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DEPARTMENT OF MEDICAL LABORATORY SCIENCES

Determination of Hematological Reference Interval for Apparently Healthy Children in Addis Ababa, Ethiopia

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This is to certify that the thesis prepared by Abebaye Mekonen, entitled:

Determination of Hematological Reference Interval for Apparently Healthy Children in Addis Ababa, Ethiopia and submitted in 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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Abbreviations

AAU Addis Ababa University

CBC Complete blood count

CLSI Clinical and Laboratory standards Institute

EDTA Ethylene diaminetetra acetic acid

HCT Hematocrit

HGB Hemoglobin

IFCC International Federation of Clinical Chemistry and Laboratory Medicine

MCH Mean corpuscular hemoglobin

MCHC Mean corpuscular hemoglobin concentration

MCV Mean corpuscular volume

MPV Mean platelet volume

NCCLS National committee of clinical laboratory standard

PCV Packed cell volume

PLT Platelet

RBC Red blood cells

RD Reference distribution

RDW Red cell distribution width

RI Reference interval

RL Reference limits

RR Reference range

RV Reference value

WBC White blood cell

WHO World Health Organization

Abstract

Background: Clinical laboratory reference intervals are an important tool to identify abnormal laboratory test results. The generating of hematological parameters reference intervals for local population is very crucial to improve quality of health care, which otherwise may lead to unnecessary expenditure or denying care for the needy. There are no well-established reference intervals for hematological parameters in Addis Ababa, Ethiopia.

Objective: To determine for apparently healthy children hematological reference Interval for apparently healthy children in Addis Ababa, Ethiopia.

Methods: A community based cross-sectional study design was employed involving 272 individual in Addis Ababa Ethiopia from April–October 2019. Blood samples of 10 ml was collected in EDTA tubes using multi sample needle. A complete blood count (CBC) was performed using Sysmex automated hematology analyzer. The data was analyzed by SPSS version 26 statistical software and a non-parametric test used to generate reference intervals based on the 2.5th and 97.5th percentiles of the data based on CLSI guideline.

Result: The reference interval of RBC count, WBC count, HB and PLT count were 4.23-5.59x10^{12}/L, 2.95-10.89x10^{9}/L, 12.02-16.04/dl and 208.90-538.9x10^{9}/L, respectively for the age category (5-11) while 4.43-5.85x10^{12}/L, 3.05-9.43x10^{9}/L,13.2-16.94g/dl, ,202.01-459.92x10^{9}/L for age group (12-14) respectively. Most of hematological parameters showed significant differences such as RBC, HGB, HCT and MCV. No significant age-specific differences were observed for MCH or MCHC, WBC and Platelet parameters.

Conclusion: This study provided population-specific hematological reference interval for children in Addis Ababa, Ethiopian.

Key words: reference interval, hematological parameter, children, Addis Ababa Ethiopia

1. Introduction

1.1 Background

The exploration of hematopoiesis begins routinely with the establishment of the complete blood count which provides the erythrocytes, leukocytes and platelet values of an individual as well as the morphological characteristics of these blood cells [1]. Indeed, a wide variety of pathologies can result in modifications of the blood count [2].

The complete blood cell count (CBC) is one of the most prescribed hematological examinations and among the most useful in common medical practice for the evaluation of the state of health is not only sick but also healthy subjects. It is by means of this examination that specific diagnoses can be suggested and that a hematological affliction can be revealed at an early stage during clinical care. For hematological analyses, this multi parameter test, prescribed by clinicians has meaning only in comparison to the results obtained from reference values which establish a major mark for clinical interpretation [3].

The reference values are the various values of results of hematological tests produced by a large population of healthy people. They appear in the form of an interval with a lower limit and upper limit determined according to the recommendations of the new concept of reference values stemming from numerous works of learned societies, in particular the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC). These recommendations aim at standardizing, harmonizing and making more rigorous the presentation of the results and improving their interpretation by clinicians [4-5].

These reference values of hematological parameters of the healthy subjects see changes according to the analytical and pre-analytical variability due to the use of different measurement systems or several factors such as age, sex, height, environment, race, nutritional state, ethnic origin, lifestyle, biorhythms or the consumption of alcohol or medicine [6, 7].

For that purpose, their determination for every country, even every region, is of major importance. In Addis Ababa Ethiopia, the reference interval used in the laboratories by the doctors are collected from other countries with different physical, biological, environmental and

behavioral characteristics. Other values are from treaties of hematology and data derived from brochures of the reagent kits which makes their liability of the reference values questionable [8].

Reference intervals (RI); generally refer to quantitative data accompanied with 97.5 upper and 2.5 lower limits. Population based RI play an important role in screening patients, follow-up, routine clinical care, and clinical management of patients as well as in clinical trials. Definitions and guidelines for each step are elaborated by the Expert Panel on Theory of Reference Value (EPRTV) [6] subsequently in 2000, National Committee for Clinical Laboratory Standards (NCCLS) [7] and also Clinical and Laboratory Standards Institute (CLSI) [9].

The most important aspect of laboratory test interpretation is the concept of reference interval (RI), where test values that fall inside the range are considered normal and those occurring outside the range are considered abnormal [1]. RIs are very useful to provide medical information that ensures correct medical decisions. As laboratory results are interpreted in comparison with these intervals, the reliability of the RI can play major role in result interpretation and as a measure of quality of the result itself [4].

Locally derived hematological reference values are essential for assessing disease and monitoring the effects of therapy during routine healthcare practice and clinical trials. It has been recommended by the Clinical and Laboratory Standards Institute (CLSI) [9].

There is scarcity of comprehensive reference values for children in Africa. Reference values from textbooks, instrument manuals and reagent inserts that have been derived from other populations are often used to interpret laboratory results in Africa [10, 11]. In some instances, hematologic results for children are interpreted by using values established with adult populations [12]. It is, however, important to emphasize that children are not small adults and reference values derived with adult populations may not be suitable for children. Also, children are constantly changing and developing and therefore, single reference values may not be appropriate for children of all ages [13]. Thus, necessitates establishing age-specific reference values to aid appropriate interpretation of hematologic results of children. The purpose of this study was establishing a comprehensive, age-specific reference values for hematological tests of healthy children in Addis Ababa Ethiopia.

1.2 Statement of the Problem

International Federation for Clinical Chemistry recommended that each laboratory establishes reference values appropriate for the population it intends to serve. However, hematologic reference values used in many countries in Africa were established by using data from populations in the industrialized countries [10–15]. This is because the process of establishing reliable local reference values is expensive and time-consuming [9]. Published literature has confirmed differences between reference values obtained for adults from the industrialized countries and those from countries in Africa [8, 10, and 16]. Furthermore, differences also exist between reference values established in different countries in Africa [16-20].

It has been shown in several studies that some of the hematological profiles exhibit considerable variations in different populations. Though hematological reference values among apparently healthy children have been established in some populations of Africans, there is a dearth of information regarding hematological normal reference values for Ethiopians of diverse ethno geographic origins [19-20].

Lack of appropriate local hematological parameters RI is a challenge in interpreting results for patient management and other decision-making. Use of in appropriate RI may increase the risk of unnecessary additional investigations failure to detect underlying disease and mismanagement of patients. This is because there are various Hematology marker values showed dynamic changes from childhood into adulthood as well as between sexes, necessitating distinct partitions throughout life. Most age partitions were necessary during childhood, reflecting the hematologic changes that occur during growth and development [21-22].

Hematological reference intervals for healthy African populations are scarce, particularly for children. Values currently used in Ethiopia are often based upon results generated from populations living in industrialized countries. There are differences in the geographic location or demographic variables of the two populations that are known to cause differences in the reference values, then a reference interval must be established locally [23-24].

Continuous and practical constraints of defining reference intervals using a population of healthy community children made it difficult for resource constrained settings to determine their own RIs

and rely on values determined for other populations. This study was, therefore carried out to establish hematological reference intervals in apparently healthy children in Addis Ababa, Ethiopia.

1.3. Significance of the study

The current established reference interval is important for patients to getting appropriate medical decision diagnosis for physician with local RI in order to make reliable medical decision or interpretation, it can serve as a baseline data for upcoming researchers and Provide information for policy makers.

2. Literature review

Reference ranges obtained with in United States (US)-based subjects, the hemoglobin (HGB), hematocrit (HCT), mean corpuscular volume (MCV), mean corpuscular hemoglobin (MCH), and absolute neutrophil count (ANC) ranges were lower in subjects who resided in rural Haiti. The upper reference limit of the red blood cell distribution width coefficient of variation (RDW-CV) was higher than the reference range for the US-based group [24].

Some comparative studies conducted in Kuwaiti pediatric population is different from UK pediatric population in RBC, HGB, MCV, MCH, WBC, ANC and platelets levels. In the early life there were slight differences between the two populations but from the age of 13 years old up to the entire adult life [25].

In the contrary compared to reference intervals from the U.S., hematological reference intervals for healthy adults in Eastern and Southern Africa found elevated eosinophil counts [17] likely due to a high prevalence of parasitic infections.

Significant differences were observed among the different age groups in a study from Nigeria; the adults show significant higher values in hemoglobin, hematocrit, and red blood count, when compared with that of the children [26]. The values also vary from apparently healthy adult residing in Zaria [27].

A study was conducted recruiting 316 male and 344 female female Malawians in 12 different age groups. The study demonstrated that WBC counts were higher in children. Hb and Hct increased in the age groups between 5 and 10 years in males while 10 and 15 years in females to adult levels. Males children aged 5 to <10 years had significantly higher Hb (13.05 g/dL) and Hct (42.50%) compared to females of the same age group; the values in females were 10.40 g/dL and 32.55%, respectively. Likewise, platelet counts variation with age also varies among the two sexes. Highest count was noted between 3 and 5 years (376×10^9/L), and decreased to lowest counts among 5 to <10 year olds (238×10^9/L). On the other hand, in females the values decreased from 402×10^9/L in 6 to <10 years olds to 226×109/L in 10 to <15 year old children.

The median MCV values were high in neonates. Sex differences in MCV values were noted. [29].

The authors explained that the difference observed in the age groups in which platelet counts drastically decreased, between 10 and 15 years in females, could be due to estrogen in females which has been associated with changes in platelet function [29].

The study from the middle belt of Ghana involving 1442 healthy children was conducted to establish age- and sex-specific reference values for hematological parameters. The results revealed that HB, HCT, MCV, RBC values in the Ghanaian children were lower when they compare their result with values from Caucasian population [30].

Reference intervals for hematological indices of infants, children, and adolescents were determined for individuals from Port Harcourt, Nigeria. The study recruited 1,021 apparently healthy children aged 0–17 years. The result showed that WBC count significantly declined with age where they noted a significant decline until the age of 14 years. On the other hand, the investigators noted that the differential WBC count did not vary between male and female children [15].

The study from Kilimanjaro region in Tanzania determined hematological reference intervals for healthy Tanzanian children. When comparing their result with similar study from Ugandan children, the authors described that median Hgb and Hct for all age groups are higher than the respective medians from the Ugandan counterparts. Moreover, they reported that HB, HCT, MCV, and platelet counts in their study participants are lower than the reference intervals determined for United States/European individuals [19].

Hematological reference interval determination data are very limited for children from Ethiopia. For example a study from the northern part of Ethiopia establish established reference intervals for apparently healthy adolescents aged 12-17 years in Mekelle City, Tigrai, Northern Ethiopia. The median and the 95% reference intervals of hematological parameters were determined. The 95% RIs determined for WBC, HB, and platelets showed significant differences between males and females [32].

Another study from southwest Ethiopia which included children revealed the following values. The median values and reference interval of RBC, WBC, and platelet count were 4.99 (4.26-5.99 $\times 10^{12}$/L), 7.04 (4.00-11.67 $\times 10^{9}$/L), and 324.00 (188.00-463.50 $\times 10^{9}$/L), respectively. Most of the hematological parameters showed significant differences compared to adult age groups [33].

