was established using umbilical cord blood (UCB) samples collected from 2000 infants and analyzed with a multi-parameter Beckman Coulter hematology analyzer between June 2008 and January 2009. Consistent with previous research, this study found no significant differences in results between male and female neonates. However, some variations were observed in the values for white blood cells (WBC), red cell distribution width (RDW), and platelet count (PLT), with WBC values being 7.1±3.4 x10^9/L for males and 7.4±3.4 x10^9/L for females, RDW values at 12.3±1.7 for males and 12.0±1.6 for females, and PLT values of 157±58 x10^9/L for males and 164±60 x10^9/L for females. The study utilized the reference values provided by the manufacturer of the Beckman Coulter analyzer and compared them with European reference values. Although no other studies were found to support their findings, the authors recommended the adoption of these reference values for hematological assessments, hematopoietic stem cell therapy, and future research(32).

From January 1 to April 30, 2013, a cross-sectional study was performed on 2,163 healthy newborns in Jeddah, Saudi Arabia, to determine the reference range for hematological parameters based on cord blood. The findings indicated no significant differences between male and female infants, with the exception of total white blood cell (WBC) counts, which were recorded at 16.2 ± 5.3 × 10^9/L for males and 17.2 ± 12 × 10^9/L for females ($p = 0.017$), and monocyte levels, which were 1.2 ± 0.2 × 10^9/L for males and 1.3 ± 0.4 × 10^9/L for females ($p = 0.037$)(33).

Ethiopian study from Gondar University Hospital in 2019 also performed another analysis of Hematological parameters among 151 newborns. According to this study all hematological parameter can't show significant difference between Females and Males. Delivery modes also not affect its hematological parameter values. The RIs of WBCs, RBCs, platelets, HGB, HCT, MCV, MCH were (7.64–22.16) x109 /l, (3.69–5.47)x1012/l, (132.74–413.4) x109 /l, (13.32–19.64) g/dl & (39.42–58.06)%, (91.6-113.22fl), and (30.48–38.02pg) Respectively (25).

Recently, from Addis Ababa at St Peter specialized hospital a cross-sectional study tries to find the values of Reference intervals of 139 Newborns by using Umbilical cord blood. According to this study all hematological parameter can't show significant difference by gestational ages(24). Earlier studies in Ethiopia have indicated absence of significant difference in cord blood lymphocytes and their subsets between Ethiopians and the western population (34). Considering the limited published data we have, this study determined comprehensive analysis of the CBC data from cord blood to determine hematological RIs to be used in the study area.

3. Objectives

3.1. General Objective

- To determine Reference Intervals of hematological parameter in umbilical cords of at Ambo University referral Hospital, Ambo Ethiopia from April to June, 2024.

3.2. Specific objectives

- To determine the association of hematological parameter with gender and birth weight.

- To compare result's findings from the study with the normal reference interval of hematological values standardized globally and also with others study.

4. Methods and materials

4.1. Study area

This study was conducted in Ambo University Referral Hospital (AURH) from April 1 – June 30, 2024. AURH is found in Ambo Town. Ambo University Referral Hospital was established in 2006 and found in Ambo town where is 114 km far from Addis Ababa (capital city of Ethiopia). The hospital is selected since it serves as a referral hospital for a catchment area of more than 2.5 million people and as teaching hospital. The hospital also provides internal medicine, pediatrics, family planning, maternity, gynecologic/obstetric, surgery, emergency, ambulatory clinic TB , also HIV services to the people of western Ethiopia.

4.2. Study design and Study period

A cross sectional study was conducted to establish the Reference Intervals for umbilical cord blood hematological parameters of newborns from Ambo and its surroundings, attending at Ambo University Referral Hospital from April 1- June 30/2024, for three months.

4.3.1. Source population

- Newborns delivered in Ambo University Referral Hospital, Ambo and the surrounds.

4.3.2. Study population

- Apparently healthy newborn delivered from healthy volunteering mothers and fulfills the eligible criteria to take part of the study in Ambo University Referral Hospital, Ambo and the surrounding areas during the study period were the study population.

4.4. Inclusion and exclusion criteria

4.4.1. Inclusion criteria

- Newborn from apparently healthy pregnant mother.
- Newborns with normal birth weight (2.5-4 Kg).

4.4.2. Exclusion criteria

- Mothers unable to provide data.
- If appearance of umbilical cord is abnormal in consider of length and knot.

4.5. Sampling technique

❖ Non probability convenience sampling method was used for the study.

4.6. Sample collection and Laboratory investigation

Cord blood (2-3ml) was collected immediately from the cord using EDTA tube. Immediately at the time of umbilical cord clamp and then cut by Obstetrician, UBC was labeled EDTA vaccutainer tube. Then sample was transported to laboratory immediately and processed within 3 hours of collection. Finally the samples analysis was done in Ambo university referral hospital using Sysmex XN-550 automated CBC analyzer.

4.7. Data collection procedure

After giving clear orientation and explanation, on the aim of the study and obtaining well-versed agreement, data on the socio-demographic and past medical history of the study participant including history of hypertension, diabetes mellitus, and history of medication was collected from interview and medical records by senior Nurse using validated structured questionnaire and checklist prepared by the principal investigator. The questionnaire was developed in English and then it was translated to our local languages of Afan Oromo. Generally all the professionals who were participated in the data collection were oriented about the aim of the study, from starting the selection of sample to analysis and storing.

4.8. Variables

4.8.1. Dependent variable

- Hematological parameters

4.8.2. Independent variable

- Mode of delivery
- Life style

4.9. Quality Assurance

To assure quality of research it is important to maintain quality of data used as input. Before the data collection, orientation was given on the objective of the study, approaching to interview, reviewing medical history and recording of data. Questionnaire which have been validated by reviewing literature and translated into local language (Amharic and Afan Oromo) was used. To check accuracy and consistency of the translated questionnaire it was re-translated to English. Any unclear point regarding the questioner and data collection procedure was clarified before collecting data. The principal investigator supervised the data collector and also participated in the data collection process. Concerning laboratory analysis all pre analytical, analytical and post analytical phases' quality were ensured by working according to Standard Operating Procedure.

The collection of Umbilical Cord Blood is safe for the clients and technically easy as compared to other blood collection sites. The quality of laboratory test results is affected by pre analytic variables such as specimen collection, specimen handling, sample size and analytic interference. Although these factors are important for samples from patients of any age, they are particularly important in the neonatal period.

4.9.1 Pre analytical

In this phase data collector strictly followed standard operating procedures (SOPs to collect the blood sample in properly labeled EDTA and in plane tube. The sample was evaluated for proper labeling, presence of clot, volume and so on.

Cord blood was collected by experienced midwives or nurses following the guideline for cord blood sample collection. In addition, orientation was given on proper collection and handling of

Cord Blood. Immediately after birth, about 2- 3 ml of umbilical cord blood was collected from the umbilical vein and put into an (EDTA) anticoagulant tube. Based on sample rejection and acceptance criteria of the hospital laboratory, any sample that did not meet the acceptance criteria was rejected and also which meets the criteria was accepted.

4.9.2. Analytical

Three level hematology quality controls were run to ensure the accuracy of sample result. All specimens were analyzed within 8 hours of collection. Sample was analyzed according to SOP after the quality control result is passed. Complete blood count was performed by using Sysmex XN-550 automated CBC analyzer strictly adhering to company instructions. The following parameters like hemoglobin (Hgb) levels, hematocrit (Hct) concentration, (RBCs) count, mean cell volume (MCV), mean cell hemoglobin (MCH), mean cell hemoglobin concentration (MCHC), red cell distribution width (RDW), while blood cell (WBC) count and differentials, and platelet count and derived parameters were determined.

4.9.3. Post analytical

In this phase result was reviewed by comparing with reference interval. Data was entered using double entry method into SPSS software.

4.10 Data analysis and interpretation

After checking completeness of the data, it was entered and analyzed using software (SPSS version 25) for the complete and accurate data analysis.

4.11. Ethical consideration

The study was conducted after obtaining ethical clearance from the Department Research and Ethics Review Committee, Department of Medical Laboratory Sciences, College of Health Science, Addis Ababa University and getting permission from Ambo university referral hospital. Written informed consent was obtained from all participants. All clinical data and laboratory findings were kept confidential and used for the sole purpose of the study.

4.12. Operational definition

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- **Hematological parameters**: includes quantified values of CBC generated by Sysmex XN-550 like WBC, RBC, PLT, HGB, HCT, MCV, MCH, MCHC, RDW, NEU, LYM, MXD, PDW, MPV, PCT, MONO, EO and BASO.
- **Cord blood**: is a blood collected from long and helical cord that connects the fetus with the mother for nutritional and other substances exchange.
- **Newborn**: is a child under 28 days of age.

5. Result

5.1. Sociodemographic Characteristics

The study used cord blood samples of 200 newborns from healthy mothers aged 18 to 45 years. In terms of education, a significant portion of respondents has completed primary education (41%), followed by those who can read and write (32%), while only 18% have reached high school and a mere 3.5% have attended college. When examining occupation, the highest percentage is in private work (47.5%), with employed individuals at 24%. Additionally, the population is predominantly urban (54%). Lastly, the marital status data reveals that 97% of individuals are married. The findings are summarized in Table 1.

Table 1 Socio Demographic Characteristics of Study participants at AURH, Oromia Region, Ethiopia from April to June, 2024.

