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Establishment of community based hematological reference intervals among apparently healthy adults (18-60 years) in Mekelle, Tigrai, Northern Ethiopia from December 2018-May 2019: a cross sectional study

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This is to certify that the thesis prepared by Gebreyohannes Teklehaimanot Gebru, entitled: **Establishment of community based hematological reference intervals among apparently healthy adults (18-60 years) in Mekelle, Tigrai, Northern Ethiopia from December 2018-May 2019: a cross sectional study** 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

BMI	Body mass index
CAR	Central Africa Republic
CI	Confidence interval
CLSI	Clinical Laboratory and Standards Institute
EDTA	Ethylene Diamine tetra acetic acid
Hct	Hematocrit
Hgb	Hemoglobin
Lym	Lymphocyte
MCH	Mean corpuscular hemoglobin
MCHC	Mean corpuscular hemoglobin concentration
MCV	Mean corpuscular volume
MPV	Mean platelet volume
Neut	Neutrophil
PDW	Platelet distribution width
Plt	Platelet
PPS	Probability proportional to size
QC	Quality control
RBC	Red blood cells
RDW	Red blood cell distribution width
RI	Reference intervals

SOP	Standard Operating Procedure
THRI	Tigrai health research institute
WBC	White blood cells
WHO	World health organization

Abstract

Background: the medical laboratory service is a key component of the overall health system. The service provides useful laboratory data to prevent, control, treat and follow up for patients. Locally derived reference interval (RI) is recommended to interpret laboratory data because there are various physiological and environmental factors which affect it. There was no reference interval established for hematological parameters in Mekelle, Tigrai, Northern Ethiopia.

Objective: Establishment of community based hematological reference intervals among apparently healthy adults (18-60 years) in Mekelle, Tigrai, Northern Ethiopia from December 2018-May 2019: a cross sectional study.

Method: a cross-sectional study was employed in 344 apparently healthy adult (18-60) individuals who live at least 5 years in Mekelle city, Tigrai, northern Ethiopia from December 2018-2019. About 4ml whole blood, stool and urine samples were collected. Hematological parameters were analyzed by Sysmex Kx-21 at Wukro hospital. Peripheral blood morphology and malarial also were screened. The urine analysis, stool wet mount and Kato Katz were examined at collection sites and the formol-ether concentration was examined at the Tigrai health research institute. Data were entered and analyzed using SPSS version 20. The 2.5^{th} and 97.5^{th} percentiles were calculated using non-parametric methods to determine 95% RI.

Result: The established reference interval for hematological parameters were White blood cell: 3-10x10^9/L; lymphocyte percentage :19.6-57.6%; neutrophil percentage :24.91-70.3% for both sexes ($p>0.005$); Red blood cell parameters were ($p<0.001$): 4.25-5.46 versus 4.7 -6.09 x 10^{12} /L, hemoglobin :12.4-15.5 versus 13.9-17.85 g/dl; hematocrit: 38-48 versus 41.6-53.2 % for males and females respectively, but platelet was higher in females than males 158.3 -399.5 versus 142-345.1 x 10^9 /L.

Conclusion: The established hematological reference interval for Mekelle city was different from other reported studies. So, this finding is important to diagnosis, treatment and follows up of the clients of the Mekelle, Tigrai, Northern Ethiopia. There was statistically significant difference based on gender difference on red blood cell, hemoglobin, hematocrit, platelet and mixed percentage.

Keywords: Apparently healthy adults, CBC, Hematology, Reference interval, Ethiopia

1. Introduction

1.1 Backgrounds

Hematological parameters are the most frequently requested tests in the health care practice worldwide. It provides a large amount of vital clinical information rapidly and therefore is integral to modern medical practice, required on a 24/7 basis. It has evolved from methods that derived cell counts from manual microscopy and hemoglobin estimation by comparison of a solution of the patient's blood to a depth of color index, through automated cell counts. It is hard to underestimate the importance of clinical laboratory test results(1). Nearly 70% of physicians' medical decisions are based on information provided by laboratory reports (2).

In clinical practice, before physiological assessments, medical diagnosis and management decisions are made, patient's laboratory results are compared with the corresponding RIs, which are bounded by a pair of reference limit (3, 4). By interpreting the results, in evaluating the state of health of individuals and populations, in identifying people at risk for disease, in assessing immune status, disease progression and treatment responses (5).

Reference intervals (RIs) are also popularly known as reference ranges, normal values, normal ranges, biological reference intervals and expected values (3). However, using the term normal may not be appropriate as not everyone outside the interval is abnormal, and people who have a particular condition may still fall within this interval (6).

Reference interval as defined it is an interval that, when applied to the population serviced by the laboratory correctly includes most of the subjects with characteristics similar to the reference group and excludes the others and also defined as the interval between which 95% of values of a reference population fall into, in such a way that 2.5% of the time a value will be less than the lower limit of this interval, and 2.5% of the time it will be larger than the upper limit of this interval (7, 8).

Hematological reference values estimated from apparently healthy subjects in a population are essential for accurate interpretation of hematological test results for that population. This is because there are various physiological and environmental factors such as sex, age, and body build, ethnicity , altitude, pregnancy, genetic , nutritional, and economic factors that affect the

hematological values (9-11). Other variables to be considered in establishing reference values are the technique, timing of collection, storage of specimens (9). Moreover, they vary from laboratory to laboratory due to differences among laboratories in clinical service needs, analytic platforms, set criteria to define populations of healthy individuals, analytic imprecisions made when RIs were determined, subject's posture when the sample is taken, and physical activity of individuals (12). So, locally-derived hematological reference ranges are recommended for proper patient management and interpretation of results (7).