As reviewed above differences in hematological reference interval have been noted between the different studies and depending on the age of the study participants age and sex differences were noted for select parameters. All underscore for the need to establish locally appropriate reference intervals a gap that this study is trying to address by recruiting children from Addis Ababa.

2.1 Factors influencing hematological reference interval

The values of hematological parameters are affected by a number of factors even in apparently healthy populations. These factors include age, sex, ethnic background, genetics, exercise, nutritional status, environmental factors and altitude contribute significantly to inter-individual variance [9].

Age

The Basis of the Canadian Health Measures Survey indicated that age partitions were necessary during childhood, reflecting the hematologic changes that occur during growth and development. Hemoglobin, red blood cell count, hematocrit, and indices (mean corpuscular volume, mean corpuscular hemoglobin, and mean corpuscular hemoglobin concentration) increased with age [34]. Comparative study conducted in India showed that there were significant decrease in RBC count, HGB, HCT, MCH, MCHC and little increase in MCV in old age due to decreased erythropoietin activity of bone marrow [35] Regarding RBC profile also reported the differences in the hematological indices among males by age, with the young adults having higher levels of HGB, HCT, RBC, and PLT as compared to adolescents [36].

Sex

The finding of significant sex differences in the red blood cell parameters (hemoglobin, hematocrit, and RBC count) among adolescents is consistent with previously evidence that adolescent males have higher values than females for these parameters. The reasons for these differences have been attributed to factors such as the influence of the androgen hormone on erythropoiesis and to menstrual blood loss in females had lower hemoglobin and hematocrit starting at puberty. Platelet count gradually decreased with age and required multiple sex partitions during adolescence and adulthood. White blood cell count remained relatively constant over life [34].

Ethnicity and Genetics

Comparative study conducted for general children's of Africans of similar study have a lower WBC than Caucasian [35]. African Americans are known to have lower WBC counts than Europeans, and Japanese people have, on average, lower levels of RBC-related traits. These observations suggest that there exist both shared and divergent genetic backgrounds for hematological traits and that they might be characterized by ethnicity [36].

Altitude

Most of the studies confirm an increase in hemoglobin level secondary to an increase in erythropoietin level at high altitude. It is well documented that ascent to high altitude is associated with expansion of red cell mass. Furthermore, erythropoietin levels have been shown to increase rapidly on ascent. Plasma volume changes significantly on ascent to altitude, with radio nucleotide studies demonstrating a reduction in volume in otherwise well subjects [37-39]. People living at high altitude are at risk of thrombosis because of the risk of high platelet count [40].

Dietary Habit

A comparative study conducted on vegetarian with omnivorous adults in terms of iron status showed that vegetarians had significantly lower HCT and HGB than omnivores. Study conducted on prevalence of anemia and iron deficiency anemia in Ethiopian women showed that, although Ethiopian diets, notably *teff*, are high in iron, there is a marked prevalence of anemia [41].

Taken together, as outlined above several factors are affecting blood parameters. Thus, there is a need for locally appropriate age and sex specific reference intervals a gap this study is trying to address.

3. Objectives

3.1 General Objective

To determine hematological reference interval for apparently healthy children from April to October 2019 in Addis Ababa, Ethiopia.

3.2 Specific objectives

- To establish hematological reference intervals for children.
- To compare the distribution of hematological parameter between children age group.

4. Materials and Methods

4.1 study area

The study was conducted in the federal capital of Ethiopia and chartered location between. Its average elevation is 2500 meter above sea level and hence has a fairly favourable climate, moderate weather conditions and a population size of more than 3 million. Since Addis Ababa is very large city, four sub-cities was selected based on Probability Proportional to Size PPS, namely Arada, Kirkos, Akaki and Yeka sub-cities.

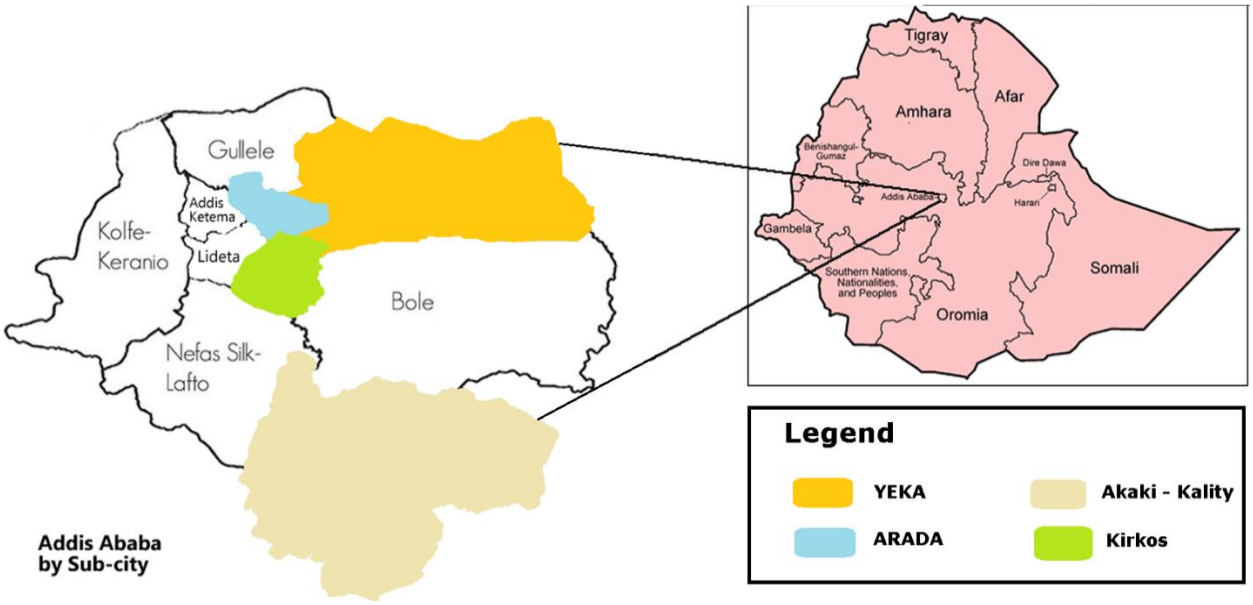

Figure 1. Addis Ababa sub city map

4.2. Study design and period

A community based cross-sectional study design was implemented from April 2019 to October, 2019 GC in Addis Ababa.

4.3. Population

4.3.1. Source population

The source population for this study was people living in Addis Ababa, with age of 5 years up to 14 years.

4.3.2. Study Population

The study populations were people with age of 5 years up to 14 that live in the selected subcities in Addis Ababa who fulfill the eligibility criteria.

4.4. Inclusion and exclusion criteria

4.4.1. Inclusion criteria for reference interval determination

Apparently healthy individuals aged five years up to fourteen and lived at least for 5 years in the area was included the study.

4.4.2. Exclusion criteria for reference interval determination

- Individuals with chronic illnesses like diabetes mellitus, chronic renal insufficiency, hypertension, ischemic heart disease, anemia, thyroid, liver diseases, cancer of any type
- Individuals taking pharmacologically active substances: all prescription drugs (none have habit of smoking and alcohol consumption)
- Children have greater than 4.3 CRP result and malaria
- Individuals who received blood transfusion within the previous 1 year

4.5. Study variables

4.5.1. Dependent variables

- Hematological Parameters (including WBC, differential, RBC, HGB, HCT, MCV, MCH, MCHC, RDW, MPV, PCT, PDW, Platelet count)

4.5.2. Independent variable

- Age

4.6. Sample size calculation and sampling method

4.6.1. Sample size determination

CLSI recommends that the best means to establish a reference interval is to collect samples from a sufficient number of reference individuals to yield a minimum of 120 samples for analysis, by non-parametric means for each partition (e.g. age range) with a power of 90% [42]. In the current proposed study, the maximum partition needed for hemoglobin determinations were 5-11 years and 12-14 years [43]; thus, two age partition groups are needed (2 x 120=240).

The current studies calculated sample size about 10% of apparently healthy population do not qualify for reference interval determination for various reasons when tested for the common viral infections. Thus, to reach the CLSI recommended total sample size of 240 for the reference interval determination, a minimum of 272 individuals will be enrolled (i.e., 10 % x 272 =27 to be excluded during data analysis; 272-27=245).

4.6.2. Sampling method

Probability Proportional to Size (PPS) sampling method was employed, where the size depends on the number of households of sub city in a town. Since Addis Ababa is very large city, four out of ten sub-cities were selected based on PPS, namely Arada, Kirkos, Akaki and Yeka sub-cities with a support from Ethiopian statistical agency; thus all woredas under the selected sub cities had been included. To recruit 344 participants, the number of households was determined by dividing the total household in the selected sub-cities for A.A by the estimated number of individuals per household. If there are no volunteers in the household the next household was considered to recruit one child per partition. Once volunteering participants fulfilling the eligibility criteria are identified by the health extension workers they were invited to go to nearby health facilities for interview using structured questionnaire and to facilitate biological sample collection. Selected children were conveniently approached from schools and youth centers as well. Letter had been written from the Federal Ministry of Health to Addis Ababa Health Bureau

and Central statistical agency to facilitate the study. The Health Bureau in turn wrote letter to the respective woredas and health centers to facilitate participants' recruitment by health extension workers and sample collection.

To determine sample size at a specific stratum methods of calculation described below.

ni = n/N x Ni	Akaki: 272/940,225 x 176, 680, 51
n = sample size 272,	Kirkos: 272/940,225 x 217, 592, 63
N = Total population = 940,225	Arada: 272/940,225 x 203,212, 59
Ni = total at single specific sub city	Yeka: 272/940,225 x 342,741, 99
ni = sample size at specific stratum **?**	

Table 1. Selected sites with household information

Selected Sites	**No. Households**	**Individuals per household**	**No. population**
Akaki	47021	3.8	176,680
Kirkos	54398	4.0	217,592
Arada	49564	4.1	203,212
Yeka	90195	3.8	342,741
Total	241,178	15.7	940,225

Note: Source for total population and number of households is from CSA 2007; *total number of household to be sampled has computed from the total sample size needed (i.e. 272) by the estimated individuals per household for each study site.

4.7. Measurement and Data collection

The study aim, risks, benefits of study participation and right to withdraw from the study at any time was explained (parents/guardians for children). From those consenting participants, demographic information and a brief medical history was collected. Then physical examination were performed by health professionals. Blood specimen was collected for hematological parameters and screening tests. Laboratory results were given to participants upon their requests according to the local Ministry of Health guidelines.