Category	Magnitude	Percentiles (%)
18-30	148	74
31-45	52	26
Unable to read and write	11	5.5
Reading and Writing	64	32.0
Elementary	82	41.0
High school	36	18.0
College and above	7	3.5
Student	14	7.0
Employed	48	24.0
Jobless	9	4.5
Private work	95	47.5
Housewife	34	17.0
NSD	193	91.5
IVD	17	8.5
between 1 and 2 years	76	38.0
between 2 and 5 years	50	25.0
None	74	37.0
Male	86	43.0
Female	114	57.0
Urban	108	54.0
Rural	92	46.0
Married	194	97.0
Divorced	3	1.5
No	175	87.5

- NSD= Normal spontaneous vaginal delivery; IVD= Instrumental vaginal delivery
- None= first pregnancy

5.2. Hematological parameters

In terms of Hemoglobin (HGB) and Hematocrit (HCT), females display slightly elevated median values compared to males; however, the P-values of 0.231 and 0.578 suggest no statistically significant differences.

The RDW parameters, RDW-CV and RDW-SD, show minimal variation between males and females, suggesting consistent red blood cell distribution within the population.

The parameters of Red Blood Cell (RBC) count, Hemoglobin (HGB), Hematocrit (HCT), Mean Corpuscular Volume (MCV), Mean Corpuscular Hemoglobin (MCH), Mean Corpuscular Hemoglobin Concentration (MCHC), and Red Cell Distribution Width (RDW) are summarized in table 2.

Table 2. Mean, Median, 95 %(2.5th-97.5th) Reference Intervals of neonates in Ambo University Referral Hospital, Ambo, Ethiopia from April 1 to June 30, 2024

Parameters	Sex		Median	2.5^{th}	97.5^{th}	P-value
RBC ($x10^{12}$/L)	M	86	4.20	3.19	4.80	0.055
	F	114	4.18	3.31	5.63	
HGB (gm/dL)	M	86	15.4	11.50	20.96	0.231
	F	114	15.8	12.18	25.23	
HCT (%)	M	86	45.9	33.60	62.14	0.578
	F	114	48.3	32.78	70.37	
MCV (fL)	M	86	109.3	92.27	122.7	0.120
	F	114	108.2	91.37	132.4	
MCH (pg)	M	86	34.7	34.25	41.95	0.202
	F	114	35.2	34.86	44.45	
MCHC (gm/dL)	M	86	34.1	33.20	43.29	0.386
	F	114	34.0	34.36	42.41	
RDW-CV	M	86	16.0	0.08	0.308	0.219
	F	114	15.2	0.08	0.205	
RDW-SD	M	86	40	38.81	47.22	0.291
	F	114	40.2	47.22	45.80	

M= Male , F= Female

Table 3 shows RI of Platelet Count (PLT), Mean Platelet Volume (MPV), Platelet Distribution Width - Coefficient of Variation (PDW-CV), and Platelet (PCT). The median PLT for males is 235 $x10^9$/L, while for females it is slightly higher at 243 $x10^9$/L, with a combined median of 240 $x10^9$/L. The P-value of 0.807 indicates no statistically significant difference between sexes, suggesting that platelet counts are relatively stable across this population.

In terms of MPV, males present a median of 10.5 fL, which is greater than the female median of 9.75 fL. The P-value for MPV is 0.057 fL, potentially significant difference that approaches conventional thresholds. The PDW-CV shows no significant differences with a P-value of 0.342. PCT values are similar, with males having a median of 1.75% and females 1.72% leading to a P-value of 0.090.

Table 3: Mean, Median, 95%(2.5th-97.5th) Reference Intervals of PLT Parameters Stratified by sex of neonates in Ambo University Referral Hospital, Ambo, Ethiopia from April 1 to June 30, 2024

Parameters	Sex		Median	2.5th	97.5th	P-value
PLT ($x10^9$/L)	M	86	235	93.05	378.65	0.807
	F	114	243	82.40	336.75	
	COM	200	240	92.00	298.97	
MPV (fL)	M	86	10.5	8.90	12.84	0.057
	F	114	9.75	8.65	13.47	
	COM	200	9.82	8.70	12.89	
PDW-CV	M	86	12.36	9.80	17.76	0.342
	F	114	11.5	10.20	18.43	
	COM	200	12.72	9.90	18.20	
PCT (%)	M	86	1.75	0.134	3.108	0.090
	F	114	1.72	0.238	3.409	
	COM	200	1.74	0.162	3.210	

Table 4 evaluates White Blood Cell Count, Neutrophils, Lymphocytes, Monocytes, Eosinophil, Basophils, and their respective percentages in a population categorized by sex. The median WBC count for males is 11.6 $x10^9$/L, while for females it is 11.2, $x10^9$/L with a combined median of 12.4 $x10^9$/L. The P-value of 0.787 indicates no significant difference between sexes, suggesting that overall white blood cell levels are similar across this population.

Neutrophil counts in males show a median of 9.44 $x10^9$/L compared to 9.17 $x10^9$/L in females, with a P-value of 0.443, indicating no significant differences. Similarly, the lymphocyte counts are comparable, with males at 4.35 $x10^9$/L and females at 4.29 $x10^9$/L, and a P-value of 0.125, further reinforcing the lack of significant sex-related differences in these parameters. However, the monocyte count presents a P-value of 0.057, suggesting a potential difference that approaches significance, with males showing a median of 2.01 $x10^9$/L compared to 2.00 $x10^9$/L in females. This trend may indicate variations in immune response or inflammation between sexes, meriting further investigation.

Notably, eosinophil exhibits a significant difference, with males having a median of 0.17 $x10^9$/L and females 0.11 $x10^9$/L, and a P-value of 0.045. This suggests that male individuals may have higher eosinophil counts, which could be reflective of differences in allergic responses or parasitic infections. Basophil counts reveal a significant difference with a P-value of 0.009, where males show a median of 0.01 $x10^9$/L and females 0.02 $x10^9$/L. The percentages of neutrophils (NEU%) and lymphocytes (LYM%) also show no significant differences. Other parameters, such as Monocyte percentage (MON%), Eosinophil percentage (EOS%), and Basophil percentage (BASO%), also did not show significant differences, indicating that the distribution of these leukocytes does not vary significantly by sex.

Table 4 Median, 95%(2.5th-97.5th) Reference Intervals of stratified by sex of neonates in Ambo University Referral Hospital, Ambo, Ethiopia from April 1 to June 30, 2024.

Parameters	Sex		Median	2.5th	97.5th	P-value
(x109/L)	M	86	11.6	8.18	23.53	0.787
	F	114	11.2	8.21	23.62	
	COM	200	12.4	8.22	26.09	
NEUT ($x10^9$/L)	M	86	9.44	3.96	17.11	0.443
	F	114	9.17	3.55	16.55	
	COM	200	9.28	3.83	16.64	
LYM ($x10^9$/L)	M	86	4.35	1.73	8.28	0.125
	F	114	4.29	2.04	8.06	
	COM	200	4.32	1.98	8.12	
MONO ($x10^9$/L)	M	86	2.01	0.51	4.40	0.057
	F	114	2.00	0.49	4.62	
	COM	200	2.00	0.50	4.44	
EOS ($x10^9$/L)	M	86	0.17	0.01	1.18	0.045
	F	114	0.11	0.01	0.75	
	COM	200	0.15	0.01	1.00	
BASO ($x10^9$/L)	M	86	0.01	0.01	0.01	0.009
	F	114	0.02	0.01	0.01	
	COM	200	0.02	0.01	0.01	
NEU%	M	86	54.7	41.66	79.72	0.219
	F	114	53.5	36.40	80.47	
	COM	200	54.0	41.19	79.99	
LYM%	M	86	36.6	12.26	40.10	0.231
	F	114	38.2	11.52	42.6	
	COM	200	37.5	12.03	40.10	
MON%	M	86	6.50	5.37	10.27	0.821
	F	114	7.04	3.71	9.24	
	COM	200	7.25	4.12	9.25	
EOS%	M	86	1.35	0.05	4.32	0.670
	F	114	1.28	0.01	4.02	
	COM	200	1.38	0.01	4.32	
BASO%	M	86	0.01	0.00	0.64	0.288
	F	114	0.02	0.00	0.84	
	COM	200	0.02	0.00	0.91	

Table 5 displays the current RIs with other studies, As shown in the Table inconsistencies are noted across the populations.