1.2 Statement of the Problem

The wealth of information provided by multiparameter analysis can notably suggest specific diagnoses when compared against RIs and can lead to the discovery of a hematological disease in a fortuitous and timely manner so that appropriate clinical management can be instigated (13).

An RI is intended to inform the clinical care provider that laboratory values within the interval indicate a no diseased condition. Because many diseases are asymptomatic, it becomes difficult to qualify people for a no diseased condition, thus biasing the selection of reference individuals. Furthermore, information on the full complement of disease conditions that influence a laboratory test may be unknown. Thus, RIs may be influenced by inappropriately selected reference populations (14).

In the absence of locally derived reference intervals, clinicians and researchers have to use reference values of western population's, thus it is important to establish local hematological reference intervals for appropriate diagnosis, treatment, and follow up of clients. The reference intervals that are currently used in Ethiopia are adopted from textbooks that refer mainly to Caucasian subjects which are different from our country (9, 15-18).

Despite the reports by previous studies in Ethiopia that Hematological RIs determined in different parts of Ethiopia are different from those currently in use in the country, adult hematological reference ranges have not been previously established in Mekelle city, Tigrai, Ethiopia. Western reference ranges documented in textbooks and from the instrument reference intervals have been adopted for interpretation of results for our patients. This study, therefore, was designed to establish hematological reference intervals in apparently healthy males and females' adults.

1.3 Significance of the study

The significant difference in the reference intervals of hematological parameters among different countries and population groups within the same country may increase the risk of either un-necessary additional investigations or failure to detect underlying disease or mismanagement of patients.

Patients will get better service as their result will be interpreted based on the locally established value; physicians will have better tool in their patient management process and medical laboratory professionals will have confidence especially flagged result.

Thus, the manufacturers' reference intervals, which were predominantly established for developed populations, may not account for variations due to race, sex, age, altitude, diet, and lifestyle. Therefore, there is an urgent need to establish accurate hematological reference intervals for Mekelle city, Tigrai, Ethiopia.

Therefore, the finding of the present study will:

- ✓ Provide reliable hematological reference intervals for health authorities to appropriately diagnosis, treat, and follow up of their patients/clients
- ✓ Encourage other researchers to conduct further researches in all around Tigrai regional state and serve as reference for such researchers.

2. Literature review

Laboratory test results are commonly compared to a reference interval before caregivers make physiological assessments, medical diagnoses, or management decisions(19). The importance of reference intervals is underscored by US regulation of the Clinical Laboratory Improvement Amendments of 1988 which require that laboratories to introduce an unmodified, US Food and Drug Administration and Centers for Medicare and Medicaid Services (CMS) Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services. The guideline indicates that a laboratory must evaluate an appropriate number of specimens to verify the manufacturer's claims for normal values or, as applicable, the published reference ranges (20).

CLSI recommends that each laboratory establish RIs from the local population (21) but, most African countries including Ethiopia use western population-derived laboratory RIs for clinical diagnosis and research activities. Studies were conducted to evaluate and establish locally derived RIs in several African countries (9, 17, 22).

A cross-sectional study was conducted in mainland France consisting of 32 919 participants aged 16–69 years. Also, 339 participants aged 70–79 years were analyzed, giving a total of 33 258 subjects. For hemoglobin concentration (Hgb), in the age group 16–69 years, the mean value is 15.0 g/dL (13.4–16.7 g/L) or men and 13.4 g/dL (11.7–15.0 g/dL) for women. For the mean cell volume (MCV), the mean value is 87.3 fl in men and 87.5(78.4–95.3) in women. For the mean cell hemoglobin concentration (MCHC), the mean value is 34.3 g/dL for men (324–363) and 33.8g/dL (319–358) for women. For the mean corpuscular hemoglobin (MCH), the mean value is 30.0 pg/cell (27.2–32.8) in men and 29.7 (26.1–32.5) in women. For the platelet (Plt) count, mean values in women are higher than those in men 269×10^9/L (171–397) men and 394×10^9/L (186–440) in women. The mean value of white blood cells (WBC) is 6.6×10^9/L in men and 6.6×10^9/L in women. For neutrophils (Neut), the mean value is 54.5% in men and 56% in women. For lymphocytes (Lym), the mean value is 34.8% in men and 33.3% in women. For monocytes (mono), the value is 6.5% in men and 5.8% in women. Those results were similar to other textbooks which were before as reference book (1).

A cross-sectional study was conducted in China involving 1,749 healthy people, 927 males, and 822 females, aged 18 – 60. The range of WBC was (3.97 - 9.15) x 10^9/L in males and (3.69 - 9.16) x 10^9/L in females. The range of RBC was (4.09 - 5.74) x 10^{12}/L in males and (3.68 - 5.13)

x 10^{12}/L in females. The range Hgb was 13.1 – 17.2g/dL in males and 11.3 – 15.1 g/dL in females. The range of MCH was 27.8 - 33.8 pg in males and 26.9 - 33.3 pg in females. The range of MCHC was 26.3 – 37.5 g/L in males and 27.8 – 37.2 g/dL in females. The range of MCV was 83.9 - 99.1 fl in males and 82.6 - 99.1 fl in females. The range of hematocrit (Hct) was 38.0% - 50.8% in males and 33.5% - 45.0% in females. The WBC, RBC, and Hgb in the females were lower than those in the males. The lower limits of the RBC, Hgb, and Hct parameters decreased slightly with age in male subjects. This decrease could be due to the gradual loss of androgens, which stimulate the increased production of erythrocytes. In contrast, RBC, Hgb, and Hct values increased slightly with age in females, consistent with the lower levels of these parameters before menopause and higher levels after menopause(23). A similar study was conducted at in Erzurum area in Turkey at moderate altitude (1869 m above sea level) in apparently healthy adults consisting of 929 females and 1204 males aged from17-95. The mean value result findings were RBC x10^{12}/L for men 5.12 and female 4.64, Hgb in g/dL for men 15.4 and women 13.6, Hct in % men 45.0 and women 40.0, WBC x10^{9}/L for men 7.8 and women 7.46, Plt x10^{9}/L for men 235 and women 253. Hematological values in this study were similar to those reported in the previous studies carried out with those living below 1869m (24).