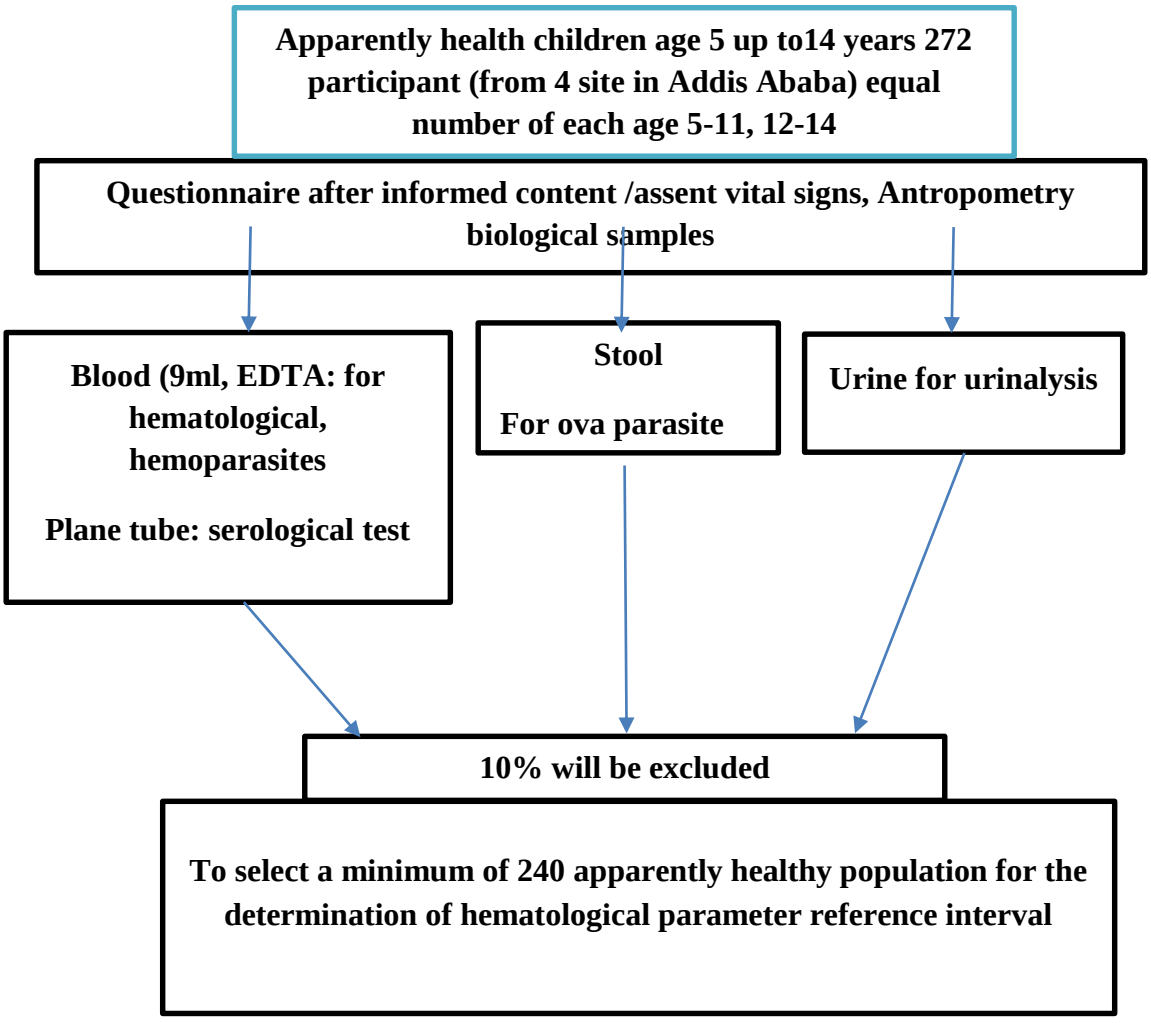

Figure 2. Data collection procedure

4.7.1. Demographic and clinical data

Socio -demographic and clinical data was collected using structured questionnaire by trained data collectors and physical examination and anthropometric measurements were carried out by clinicians.

The data collection tool had 6 parts; part I is about general information on address; part II is personal information; part III socio-demographic characteristics; part IV clinical information; part V Nutritional habit and life style; and part VI is Anthropometric measurement (detail is annexed).

4.7.2. Sample collection for laboratory analysis

Blood samples of about 9 ml were collected in EDTA vacationer and plane tubes using multi sample needle. The indicated volume was within allowable blood volume that can be collected from children 5-14 years. To minimize diurnal variation of some analyses blood samples were collected before 11:00 am.

Whole blood was used for hematological analysis and hemo parasites identification while serum samples for screening CRP. Stool sample was collected for parasitological analysis and urine for Urinalysis. Leak proof clean containers were used to collect urine and stool samples.

All samples were labeled with unique identification number (Site name plus 001 to 344). Hematological analysis was performed according to the keeping time for each test and maximum within 8 hours at Addis Ababa University teaching laboratory and EPHI. Direct stool analysis was performed on site in the respective health facilities where participants are invited while concentration at the Department of Medical Laboratory Sciences teaching laboratory. Serum and left over plasma were collected and stored at -20^0C in the respective laboratories for analysis of serological tests.

4.7.3. Laboratory analysis

A complete blood count (CBC) was performed using automated hematology analyzer Sysmex 4000i. Automated hematology analyzers enumerate white blood cells (WBC), red blood cells (RBC), hemoglobin concentration (HGB), hematocrit (HCT), platelets and their indices (PCT, MPV, PDW), absolute and relative lymphocytes, neutrophils and mid populations, and the red

cells indices (MCV, MCH, MCHC, RDW). All laboratory assays were carried out following standard operating procedures by experienced medical technologists. Serum samples were used to analyze CRP using chemistry analyzer cobas 6000.

4.8. Quality assurance and quality control

Pre-analytical variables (sample collection and processing) were considered and specimen integrity was ensured by strictly adhering to standard operating procedures.

Analytical variables (reagents, instrumentation, equipment, technique) were controlled and commercial three level controls (High, Normal, Low) were used to continuously monitor the testing system following manufacturer recommendations. Samples meeting the acceptance criteria of the laboratory were analyzed (adequate, labeled sample with no clot or hemolysis).

Post-analytical variables (reporting results) were controlled by proper documentation. Questionable results were investigated before reporting, e.g., inconsistent values (HGB does not match the HCT).

The controls are commercially prepared whole-blood products used to verify that the analyzer is functioning properly. They are available in low, normal, and high levels. Every eight hours use of all levels verifies the operation of the analyzer and ensures reliable results are obtained. The calibrators are commercially prepared whole-blood products used to calibrate the analyzer. The controls and calibrators were stored as instructed by their instructions for use.

4.9. Data analysis and interpretation

Data were cleaned, edited, checked for completeness and entered into SPSS version 26 for statistical analysis. The mean, median and standard deviation of hematological parameters were determined using descriptive statistics and comparison made with one way ANOVA. The 2.5-97.5th percentile was determined using the nonparametric method as per CLSI guide and taken as a reference interval.

4.10. Operational definition

Apparently Healthy children: children with no known illness and who pass the clinical examination and have negative CRP, Stool and Urine examination.

Reference range: the range between, and including two reference values defined by a specific percentage (usually 95%) for hematological parameters of healthy individuals; that is, RI between and including the 2.5th percentile and the 97.5th percentile.

Hematological parameters: in this study includes WBC, differential, RBC, HGB, HCT, MCV, MCH, MCHC, RDW, Platelet count, MPV, PCT, PDW,

4.11. Ethical consideration

Before starting the research work, ethical clearance was obtained from Addis Ababa University College of Health Sciences, Department of Medical Laboratory Sciences. A formal letter of cooperation was requested from Addis Ababa Health Bureau through the Federal Ministry of Health. The information sheet for participant, parents/guardian explained the general information and benefit of the study, including their right to withdraw from the study anytime. Based on this they send back the consent with their signature to express their willingness. Apart from obtaining informed consent, confidentiality of data was obtained throughout the study by locking hard copies and password protection of electronic data. Participants were communicated their result through health workers.

4.12. Dissemination of results

The findings of this study were submitted to Department of Medical Laboratory Sciences of Addis Ababa University to serve as a reference material. The findings will be communicated to physicians or any health professionals, researchers, experts and policy makers for intervention. In addition, a copy of this material will be given to Addis Ababa Health Bureau and Ministry of Health. Additional effort will also be made to present the findings on conferences to reach the medical/scientific community and publish the article on reputable Journals after the final reports.

5. Result

5.1. Socio-demographic characteristics

This study recruited 351 participants. Of them 6.2 % (n= 22) were excluded due to CRP and 2% (n=7) were excluded with post exclusion criteria which is out of range results during data analysis. Finally, the actual sample size used for final analysis was 322.

Of the 322 children, 164 were 5-11 years old and 158 were aged 12-14 years. These were included in the final statistical analysis for hematological RI estimation. From these, 159 were males and 163 were females. The mean age of the study participants was 11.12 years with range of 5–14 years (Table 2).

Table 2. Socio demographic characteristic of children in Addis Ababa, Ethiopia, 2019. n = 322

Variable	**Socio demographic Characteristic**	**Frequency**	**Percentage (%)**
Sex	Male	159	49.4
	Female	163	50.7
Age group	5 – 11	164	50.9
	12 – 14	158	49.1
Educational status(n=320)	well iterate	2	0.6
	Primary (1-8)	304	95.0
	Secondary (9-12)	14	4.4
Family educational status	< or = primary school		>or = secondary school
Mothers	54.4% (175)		33.3% (107)
Fathers	43.8% (141)		47.2% (152)
Monthly Income	<1500 24.3%(45)		10,001-20,000 3.8%(7)
	1500-5000 51.4%(95)		>20,000 1.6%(3)
	5001-10,000 18.9% (35)		

Nutritional states	Roots &Tuber	Legumes	Cereals	Vegetables	Fruits	Meat	Milk & egg	Milk products
Ones& more Than a day	121 (10.6%)	159 (50.9%)	261 (81.6%)	102 (32%)	26 (8.2%)	16 (5%)	45 (14.2%)	39 (12.2%)
Occasionally	281 (87.8%)	151 (47.2%)	55 (17.2%)	207 (64.9%)	288 (90.6%)	292 (91.2%)	233 (73.3%)	266 (83.4%)
Never	5(1.6%)	7(2.2%)	4(1.2%)	8(3.1%)	4(1.2%)	12(3.7%)	40(12.6%)	14(4.4%)

5.2. Hematological RI for children by age group

The means, standard deviations, medians and reference intervals of the various parameters of the blood count according to age groups are presented, for red blood cell (RBC) parameters were shown in (Table 3); white blood cell (WBC) parameters were given in (Table 4), and platelet counts in (Table 5).

5.2.1. Evaluation of hematological RI with in age groups

Table 3 shows the means, medians, and 95 percent reference ranges for the hematological parameters measured for 322 children in Addis Ababa Ethiopian, grouped according to age. As a result, the distributions of the RBC parameters (median RBC, HB, HCT and MCV) were statistically different by age; children aged 5-11 years had lower values than those aged 12-14 years (P<0.001). No age-specific differences were observed for MCH or MCHC.

Table 3. Mean, Median, 95% reference value with 90% CI by age group for RBC parameter of children in Addis Ababa, Ethiopia, 2019G.C. n= 322

Parameter	**Age (years)**	**Unit**	**N**	**Median**	**Mean**	Percentile with 90% CI		**P-value**
						2.5th (90% CI)	**97.5th (90% CI)**	
RBC	5-11	10^{12}/L	164	5.0	4.9	4.3(2.5-4.4)	5.5(5.5-5.6)	
	12-14		155	5.1	5.1	4.4(4.3-4.5)	5.8(5.7-5.9)	0.03*
HGB	5-11	g/dl	164	14.4	14.3	12.0(8.2-12.3)	16.0(15.8-16.2)	
	12-14		156	15.0	15.0	13.2(12.8-13.5)	16.9(16.6-17.8)	0.00*
HCT	5-11	%	158	41.4	40.9	35.4(21.1-37.0)	45.9(45.3-46.8)	
	12-14		157	43.1	43.1	37.8(37.2-38.9)	48.1(47.1-51.1)	0.00*
MCV	5-11	FL	163	82.1	82.6	74.0(72.0-76.3)	92.2(88.8-97.2)	
	12-14		152	84.0	84.4	75.3(73.6-77.3)	93.9(92.6-98.8)	0.00*
MCH	5-11	pg.	163	28.9	28.9	24.5(24.0-25.6)	31.6(30.8-31.6)	
	12-14		153	29.6	29.4	25.5(24.8-26.7)	33.0(32.2-33.8)	0.16
MCHC	5-11	g/l	164	34.3	35.0	32.9(32.9-33.4)	37.3(36.4-38.6)	
	12-14		156	34.8	34.84	32.5(32.3-33.0)	36.9(36.5-37.0)	0.93

**All p values (Mann-Whitney U test) for comparison of medians for 5-11 and 12-14 age groups.*

**RBC=Red Blood Cell; HB=Hemoglobin; HCT=Hematocrit; MCV=Mean Cell Volume; MCH=Mean Cell Hemoglobin; MCHC=Mean Cell Hemoglobin Concentration; CI=confidence interval*

WBC differential counts displayed below in table 4 shows the median, mean and 95% reference intervals with 90% confidence interval for absolute count and percentages, respectively WBC subsets. It can be concluded that the various WBC subsets values are not statistically different between 5-11 and 12-14 age groups, except that Basophil difference is marginally significant (P=0.05).