Table 5 Mean±SD or Median Comparison with Other studies

Parameters	**Our Study**		**Ethiopia (Addis Ababa) (24)**		Sudan (31)	Nigeria (30)	South India (34)	**Greece (32)**
	Mean±SD	**Median**	**Mean±SD**	**Median**	Mean±SD	Mean±SD	Mean±SD	**Mean±SD**
WBC(x10^9/L)	**14.4±5.08**	**12.4**	**12.4±3.38**	**12.6**	12.3±4.17	13.1±5.2	15.9±5.1	7.2±3.4
RBC(x10^9/L)	**4.13±0.49**	**4.18**	**4.51±4.49**	**4.5**	4.34±0.6	4.05±0.55	4.10±0.40	2.46±0.82
HGB(g/dL)	**15.9±2.88**	**15.8**	**15.8±1.64**	**15.8**	14.4±1.55	13.9±1.5	14.9±1.7	8.8±2.9
HCT (%)	**47.2±8.28**	**47.3**	**46.1±4.62**	**45.9**	44.1±5.14	44.8±5.78	44.6±5.3	25.9±8.8
MCV (fL)	**127.2±9.97**	**127.9**	**101.2±5.97**	**102.1**	105.5±5.14	110.4±11.9	108.1±4.8	105±6
MCH (Pg)	**35.1±1.97**	**35.3**	**35.1±1.97**	**35.3**	33.5±1.99	32.6±4.13	36.0±1.7	35.8±3.1
MCHC (g/L)	**40.5±4.17**	**34.6**	**34.5±1.17**	**34.3**	33.1±1.19	29.8±1.64	33.3±0.8	34.3±7.3
RDW-CV(%)	**14.4±3.60**	**15.8**	**15.4±1.6**	**15.6**	NA	19.8±4.26	NA	12.1±1.6
PLT(x10^9/L)	**207.1±55.29**	**240**	**245.5±69.78**	**236**	261±83.16	225.1±72.2	215±67	160±59
LYM%	**37.2±6.96**	**38.2**	**38.2±10.96**	**37.5**	NA	**NA**	35.9±12.2	36.7±1.29
NEU%	**58.3±9.04**	**54.0**	**53.9±10.84**	**53.7**	**NA**	**NA**	50.3±12.2	46.9±1.8
MPV (fL)	**11.2±8.60**	**9.82**	**9.5±0.9**	**9.4**	**NA**	**NA**	**NA**	8.0±0.7
PDW-CV (%)	**13.6±2.57**	**12.7**	**11.5±1.85**	**11.0**	**NA**	**NA**	**NA**	**NA**

NA stands for not available

6. Discussion

Umbilical Cord blood is a blood collected from long and helical cord that connects the fetus with the mother for substances exchange and also reference intervals of their hematological parameters are vital in neonatal care and transplantation medicine. The cord is formed by the fifth week of development and it functions throughout pregnancy to protect the vessels that travel between the fetus and the placenta (9, 11, 35).

According to the information we obtained from the Ambo town health bureau, all health facilities in the town use the reference range of the manufacturer. Neither the town nor Ambo University has developed their own reference range. There is no uniform Reference Interval as most types of CBC analyzers are available, such as Cell DYN, Mindray, Emerald, Human, Beckman Coulter, and Sysmex. However, since Sysmex XN-550 is used for the current study, the Reference Interval of CBC result was used for comparison. There is no established RI for umbilical cord Ambo town. Therefore, this study is expected to be very useful for hospitals and health facilities in the town and it is the first study to establish hematological Reference Interval for umbilical cord blood in Ambo town.

Many scholars have shown that Reference Intervals are influenced by a number of variables, including sex, **I**t is understood that established hematological reference interval is specific for the subgroup of the population whose measurements are greatly affected by Many Factors like; Age ,Sex Race Altitude, Physiological conditions of pregnancy, Condition of assay and variations in instrumentation. Accordingly, for the majority of the hematological parameters, attention must be paid to sex-specific Reference Intervals. That is why establishing appropriate and exact reference interval is demanding to give the right clinical decision for the observed or measured laboratory results.

This study was carried out in 200 newborns delivered at Ambo University Referral Hospital and also the main aim of this study is to establish the exact reference range of all hematological parameters locally. Generally the values of reference range of hematological parameter vary from continent to continent and also from county to country. Likewise reference ranges vary from country to other country, locally derived values of hematological parameters is representative for the population of that specific area.

Our study reports a white blood cell (WBC) count of 14.4 ± 5.08 $x10^9$/L, which is higher than Sudan (12.3 ± 4.17), Nigeria (13.1 ± 5.2) and in Addis Ababa, Ethiopia (12.4±3.38), yet slightly lower than those in Saudi Arabia (15.9 ± 5.1) and Greece (16.1). This suggests potential variations in immune response or health status across these populations.

Red blood cell count in our study is 4.13 ± 0.49 $x10^{12}$/L, comparable to Nigeria (4.05 ± 0.55) (30) and South India (4.10 ± 0.40) (34), but lower than Sudan (4.34 ± 0.6) (31) and Addis Ababa, Ethiopia (4.51±4.49) (24) and significantly lower than Saudi Arabia (5.6 ± 10.7)(33), which may reflect diverse health conditions affecting RBC levels. Hemoglobin levels in our study (15.9 ± 2.88 gm/dL) are notably higher than those in Nigeria (13.9 ± 1.5), Sudan (14.4 ± 1.55) and slightly higher than that of Ethiopia, Addis Ababa (15.8±1.64), indicating better oxygen-carrying capacity, though still lower than Saudi Arabia and Greece (both 17.7). The hematocrit (HCT) value of 47.2 ± 8.28% in our study exceeds those from Nigeria, Sudan and Ethiopia Addis Ababa, suggesting advantages in hydration or health. However, Saudi Arabia and Greece report higher HCT levels (53.2%), potentially influenced by environmental factors or altitude.

The mean corpuscular volume (MCV) in our study is strikingly elevated at 127.2 ± 9.97 FL, indicating possible macrocytic red cells, while other regions report lower values, which might reflect dietary differences or genetic factors affecting red blood cell production. Additionally, the mean corpuscular hemoglobin (MCH) in our study is 35.1 ± 1.97 pg, comparable to other regions, suggesting consistent hemoglobin content in red blood cells across populations. In terms of platelet count, our study shows a value of 207.1 ± 55.29 $x10^9$/L, lower than Sudan (261.0)and Addis Ababa, Ethiopia (245.5±69.78)(24) but comparable to Nigeria (30) and south Sudan (34)(both around 215.0). This variability may indicate differing levels of inflammation or nutritional status among the populations.

Clinically, these findings emphasize the importance of understanding hematological variations by sex, which can be crucial for diagnosing and managing blood-related disorders. The absence of significant differences in HGB and HCT suggests that clinicians may not need to adjust their assessments based solely on sex. Nonetheless, it is important to recognize the study's limitations, including sample size and sociodemographic factors, which may influence the generalizability of the results.

Future research should aim to address these limitations by exploring the impact of age, ethnicity, and comorbid conditions on these hematological parameters. Additionally, investigating the effects of lifestyle factors, such as diet and physical activity, could provide further insights into the determinants of these measurements. In conclusion, while some differences in hematological indices were observed, the overall lack of significant findings underscores the need for continued investigation in diverse populations to better understand the complexities of blood parameters in relation to sex.

Furthermore, the lymphocyte percentage (LYM %) in our study is 37.2 ± 6.96, higher than the values reported in Saudi Arabia (35.9 ± 12.2) and Greece (25.2), suggesting a potentially healthier immune system or lower stress levels in our population. On the other hand slightly lower than the values reported in St Peter specialized hospital, Addis Ababa (38.2±10.96). The neutrophil percentage (NEU %) in this study is 58.3 ± 9.04, which is higher than Saudi Arabia (50.3 ± 12.2), Greece (46.9) and in St Peter specialized hospital, Addis Ababa (53.9±10.84), indicating possible variations in infection rates or inflammatory responses. Overall, the current study presents a unique hematological profile, underscoring the influence of genetics, nutrition, and environmental factors on health across different populations, and highlights areas for further exploration in public health initiatives.

The findings emphasize the importance of white blood cell metrics in clinical settings, particularly concerning sex differences in immune responses. While most parameters showed no significant differences, notable findings regarding eosinophils and basophils warrant further investigation into their immunological implications. Future research should explore the biological mechanisms behind these differences and involve larger, more diverse populations to enhance generalizability. Overall, while some trends in white blood cell parameters by sex were observed, the lack of significant differences in many measures highlights the need for continued research into immune function across various populations.

Platelet counts (PLT) in this study (207.1 ± 55.29 $x10^9$/L) are lower than those in Sudan (261 ± 83.16), Nigeria (225.1 ± 72.21) and St Peter specialized hospital, Addis Ababa (245.5±69.78), indicating potential variations in inflammatory responses. Mean platelet volume (MPV) in the current study is reported at 11.2 ± 8.60, are higher than in St Peter specialized hospital, Addis Ababa, Ethiopia (9.5±0.9) (24). Higher MPV typically indicates larger platelets, which can be

associated with increased platelet production or activation. The platelet distribution width (PDW-CV) in the current study (13.6 ± 2.57) and in St Peter specialized hospital, Addis Ababa, Ethiopia (11.5±1.85) (24) reflects variability in platelet size.

The absence of significant differences in PLT and PDW-CV suggests that sex alone may not necessitate adjustments in assessments. However, the nearly significant difference in MPV warrants further exploration of the underlying biological mechanisms. Future research should include larger, more diverse populations and investigate the influence of factors such as age, lifestyle, and health conditions on platelet parameters. Overall, while some trends in platelet metrics by sex were noted, the lack of significant findings highlights the importance of continued research to better understand platelet physiology across different populations.

7. Strength and limitation

7.1. Strength of the study

Our study assessed all hematological parameters for newborns with regards to hematological reference intervals in umbilical cord blood and also it could fill the gap which lacks specific reference intervals for newborns (specifically for ambo and the surrounding areas) locally. The result from this study could also uses as a good informative for health related intervention.