Hematological tests were carried out on 528 blood samples from healthy male donors from eastern India. The results were WBC 4.42 – 11.10 (x10^{9}/L), RBC 3.88 – 5.71 (x10^{12}/L), Hgb 11.00 – 16.38 (g/dL), Hct 32.51 – 47.50 (%), MCV 72.32 – 96.70 (fl), MCH 23 – 34(pg) MCHC 30.02 – 37.25 (g/dL), Plt 73.35 – 273.48 (x10^{9}/L). The authors stated that platelet count was less than the other studies and this may be due to the readings given by the auto analyzers may not be sometimes reliable. Hence, it need to be confirmed by manual counting method and smear review (25).

A project was carried out on 2,040 healthy individuals with ages ranging 17 to 28 years from at Aljouf region of Saudi Arabia. The mean platelet results of male (252.1 x10^{9} /L) were less than females (294.7 X10^{9} /L) of other studies. This may be as a result of the differences in hormone types and concentrations in the different sexes and the consequence of Thrombopoietin release in response to regular menstruation cross-stimulating thrombopoiesis. The main cause for these lower values is still unknown and therefore further research is essential. However, other studies

documented that these lower values might be due to the diet, genetic factors or other environmental factors(26).

A cross-sectional study was conducted in different African countries aged from 18-65 among 396 apparently healthy individuals. The result was Hgb (g/dl) for males 13.75-15.05 and for females 11.8-13.2, RBC x 101^{12}/l for males 4.64-5.24 and for females 4.03-4.48, Hct(%) for males 39.5-44.5 and for females 35-39, MCV (fl) for male 83.75-89.25 and females 80.25-86.75, MCHC(g/dl) for males 33.2-34.6 and for females 32.45-33.95, MCH (pg) for males 29.95-31.25 and for females 29-30.8, platelet ($x10^9$/l) for males 174-254 and for females 210.5-277.5, WBC (10^9/l) for males 4.15-5.85 and for females 4.55-6.45. The mean value of Neut, Lym, mixed for males was 48.2, 41, 10.8 and females 50.2%, 43%, 6.8% respectively (27).

A total of 213 healthy individuals aged between 18-59 years were recruited in a cross-sectional study in Mali. The median WBC ($x10^9$ /L) was 3.08-11.13 for men and 3.80-12.50 for women but the difference was not statistically significant. Hgb (g/dl) for males was 12.4-17.6 and 12.0-14.9 for females. For RBC ($x10^{12}$ /L) it was 4.16-6.23 for men and 3.88-5.75 for women, Hct (%) 33.2-54.6 for males and 26.8-52.5 for females. Plt ($x10^9$ /L) count was 133-460 for males and 151-532 for females. The Lym count for female 1.4-4.6 and for males 1.2-8.8, Neut count for females is 1.2-7.4 and 1.0-4.4 for males (28).

A similar cross-sectional study was conducted in Togo involving a total of 2571 voluntary blood donors. Males had higher median RBC (5.0×10^{12} /L versus 4.5×10^{12}/L), hemoglobin (15.1 g/dL versus 13.0 g/dL), hematocrit (42.8% versus 38.1%), MCV (85 fl versus 84 fl), and MCH (29.7 pg. versus 29.3 pg) than females. The medians of MCHC were 35.1 g/dL in both males and females. No gender difference was noticed for WBC parameters. The authors stated that the total WBC and neutrophil count of black peoples are lower than the white peoples. The hypothesis of an excess of marginated neutrophils pool is often proposed but a recent study did not confirm it. The platelet count in males was 236×10^9 /l and 247×10^9 /L in females (29).

A cross-sectional study was conducted involving 15840 adult volunteers aged 18 to 50 years old from Northwest of Morocco in 2016. The complete blood count was measured by the Sysmex KX21N® analyzer. The respective reference interval for men and women were: RBC ($x10^{12}$ /L) count 4.37-5.96 versus 3.86-5.20, HGB (g/dL) 13-17.1 versus 11-14.8, Hct 38.3-50% versus

33.5-43.9 %, MCV 77.4-94.2 fl versus 75.1-94.7 fl, MCH 5.2-32.3 pg versus 29.2 24-32.3 pg and MCHC 31.7-36 g/dL versus 31.2-36 g/dL. WBC 4.1-10.8×10^9 /L and 4.1-10.7×10^9 /L, neutrophil (Neut), was 57.3% and 58.7, Lym was 26.2% in men and women 28.1%. For mixed cells, the median value was for men 15.1 and 15.4% for women. For the platelet(x10^9/L), 145-338 for men and 150-378 for women. The low Hgb of Morocco than the Caucasian population may be due to iron deficiency and the sex difference in RBCs parameters are due to the difference in physiological changes and iron deficiencies in a woman during pregnancy and menstruation, or, on the other hand, hormonal influences which is more prevalent in men (30).