Table 4. Mean, median and 95% reference intervals with 90% CI by age group for WBC parameters of children in Addis Ababa, Ethiopia, 2019 n=322

Parameter	**Age (Years)**	**Unit**	**N**	**Median**	**Mean**	**Percentile with 90% CI**		**P –Value**
						2.5th	**97.5th**	
WBC	5-11	10^9/L	163	6.2	6.6	2.9(2.7 – 3.4)	10.8(9.8-12.3)	
	12-14		154	5.87	5.95	3.0(2.8-3.3)	9.4(9.0-10.2)	0.71
Neutrophil	5-11	10^9/L	162	2.8	2.8	0.8(0.6-0.9)	6.8(5.3-7.7)	
	12-14		155	2.71	2.86	0.9(0.8-0.9)	6.1(5.0-6.6)	0.90
Lymphocyte	5-11	10^9/L	162	2.37	2.5	1.3(1.1-1.4)	4.4(3.9-5.4)	
	12-14		153	2.28	2.41	1.3(1.2-1.5)	4.0(3.6-4.2)	0.67
Monocyte	5-11	10^9/L	164	0.47	0.51	0.2(0.2-0.3)	0.9(0.8-1.1)	
	12-14		154	0.45	0.47	0.2(0.2-0.3)	0.79(0.75-0.84)	0.47
Eosinophil	5-11	10^9/L	161	0.13	0.18	0.02(0.01-0.03)	0.80(0.48-1.21)	
	12-14		149	0.11	0.17	0.02(0.02-0.03)	0.93(0.50-1.07)	0.98
Basophil	5-11	10^9/L	164	0.02	0.32	0.01 (0.00-0.01)	0.1(0.09-0.16)	
	12-14		154	0.02	0.02	0.00(0.00-0.00)	0.07(0.06-0.08)	0.05*

WBC (White Blood Cell Count) values in parentheses are 90% confidence intervals of the lower 2.5th and upper 97.5th percentiles. P values (Mann-Whitney U test) for comparison of medians for 5-11 and12-14 Age group.

Table 5 shows the means, medians, and 95% Reference intervals with 90% confidence intervals for the lower 2.5th and upper 97.5th percentiles for platelet parameters grouped according to age. The values were not statistically different between ages.

Finally as displayed in Table 6, comparison with company provided values and other studies revealed the lower WBC limit is lower while RBC parameters higher in the current study. Of note the neutrophil count lower limit is remarkable lower compared to company values as well as from Ghana and the western populations from US and Europe (Table 6).

Table 5. Mean, median and 95% reference intervals with 90% CI of platelet parameters for children in Addis Ababa, Ethiopia, 2019. n=322

Parameter	**Age (years)**	**Unit**	**N**	**Median**	**Mean**	**Percentile with 90% RI**		**P value**
						2.5th	**97.5th**	
PLT	5-11	10^{12}/l	164	334.0	339.0	193.7(169-228)	510(432-551)	
	12-14		158	313.5	315.8	204(192-218)	467(434-554)	0.08
PDW	5-11	%	164	11.6	12.1	9.3(9.2-9.7)	15.9(15.1-16.9)	
	12-14		158	12.2	12.4	9.3(8.7-9.8)	17.1(15.4-19.0)	0.32
MPV	5-11	FL	164	10.4	10.5	8.9(8.8-9.2)	12.3(11.84-12.6)	
	12-14		158	10.6	10.6	8.9(8.5-9.2)	12.5(12.3-13.3)	0.56
PCT	5-11	%	164	0.35	0.35	0.2(0.2-0.25)	0.5 (0.45-0.56)	
	12-14		158	0.33	0.34	0.2(0.22-0.24)	0.5(0.42-2.5)	0.90

PLT values in parentheses are 90% confidence intervals of the lower 2.5th and upper 97.5th percentiles. P values (Mann-Whitney U test) for comparison of medians for 5-11 and 12-14 age group. PLT=platelet; PDW=platelet distribution width; MPV=mean platelet volume; PCT=plateletcrit.

Table 6. Comparison of current study hematological values with values from other studies in Africa and US/Europe

Parameter	Us/Europe [45]		Ghana [30]		Manufacturer RI [46]	Adult [49]		Current study	
	5 – 11	12 – 14	5 – 11	12 - 14		Male	Female	5 – 11	12 – 14
WBC x 10^9/L	4.5 – 14.5	4.5 - 13.0	4.1 – 11.9	3.7 – 9.4	3.98–10.04	3.7-9.7	3.9-11.7	2.95 – 10.89	3.05 – 9.4
RBC x 10^{12}/L	4.1 – 5.2	4.2 - 5.3	3.4 – 5.2	3.5 – 5.5	3.93 – 6.08	4.5-5.78	3.85-5.16	4.32 – 5.59	4.43 – 5.85
HGB g/dl	11.5 – 15.5	13.5 – 16.5	9.1 – 13.5	9.5 – 14	11.2 – 17.5	13.3-17.2	12.0-15.0	12.02 – 16.04	13.10 – 16.94
HCT %	35 – 45	34 – 49	27.3 – 41.5	29 – 44	34.1 – 51.0	38.9-50.9	34.8-45	35.45 – 45.90	37.65 – 48.04
MCV fl	77 – 95	78 -98	58 – 89	67 – 93	79.0 – 94.8	81.2-94.0	78.5-96.4	74.08 – 92.26	75.35 – 93.89
MCH pg	26.3 – 31.7	26.3 – 31.7	21.4 – 30.3	21 -32	25.6 – 32.2	27.1-32.5	26.4-33.2	24.52 – 31.60	25.57 – 32.99
MCHC g/dl	32.5 – 35.2	32.5 – 35.2	30.9 – 36.0	30 – 36	32.2 – 36.5	32.5-36.7	31.8-35.9	33.0 – 36.67	32.5 – 36.90
RDW %	11.4 – 13.4	12.4 – 13.4	11.5 – 17.9	11 -16	11.6 – 14.4	11.5-14.1	11.3-14.7	12.23 – 14.70	12.11 – 15.66
PLT x 10^9/L	150 – 400	150 – 400	117 – 417	113– 363	163 – 369	179-373	172-440	193.7 – 510	204.0 – 467
PDW %	11.5 – 14.0	11.5 – 14.0	12.1 – 20.5	12 – 22	9.0 – 17			9.3 – 15.98	9.3 – 17.5
MPV fl	6.6 – 9.8	7.0 – 10.0	NA	NA	9.0 – 13	6.1-8.9	6.3-9.1	8.9 – 12.7	8.9 – 12.6
PCT %	NA	NA	NA	NA	0.17 – 0.35			0.2 – 0.5	0.2 – 0.48
Neutrophil x 109/L	1.5 – 8.0	1.5 – 6.0	1.6 – 6.2	1.6 – 5.2	1.56 – 6.13	2.0-6.7	1.9-7.9	0.83 – 6.83	0.90 – 6.11
Lymphocyte x 10^9/L	1.5 – 5.0	1.5 – 4.5	1.6 – 5.8	1.4 – 4.0	1.18 – 3.74	1.1-3.3	1.3-3.6	1.38 – 4.44	1.30 – 4.04
Monocyte x 10^9/L	NA	NA	0.2 – 1.1	0.2 – 0.9	0.24 – 0.86	0.2-0.70	0.2-0.5	0.25 – 0.99	0.24 – 0.78
Eosinophil x 10^9/L	0.05 – 0.8	0.02 – 0.12	NA	NA	0.04 – 0.54	0.0-0.4	0.0-0.4	0.02 – 0.80	0.02 – 0.92
Basophil x 10^9/L	0.02 – 0.12	0.02 – 0.12	NA	NA	0.01 – 0.08	0.0-0.1	0.0-0.1	0.01 – 0.13	0.00 – 0.07

Table 7. Independent Kruskal-Wallis test to compare the age groups by hight and weight for children

Descriptive Statistics

	N	Mean	Std. Deviation
AGE GROUP	322	1.4907	.50688
Height (in cm)	322	140.361	15.4925
weight (in kg)	322	34.088	10.3383
Z score : Height (in cm)	322	.0000000	1.00000000
Z score: weight (in kg)	322	.0000000	1.00000000
Valid N (list wise)	322		

Descriptive Variables=Age group Height Weight Z height Z weight

/Statistics=Mean Std dev.

ANOVA[a]

Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	36.338	2	18.169	125.630	.000[b]
	Residual	46.134	319	.145		
	Total	82.472	321			

a. Dependent Variable: AGEGROUP

b. Predictors: (Constant), weight (in kg), Height (in cm)

: Degree of freedom.*P<0.05 by Kruskal–Wallis test age groups with height and weight.

6. Discussion

The aim of this study was to establish hematological reference intervals for children aged 5 to 14 years so as to aid interpretation of laboratory results. The study population consisted of 322 apparently healthy children who live in the selected sub cities of Addis Ababa.

Hematology reference intervals that are commonly used for children in Ethiopia like in many African countries are derived from other populations and are provided by the manufacturers of the automated hematology analyzers. Here, the present results are useful not only for diagnosis and treatment but also enrolling, follow-up evaluation and care of children in clinical trials, including for accurate detection of adverse events in children from Addis Ababa, Ethiopia However, many studies have demonstrated that CBC reference intervals differ from population to populations as has been reported by studies from Nigeria [15], Tanzania [19], Malawi [29], southwest Ethiopia [33].

The current study found significant differences between the age groups in which children in the age group 5-11 had lower RBC, HGB, HCT and MCV than those aged 12-14 years. The reason for the differences among ages may be due to hormonal variations. For example, erythropoietin release is different in response to the hormonal production In other previous reports from Tanzania ,Uganda and south west Ethiopia [19, 31, 33] there was no significant difference in the children's age groups with regard to RBC count, HGB concentration, and HCT.

This study confirms that, whereas Addis Ababa children have hematology parameter medians that are comparable with the corresponding value of the reference ranges for Caucasian populations, the HGB in the current study from the age 5-11 and 12-14 are slightly lower than the minimum levels for Caucasians. This disparity may be attributed to several factors including iron-deficiency, chronic blood loss due to hookworm infestation [47].

The red blood cell parameters for the current study population are slightly higher compared with those US/Europe [4-5] and Ghana [30]. The RBC parameters of Ethiopia are consistently higher than those of many other African countries [30-32]. This difference may be due to Altitude induced erythropoiesis and/or dietary factors could play a role in causing these variations. Addis Ababa is located at about 2400 meter above sea level and hence this finding is expected.

The effect of altitude is to reduce plasma volume, increase the HGB concentration and HCT value, and raise the number of circulating red cells with a lower MCV. These differences appear to be the result of both increased erythropoiesis which is secondary to the hypoxic stimulus and decrease in plasma volume that occurs at high altitudes [37].

The current study showed no difference between the two age groups with respect to total WBC count which is comparable with the studies done in Ghana [30], and Nigeria [15] but lower than Caucasian RI [45] with low neutrophil count. The cause of WBC and neutrophil count variability may be partly explained on the basis of diet and other extraneous influences like exclusion of CRP>4.5 and have sign and symptom, measured BP, pulse, and take clinical history. But there might be also a true biological difference [48].

In the current study, higher eosinophil and lower basophil RIs were observed than the Caucasians. Monocyte RI in the present study was slightly lower than Ghana [30], and south west Ethiopia [33] studies. In this study also had higher eosinophil count than the Caucasian populations. These observed differences may be suggestive of different factors such as environmental difference, dietary role, ethnic variation, and subclinical illnesses. The higher eosinophil count may be attributed to paste exposer of disease-related causes, Food allergy and some infection [1, 45].