7.2. Limitation of the study

From the beginning this study had a few limitations to get sufficient amount of sample (study population) to establish the reference interval. However the study demonstrated no significant difference between the sexes except for eosinophil and basophil count and marginal for RBC, MPV, and monocyte count. Thus, it fulfills the minimum sample size as per the CLSI guideline for most of the common hematological parameters. The other one is also the scarcity of getting enough literature done on this area. To compare the value of RDW and platelet indices, there was rare literature.

8. Conclusion and Recommendation

8.1. Conclusion

Our study underscores the necessity for establishing localized hematological reference intervals for umbilical cord blood in newborns from Ambo, revealing significant variations compared to other populations. The observed differences in key parameters—including white and red blood cell counts, hemoglobin, mean corpuscular volume, and platelet counts—highlight the influence of demographic, environmental, and possibly genetic factors on neonatal hematology. These findings point to the importance of using region-specific reference values for accurate clinical assessment and diagnosis. While most parameters showed no significant sex-based differences, trends in eosinophil and basophil counts suggest further research is warranted. Expanding future studies to include broader demographic profiles and additional variables will strengthen the evidence base, ultimately informing better clinical practices and public health strategies tailored to local needs.

8.2. Recommendation

It is recommended that healthcare providers in Ambo and similar regions utilize localized Hematological Reference Intervals for parameters of Umbilical cord blood to enhance the accuracy of neonatal assessments.. Investigating the roles of dietary patterns, genetic factors, environmental influences, and maternal health is essential, particularly in relation to the observed elevated mean corpuscular volume. Additionally, the lower platelet counts and notable trends in eosinophil and basophil levels warrant further study to better understand their clinical and immunological significance. Medical facilities are encouraged to update their laboratory protocols to incorporate these localized findings, while healthcare professionals and policymakers should be made aware of the importance of region-specific reference values to support effective neonatal health strategies. Future research should also consider a wider range of variables, such as maternal age, neonatal age, birth weight, mode of delivery, and comorbid conditions, to provide a more comprehensive understanding of hematological variations in newborns.

9. REFERENCE

1. Zeh CE, Odhiambo CO, Mills LA. Laboratory reference intervals in Africa. Blood cell-an overview of studies in hematology: IntechOpen; 2012.
2. Ali H, Al-Mulla F. Defining umbilical cord blood stem cells. 2012.
3. Proytcheva MA. Issues in neonatal cellular analysis. American journal of clinical pathology. 2009;131(4):560-73.
4. Lanzkowsky P, Lipton J, Fish JD. Lanzkowsky's manual of pediatric hematology and oncology: Elsevier; 2016.
5. Glasser L, Sutton N, Schmeling M, Machan J. A comprehensive study of umbilical cord blood cell developmental changes and reference ranges by gestation, gender and mode of delivery. Journal of Perinatology. 2015;35(7):469-75.
6. Cumbane V, Imbach M, Chissumba RM, Macicame I, Eller LA, Lawlor J, et al. Determining hematological, biochemical and immunological reference values in healthy adults with high-risk for HIV acquisition in Mozambique. PloS one. 2020;15(4):e0232018.
7. Dohbit J, Agala V, Chinwa-Banda P, Anane-Fenin B, Maduka O, Edewor U, et al. Improving maternal health: the safe childbirth checklist as a tool for reducing maternal mortality and morbidity. Mivšek AP, editor. 2019:87-110.
8. Berg J, Lane V. Pathology Harmony; a pragmatic and scientific approach to unfounded variation in the clinical laboratory. SAGE Publications Sage UK: London, England; 2011. p. 195-7.
9. Carroll PD, Christensen RD. New and underutilized uses of umbilical cord blood in neonatal care. Maternal health, neonatology and perinatology. 2015;1:1-7.
10. Jaleel R, Deeba F, Khan A. Timing of umbilical cord clamping and neonatal haematological status. JPMA The Journal of the Pakistan Medical Association. 2009;59(7):468-70.
11. Spurway J, Logan P, Pak S. The development, structure and blood flow within the umbilical cord with particular reference to the venous system. Australasian journal of ultrasound in medicine. 2012;15(3):97-102.
12. Camitta BM, Slye RJ. Optimizing use of the complete blood count. Pediatria Polska. 2012;87(1):72-7.
13. Sikaris KA, Streichert T, Macri J. Distinguishing reference intervals and clinical decision limits–A review by the IFCC committee on reference intervals and decision limits. 2018.
14. Kataoka MC, Carvalheira APP, Ferrari AP, Malta MB, de Barros Leite Carvalhaes MA, de Lima Parada CMG. Smoking during pregnancy and harm reduction in birth weight: a cross-sectional study. BMC pregnancy and childbirth. 2018;18:1-10.
15. Nykjaer C, Alwan NA, Greenwood DC, Simpson NA, Hay AW, White KL, Cade JE. Maternal alcohol intake prior to and during pregnancy and risk of adverse birth outcomes: evidence from a British cohort. J Epidemiol Community Health. 2014;68(6):542-9.
16. Cloherty JP, Eichenwald EC, Stark AR. Manual of neonatal care: Lippincott Williams & Wilkins; 2008.
17. Chang Y-H, Yang S-H, Wang T-F, Lin T-Y, Yang K-L, Chen S-H. Complete blood count reference values of cord blood in Taiwan and the influence of gender and delivery route on them. Pediatrics & Neonatology. 2011;52(3):155-60.
18. Ceriani Cernadas JM, Carroli G, Pellegrini L, Otano L, Ferreira M, Ricci C, et al. The effect of timing of cord clamping on neonatal venous hematocrit values and clinical outcome at term: a randomized, controlled trial. Pediatrics. 2006;117(4):e779-e86.
19. Jaiswal P, Upadhyay A, Gothwal S, Singh D, Dubey K, Garg A, Vishnubhatla S. Comparison of Umbilical Cord Milking and Delayed Cord Clamping in Term Neonates-A Randomized Controlled Trial. Academic Journal of Pediatrics & Neonatology. 2015;1(1):1-7.

20. Tian X, Kaufman DS. Differentiation of embryonic stem cells towards hematopoietic cells: progress and pitfalls. Current opinion in hematology. 2008;15(4):312-8.
21. Hillyer CD, Hillyer C, Strauss R, Luban N. Handbook of pediatric transfusion medicine: Elsevier; 2004.
22. Lewis SM, Bain B, Bates I. Reference ranges and normal values. Dacie and Lewis practical haematology. 2006;10:11-21.
23. Benirschke K, Kaufmann P, Baergen R. Classification of villous maldevelopment. Pathology of the human placenta. 2006:491-518.
24. Angelo A, Derbie G, Demtse A, Tsegaye A. Umbilical cord blood hematological parameters reference interval for newborns from Addis Ababa, Ethiopia. BMC pediatrics. 2021;21:1-9.
25. Tiruneh T, Kiros T, Getu S. Hematological reference intervals among full-term newborns in Ethiopia: a cross-sectional study. BMC pediatrics. 2020;20:1-6.
26. Eslami Z, Ghilian R, Abbasi F. Evaluation of hemoglobin concentration of cord, capillary and venous sampling in neonates. Iranian journal of pediatric hematology and oncology. 2012;2(4):159.
27. Al-Marzoki JM, Al-Maaroof ZW, Kadhum AH. Determination of reference ranges for full blood count parameters in neonatal cord plasma in Hilla, Babil, Iraq. Journal of blood medicine. 2012:113-8.
28. Basnet S, Singh SK, Sathian B, Mishra R. Reference ranges for hematological values in umbilical cord blood in Pokhara, Nepal. Journal of Nepal Paediatric Society. 2016;36(2):160-4.
29. Pasha W, Ali W, Ahmed N, Khattak AL, Idris M, Nayyer ZA. Reference haematological values for full term healthy newborns from rural Sindh, Pakistan. Journal of Ayub Medical College Abbottabad. 2015;27(2):375-7.
30. Allam AA, El Gendy FM, Allam MM, Allam RK. Haematological parameters of newborns delivered vaginally versus caesarean section. Menoufia Medical Journal. 2016;29(2):259-64.
31. Elgari MM, Waggiallah HA. Cord blood hematological profile of Sudanese neonates at birth in Khartoum State. NJIRM. 2014;5(4):22-5.
32. Katsares V, Paparidis Z, Nikolaidou E, Karvounidou I, Ardelean K-A, Drossas N, et al. Reference ranges for umbilical cord blood hematological values. Laboratory Medicine. 2009;40(7):437-9.
33. Alharbi S, Alkhotani A. Hematological reference values for full-term, healthy newborns of Jeddah, Saudi Arabia. Journal of Clinical Neonatology. 2017;6(1):19-22.
34. Tsegaye A, Wolday D, Otto S, Petros B, Assefa T, Alebachew T, et al. Immunophenotyping of blood lymphocytes at birth, during childhood, and during adulthood in HIV-1-uninfected Ethiopians. Clinical Immunology. 2003;109(3):338-46.
35. EA S. How to define and determine reference intervals in the clinical laboratory. Approved Guideline. 2000.
36. Shek Vugrovečki A, Vojta A, Šimpraga M. Establishing reference intervals for haematological and biochemical blood variables in Lika pramenka sheep. Veterinarski arhiv. 2017;87(4):487-99.
37. Ozarda Y, Sikaris K, Streichert T, Macri J, intervals ICoR, Limits D. Distinguishing reference intervals and clinical decision limits–A review by the IFCC Committee on Reference Intervals and Decision Limits. Critical reviews in clinical laboratory sciences. 2018;55(6):420-31.
38. Milcic TL. The complete blood count. Neonatal Network. 2010;29(2):109-15.
39. Qaiser DH, Sandila MP, Kazmi T, Ahmed ST. Influence of maternal factors on hematological parameters of healthy newborns of Karachi. Pakistan Journal of Physiology. 2009;5(2):34-7.