A total of 691 adults aged between 18- and 59-years who were residents in the Kintampo North Municipality and South District in the central part of Ghana were enrolled in a cross-sectional study. WBC (x 10^9 /L) 5.5 males and 5.3 females, Lym 41% males and 42.3 females, monocyte 9.5% males and 8.4% females , RBC(x 10^{12} /L) 4.84 males and 4.32 females, Hgb 12.3 g/dl (males) and 12.5 g/dl (females); Hct 42.2% (males) and 36.9% (females); MCV 88fl (males) and 86fl (females); MCH 29.1pg (males) and 28.4 pg (females); MCHC 33.1 for both males and females; platelet 208 x10^9/liter (males) and 224x10^9/liter (females) (16).

Cross-sectional study was conducted in 2015 in Asmara (Eritrea) on 600 volunteers ages ranging between 18 and 49 years. The city is located at an altitude of 2230 m above sea level. The results were WBC (x10^9 /L) 3.7–9.3 versus 3.3–8.9, Lym 22–59.9 % versus 22.3–58.2%, granulocyte 31.7–73.6 % versus 33.5–70.5 %, platelet (x10^9/L) 128.4–318.4 versus 145.4–351.6, RBC (x10^{12} /L) 4.2–6.07 and 4.0–5.7 for males and females respectively. There was a gender-based difference in the RIs for specific RBC parameters including RBC count, Hgb, Hct and RBC indices like MCH and MCHC. Historically, the observed gender differences have been attributed to a range of factors including menstruation, hormonal influences of androgen, estrogens, and testosterone on erythropoiesis, and the relatively high prevalence of iron deficiency anemia in women. The RBC, Hgb, and Hct were high from other studies conducted in Africa due to high altitude (18).

The first comprehensive hematological interval determination in Ethiopia was carried out back in 1999 in a study which involves 485 healthy HIV negative adults who were participating in a long-term cohort study on the progression of human immunodeficiency virus type 1 (HIV-1) infection by the Ethio-Nethrland AIDS Research Project. Mean values were as follows: WBC (x

10^9 /L) 5.9 (both genders), RBC (x 10^{12} /L) 5.0 for males and 4.5 for females, Hgb (g/dl) 16.1 for male and for 14.4 female, Hct 48.2% for male and 42.1% for female, platelets (x 10^9 /L) 203 for males and 193 for females. The Hgb was high as compared to other African population possibly due to high altitude induced erythropoiesis and / diet factors. The 95% RIs were as follows: WBC both sexes 3.0–10.2 x10^9/L, RBC (x10^{12}/L) 4.3–5.9 (male) versus 3.7–5.2 (female), Hemoglobin in gm/dL 13.9–18.3 (male) 12.2–16.6 (females), Hematocrit (%) 41.6–55.1 (males) 35.3–48.8 (females), Platelet 98–337 x10^9/L (both sexes), Granulocytes 17–59%, Monocytes 3–10%, Lymphocytes 31–78% (for both male and female). The study concluded that the WBC and platelet values of healthy HIV-negative participants are lower than the adopted reference values in Ethiopia (9).

A cross-sectional study was conducted in Amhara Regional State, Ethiopia with a total of 1040 blood donors (aged from 18-61). The combined 95th percentiles for both genders were as follows: 3–11.2 10^9/L for WBC, 27.2–71.9% for Neut, 19.8–57.4 % Lym, 5.2–26.4 % for mixed cells, 90–399 10^9/L for platelet, 81–100 fl for MCV, 25.3–34.6 pg for MCH,28.8– 36.9% for MCHC, 13.2 (11.6–15.4. Hgb for males and females was 12–18.9 and 10.7–17.5respectively. The Hgb concentration was lower than other studies of Africa and western textbooks but higher in other studies conducted in Ethiopia. The difference might be due to geographical variation, environment, diet, ethnic background, method and instrument used for analysis. The neutrophil and Lym of the upper limits are higher than the other African and lower than the Caucasian population. These variations are usually associated with well-known differences in altitude, environment, diet and ethnic background (15).

A community-based cross-sectional study was conducted involving 240 adult individuals from Northwest Ethiopia. The hematological RI was as follows: WBC x10^9/L, 3.2–8.8, Lym (%) 22–55, Neut (%) 36–69, Mixed (%) 6–13, Plt x10^9/L 128–432, MCV 85–100 for both sexes. For RBC (x10^{12} /L) the intervals were 3.45–6.25 and 3.53–6.93, Hgb (g/dl) 11.0–16.7 and 11.5–18.0, Hct (%) 32.1–56.6 and 36.2–58.6 for females and males respectively (31).

All in all, as outlined above, hematological intervals vary greatly among populations. Despite this, to the best of my knowledge there is no published RI for Mekelle city residents, a gap this study is trying to address.

3. Objectives

3.1 General objective

Establishment of community based hematological reference intervals among apparently healthy adults (18-60 years) in Mekelle, Tigrai, Northern Ethiopia from December 2018-May 2019.

3.2 Specific objectives:

- To establish sex specific hematological reference interval among adult apparently healthy individuals
- To compare the established hematological reference ranges by sex

4. Materials and Methods

4.1 Study area

This study was carried out at Mekelle city, which is located around 780 kilometers from the Ethiopian capital Addis Ababa, with an elevation of 2,254 meters above sea level. Administratively, Mekelle is considered a Special Zone, which is divided into seven sub-cities which are Hawelti, Kedamay weyane, Ayder, Quiha, Hadnet, Semien and Adi haki (32). The study was conducted in Hawelti, Semien and Ayder sub-cities. According to the central statistical agency (CSA), the total population of Mekelle is 310,436 people (33) . The sample was collected from apparently healthy individuals and was analyzed at the Tigrai health research institute and Wukro hospital. The institute is found in Hawelti sub-City and Wukro hospital is found 45 km far from Mekelle but identified for hematological analysis due to willingness of the hospital (32).