The platelet values for current study were higher than those for the developed countries. Comparable findings have been observed higher than in Africa such as Ghana [30], Uganda [31] and Nigeria [15]. However, the cause of these results is unknown, although undetected illness, environmental and genetic factors have been proposed [40, 48].

7. Strength and Limitation

7.1 Strength

The strength of this study is that it is the first community based study in Addis Ababa Ethiopia children and support previous findings that regional differences exist for hematological RI. The large sample size in the study are strengths of the study. Moreover, all the laboratory procedures were done based on the SOPs by qualified personnel in an accredited facility.

7.2 Limitation

The study not included gender classification because of shortage sample size. Participants were not screened for all medical conditions which might have effect on hematological parameters, such as hepatitis B. However, the inflammatory marker CRP was measured and used to exclude individuals in addition to the other screening procedures. Sample was collected only fasting so lower age children was difficult to participate.

8. Conclusion and Recommendation

8.1. Conclusion

Hematological reference intervals established from apparently healthy children from Addis Ababa, Ethiopia (from the selected four sub city). There was difference in hematological parameters RI of children in Addis Ababa Ethiopian from other Africa countries and the Caucasian populations.

These differences should be considered when defining normal and 'abnormal' hematological values. Notably, our HGB, PCV and platelet were higher than those reported for Caucasians while WBC, and neutrophil values were lower than those reported for Caucasians.

8.2. Recommendation

- Patient management and interpretation of laboratory findings of the children should be based on the locally derived hematological values.
- We recommend conducting similar nationwide study to determine the hematological reference values of the Ethiopian children as a whole.

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http://www.pubinfo.vcu.edu/pathlabs/print menu/appendix hematology reference ranges.pdf.

10. Annex

SOP

1. SOPs for Blood Sample Collection

Prepare the participant to conscious follow the steps outlined below

- Introduce yourself to the participant, and ask to state their full name and demographic information
- Check the questioner form, all the records must be completed.
- Ask whether the participant is latex sensitivity if so use non-latex supplies where appropriate.
- Ask whether phobias or has ever fainted during previous injections or blood draws.
- If the participant is anxious or afraid, reassure the person and ask what would make them more comfortable.
- Make the participant comfortable in a supine position (if possible).
- Discuss the test to be performed and obtain verbal consent. The participant has a right to refuse a test at any time before the sampling, so it is important to ensure understood the procedure.

Patient Reassurance

- Describe procedure to the participant
- Get oral consent from the participant
- Tell the participant it is going to be slightly painful
- Gain patient's confidence
- Refuses - Never force.
- Describe the use of the study to the participant.

Assemble supplies and position patient

- Inspect all supplies for possible defect and applicable expiration dates.
- For patient safety, draw all specimens with the participant seated comfortably in an appropriately.

Each specimen must be clearly labelled with the following:

- Participant code identifiers, usually participant name

Note: labels should always be placed on the specimen bottle, tubes and cups, etc., not on the lid

Apply Tourniquet

- Tourniquet is used to increase intravascular pressure, which facilitates vein palpation and filling of the tube (s).
- Tourniquet application should not exceed one minute as localized stasis with hemo-concentration and infiltration of blood into tissue can occur.
- Wrap the tourniquet around the arm 3-4 inches (7.5-10 cm) above the puncture site.
- Ask the participant to form a fist, but avoid vigorous hand exercise.
- Collect blood form median capital (H pattern) and median (M pattern) veins because these veins are typically closer to the surface of the skin, more stationary, less painful upon needle insertion, and less likely to injure nerves if needle placement is not accurate.

Put On Gloves

- The collector must put gloves on before the veni-puncture is performed with consideration for latex sensitivity as discussed.

Cleanse vein-puncture Site

- Use a gauze pad with 70% isopropyl alcohol solution, or a commercially prepared alcohol pad.
- Cleanse the site with a circular motion from the centre to the periphery.
- Allow the area to air dry.
- If the vein-puncture proves difficult and the vein must be touched again to draw blood, the site must be cleansed again.

Vein-puncture procedure using vacutener needle

- Prepare the participant by informing him/her that the vein puncture is about to occur.

- With the bevel up, puncture the vein with the needle at angle of insertion of 30 degrees or less.
- Keeping the needle as stable as possible in the vein, slowly withdraw the desired amount of blood and ask the participant to open his/her arm.
- Release the tourniquet as soon as possible, after the blood begins to flow.
- Mix the additive tubes by inversion. Do not shake tubes.

Additional Considerations

Hemolysis

To prevent hemolysis; allow the vein-puncture site to air dry after cleansing, never draw blood through a hematoma & make sure the needle is fitted securely on a syringe to avoid frothing.

Hematoma

To prevent hematoma, the collector should make sure the needle fully penetrates the upper most wall of the vein, remove the tourniquet before removing the needle, use the major superficial veins, apply small amount of pressure to puncture site.

Materials and Supplies required for the collection, storage and shipment of the sample from the sit.

1. 70% ethanol in spray bottle or skin disinfectant alcohol wipesAlcohol resistant marker.
2. Bench top biohazard waste bag and holder.
3. Clean laboratory coats.
4. Disposable powder-free, latex or non-latex gloves.
5. EDTA, Sodium citrate and plain tube.
6. Gauze or cotton wool.
7. Lab forms/labels.
8. Vacationer.
9. Paper towels/absorbent pads.

10. Pastor Pipette.
11. Sharp disposal container for used Needle

For urine and stool collection, material, equipment and supplies

1. Urine and stool contener
2. Formalin for concentration proceder of stool
3. Microscop
4. Normal salin for direct test
5. Slid and cover slid
6. Uplicator stices
7. Urine strip
8. Glove

2. Sop for sysmex -4000i

PRINCIPLE:

The System XT-4000i is a quantitative automated hematology analyzer for in-vitro diagnostic use for determining 21 hematological parameters. Examination of the numeric and/or morphologic findings of the complete blood count are useful in diagnosis of such disease states as anemias, leukemia's, allergic reactions, viral, bacterial, and parasitic infections. The Sysmex XT-4000i analyzer directly measures the WBC, RBC, HGB, HCT, PLT, NEUT#, LYMPH#, MONO#, EO#, and BASO#. The remaining parameters are calculated or derived: MCV, MCH, MCHC, RDW-CV, RDW-SD, MPV, and differential percentages.

The Sysmex XT-4000i counts and sizes red blood cells (RBC) and platelet (PLT) using electronic resistance detection enhanced by hydrodynamic focusing. 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 SLS-hemoglobin and read photometrically. WBC count and differential are evaluated using flow cytometry with a semiconductor laser utilizing

scattered light and fluorescence to determine the differences in cell size, complexity and RNA/DNA content. The WBC differential channel classifies neutrophils (NEUT), lymphocytes (LYMPH), monocytes (MONO), eosinophils (EO), and basophils (BASO) by cellular complexity and nucleic acid content. The differential cell placement is then enhanced utilizing Adaptive Cluster Analysis.

SPECIMEN:

A. The specimen – Whole blood anticoagulated with potassium EDTA is preferred.

B. Specimen Volumes required:

1. Optimal draw is a tube drawn to capacity. The collecting tube must be filled to a minimum of one-half full for acceptable results.

2. A minimum of 1 ml whole blood is required for running specimen in the sampler or manual mode.

3. An EDTA micro-container filled above the 250ul line is adequate for testing in the manual mode.

Stored Specimen Stability:

1. If stored at 4^0c – 8^0c within 6 hours of collection, EDTA blood samples with normal results may be analysed up to 48 hours without significant loss of differential stability.

2. Sample stability at room temperature is 8 hours. Samples stored at room temperature may exhibit an increase in MCV after 24 hours. This may be minimized by refrigeration.

3. Allow refrigerated samples to come to room temperature 30 minutes and mix by hand inversion before analysis.

Sysmex Reagents

1. Four Sysmex reagents and bleach are used on the Sysmex XS-4000i.

2. All reagents are stored at room temperature and are to be used within the manufacturer's expiration date on each container.

3. Record date received and date opened and date expired on container. Record the lotnumber, expiration date and opened date on XS-4000i reagent log.

4. All reagents are azide free, and intended for in vitro diagnostic use only; do not ingest.

Reagent Abbreviation Open Expiration

Sysmex CELLPACK EPK 60 days

Sysmex STROMATOLYSER-4DL FFD 60 days

Sysmex STROMATOLYSER-4DS FFS 90 days

Sysmex SULFOLYSER SLS 60 days

DILUENTS:

A. Sysmex CELLPACK (EPK) is a whole blood diluent for use in the determination of haemoglobin and impedance counting and sizing of blood cells. Sysmex CELLPACK also forms a laminar sheath flow around the diluted sample for hydrodynamic focusing of the RBC and PLT.

   Patient Sample Processing

   1. Manual Mode – (20 uL aspirated sample volume) minimum of 500 uL in tube or 90 uL in a micro-sample container.

   a. On the IPU, click (Manual) or press (F2).

   b. Enter the specimen number (alpha or numeric characters) using the keyboard or using the handheld bar code reader.

   c. Click on CBC or CBC + Diff if this information is not being provided by the Host Computer.

d. Click (OK).

e. Attach appropriate sample tube adapter.

f. Mix the patient sample 10 times by end-to-end inversion.

g. Place sample in sample tube adapter. It is not necessary to remove the cap except when using non-pierce able micro-sample containers.

WARNING: Potential biohazard exposure when handling open patient specimens. Follow standard precautions outlined by laboratory safety guidelines.

Recommended: Wear gloves, a lab coat and safety glasses. Use plastic lined gauze when opening specimen tubes.

h. Press Start switch. (Located above the sample tube position on the Main Unit of the XT-4000i without Sampler; inside the sampler cover on the XT-4000i-1 with Sampler).

i. When Ready LED is lit green, repeat steps a – I for each additional sample.

2. Sampler Mode with Bar Codes – XS-4000i with Sampler (20 uL aspirated sample volume). A minimum of 1.0 cc of blood is required in the tube for the sampler mode.

a. Place a Sysmex rack in a rack position of the Sampler with the notch on the rack to the right.

b. Place up to 2 racks at one time (up to 20 samples).

c. Place bar coded specimens in the rack. Ensure that labels are smooth with no loose edges.

d. Attach the appropriate sample tube adapter.

e. Close the Sampler cover.

f. On the IPU, click (Sampler) or press (F3). The Sample number dialog box displays.

g. Click on the starting position for the rack and tube position in which the tubes have been placed. Press (OK)

Cobas 6000 chemistry Analyzer

Principle

The Roche/Hitachi Cobas 6000 analyzer series is a fully automated, random-access, software- controlled system for immunoassay and photometric analyses intended for qualitative and quantitative *in vitro* determinations of a wide variety of tests. The Cobas 6000 analyzer is optimized for workloads using a combination of photometric and ion selective electrode (ISE) determinations (c501 module), and electro chemi luminescence (ECL) technology in the immunoassay analysis module (e601 module). The ISE system is used in the quantitation of sodium, potassium and chloride. The photometric system can measure colorimetric or immune turbid metric reactions utilizing end point or kinetic (rate) absorbance measurements. Test ordering and execution on the Cobas 6000 and data entry in the StarLIMS host computer system may be done manually or these tasks may be executed via a barcode-based bi-directional interface. The Cobas 6000 can utilize both of these two systems simultaneously.

Questioners

1. Information sheet for children aged 12-14 years

Project Title: Determination of Hematological Reference Interval for Apparently Healthy Children in Addis Ababa, Ethiopia

Project PI: Abebaye Mekonen

Sponsor: Ministry of Science and Technology (MOST/MiNT)

Introduction:

Hello! My name is _____ and I am working with researchers with Medical Laboratory Science Department of Addis Ababa University as part of a national project which aims to establish In-House Quality Control Material and Hematological Reference Intervals for Ethiopians starting from the age 5years from various localities in the country. For the purpose of this study age group 5-14 will be included.