10. Annexes

Annex I – Standard Operating Procedure (SOP)

SOP for Sysmex XN- 550 Hematology Analyzer

1. Purpose: To determine complete blood count using Sysmex® automated haematology analyser XN-550

2. Principle: The Sysmex XN-550 is a quantitative automated hematology analyzer for in vitro diagnostic use for determining 18 hematological parameters. Examination of the numerical and/or morphologic findings of the complete blood count are useful in diagnosis of such disease states as anemias, leukemias, allergic reactions, viral, bacterial, and parasitic infections. The Sysmex XN-550 analyzer directly measures the WBC, RBC, HGB, HCT, and PLT, LYM #, MIXED #and NEUT #. The remaining parameters are calculated or derived MCV, MCH, MCHC, MPV, RDW-CV and RDW-SD, and differential percentages LYM%, MIXED%, NEUT%. The XN-550 counts and sizes red blood cells (RBC) and platelets (PLT) using electronic resistance detection. Hematocrit (HCT) is measured as the ratio of the total RBC volume to whole blood using cumulative pulse height detection. Hemoglobin (HGB) is converted to methemoglobin, and read photometrically at 555 nm. White blood cells (WBC) are analyzed by direct current and discriminated into a three-part differential using Particle Distribution Analysis (PDA). The resulting WBC histogram is discriminated into lymphocyte, neutrophil and mixed cell populations. The mixed cell population contains monocytes, basophils and eosinophils.

3. Abbrevations

EDTA: Ethylene diamine tetra acetate

LCD: liquid crystal display

4. Materials Reagents:

-Diluent: CELLPACK (20 L)

-WBC/HGB lyse: STROMATLYSER-WH (500 mL X 3)

-Detergent: CELLCLEAN (50 ml)

Reagent preparation Reagent stability and storage:

- Leave the reagent at room temperature (15 - 30°C) for at least 24 hours before using

- Use reagents within the expiration date

Procedures for Cord Blood Collection

A. All the needed equipment for the procedure including needle and syringe put in place within safe and easily reachable materials like tray and trolley, ensuring that all the items are clearly visible.

B. Perform hand hygiene of the phlebotomist

C. Put on well-fitting gloves

D. After delivery of the newborn, double-clamped the umbilical cord and cut.

E. Remove any blood from the surface of the cord with gauze

F. Insert the needle just above the clamp that remains on the cord

G. After collecting sufficient amount of blood, withdraw the needle gently.

H. The tube was labeled with the medical registration number and date

I. Discard the used needle and syringe or blood-sampling devices into a puncture resistant container.

J. Dispose the used gloves appropriately and perform hand hygiene

Annex II

Subject Information Sheet (For Pregnant Mothers, English Version)

Addis Ababa University

College of Health Sciences

Department of Medical Laboratory Sciences

Subject Information Sheet for Mother Whose Cord Blood is to be used in the Establishment of Hematological Reference intervals You are invited to participate in a study to be conducted by MSc student at Addis Ababa University, College of Health Sciences, Department of Medical Laboratory Sciences.

Please read the following statements and ask any unclear points before you agree to participate. Introduction

The topic of this study "Establishing Reference Interval for Umbilical cord Blood Hematological Parameters of Newborns Delivered in Ambo University Referral Hospital from April to June 30, 2023."

The aim of the study is to establish reference intervals that can be used as a baseline for clinical decisions associated with anemia, thrombocytopenia and infection in newborns. Participation in this study is exclusively voluntarily. If you are not interested to participate or if you once decide to participate and withdraw at any time, there will be no consequences and you will get all the services provided in the hospital with no problems. If you decide to participate, you have to sign on the consent form and you may obtain a copy of this information sheet.

What is expected from me as a participant of the study?

As a participant of this study, you are expected to agree that 2-3mL blood will be collected from the cord immediately after your delivery before the expulsion of the cord. In addition, you are expected to give answers for some questions about your health and socio-demographic conditions. You need to know that your results might be discussed with other appropriate individual out of this hospital. But your name, address and phone number will not be disclosed and rather than identification code will be used in such conditions.

How much time will I spent to participate in this study?

You will spend 20-25 minutes until the specimen is collected, the consent form is signed and the questionnaire is filled.

What are the risks of participating in this study?

The sample collection will pose minimal pain on you and the only thing you spend is just your time to fill the questionnaire

How my information is to be kept in secret?

All information that you give and the results from your sample will be used for this study only, only limited numbers of professionals will have access to the information. All the information will be encoded in a computer and saved with password protection.

What are the benefits from participation?

Since this study is MSc student research, there will not be payments for participants. But your participation is important for the establishment of reference values that can be useful for the correct interpretation of hematological parameters in newborns.

What are my rights as a participant of this study?

You have the right to withdraw yourself from the study at any time and all the services provided in the hospital will not be discontinued. You are also welcomed if you have any questions for further explanations about the study. You may also get the results of the analysis.

What can I do if I have a problem or a question?

Please direct any questions or problem you may encounter during this study to:

Barecha Soboka

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College of Health Sciences,

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Agree to participate? Yes ……. No ……

Annex III –

Subject Information Sheet (For Pregnant Mothers, Afaan Oromoo Version)

Yuuniversiitii Addis Ababaa

Kolleejjii Fayyaa

Diippaartimantii Meedikaala Fayyaa

Odeeffannoo Bu’aa qorannoo dhiigaa kan hidda handhuuraa irraa Fudhatamee (CBC) Birqabaan ilaaluuf qophaaye.

Yuuniversiitii Addis Ababaa

Kolleejjii Fayyaa

Diippaartimantii Meedikaala Fayyaa

Bu’aa qorannoo barataa kan digirii lammaffaa irratti akka hirmaattaniif afferamtaniittu. Akkasumas immoo hirmaannaa kana taasisuun duratti dubbisa kanatti aananii jiran haalaan erga hubattanii gaaffilee barbaaddan hunda gaafachuu ni dandeessu.

Seensa

Mata dureen qorannoo kana kan qorannoo dhigaa waliigalaa(CBC) hidda handhuuraa irratti raawwatamu wal-dorgomsiisuudha. Kaayyoon isaas gatii qorannoo dhigaa waliigalaa(CBC) hidda handhuuraa irratti raawwatamu wal-dorgomsiisuu argachuuf yoo tahu faayidaan isaas bu’aa qorannoo kanaa irraa argame hanga (gatii) qorannoo dhigaa waliigalaa(CBC) hidda handhuuraa irratti raawwatamu wal-dorgomsiisuu kana haala gaariin hiikaa isaa mutreessuufidha. Kanuma hubachuudhaan isinillee hirmaannaa taasisuudhaan qaama bu’aa qorannoo kanaa tahuu ni dandeessu garuummoo yoo hirmaannaa kanaaf isinii mijachuu dide yookiin hirmaachuuf eeyyamaamaa tahuu dhiistan mirga guutuu qabdu, dabalataanis immo tajaajila hospitaala keessatti argamu kamiyyuu itti fufuu ni dandeessu.

Hirmaannaa kana taasisuuf immoo eeyyamamaa yoo taatan , gaaffileewwaan waraqaa guca barbaachisoo irratti argamu guutuudhaan hirmaachuu keessan mirkaneessuuf mallattoodhaan mirkaneessuu qabdu. Dabalataanis bu’aa isaa fuula tokko fudhachuu ni dandeessu.

Qorannoo kana irratti Hirmaannaa taasisuuf maaltu narraa eegama ?Yoo hirmaanna kana taasistan hidda hadhuuraa irraa dhiiga qoratamuuf miilileetira 2-3 kan tahu yeroo dahumsaa irratti kan fudhatamee ittin qoratamu tahuu isaa isin beeksisna.Akkasumas immo ragaalee bu'aa qorannoo kana irraa argame namoota dhimma kana waliin wal qabatu tahee kan hospitaala kanaa alatti argamaniif illee agarsiisuuf mirga guutuu qabdu. Lakkoofsa bilbilaa fii maqaa garagaraa fayyadamuu hin barbaachisu, garuummoo bifa koodiidhaan mallattoo adda fayyadamuu ni dandeenya. Ragaaleen argaman bu'aa qorannoo garaagaraatiif ni oola akkasumas odeeffannoo dabalataatiif ni oola. Walumaa galatti yeroo haalota fayyaa waliin walqabatan garaa garaa irratti gaaffii isiniif dhiyeessinutti eyyamamaa akka nuuf taatan kabajaan isin gaafanna.

Yeroo ammam(hangam) fudhachuu dandaha ?

Gaaffilee guca irratti dhiyaatan guutanii xumuruuf daqiiqaa 20-30 fudhata.

Hirmaannaa kana taasisuuf rakkoon mudatu maalidha ?

Yeroo samuuda dhiigaa kennitan kanatti rakkoo isiinirra gahu hin jiru garuummoo yeroo daqiiqaa 30 gahuu dandahu kana qofa gaaffilee dhaaf deebii kennuuti daqiiqaa 30 isin irraa fayyadamuu qofa.