4.2 Study design and period

A cross-sectional study design was employed to determine the hematological reference intervals in Mekelle city, Tigrai, Northern Ethiopia from December 2018- May 2019.

4.3. Population

4.3.1. Source population

The source populations for this study were all adult individuals who live in the Mekelle city, Tigrai, Northern Ethiopia.

4.3.2. Study population

The study populations were volunteering individuals aged from 18-60 years and who live in Mekelle city, Tigrai, northern Ethiopia that fulfills the eligibility criteria.

4.4. Inclusion and Exclusion criteria

4.4.1Inclusion criteria

Apparently healthy individuals aged from 18-60 years, both sexes who lived at least for 5 years in the study area were included in the study**.**

4.4.2. Exclusion criteria for reference interval determination

- Individuals with any acute and chronic illnesses
- Individuals taking pharmacologically active substances: all prescription drugs, and have a habit of smoking

- Individuals who have Hemoparasites and intestinal parasite
- Individuals who donated blood within the previous 3 months
- Individuals who received blood transfusion within the previous 1 year
- Pregnant women

4.5. Study variables

4.5.1. Dependent variables

- Hematological parameters;
  - ✓ RBC parameters
  - ✓ WBC parameters
  - ✓ Platelet parameter

4.5.2. Independent variables

- ✓ Sex

4.6. Sample size determination and sampling technique

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. sex, age range) (21). The dominant form of partitioning applied in clinical laboratory medicine is by social consensus, usually adult age individuals begin from 18 age to the age of retirement which is 60 years (34).

According to previous studies in other African countries, in such studies about 30% of apparently healthy population (35) do not qualify for reference interval determination for various reasons when tested for the common viral infections and syphilis. Considering a 30% exclusion from data analysis, to reach the CLSI recommended total sample size of 240 for the reference interval determination, a total of 344 individuals was enrolled (i.e., x-30 % x =104 to be excluded during data analysis; 344-104= 240); thus, giving a total minimum sample size of 344.

Thus, 344 participants were recruited from Mekelle city, Tigrai, Ethiopia. The study participants were selected using multistage by considering sub-city as a sampling frame for the city and then households the final selection units. All individuals in the household fulfilling the eligibility criteria and willing to participate were included.

4.6.2. Sampling technique

Three sub-cities from the total seven sub-cities in Mekelle city (Ayder, Hawelti, and Semien) through a simple random sampling method and then the total sample (344) was categorized based on the relative household size in each sub-city. The total household numbers of the 3 sub-cities were 68,477 (18266, 33319 and 16892 in Semen, Hawelti and Ayder respectively). The total sample size was distributed to each sub-city by probability proportional to size (PPS) method based on house hold. Thus, 92, 167 and 85 individuals were recruited from Semen, Hawelti, and Ayder house hold respectively. In each sub-cites, there were 5 Kebelles, and then we were also recruiting from each Kebelle based on the size of household. After that, data and specimen were collected from each Kebelle based on systematic sampling technique (K^{th}). If more than participants were present in one house hold, random sampling technique was used to select the one participant. The table below shows the number of individuals that has been recruited from each Kebelles.

Table 1 Selected sub cities with household information

Sub-cities	Kebelle	Total number of household	Total number of samples recruited	Age of 18-60 male	Age of 18-60 female
Semen	Mesfin	4615	24	12	12
	Dedebit	2870	14	7	7
	Yekatit	3216	16	8	8
	Industry	2451	12	6	6
	Meles	5114	26	13	13
	Total	18266	92	46	46
Hawelti	Selam	3397	18	9	9
	Hayelom	4614	24	12	12
	Adi shimduhun	8793	44	22	22
	Momona	7731	38	19	19
	Hidase	8784	44	22	22
	Total	33319	168	84	84

Ayder	Sertse	3483	16	8	8
	Ginbot 20	3487	18	9	9
	Marta	3637	20	10	10
	Adi ha	5046	24	12	12
	Maryam Dihan	1239	6	3	3
	Total	16892	84	42	42

Note: Source for number of households is from municipal of Mekelle city, 2018

4.7. Measurement and Data collection

The study aims, risks, benefits of study participants and right to withdraw from the study at any time were explained by the study team. From those consenting participants, demographic information and a brief medical history were collected. Then physical examination was performed by health professionals. The nurse professionals were trained by a physician related to the research. A blood specimen was collected for hematological analysis, peripheral blood morphology and malaria. Stool and urine analyses were also done to screen the participants. Laboratory results were given to participants upon their requests and individuals with positive findings were linked to health facilities.