Purpose of the research:

The health laboratory plays an indispensable role in the health care system. It supports diagnosis (to rule in or rule out a diagnosis), monitoring of response to treatment, epidemiological surveillance, prevention as well as Research (to understand the pathophysiology of a particular disease process). Especially there is lack of local reference interval for indigenous population and local quality control materials. Therefore, the purpose of this proposed study is to establish haematological Reference Intervals for Ethiopians aged 5years up to 14 in Addis Ababa Ethiopia.

You have been chosen for this study as well your guardian/family has been asked and gave consent for your participation in the study. Therefore, I invite you to take part in this study and contribute to the establishment of indigenous reference values which are needed for providing quality laboratory service. Thus, result from this study is anticipated to improve the health status of the children at large in Ethiopia Addis Ababa.

Procedures: After agreeing that you can take part, one or more of my research staff will visit your school/house/center on a certain day and ask you/your parents some questions which will take up to 15 minutes. Your weight, height and vital signs will be measured. You will be asked to provide urine and fresh stool on a particular container provide. I will also collect 9 ml venous blood (about 1 table spoon) from you by sterile-disposable vacationer tube and needle (5ml in plane tube and 4 ml in tube containing EDTA). I will conduct laboratory examination to determine different haematological, serological and parasitological parameters.

Confidentiality:

The information obtained during the study will remain confidential. Disclosure of any of the data to third parties other than those allowed in the Informed Consent form will not be permitted. The results of the research study may be published, but participants' names or identities will not be revealed. To maintain confidentiality, the investigator will keep records in locked cabinets in a locked room at the office and the results of the tests will be coded to prevent identification of the volunteers. Access to data entered into computerized files will be permitted only for authorized personnel directly involved with the study and will be password protected. Individual-specific information may be provided to responsible local medical personnel only with your permission. Urine, stool and blood collected will not be used for other purposes. The leftover samples will be stored at the Department of Medical Laboratory Sciences of AAU in a secure place for additional tests as needed. Finally, all the biological wastes, after analysis will be safely disposed in an environmentally friendly manner.

Risks and Discomfort:

There will be minimal discomfort in giving urine and stool samples. However, there might be some minimal risk and discomfort when I take venous blood. Nevertheless, I will try to minimize the discomfort as much as possible, as the blood samples will be taken by experienced laboratory professionals.

Safety:

The venous blood sample will be collected using sterile vacationer tube/syringe and needle by experienced health professional after disinfecting the site of picture by 70% ethanol. Moreover, leftover stool, urine and blood sample (that is not stored) will be discarded following the guideline of bio-safety.

Benefits: By participating in the study, you will directly benefit by being investigated for any pathogenic organisms and other clinical and haematological abnormalities. Establishing the reference interval and developing the in-house quality control materials will be used in the future to improve the general health status of Ethiopians.

Incentives:

Any positive finding in your stool/urine/blood will be taken care of by referring you to the nearby health institution; you will get all the laboratory investigation results for free. However, I will not pay you for taking part in this study as well as your treatment costs. But, I will thank you for your participation.

Right to refuse or withdraw:

I assure you that our best care will be taken if you agree to take part in the study. You should also know that you are free to withdraw from the study at any time and that you will not be discriminated in any form of service like health.

Whom to contact:

If you have any questions, you may ask the person whom you are giving your urine, stool and blood or the principal investigator (PI) of the study or the investigators/focal persons using the following addresses:

1. Abebaye Mekonen 0910505604

Code No. _____

2. Assent form for children aged 5.14 years

I have read the information above, or it has been read to me. I have been given the opportunity to ask questions and my questions have been answered to my satisfaction. I voluntarily assent that I would participate in this study provided my parents/guardians give their consent.

To give my stool ☐

To give my urine ☐

To collect my blood ☐ and be a participant in this study and understand that I have the right to withdraw from the study at any time. ☐

Print name of participant, date and signature or thumb impression of participant

_____ ____ /____ /____ (dd/mm/yy)

_____

If illiterate:

Print name of independent literate witness, date and signature of witness (if possible, this person should be selected by the participant and should have no connection to the research team)

_____ ____/____/_____ (dd/mm/yy) _____

Phone number (parents/guardians)

Print name of researcher, date and signature of researcher

_____ _____/____/_____ (dd/mm/yy) _____

3. Information sheet for Parents/guardians

Project Title: Establishment of Selected hematological parameters Reference Intervals for Addis Ababa Ethiopians.

Project PI: Abebaye Mekonen

Organization: Ethiopian Medical Laboratory Universities, Addis Ababa, Ethiopia

Introduction:

Hello! My name is _____ and I am working research. I conducting a study to Establish Hematological Reference Intervals for Addis Ababa Ethiopians aged from 5years up to seventeen from the selected sub city in Addis Ababa Ethiopia

Purpose of the research:

The health laboratory plays an indispensable role in the health care system. It supports diagnosis (to rule in or rule out a diagnosis), monitoring of response to treatment, epidemiological surveillance, prevention as well as Research (to understand the pathophysiology of a particular disease process). Especially there is lack of local reference interval for indigenous population. Therefore, the purpose of this proposed study is to Hematological Reference Intervals for Addis Ababa Ethiopians aged 5 up to fourteen years in various sub city of Addis Ababa Ethiopia.

Your child has been chosen for this study. Therefore, invite you and your child to take part in this study and contribute to the establishment of indigenous reference values and to develop in-house quality control materials. Both are needed for providing quality laboratory service. Thus, result from this study is anticipated to improve the health status of children at large in Ethiopia.

Procedures:

After agreeing that your child can take part, one or more of our research staff will ask you some questions which will take up to 15 minutes. Your child's weight, height and vital signs will be measured. Your child will be asked to provide urine and fresh stool on a particular container we provide. We will also collect 9 ml venous blood (about 1 table spoon) from your child by sterile-disposable vacationer tube and needle (5ml in plane tube and 4 ml in tube containing EDTA).

We will conduct laboratory examination to determine different hematological, serological and parasitological parameters.

Confidentiality:

The information obtained during the study will remain confidential. Disclosure of any of the data to third parties other than those allowed in the Informed Consent form will not be permitted. The results of the research study may be published, but participants' names or identities will not be revealed. To maintain confidentiality, the investigator will keep records in locked cabinets in a locked room at the office and the results of the tests will be coded to prevent identification of the volunteers. Access to data entered into computerized files will be permitted only for authorized personnel directly involved with the study and will be password protected. Individual-specific information may be provided to responsible local medical personnel only with your permission. Urine, stool and blood collected will not be used for other purposes. The leftover samples will be stored at the Department of Medical Laboratory Sciences of AAU in a secure place for additional tests as needed. Finally, all the biological wastes, after analysis will be safely disposed in an environmentally friendly manner.

Risks and Discomfort:

There will be minimal discomfort in giving urine and stool samples. However, there might be some minimal risk and discomfort when we take venous blood. Nevertheless, we will try to minimize the discomfort as much as possible, as the blood samples will be taken by experienced laboratory professionals.

Safety:

The venous blood sample will be collected using sterile vacationer tube/syringe and needle by experienced health professional after disinfecting the site of picture by 70% ethanol. Moreover, leftover stool, urine and blood sample (that is not stored) will be discarded following the guideline of bio-safety.

Benefits:

By participating in the study, your child will directly benefit by being investigated for any pathogenic organisms and other clinical and hematological abnormalities. Establishing the reference interval will be used in the future to improve the general health status of children in Addis Ababa Ethiopians.

Incentives:

Any positive finding in your child's stool/urine/blood will be taken care of by referring him/her to the nearby health institution; you will get all the laboratory investigation results for free. However, we will not pay you/your child for taking part in this study as well as for your child's treatment costs. But, we will thank you for your participation.

Right to refuse or withdraw:

We assure you that our best care will be taken if you agree to take part in the study. You should also know that you/your child are free to withdraw from the study at any time and that you/your child will not be discriminated in any form of service like health.

Whom to contact:

If you have any questions, you may ask the person whom you are giving information or the principal investigator (PI) of the study or the investigators/focal persons using the following addresses

1. Abebaye Mekonen 09 11 696085

4. Information sheet for Parents/guardians (ለወላጆች/አሳዳጊዎች መረጃ)

የፕሮጀክቱ ርዕስ: ‘‘እድሜአቸው ከ አምስት ዓመት እስከ አስራ አራት አመት ለሆኑ የ አዲስ አበባ ህጻና በጤናማ ደም ውስጥ የሚገኙ የክሊኒካል ላቦራቶሪ ምርመራዎች መጠን ሪፈረንስ ኢንተርቫል የሚሰራ ጥናት ‘‘

የፕሮጀክቱ ተመራማሪ: አበባዬ መኮንን

መግቢያ:

ጤና ይስጥልኝ! ስሜ አበባዬ መኮንን ነው፡፡ በላቦራቶሪ ውስጥ የጥራት መመርመሪያ ንጥረ ነገር እና የጤናማ ሰው ደም ውስጥ የሚገኙ የሄማቶሎጂና ምርመራ መጠን ሪፈረንስ ኢንተርቫል እድሜአቸው አምስት ዓመት እስከ አስራ አመት ለሆኑ ህጻናት ለመስራት በ አዲስ አበባ ጥናት እያካሄድኩ ነው፡፡

የምርምር ጥናቱ አላማ:

የህክምና ላቦራቶሪ በጤናው አገልግሎት ውስጥ ከፍተኛ ሚና ይጫወታል፡፡ ምርመራን ለማረጋገጥ፣ ህሙማን ለመድሃኒቶች ምላሽ መስጠታቸውን ክትትል ለማድረግ፣ የበሽታዎችን ስርጭት ለማጥናት፣ በሽታ ለመከላከል እና ስለበሽታዎች ምንጭ ምርምር ለማድረግ አስተዋፅዎ ያደርጋል፡፡ በተለይም በአገራችን የጤናማ ሰው የላቦራቶሪ ውጤት ማወዳደሪያ ሪፈረንስ ኢንተርቫል እና በአገር ውስጥ የሚመረት የጥራት መመርመሪያ የለም፡፡ ስለሆነም የዚህ ጥናት ዓላማ በአገር ውስጥ በላቦራቶሪ የሚመረት የጥራት መመርመሪያ እና የጤናማ ህጻናት የሄማቶሎጂ ውጤት ማወዳደሪያ ሪፈረንስ ኢንተርቫል እድሜአቸው አምስትና እስከ አስራ አራት አመት ለሆኑ ህጻናት በ አዲስ አበባ መሥራት ነው፡፡

ልጅዎ ለዚህ ጥናት ተመርጧል/ጣለች፡፡ ስለዚህ በዚህ ጥናት እንድትሳተፉና በአዲስ አበባ በላቦራቶሪ ውስጥ የሚመረት የጥራት መመርመሪያ እና የጤናማ ሰው የሄማቶሎጂና ውጤት ማወዳደሪያ ሪፈረንስ ኢንተርቫል ለመስራት አስተዋፅዎ እንዲያደርጉ ተጋብዘኃል፡፡ ጥራት ያለው የላቦራቶሪ አገልግሎት ለመስጠት አስፈላጊ ነው፡፡ ስለዚህ የዚህ ጥናት ውጤት አዲስ አበባ ውስጥ የልጆችን ጤና ለማሻሻል ይረዳል፡፡

የጥናቱ አካሄድ:

በጥናቱ ልጅዎ እንዲሳተፍ ከተስማሙ 15 ደቂቃ የሚወስድ ጥያቄ እጠይቁዎታለሁ፡፡ የልጅዎ ክብደት፣ ቁመት፣ የክንድ እና የደም ግፊት ልኬት ይወሰዳል፡፡ ልጅዎ ሽንትና አይነምድር በምንሰጠው እቃ እንድትሰጠን/እንዲሰጠን እንጠይቃለን፡፡ በተጨማሪም ሚሊ ሊትር በንፁህ ቫኩቴይነር ብልቃጥ እና መርፌ እንቀዳለን (5ሚሊ ሊትር በባዶ ቲዩብ፣ 4 ሚሊ ሊትር ደም እንዳይረጋ የሚያደርግ ንጥረ ነገር ፣ኢዲቲኤ፣ ባለበት ቲዩብ)፡፡ የሄማቶሎጂ፣ ሴሮሎጂ፣ ፓራሲቶሎጂ እና ምርመራዎችን እናካሂዳለን፡፡

ሚስጥር ስለመጠበቅ:

በዚህ ጥናት የሚሰበሰብ መረጃ በሙሉ በሚስጥር ይጠበቃል፡፡ መረጃ በዚህ የስምምነት ቅፅ ከተፈቀደው ውጪ ለሶስተኛ ወገን ተላልፎ አይሰጥም፡፡ የዚህ ጥናት ውጤት ሊታተም ይችላል ነገር ግን የጥናቱ ተሳታፊዎች ስምና ማንኛውም መለያ አይገለፅም፡፡ ሚስጥራዊነቱን ለመጠበቅ የዚህ ጥናት መረጃዎችን በተቆለፈ ክፍል በተቆለፈ ካቢኔት ውስጥ ይቀመጣሉ፣ የፈቃደኛ ተሳታፊዎችን ማንነትን ላለማሳወቅ ውጤቶችም በኮድ ይቀመጣሉ፡፡ በኮምፒዩተር ውስጥ ለተቀመጡ ፋይሎች ለጥናቱ ተመራማሪ ብቻ የሚፈቀዱና በሚስጥር ቁልፍ የሚጠበቁ ይሆናል፡፡ የተሳታፊ ውጤት ለህክምና ባለሞያ ሊተላለፍ የሚችለው በተሳታፊው ፈቃድ ብቻ ነው፡፡ የተሰበሰበው ሽንት፣ ዓይነምድርና ደም ለሌላ አገልግሎት አይውልም፡፡ የሚተርፉት ናሙናዎች በአዲስ አበባ ዩኒቨርስቲ ህክምና ላቦራቶሪ ትምህርት ክፍል ደህና ቦታ ተቀምጠው ለተጨማሪ ምርመራዎች እንደ አስፈላጊታቸው ጥቅም ላይ ይውላሉ፡፡ በመጨረሻም ተሰርቶባቸው የተራረፉ የሚደፉ ናሙናዎች አካባቢን በማይበክል መልኩ በጥንቃቄ ይወገዳሉ፡፡

ጥናቱ የሚያስከትላቸው የጤና ችግሮችና አለመመቸት:

ሽንትና ዓይነምድር በመስጠት መጠነኛ አለመመቸት ሊኖር ይችላል፡፡ ሆኖም ደም በሚቀዳበት ጊዜ መጠነኛ መጎዳትና የተወሰነ አለመመቸት ሊኖር ይችላል፡፡ ይሁን እንጂ በተቻለ መጠን ልምድ ያለው የላቦራቶሪ ባለሞያ በመጠቀም አለመመቸቱን ለመቀነስ እንሞክራለን፡፡

ደህንነት:

የደም ናሙና በሚወሰድበት ጊዜ በንፁህ የደም መቅጃ በመጠቀም የሚቀዳውን ቦታ በ70% አልኮል በማፅዳት ልምድ ባለው ባለሞያ ይከናወናል፡፡ በተጨማሪም ጥቅም ላይ ከዋሉ በኋላ ለማስቀመጥ የማይሆኑ የሚደፉ የዓይነምድር፣ ሽንት እና ደም ትራፊዎች የላቦራቶሪ ደህንነት መመሪያ በመከተል ይወገዳሉ፡፡

ጥቅማ ጥቅሞች፡

በዚህ ጥናት በመሳተፍ ለበሽታ አምጪ ተህዋስያን፣ ደምና ሽንት ምርመራ በማድረግ የልጅዎን ጤንነት ሁኔታ ማወቅ ይቻላል፡፡ በአገር ውስጥ በላቦራቶሪ ውስጥ የሚመረት የጥራት መመርመሪያ እና የጤናማ ሰው የሄማቶሎጂ ውጤት ማወዳደሪያ ሪፈረንስ ኢንተርቫል እድሜአቸው ከአምስት እስከ አስራ አምስ ከዚያ በላይ ለሆኑ በአዲስ አበባ ለሚኖሩ ኢትዮጵያውያን መሰራቱ የኢትዮጵያውያንን የጤና ሁኔታ ለማሻሻል ይረዳል፡፡

በጥናቱ ለመሳተፍ ማትጊያ:

ከዓይነምድር፣ ሽንት እና ደም ምርመራ ጤናማ ያልሆነ ውጤት ከልጅዎ ከተገኘ በአቅራቢው ወደ ሚገኝ ጤና ተቋም ይላካሉ፣ የልጅዎን ላቦራቶሪ ውጤቶች በነፃ ያገኛሉ፡፡ ይሁን እንጂ በዚህ ጥናት ለመሳተፍም ሆነ ለመድሃኒት ክፍያ አይሰጥም፡፡ ስለተሳትፎዎ ግን እናመሰግናለን፡፡

ያለመሳተፍ መብት:

በዚህ ጥናት ከተሳተፉ የቻልነውን ሁሉ እንከብካቤ እናደርጋለን፡፡ በማኛውም ሰዓት እርስዎም ሆነ ልጅዎ ከጥናቱ መውጣት እንደሚቻልና ይህም እርስዎም ሆኑ ልጅዎ በሚያገኙት አገልግሎት ላይ (ለምሳሌ የጤና አገልግሎት) ምንም አይነት ልዩነት አይደረግም፡፡

ጥያቄ ካለ ለማነጋገር:

ምንም ዓይነት ጥያቄ ካለ የዓይነምድር፣ ሽንት እና የ ደም ናሙና የሰጡትን ሰው መጠየቅ ይቻላል ወይም የፕሮጀክቱ ተመራማሪን በሚከተለው አድራሻ መጠየቅ ይቻላል፡፡

1.ወ/ት አበባዩ መኮንን 09 10 505604

5. Consent form for parents/guardians (ለወላጆች/አሳዳጊዎች የስምምነት ቅፅ)

ከላይ የተገለፀውን መረጃ አንብቤአለሁ /ወይም ተነቦልኛል፡፡ ጥያቄ ለመጠየቅ ዕድል ተሰጥቶኝ ጠይቄ በሚያረካ መልኩ ተመልሶልኛል፡፡ ልጄ እንዲሳተፍ/እንድትሳተፍ ተስማምቻለሁ፡፡ ልጄ ከተስማማ/ማች በዚህ ጥናት እንድትሳተፍ/እንዲሳተፍ ፈቃደኝነቴን ገልጫለሁ፡፡

የ ዓይነምድር ናሙና ለመስጠት ☐

የሽንት ናሙና ለመስጠት ☐

ደም ለመቀዳት ☐

እና በዚህ ጥናት ተሳታፊ ለመሆን፣ በማንኛውም ሰዓት ልጄን ከጥናቱ ለማስወጣት መብት እንዳለኝም ተረድቻለሁ . ☐

የተሳታፊ ስም፣ ቀን እና ፊርማ (ወይም አሻራ) ከዚህ በታች ይፃፉ

_____ ____ /____ /____ (ቀን/ወር/ዓመተ ምህረት)

ያልተማሩ ከሆኑ;

የተማሩ ገለልተኛ እማኝ ሰው ስም፣ ቀንና ፊርማ (ከተቻለ ይህ ሰው በተሳታፊው ቢመረጥና ከተመራማሪ አባላት ግኑኝነት የሌለው ቢሆን)

_____ ____/____/_____ (dd/mm/yy) _____

ስልክ ቁጥር

የተመራማሪው ስም፣ ቀንና ፊርማ

_____ _____/____/_____ (dd/mm/yy) _____

6. Information sheet for children 5—14 years (5-14 ዓመት ለሆኑ ህፃናት መረጃ)

የፕሮጀክቱ ርዕስ፡ ‘‘እድሜአቸው ከአምስት ዓመት እስከ አስራ ሰባት ለሆኑ ኢትዬጵያውያን የጤናማ ሰው ደም ውስጥ የሚገኙ የክሊኒካል ላቦራቶሪ ምርመራዎች መጠን ሪፈረንስ ኢንተርቫል እና በላቦራቶሪ ውስጥ የጥራት መመርመሪያ ንጥረ ነገር መስራት የሚሰራ ጥናት

ተመራማሪ አበባዬ መኩንን

ጤና ይስጥልኝ! ስሜ _____ በላቦራቶሪ ውስጥ የጥራት መመርመሪያ ንጥረ ነገር እና የጤናማ ሰው ደም ውስጥ የሚገኙ የሄማቶሎጂ መጠን ሪፈረንስ ኢንተርቫል እድሜአቸው ከአምስት እስከ አስራ አራት አመት ለሆኑ ኢትዮጵያውያን ለመስራት በአገራችን በ አዲስ አበባ ጥናት እያካሄድኩ ነው፡፡

የምርምር ጥናቱ አላማ:

የህክምና ላቦራቶሪ በጤናው አገልግሎት ውስጥ ከፍተኛ ሚና ይጫወታል፡፡ ምርመራን ለማረጋገጥ፣ ህሙማን ለመድሃኒቶች ምላሽ መስጠታቸውን ክትትል ለማድረግ፣ የበሽታዎችን ስርጭት ለማጥናት፣ በሽታ ለመከላከል እና ስለበሽታዎች ምንጭ ምርምር ለማድረግ አስተዋፅዎ ያደርጋል፡፡ በተለይም በአገራችን የጤናማ ሰው የላቦራቶሪ ውጤት ማወዳደሪያ ሪፈረንስ ኢንተርቫል እና በአገር ውስጥ የሚመረት የጥራት መመርመሪያ የለም፡፡ ስለሆነም የዚህ ጥናት ዓላማ በአገር ውስጥ በላቦራቶሪ ውስጥ የሚመረት የጥራት መመርመሪያ እና የጤናማ ሰው የሄማቶሎጂና የክሊኒካል ኬሚስትሪ ውጤት ማወዳደሪያ ሪፈረንስ ኢንተርቫል እድሜአቸው ከአምስት እስከ አስራ አራት አመት ለሆኑ በአዲስ አበባ ለሚኖሩ ኢትዮጵያውያን መሥራት ነው፡፡

አንተም/አንቺም በዚህ ጥናት እንድትሳተፍ/ፊ እየጋበዝኩ ወላጆችሽ/ወላጆችህ ፈቃዳቸውን ገልፀዋል፡፡፡ ስለዚህ በዚህ ጥናት በመሳተፍ በአዲስ አበባ በላቦራቶሪ ውስጥ የሚመረት የጥራት መመርመሪያ እና የጤናማ ሰው የክሊኒካል ላቦራቶሪ ውጤት ማወዳደሪያ ሪፈረንስ ኢንተርቫል ለመስራት አስተዋፅዎ እንድታደርግ/ጊ ተጋብዘሃል/ሻል፡፡ ጥራት ያለው የላቦራቶሪ አገልግሎት ለመስጠት አስፈላጊ ናቸው፡፡ ስለዚህ የዚህ ጥናት ውጤት ኢትዮጵያ ውስጥ የአዋቂ ሰዎች ጤናን ለማሻሻል ይረዳል፡፡

የጥናቱ አካሄድ:

በጥናቱ ለመሳተፍ ከተስማማህ/ሽ የጥናቱ አባል/አባላት 15 ደቂቃ የሚወስድ ጥያቄ ይጠይቁሃል/ሻል፡፡ ክብደት፣ ቁመት፣ የክንድ እና የደም ግፊት ልኬት ይወሰዳል፡፡ ሽንትና አይነምድር በምንሰጠው እቃ እንድትሰጠን/ጭን እንጠይቃለን፡፡፣ በተጨማሪም 10 ሚሊ ሊትር (አንድ የሾርባ ማንኪያ የሚሆን) በንፁህ ቫኩቴይነር ብልቃጥ እና መርፌ እንቀዳለን (7ሚሊ ሊትር በባዶ ቲዩብ፣ 3 ሚሊ ሊትር ደም እንዳይረጋ የሚያደርግ ንጥረ ነገር ፣ኢዲቲኤ፣ ባለበት ቲዩብ)፡፡ የሄማቶሎጂ፣ ሴሮሎጂ፣ ፓራሲቶሎጂ እና የክሊኒካል ኬሚስትሪ ምርመራዎችን እናካሂዳለን፡፡

ሚስጥር ስለመጠበቅ:

በዚህ ጥናት የሚሰበሰብ መረጃ በሙሉ በሚስጥር ይጠበቃል፡፡ መረጃ በዚህ የስምምነት ቅፅ ከተፈቀደው ውጪ ለሶስተኛ ወገን ተላልፎ አይሰጥም፡፡ የዚህ ጥናት ውጤት ሊታተም ይችላል ነገር ግን የጥናቱ ተሳታፊዎች ስምና ማንኛውም መለያ አይገለፅም፡፡ ሚስጥራዊነቱን ለመጠበቅ የዚህ ጥናት አባላት መረጃዎችን በተቆለፈ ክፍል በተቆለፈ ካቢኔት ውስጥ ያስቀምጣሉ፣ የፈቃደኛ ተሳታፊዎችን ማንነትን ላለማሳወቅ ውጤቶችም በኮድ ይቀመጣሉ፡፡ በኮምፒዩተር ውስጥ ለተቀመጡ ፋይሎች ለጥናቱ ተመራማሪዎች ብቻ የሚፈቀዱና በሚስጥር ቁልፍ የሚጠበቁ ይሆናል፡፡ የተሳታፊ ውጤት ለህክምና ባለሞያ ሊተላለፍ የሚችለው በተሳታፊው ፈቃድ ብቻ ነው፡፡ የተሰበሰበው ሽንት፣ ዓይነምድርና ደም ለሌላ አገልግሎት አይውልም፡፡ የሚተርፉት ናሙናዎች በአዲስ አበባ ዩኒቨርስቲ ህክምና ላቦራቶሪ ትምህርት ክፍል ደህና ቦታ ተቀምጠው ለተጨማሪ ምርመራዎች እንደ አስፈላጊታቸው ጥቅም ላይ ይውላሉ፡፡ በመጨረሻም ተሰርቶባቸው የተራረፉ የሚደፉ ናሙናዎች አካባቢን በማይበክል መልኩ በጥንቃቄ ይወገዳሉ፡፡

ጥናቱ የሚያስከትላቸው የጤና ችግሮችና አለመመቸት:

ሽንትና ዓይነምድር በመስጠት የሚደርስ መጠነኛ አለመመቸት ሊኖር ይችላል፡፡ ሆኖም ደም በሚቀዳበት ጊዜ መጠነኛ መነዳትና የተወሰነ አለመመቸት ሊኖር ይችላል፡፡ ይሁን እንጂ በተቻለ መጠን ልምድ ያለው የላቦራቶሪ ባለሞያ በመጠቀም አለመመቸቱን ለመቀነስ እንሞክራለን፡፡

ደህንነት:

የደም ናሙና በሚወሰድበት ጊዜ በንፁህ የደም መቅጃ በመጠቀም የሚቀዳውን ቦታ በ70% አልኮል በማፅዳት ልምድ ባለው ባለሞያ ይከናወናል፡፡ በተጨማሪም ጥቅም ላይ ከዋሉ በኋላ ለማስቀመጥ የማይሆኑ የሚደፉ የዓይነምድር፣ ሽንት እና ደም ትራፊዎች የላቦራቶሪ ደህንነት መመሪያ በመከተል ይወገዳሉ፡፡

ጥቅማ ጥቅሞች፡

በዚህ ጥናት በመሳተፍ ለበሽታ አምጪ ተህዋስያን፣ ደምና ሽንት ምርመራ በማድረግ የጤንነት ሁኔታ ማወቅ ይቻላል፡፡ በአገር ውስጥ በላቦራቶሪ ውስጥ የሚመረት የጥራት መመርመሪያ እና የጤናማ ሰው የሄማቶሎጂና የክሊኒካል ኬሚስትሪ ውጤት ማመዳደሪያ ሪፈረንስ ኢንተርቫል እድሜአቸው አምስትና ከዚያ በላይ ለሆኑ በተለያየ ክልል ለሚኖሩ ኢትዮጵያውያን መሰራቱ የኢትዮጵያውያንን የጤና ሁኔታ ለማሻሻል ይረዳል፡፡

በጥናቱ ለመሳተፍ ማትጊያ:

ከዓይነምድር፣ ሽንት እና ደም ምርመራ ጤናማ ያልሆነ ውጤት ከተገኘ በአቅራቢው ወደ ሚገኝ ጤና ተቋም ትላካለህ/ትላኪያለሽ፣ የላቦራቶሪ ውጤቶቹን በነፃ ታገኛለህ/ታገኚያለሽ፡፡ ይሁን እንጂ በዚህ ጥናት ለመሳተፍም ሆነ ለመድሃኒት ክፍያ አይሰጥም፡፡ ስለተሳትፎህ/ህ ግን እናመሰግናለን፡፡

ያለመሳተፍ መብት:

በዚህ ጥናት ከተሳተፍክ/ሽ የቻልነውን ሁሉ እንከብካቤ እናደርጋለን፡፡ በማኛውም ሰዓት ከጥናቱ መውጣት እንደሚቻልና ይህም በምታገኘው/ኚው አገልግሎት ላይ (ለምሳሌ የጤና አገልግሎት) ምንም አይነት ልዩነት አይደረግም፡፡

ጥያቄ ካለ ለማነጋገር:

ምንም ዓይነት ጥያቄ ካለ የዓይነምድር፣ ሽንት እና የ ደም ናሙና የሰጠኸውን/የሰጠሽውን ሰው መጠየቅ ይቻላል ወይም የፕሮጀክቱ ዋና ተመራማሪን ወይም ተባባሪዎችና በየተቋሙ የሚገኙ ተወካዮችን በሚከተለው አድራሻ መጠየቅ ይቻላል፡፡

1. አበባየ መኮንን 09 110505604

ኮድ. _____

7. Consent form for children 5.14 years 5.14ዓመት ለሆኑ ህፃናት የስምምነት ቅፅ)

ከላይ የተገለፀውን መረጃ አንብቤአለሁ /ወይም ተነቦልኛል፡፡ ጥያቄ ለመጠየቅ ዕድል ተሰጥቶኝ ጠይቄ በሚያረካ መልኩ ተመልሶልኛል፡፡ ወላጆቼ እስከፈቀዱ ድረስ በዚህ ጥናት ለመሳተፍ ተስማምቻለሁ፡፡

የ ዓይነምድር ናሙና ለመስጠት ☐

የሽንት ናሙና ለመስጠት ☐

ደም ለመቀዳት☐ እና በዚህ ጥናት ተሳታፊ ለመሆን፣ በማንኛውም ሰዓት ከጥናቱ ለመውጣት መብት እንዳለኝም ተረድቻለሁ ☐

የተሳታፊ ስም፣ ቀን እና ፊርማ (ወይም አሻራ) ከዚህ በታች ይፃፉ

_____ ____ /____ /____ (ቀን/ወር/ዓመተ ምህረት)

ያልተማሩ ከሆኑ;

የተማሩ ገለልተኛ እማኝ ሰው ስም፣ ቀንና ፊርማ (ከተቻለ ይህ ሰው በተሳታፊው ቢመረጥና ከተመራማሪ አባላት ግኑኝነት የሌለው ቢሆን)

_____ ____/____/_____ (dd/mm/yy) _____

ስልክ ቁጥር (የወላጅ ወይም አሳዳጊ)

የተመራማሪው ስም፣ ቀንና ፊርማ

_____ _____/____/_____ (dd/mm/yy) _____

10.3. Questionnaires to be filled by health professionals

Part I. General information

Code Number_____ Region _____ Zone _____

Woreda_____ / city /_sub city _____ Kebele _____

Part II. Personal information

1. Age (in years) _____

2. Sex _____

3. Place of Birth _____

4. For how long (years) did you live in the birth place? _____

5. How long do you live in this specific area? (If different from the birth place) _____years

No.	Questions	Responses
	Part III. SOCIO-DEMOGRAPHIC INFORMATION	
6.	Educational status	1. Illiterate 2. Read and write 3. Primary (1-8) 4. Secondary (9-12)
7.	Occupation	1. Student 2. House wife 3. Government employee 4. Private employee 5. Farmer 6. Others (specify) _____
8.	Marital status	1. Single 2. Married 3. Divorced 4. Widowed 5. Not applicable (children)

9.	Religion	1. Orthodox Christian 2. Muslim 3. Protestant 4. Catholic 5. Others(Specify) _____
10.	Ethnicity	_____ If mixed, specify _____
11.	Residence	1. Rural 2. Urban
Questions 7-12 are additional questions to Students		
12.	Father's Age	_____
13.	Mother's Age	_____
14.	Father's Educational Level	1. Illiterate 2. Read and write 3. Primary (1-8) 4. Secondary (9-12) 5. College diploma/degree and above
15.	Mother's Educational Level	_____
16.	Father's Occupation	
17.	Mother's Occupation	
18.	Monthly income (in birr collected from salary, rent, and other income)	_____Birr
19.	Family Size (Number of People)	_____
20.	Source of water	1. Pipe 2. Spring water 3. Well water 4. River 5. Other sources (specify)
21.	Type of house	1. Mud 2. Cement 3. Wood 4. Bricks 5. others/specify_____
22.	Presence of or contact with Pet animals (e.g. Cat, Dog)	1. Yes 2. No
23.	Presence of domestic animals	1. Yes 2. No
	Part IV. Clinical information	
24.	Did you take any type of drug for any illness for the last three month?	1. Yes 2. No

25.	If yes to Q24, what type of drug? (more than one answer possible)	1. Anti-protozoa 2. Anti-helminthic 3. Anti-allergy 4. Birth control pills 5. Anti-bacterial 6. Anti-TB 7. Other (specify) _____
	History of common diseases	
26.	History of diabetes	1. Yes 2. No
27.	History of Hypertension	1. Yes 2. No
28.	History of Blood transfusion for the last 1 year	1. Yes 2. No
29.	Any history of blood transfusion	1. Yes 2. No
30.	History of Hospital Admission for the last 1 year	1. Yes 2. No
31.	History of Surgical procedure for the last three years?	1. Yes 2. No
32.	History of chronic gastritis	1. Yes 2. No
33.	History of Malaria for the last 6 month	1. Yes 2. No
34.	History of TB for the last two years	1. Yes 2. No
35.	History of Cancer	1. Yes 2. No
36.	History of Cardiac illness	1. Yes 2. No
37.	History of Bleeding disorders	1. Yes 2. No
38.	History of allergy	1. Yes 2. No
39.	History of Wheezing	1. Yes 2. No

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: **Abebaye Mekonen (B.Sc.)**

Signature: _____

Date of submission: _____

This thesis has been submitted with our approval as advisors.

Advisor: **Aster Tsegaye (MSc, PhD)**

Signature: _____

Date: _____

Place: Addis Ababa, Ethiopia.

Advisor: **Fekadu Urgessa (MSc, PhD candidate)**

Signature: _____

Date: _____

Place: Addis Ababa, Ethiopia.