Ragaan qorannoo kana iirraa argame akkamitti icciitiin naaf turuu dandaha ?

Bu'aa qo'annoo kana irraa argames tahee garaa dhuunfaa keessanii qamni argu yoo jiraate namoota baayyee murtaahee qaama deeggartoota hojii kana keessatti argaman qofadha. Akkasumas ragaaleewwan kun bifa koompitaraatiin yeroo tahu haala icciitiin ittin qabamuu dandahuun qabiyyee gaariidhaan qabama.

Faayidaan bu'aa qo'annoo kana irraa argamu maalidha ?

Faayidaawwan qarshii waliin wal qabate homtuu hin jiru, garuu barnoota digrii lammaffaa xumuruudhaaf bu'aa qorannoo kana irratti hirmaachuun xumura barnoota kanaaf ni fayyada. Akkasumas daa'ima dhalatuuf ragaan qorannoo kana irraa argamu haala fayyummaa daa'imaatiif hiika kennuufi hubachuudhaaf ni fayyada.

Yeroon hirmaanna kana taasisutti mirgi ani qabu maalidha ?

Haalaa fi yeroo barbaaddan irratti hirmaannaa kana keessatti gaaffilee qabdan hunda dhiyeessuuf mirga guutuu qabdu. Yoo fedhii qabaachuun keessan hafe illee hirmaannaa keessan yeroo barbaaddanitti addaan kutuu ni dandeessu. Dabalataa illee ragaan qorannoo dhiigaa kan waliigalaa kan daa'imaa bilisaan isiniif kennama.

Gaaffii yookiin rakkoon yoo mudate maal gochuutu naaf wayya ?

Walumaagalatti gaaffilee fi rakkoo isin mudate kan bu'aa qoranno kana waliin wal-qabate kamiifuu teessoo armaan gaditti argamu kanaan gaafachuu ni dandeessu.

Bareechaa Sobbooqaa

Diippartimantii meedikaalaa laaboraatoorii

Kolleejjii Fayyaa

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kaadhimamaa pirooferasaa Fiqaaduu Urgeessaa 0934442555

Odeeffannoo dabalataatiif gaafanno boordii yuuniversiitii addis ababaa kan dhaabbata kolleejjii fayyaa fayyadamuu ni dandeessu.

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Finfinnee：Itiyoophiyaa

Hirmaannaa ni taasistuu ?

Eeyyee …….. Lakki ……

Annex IV- Subject Information Sheet (For Pregnant Mothers, Amharic Version)

አዲስ አበባ ዩኒቨርሲቲ

የጤና ሳይንስ ኮሌጅ

የሕክምና ላቦራቶሪ ሳይንስ ት/ክፍል

<u>ከእትብት ላይ ደም ተወስዶ ለሚሰራው አጠቃላይ የደም ምርመራ (CBC) ውጤት የማወዳደሪያ ዋጋ ጥናት ለሚሳተፉ እናቶች የተዘጋጀ መረጃ</u>

አዲስ አበባ ዩኒቨርሲቲ፤ የጤና ሳይንስ ኮሌጅ፤ የሕክምና ላቦራቶሪ ሳይንስ ት/ክፍል በማስተርስ ዲግሪ ተማሪ የመመረቂያ ጥናት ላይ እንዲሳተፉ ተጋብዘዋለው፡፡ እባክዎ በዚህ ጥናት ለመሳተፍ ከመስማማትዎ በፊት ከዚህ ቀጥሎ የሚገኘውን ምንባብ በጥሞና ያንብቡና ግልፅ ያልሆነልዎትን ማንኛውም ሃሳብ ይጠይቁ፡፡ <u>መግቢያ</u>

የጥናቱ ርዕስ በእትብት የደም ናሙና ላይ የሚሰራ የአጠቃላይ ደም ምርመራ (CBC) ውጤት ማወዳደሪያ ነው፡፡ አላማውም አጠቃላይ ደም ምርመራ ውጤቶች ማወዳደሪያ ዋጋ ማግኘት ሲሆን ጥቅሙም ጨቅላ ህፃናትና አዲስ ለተወለዱ ህፃናት የሚኖራቸውን የእነዚህን አጠቃላይ ደም ምርመራ ውጤቶች ዋጋ በትክክል ለመተርጎም ይጠቅማል፡፡

እርስዎ በዚህ ጥናት ላይ የሚኖርዎት ተሳትፎ ሙሉ በሙሉ በበጎ ፈቃደኝነት ላይ የተመሰረተ ሲሆን በዚህ ጥናት ውስጥ ላለመሳተፍ ሆነ ለመሳተፍ ከወሰኑ በኋላ ለማቋረጥ የሚወስኑ ቢሆንም እንኳን በዚህ ሆስፒታል ውስጥ የሚገኝ ማንኛውም አገልግሎት አይቋረጥም፡፡ በጥናቱ ለመሳተፉ ከፈለጉ የስምምነት ቅጹ ላይ በፅሁፍ ወይም በጣት ፊርማ ማረጋገጥ ይኖሩበታል፡፡ ከፈለጉም ይህን የመረጃ ቅፅ አንድ ቅጂ ለራስዎ መውሰድ ይችላሉ፡፡

በጥናቱ ተሳታፊ በመሆኔ የሚጠበቅብኝ ምንድን ነው?

በዚህ ጥናት ላይ ለመሳተፍ የሚስማሙ ከሆነ 2-3ሚ.ሊ የደም ናሙና በሚወልዱበት ጊዜ ከእትብት ላይ እንደሚወሰድ እና ለጥናቱ እነደሚውል መስማማት ይጠበቅቦታል፡፡ ከተወሰደው ናሙና ላይ የሚገኙ መረጃዎች ከዚህ ሆስፒታል ውጭ ለሚገኙናለስራዉ አግባብነት ላላቸው ሰዎች ቢነገር የማይቃወሙ መሆኑን መስማማት ይጠበቅቦታል፡፡ የስልክ ቁጥር የመሳሰሉትን መረጃዎችን አይጨምርም፡፡ ይልቁንም ለዚህ ጥናት አገልግሎት ብቻ የሚውል እርስዎን

ለማወቅ የሚያስችል መለያ ቁጥር ጥቅም ላይ እንዲውል ይደረጋል፡፡ በተጨማሪም ስለ እርስዎ አጠቃላይ የጤና ሁኔታ ለሚቀርቡ አንዳንድ ተጨማሪ ጥያቄዎች መልስ መስጠት ይጠበቅቦታል፡፡

በዚህ ጥናት መሳተፍ ምን ያህል ጊዜ ይፈጃል?

የተዘጋጀውን መጠይቅ ለመሙላት የስምምነት ቅጹ ላይ ለመፈረም ከ20-25ደቂቃ ያስፈልጋል፡፡

በዚህ ጥናት መሳተፍ የሚያስከትላቸዉ ችግሮች ምንድን ናቸው?

ናሙና በሚወሰድበት ጊዜ ምንም አይነት የህመም ስሜት አያስከትልብዎትም ስለዚህም የሚያጡት ነገር ቢኖር መጠይቁን ለመሙላት የሚያጠፉት ጊዜ ነው፡፡

የህክምና መረጃዬ በሚስጢር ተጠብቆ መቆየት የሚችለዉ እንዴት ነዉ?

ስለራስዎ የሰጡት ማንኛውም መረጃና ከተወሰደው ናሙና ላይ የተገኘው የላቦራቶሪ ውጤት የሚውለው ለጥናቱ አላማ ብቻ ነው፡፡ ይህን ማህደር ሊያገኙ የሚችሉት የተወሰኑ የጥናቱ ተባባሪ ሰራተኞች ብቻ ናቸው፡፡ ከዚያም በላይ ስለእርስዎ ያለውን ማንኛውም መረጃ የተለየ የይለፍ ቃል ባለው ኮምፒዩተር የመረጃ ማህደር ውስጥ እነዲቀመጥ ይደረጋል፡፡

በዚህ ጥናት ላይ መሳተፍ የሚያስገኛቸው ጥቅሞች ምንድን ናቸው?

ይህ ጥናት የማስተርስ ዲግሪ ተማሪ መመረቂያ እንደመሆኑ መጠን ለተሳታፊዎች ገንዘብ አይከፈልም፤ ነገር ግን የእርስዎ ተሳትፎ አዲስ የሚወለዱ ህፃናትን ለመርዳትና በህፃናቱ ላይ የተገኘውን የአጠቃላይ ደም ምርመራ ውጤቶችን ለመተርጎም ይጠቅማል፡፡

በዚህ ጥናት ተሳታፊ በመሆኔ መብቶቼ ምንድን ናቸው?