4.7.1. Demographic and clinical data

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

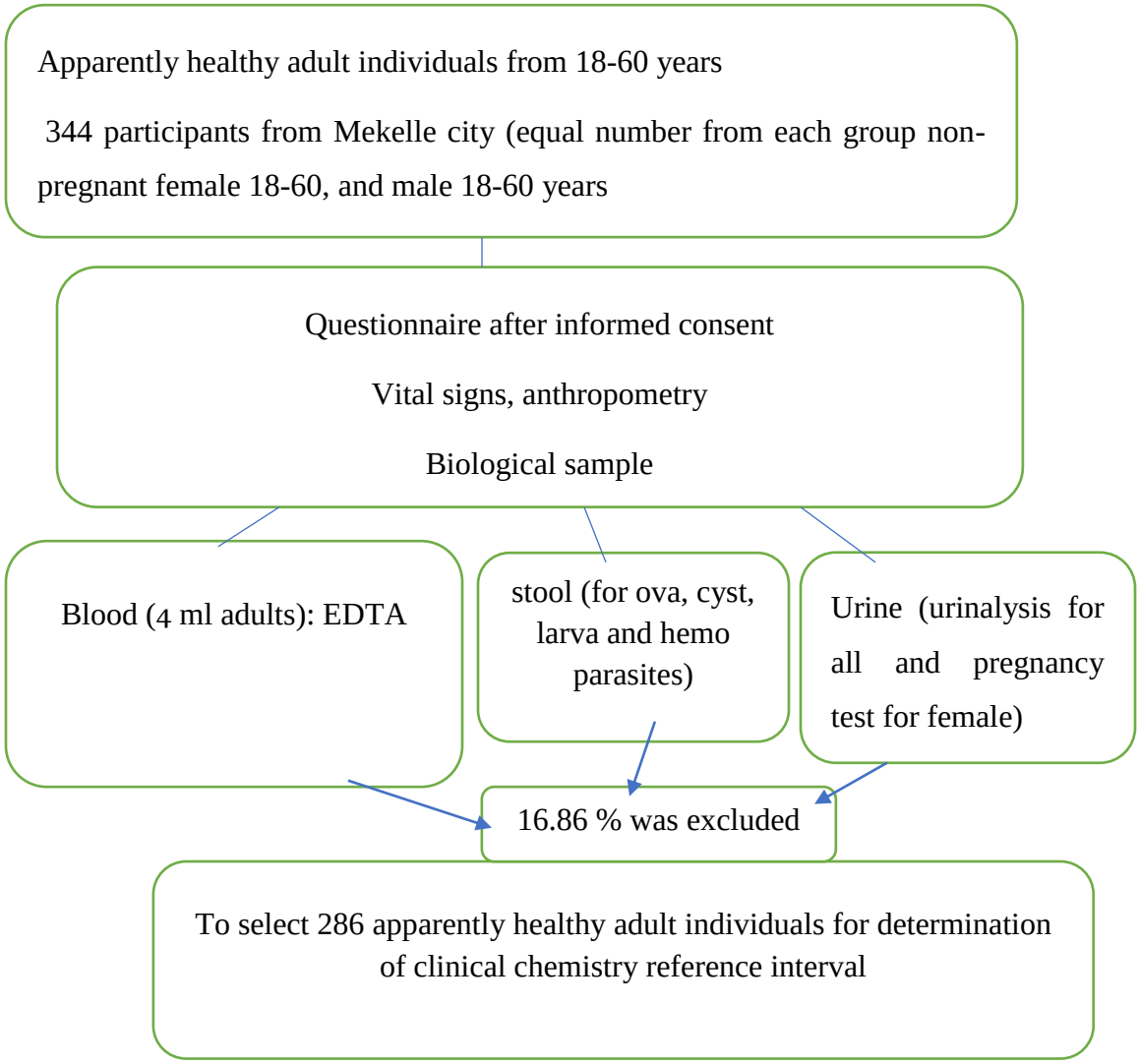

Figure 1. Data collection procedure

4.7.2. Sample collection for laboratory analysis

Blood samples of about 4 ml from adults were collected in EDTA vacutainer using a multi-sample needle from 8 am -11 am. Whole blood was used for hematological analysis and hem-parasites identification. A stool sample was collected for parasitological analysis and urine for Urinalysis and determining pregnancy status. Leak-proof clean containers were used to collect urine and stool samples.

All samples were labeled with a unique identification number and site of blood collection place (001 to 344). The hematological analysis was performed according to the keeping time for each test and maximum within 8 hours in Wukro hospital and the Tigrai health research institute.

Stool wet mount and Kato Katz was performed on site in the respective health facilities where participants are invited to. The concentration stool analysis was done at THRI.

4.7.3. Laboratory testing and analysis

A complete blood count (CBC) was analyzed using Sysmex Kx-21N automated hematology analyzer (Sysmex Corporation Kobe, Japan). Automated hematology analyzers enumerate white blood cells (WBC), red blood cells (RBC), hemoglobin concentration (Hgb), hematocrit (Hct), platelets and their indices (Pct, MPV), absolute and relative lymphocytes, neutrophils and mid populations, and the red cells indices (MCV, MCH, MCHC).

A peripheral blood smear was done for peripheral blood morphology to check the morphology of red blood cells, white blood cells, and platelets. All laboratory assays were carried out following standard operating procedures by experienced medical laboratory technologists.

Principle of the SYMESX KX-21N

For WBC and RBC electrical impendence (DC detection method), and for Hgb is Non-cyanide hemoglobin analysis method.

4.8 Data quality control

The questionnaire was pre-tested with 18(5%) individuals, other than study subjects at Wukro. This pre-testing of a research instrument was entailed a critical examination of each question as to its clarity, understanding, wording, and meaning as understood by potential respondents to remove possible problems with the question. Besides, adequate training was given to the data collectors before the collection period. Participants were also be adequately oriented on how to collect specimens. The quality of laboratory analysis was maintained by following standard operating procedures of the pre-analytical, analytical, and post-analytical stages, which involves the following steps.

Pre-analytical stage

Regular supervision and orientation of participants on specimen collection, checking specimen containers for leakage, contamination, and label Checking reagents for expiry date, make sure specimens reach laboratory as soon as possible**,** Proper labeling, processing, preservation, storage, and transporting of specimen were assured. The hematological sample was transported

to Wukro general hospital. This hospital was in accreditation process by Ethiopian national accreditation organization. With a temperature cold box. In the cold box there was a thermometer to check the temperature which was from of 2-8^{o} c. The sample was waited at room temperature for 30 minutes before analysis.

Analytical stage

Cross-checking of the sample with its questionnaire, implementing the Quality Controls (QC) sample for the complete blood count and peripheral morphology through the whole processes of laboratory works. For the hematological tests the low, normal, high QC, and delta check also was performed. For blood film and PBM known negative and positive smears was screened to check the Geimsa.