በጥናት ውስጥ ያልዎትን ተሳትፎ በማንኛውም ጊዜ የማቋረጥሙሉ መብትዎ የተጠበቀ ከመሆኑም በላይ ራስዎን ከጥናቱ በማግለልዎ ምክንያት ምንም አይነት የሆስፒታሉ አገልግሎት አይቋረጥብዎትም፡፡ ከዚህም በተጨማሪ ጥናቱን በተመለከተ ማንኛውም ጥያቄ የመጠየቅና ገለፃ የማግኘት መብት አሉዎት፡፡ የላቦራቶሪ ምርምራ ዉጤቱንም በነፃ ማግኘት ይችላሉ፡፡

ጥያቄ ካለኝ ወይም ችግር ቢያጋጥመኝ ምን ማድረግ ይገባል? ይህን ጥናት በተመለከተ ወይም ከዚህ ጥናት ጋር በተዛመደ መልኩ ስለሚያጋጥሙ ድንገተኛ አደጋዎች ወይም ጥያቄ ካልዎት በሚከተለው አድራሻ ይጠቀሙ፡፡

በረቻ ሰቦቃ

የህክምና ላቦራቶሪ ሳይንስ ት/ክፍል፤

የጤና ሳይንስ ኮሌጅ

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ጥናት አማካሪዎች፡ ፕ/ር አስቴር ፀጋዬ 0911696085 ፤ **ፈቃድ ርሳ** 0934442555

ለተጨማሪ መረጃ የአዲስ አበባ ዩኒቨርሲቲ ህክምና ፋከልቲ ኢንስቲትዩሽናል ሪቪዩ ቦርድ ይጠይቁ፡፡

ስ.ቁ፡ +251918797598

ፋክስ፡ +251115511513099

አዲስ አበባ ፤ ኢትዮጵያ

ለመሳተፍ ይስማማሉ?

እስማማለሁ ……..

አልስማማም……

Annex V Consent **Form (Pregnant Mothers, English Version)**

Code Number----------

I have been informed about the study which is aimed at establishing reference values from cord blood. For this study blood is required from the cord. The aim of the study was explained to me. I am also informed that all the information contained within the questionnaire is to be kept confidential. Moreover, I have been well informed of my right to keep hold of information, decline to cooperate and make myself withdraw from this study. It is therefore, with full understanding of the situation that I gave the informed consent voluntarily to the researcher to use the blood taken from the cord for the investigation. In addition, I have also been informed that the benefit of the participation is to get the results of the analysis measured for free via the counselor. Participant's signature/ finger print----------

Name of deponent (mother unable to read) ----------Signature----------Date--------
Name of Counselor----------Signature----------Date----------
Please direct any questions or problem you may encounter during this study to:

Barecha Soboka

Department of Medical Laboratory Sciences

College of Health Sciences

Addis Ababa University

Mob: +251918797598

Email: barechasoboka3403@gmail.com

Advisors: Prof Aster Tsegaye 0911696085; Mr Fikadu Urgesa (PhD fellow) 093442555

For additional information, please contact Department of Medical Laboratory Sciences,

Addis Ababa University, Institutional Review Board (IRB) office; Tel: +2511911107099 P.O Box: 9086, Addis Ababa, Ethiopia.

Annex VI

Consent Form (For Pregnant Mothers, Amharic Version)

<u>የስምምነት ቅጽ (ለእናት)</u>

የምስጢር ቁጥር ----------

እኔ ስሜ ከላይ የተጠቀሰው ተሳታፊ በእትብት ላይ ስለሚሰራው የአጠቃላይ ደም ምርመራ (CBC) ውጤት ማወዳደሪያ ጥናት በቂ ገለፃ ተደርጎልኛል። ለጥናቱም ከእትብት የተወሰደ የደም ናሙና እንደሚያስፈልግ ተገለፆልኛል። የጥናቱን አላማዎችንም ተረድቻለው። በመጥይቁ ላይ የገለፅኳቸው መረጃዎች በሙሉ በምስጥር የተጠበቁ እንደሚሆኑ ተነግሮኛል። በጥናቱ ላይ ያለመሳተፍና ማንኛውም መረጃ ያለመስጠት እንዲሁም በማንኛውም ጊዜ ከጥናቱ እራሴን የማግለል መብቱ የተጠበቀ መሆኑን ተገለፆልኛል። ስለዚህ ለዚህ ጥናት መረጃና የስምምነት ቃሌን የሰጠሁት በአጠቃላይ ሁኔታውን በመረዳትና ፍፁም ፈቃድኝነት ነው። ከእትብት ላይ የሚወሰደዉ ናሙና የልጁ/ጅቷ ጤና ሁኔታ ለማወቅ እና ለምርምር እነደሚውልም ተረድቻለው። በተጨማሪም ጥያቄ እንድጠይቅ ተፈቅዶልኝ ለማወቅ የፈለጉትን ማብራሪያ አንግቻለሁ። የዚህ ጥናት ተሳታፊ በመሆኔ የላቦራቶሪ ምርምራ በነፃ ማግኘት እንደሆነ ተረድቻለው።

የተሳታፊዋ ፊርማ/ የጣት አሻራ----------

የምስክር ስም---------- ፊርማ---------- ቀን----------

(የስምምነት ቅጹን ማንበብ ለማይችሉ ተሳታፊዎች)

የአማካሪ ስም----------ፊርማ---------- ቀን----------

ይህን ጥናት በተመለከተ ወይም ከዚህ ጥናት ጋር በተዛመደ መልኩ ስለሚያጋጥሙድንገተኛ አደጋዎች ወይም ጥያቄ ካልዎት በሚከተለው አድራሻ ይጠቀሙ።

በረቻ ሰቦቃ

የህክምና ላቦራቶሪ ሳይንስ ዲፓርትመንት

የጤና ሳይንስ ኮሌጅ፤

አዲስ አበባ ዩኒቨርሲቲ

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ኢሜይል፡ barechasoboka3403@gmail.com

ጥናት አማካሪዎች፡ ፕ/ር አስቴር ፀጋዬ 0911696085 ፤ **ፈቃድ ርገሳ** 0934442555

ለተጨማሪ መረጃ

የአዲስ አበባ ዩኒቨርሲቲ

ህክምና ፋከልቲ ኢንስቲትዩሽናል ሪቪዩ ቦርድ ይጠይቁ፡፡

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ፋክስ፡ +251115511513099

ፖ.ሳ.ቁ፡ 9086፣

ኢትዮጵያ

Annex VII Assent form (Amharic Version)

የስምምነት ቅጽ (ለልጁ/ጅቷ)

የምስጢር ቁጥር ----------

እኔ ስሜ ከላይ የተጠቀሰው ተሳታፊ በእትብት ላይ ስለሚሰራው የአጠቃላይ ደም ምርመራ (CBC) ውጤት ማወዳደሪያ ጥናት በቂ ገለፃ ተደርጎልኛል። ለጥናቱም ከእትብት የተወሰደ የደም ናሙና እንደሚያስፈልግ ተገለፆልኛል። የጥናቱን አላማዎችንም ተረድቻለው። በመጥይቁ ላይ የገለፅኳቸው መረጃዎች በሙሉ በምስጥር የተጠበቁ እንደሚሆኑ ተነግሮኛል። በጥናቱ ላይ ያለመሳተፍና ማንኛውም መረጃ ያለመስጠት እንዲሁም በማንኛውም ጊዜ ከጥናቱ እራሴን የማግለል መብቴ የተጠበቀ መሆኑን ተገለፆልኛል። ስለዚህ ለዚህ ጥናት መረጃና የስምምነት ቃሌን የሰጠሁት በአጠቃላይ ሁኔታውን በመረዳትና ፍፁም ፈቃድኝነት ነው። ከእትብት ላይ የሚወሰደዉ ናሙና የልጁ/ጅቷ ጤና ሁኔታ ለማወቅ እና ለምርምር እነደሚውልም ተረድቻለው። በተጨማሪም ጥያቄ እንድጠይቅ ተፈቅዶልኝ ለማወቅ የፈለጉትን ማብራሪያ አንግቻለሁ። የዚህ ጥናት ተሳታፊ በመሆኔ የላቦራቶሪ ምርምራ በነፃ ማግኘት እንደሆነ ተረድቻለው። የተሳታፊዋ ፊርማ/

የጣት አሻራ---------- የምስክር ስም---------- ፊርማ---------- ቀን----------

(የስምምነት ቅጹን ማንበብ ለማይችሉ ተሳታፊዎች)

የአማካሪ ስም----------ፊርማ---------- ቀን---------- ይህን ጥናት በተመለከተ ወይም ከዚህ ጥናት ጋር በተዛመደ መልኩ ስለሚያጋጥሙድንገተኛ አደጋዎች ወይም ጥያቄ ካልዎት በሚከተለው አድራሻ ይጠቀሙ።

በረቻ ሰቦቃ

የህክምና ላቦራቶሪ

ሳይንስ ዲፓርትመንት

የጤና ሳይንስ ኮሌጅ፤

አዲስ አበባ ዩኒቨርሲቲ

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ኢሜይል፡ barechasoboka3403@gmail.com

ጥናት አማካሪዎች፡ ፕ/ር አስቱር ፀጋዬ 0911696085 ፤ **ፈቃድ ኢርገሳ** 0934442555

ለተጨማሪ መረጃ የአዲስ አበባ ዩኒቨርሲቲ ህክምና ፋክልቲ ኢንስቲትዩሽናል ሪቪዩ ቦርድ ይጠይቁ፡፡

ስ.ቁ፡ +2511911107099

ፋክስ፡ +251115511513099

ፖ.ሳ.ቁ፡ 9086፣

አዲስ አበባ

ኢትዮጵያ

Annex VIII

Assent Form (Pregnant Mothers, English Version) Code Number----------

I have been informed about the study which is aimed at establishing reference values from cord blood. For this study blood is required from the cord. The aim of the study was explained to me. I am also informed that all the information contained within the questionnaire is to be kept confidential. Moreover, I have been well informed of my right to keep hold of information, decline to cooperate and make myself withdraw from this study. It is therefore, with full understanding of the situation that I gave the informed consent voluntarily to the researcher to use the blood taken from the cord for the investigation. In addition, I have also been informed that the benefit of the participation is to get the results of the analysis measured for free via the counselor. Participant's signature/ finger print----------

Name of deponent (mother unable to read) ----------Signature----------Date--------
Name of Counselor----------Signature----------Date----------

Please direct any questions or problem you may encounter during this study to:

Barecha Soboka

Department of Medical Laboratory Sciences College of Health Sciences

Addis Ababa University

Mob: +251918797598 , Email: barechasoboka3403@gmail.com

Advisors: Professor Aster Tsegaye 0911696085; Mr Fikadu Urgesa (PhD fellow) 0934442555 For additional information, please contact Department of Medical Laboratory Sciences, Addis Ababa University, Institutional Review Board (IRB) office;

Tel: +2511911107099 P.O Box: 9086,

Addis Ababa, Ethiopia.

Annex IX Questionnaire (For Pregnant Mothers, English Version)

Addis Ababa University

College of Health Sciences

Department of Medical Laboratory Sciences

Questionnaire for Data Collection from Mothers Whose Cord Blood is to be used in the Establishment of Hematological Parameters Reference Values.

.Introduction Subject identification number ---------- MRN ---------- Age of the mother (in years) ------- Residential Place---------- Tel: -----

Educational level ; Unable to write and read …College diploma/degree and above …..Read and Write …….Primary (1-8) …..High School (9-12) ….

3 .Occupation ; Student ….. House wife ……Employed….Jobless …….Private work… Other (specify)…….

4. Marital status 1. Single . 2. Married …… 3. Divorced 4. Widowed…..

5. How many children previously delivered? This is my first pregnancy 1 child 2 and above

6. If you delivered for question 5, on how many interval? 1 year 1 year 6 month 2 year 2 year and above.

7. If yes for question 5, what was the mode of previous delivery?

Normal spontaneous delivery …….Induced vaginal delivery …….

Vaginal delivery with forceps ……Cesarean section……

8. Did you drink alcohol during pregnancy? Yes …..No……

9. If your answer for question 8 is ‘yes’, how often do you drink alcohol? 60 Daily Every weekend occasionally

10. Did you smoke cigarettes during pregnancy? Yes ……No ……..

11. If your answer is ‘yes’ for question 10, specify pack number smoked per day----------

12. Did you chew khat during pregnancy? Yes …..No ……

13. If your answer for question 11 is ‘yes’, how often do you chew chat?

Daily …..Every weekend ……occasionally……

14. Have you been sick for the last 3 months? Yes……. No…….

If yes, when ---------- describe illness ----------

15. Are you taking any prescribed medication Yes ….No…..

16. If yes, specify the name? ----------

Thank you!

Annex X – Questionnaire (For Pregnant Mothers, Amharic Version)

አዲስ አበባ ዩኒቨርሲቲ

የጤና ሳይንስ ኮሌጅ

የሕክምና ላቦራቶሪ ሳይንስ ት/ክፍል

ከእትብት ላይ ደም ተወስዶ ለሚሰራው አጠቃላይ የደም ምርመራ ሁኔታ የማወዳደሪያ ዋጋ ጥናት ለሚሳተፉ እናቶች የተዘጋጀ መጠይቅ

<u>መግቢያ</u>

መለያ ቁጥር---------- ካርድ ቁጥር ---------- የእናት እድሜ (በአመት)-------- መኖሪያ አድራሻ ---------- ስልክ ቁጥር ----------

የትምህርት ደረጃ

ሀ. ማንበብና መፃፍ የማትችል መ. ሁለትኛ ደረጃ (9-12ኛ)

ለ. ማንበብና መፃፍ የምትችል ሠ. ኮሌጅ ሰርቲፊኬት/ዲፕሎማ/ድግሪ እና ከዛ በላይ

ሐ. መጀመሪያ ደረጃ (5-8ኛ)

የስራ ሁኔታ ሀ. ተማሪ ለ. ተቀጣሪ (የመንግስት/የግል) ሐ. የግል

መ. የቤት እመቤት ሠ. ስራ የሌላት ረ. ሌላ.

የትዳር ሁኔታ ሀ. ያገባ ለ. ያላገባ ሐ. የፈታ መ. የሞተባት

ከአሁን በፊት ምን ያህል ልጆችን ወልደዋል? ሀ. ይህ የመጀመሪያዬ እርግዝና ነው ለ. አንድ ሐ. ሁለት መ. ሶስትና ከዚያ በላይ

ለ 5ኛው ጥያቄ ከዚህ በፊት ወልደው ከሆነ በምን ያህል ጊዜ ልዩነት? ሀ. በ1 አመት ለ. በ1 አመት ከ 6ወር ሐ. በ2 አመት መ. ከ2 አመት በላይ.

ለ5ኛው ጥያቄ ወልደው ከሆነ በምን አይነት መንገድ ወለዱ? ሀ. በተፈጥሮ ምጥ

ለ. በመሳሪያ የታገዘ ምጥ ሐ. በመድሐኒት የታገዘ ምጥ መ. በቀዶ ጥገና.

አልኮል ይጠጣሉ? ሀ. እጠጣለሁ ለ. አልጠጣም

ለ 8ኛው ጥያቄ መልሰዎ እጠጣለሁ ከሆነ በየስንት ጊዜዉ ይጠጣሉ? ሀ. በየቀኑ ለ. በሳምንቱ መጨረሻ ቀናት ሐ. አልፎ አልፎ

ሲጋራ ያጨሳሉ? ሀ. አጨሳለሁ ለ. አላጨስም

ለ10ኛው ጥያቄ መልስዎ አዎ ከሆነ፤ ምን ያህል እሽግ በቀን ያጨሳሉ? --------

ጫት ይቅማሉ? ሀ. እቅማለሁ ለ. አልቅምም

ለ11ኛው ጥያቄ መልስዎ እቅማለሁ ከሆነ በየስንት ጊዜዉ ይቅማሉ?

ሀ. በየቀኑ ለ. በሳምንቱ መጨረሻ ቀናት ሐ. አልፎ አልፎ

በአለፈው 3ወር ዉስጥ ታመው ነበር? ሀ.አዎ ለ. አልታመምኩም

አዎ ከሆነ መልስዎ መች?----------ህመሙ ምን እንደነበር ይግለጹ----------

መድሐኒት በመውሰድ ላይ ነዎት? ሀ. አዎ ለ. አይደለም ከወሰዱ የመድሐኒቱን ስም? ----------

መጠይቁን ጨርሰዋል

አመሰግናለሁ!

Annex XI - Pregnant Mother and Newborn Medical and Diagnostic Information Sheet

Addis Ababa University

College of Health Sciences

Department of Medical Laboratory Sciences

Code Number ----------

Physical examination and Medical History the Mother

Weight (in Kg) ---------- Hypertension ----------

Height (in meter) ---------- Diabetes Mellitus ---------- ----------

Gestational Week ---------- Psychological Disorder ----------

Body Temperature (0C) ---------- Obstetric Problems ---------- ----------

Laboratory & Diagnostic Test Results

Blood Type (ABO & Rh) ---------- Syphilis ----------

HGB ----------g/dL HIV ---------- Hepatitis B ----------

Malaria --------- Ultrasound ----------

Information about the Newborn

Gender Male_____ Female_____

Fetal Life (hr.) ---------- Current Delivery Mode ----------

Weight (in Kg) ---------- Appearance (color) ---------- Pulse Rate/min ---------- Umbilical cord appearance ---------- Breathing Rate/min ----------

Initial & Sign. ---------- Date ----------

Sample Collector Initial & Sign. ---------- Date ----------

Annex XII Laboratory Request and Result Report Form for Cord Blood

Addis Ababa University

College of Health Sciences

Department of Medical Laboratory Sciences

Code: ----------

Blood Type (ABO & Rh) ---------- Hepatitis B ------- Syphilis ------- HIV -------

Complete Blood Count (CBC)

WBC ---------- /uL LYM --------- % PDW-CV -------%

RBC ---------- /uL MXD --------- %

HGB ---------- g/dL NEU ---------- %

HCT ---------- #LYM ----------

MCV ---------- fL #MXD ----------

MCH ----------Pg #NEU ---------

MCHC ---------- g/L

PLT --------- /uL RDW-CV ---------- % MPV -------- fL

Nucleated RBC ---------- ----------

WBC Morphology ----------

RBC Morphology ----------

---------- Platelet Morphology ---------- Lab Tech Initial & Sign. ----------

---------- Date ---------- (G.C)

PI Sign. ----------Date ---------- (G.C)

11. Declaration

I, the undersigned declare that this M.Sc. thesis is my original work, has not been presented for a degree in this or any other university and that all sources of materials used for the thesis have been duly acknowledged.

M.Sc. candidate: **Barecha Soboka (B.Sc.)**

Signature: _____

Date of submission: _____

This thesis has been submitted with our approval as advisors.

Advisor: **Prof Aster Tsegaye**

Signature: _____

Date: _____

Place: Addis Ababa, Ethiopia.

Advisor: Fikadu Urgesa (PhD Fellow)

Signature: _____

Date: _____

Place: Addis Ababa, Ethiopia.