Post-analytical stage

Recording of results on appropriate reporting format**, i**nterpreting test results correctly. Verification of test result was check by rule of three.

4.9 Data analysis and interpretation

Data was entered and analyzed using the Statistical Package for Social Sciences (SPSS) version 20. Tables were used for descriptive data. The data normal distribution was checked by Kolmogorov–Smirnov, and Shapiro–Wilks test. The data was not normally distributed, so it was analyzed by non-parametric analysis. Data that was observed to be lower than 1.5 × IQR of the first quartile, or higher than 1.5 × IQR of third quartile (Whisker and plot method) was considered as outliers and the outliers was manually deleted. The mean, median, standard deviation (SD), 2.5th and 97.5th percentile was subsequently calculated according to the guideline of the CLSI. Differences between males and females were evaluated using the Mann–Whitney U test. "P-value < 0.05" was considered to be statistically significant at 95% confidence intervals, and also 90% CI for the lower and upper limits of RI for each test.

4.10 Ethical considerations

Ethical clearance was obtained from the research and an ethical review committee of Medical Laboratory Sciences of Addis Ababa University, Ethiopia. Before the starting of data collection, permission was obtained from Tigrai health bureau and the selected sub-cities. Also, after

explaining the purpose and relevance of the study, informed written consent was obtained from each study participant. To ensure confidentiality, the name and other personal identifiers of participants was not registered in the questionnaire. Participants were informed that the selection to the study is random and they have the right not to respond for questions that they are not comfortable with. Those study participants who have any findings was immediately treated either by consulting to physicians. The health extension workers were taken the laboratory findings and they were communicated with the study participants and the physicians.

4.11 Dissemination of results

The findings of this research will first be presented to scientific communities of Addis Ababa University, Department of medical laboratory science. After getting approval from Addis Ababa University, a copy of the thesis report will be disseminated to the study participants (Mekelle city). The result will be communicated to Tigray regional health bureau and other concerned institutions. Finally, it will be sent to appropriate journals for publication.

4.12 Operational definition

Hematological parameters are parameters such as RBC parameters including; RBC count, HB, HCT, RBC indices like MCV, MCH MCHC; WBC parameters including total WBC counts, differential and an absolute number of the three type of WBC and platelet parameters including total platelet count, MPV. Values outside reference interval are diagnostic for disorders, including cancer, immune diseases, and cardiovascular diseases.

Reference individual: A person selected for testing based on well-defined criteria. **Reference population:** A group consisting of all the reference individuals.

Apparently healthy: An individual who has no sign and symptoms and history for any disease

5. Work flow

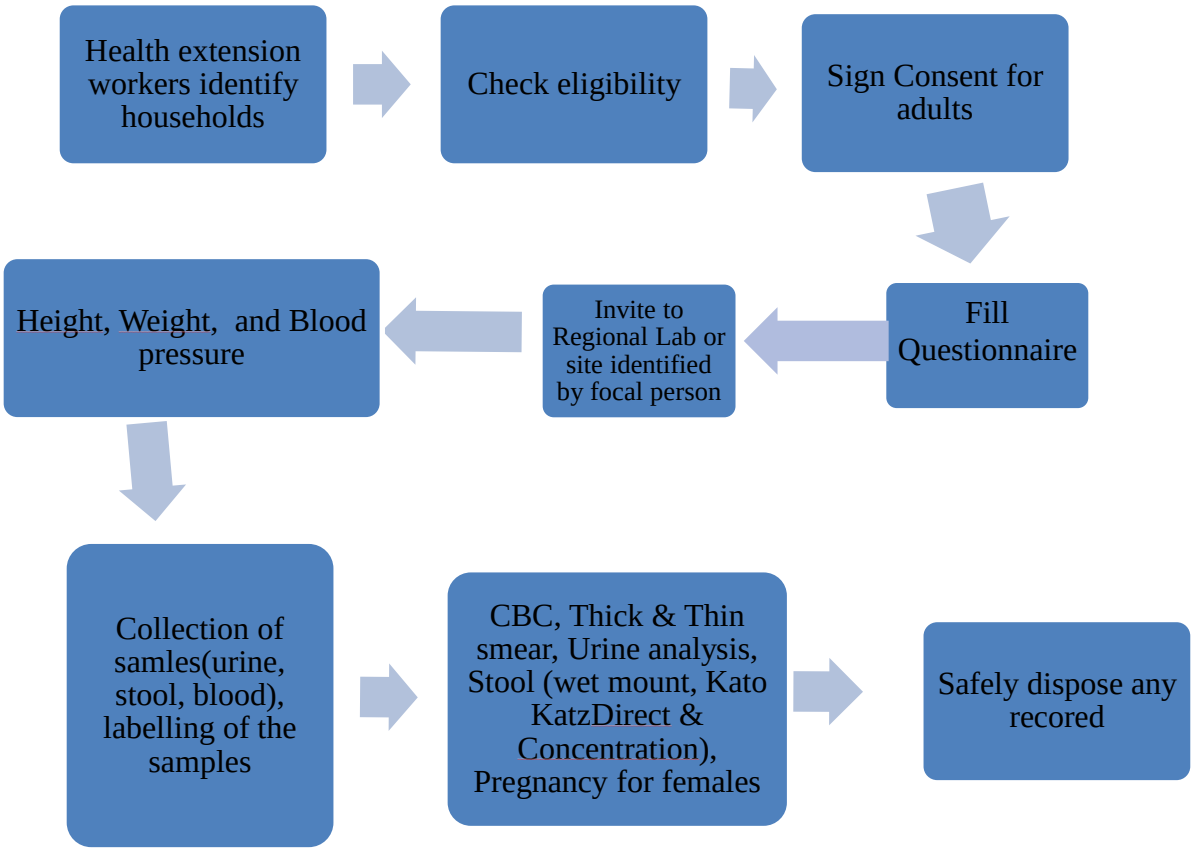

Figure 2 work flow

6. Result

6.1 General Socio-demographic characteristics of the study population

The study was performed on 344 apparently healthy individuals aged from 18-60 years. Of the total 172 (50%) were females. Among those 286 of participants were eligible (51 % females) to establish this hematological RI as shown in table 2. The mean age of the participants was 34.3years. Overall, 58(16.86%) participants were ineligible due to parasitic infection (10.8%), abnormal morphology of RBCs (2.9%), insufficient sample (0.58%), hemolysis (0.58%), positive for urine HCG (0.58%), urinary tract infection (1.45%), and due to outliers. The number of rejected outliers are different among the hematological parameters see table 3,4 and 5.

Table 2 Socio-demographic profile of the study participants Mekelle City, Tigray Region, Northern Ethiopia, 2019 (N= 286)

		Frequency	Percent
Sex	Female	145	50.7
	Male	141	49.3
Sub city of the participant	Ayder	71	24.8
	Hawelti	138	48.3
	Semen	77	26.9
Level of education	Illiterate	5	1.7
	Read and write	1	0.3
	Primary (1-8)	17	5.9
	Secondary (9-12)	192	67.1
	Diploma and above	71	24.8
Occupation	Student	136	47.6
	House wife	6	2.1
	Government employee	57	20.0
	Private employee	87	20.3
Age of the participants	18-30	161	56.2
	31-60	125	43.8
religious of the participant	Orthodox	271	94.8
	Muslim	12	4.2
	Protestant	3	1
Place of birth	Mekelle	165	57.7
	Adigrat	26	9
	Asmera	10	3.5

Marital status	Single	146	51
	Married	125	43.7
	Divorced	15	5.3

6.2 Hematological parameters RI

The data was not normally distributed, so to establish RI for hematological parameters median, 95% range (2.5^{th} -97.5^{th} percentile) and 90% CI for the lower and upper limits was calculated as shown in tables 3, 4 and 5. As shown in Table 3, the total WBC RI was 3.0- 10.08 $x10^9$/L, Lym 19.6-57.6%, and MID 4.98-23.63% which was significantly higher in females (MID=3.49-20.78 in males versus 5.40-25.55 in females, p=0.00

Table 3. Calculated WBC Parameters RI for adult population Mekelle City, Tigray Region, northern Ethiopia, 2019 (N= 286)

Parameters	Sex	No	Mean	Median	95% CI for the mean	95% range	2.5^{th} (90%CI)	97.5^{th}h (90%CI)	P-value (sex)
WBC	C	284	5.92	5.6	5.92-6.13	3.0- 10.08	2.75 - 3.4	9.24 - 10.7	0.430
$X10^9$/L	F	145.0	6.04	5.6	5.73-6.35	3.09-10.7	2.55-3.45	9.3 - 11.27	
	M	139.0	5.79	5.7	5.52-6.06	3.0-9.7	2.46-3.4	8.5-10.26	
Lym (%)	C	284	37.69	36.5	36.53-38.86	19.60-57.6	17.4 - 21.65	55.80-59.38	0.033*
	F	145	39.01	37.15	37.38-40.64	21.02-56.79	18.75-23.09	54.74-58.84	
	M	139	36.37	35.7	34.71-38.02	18.00-58.45	14.11-20.89	54.10-60.8	
Neut (%)	C	284	48.44	49.35	47.04-49.84	24.91-70.29	21.55-26.27	67.64 - 70.94	0.971
	F	145	48.49	48.9	46.55-50.44	26.06-70	22.34-27.75	67.13 - 79.59	
	M	139	48.38	49.9	46.34-50.41	22.03-71.77	20-24.878	67.48-75.06	
Mixed (%)	C	284	12.32	11.7	11.78-12.88	4.98-23.63	3.60 – 6.36	21.4– 23.63	0.001*
	F	145	11.21	10.8	10.53-11.89	3.49-20.78	2.35-6.74	18.39-23.17	
	M	139	13.54	13.2	12.70-14.37	5.40-25.55	3.03 – 7.77	22.43-28.57	

Lym count /L	C	284	2.12	2.1	2.06-2.18	1.20-3.3	1.1 -1.33	2.95-3.3.62	0.03*
	F	145	2.22	2.2	2.12-2.13	1.30-3.4	1.05-1.50	3.0-3.68	
	M	139	2.02	2	1.94-2.10	1.15-3.1	1-1.28	2.87-3.23	
Neut count/ L	C	284	3	2.8	2.84-3.18	0.9-6	0.7 -1.07	5.6 -6.2	0.411
	F	145	3.11	2.7	2.86-3.37	1 -6.54	0.83-1.17	5.96-7.12	
	M	139	2.89	2.8	2.86-3.36	0.85-5.9	0.63-1.06	5.34-6.23	
Mixed count/ L	C	284	0.72	0.7	0.68-0.75	0.30-1.33	0.25-0.35	1.17 -1.49	0.03*
	F	145	0.66	0.6	0.62-0.7	0.2-1.2	0.1-0 .3	1.1 -1.3	
	M	139	0.78	0.7	0.72-0.83	0.30-1.5	0.23-0.37	1.37-1.63	

*RI: reference interval; CI: confidence interval; WBC: white blood cell; Lym: lymphocyte, Neut: neutrophil, C: combined: male; F: female; N: number of participants: *P < 0.05 by (Mann–Whitney U test) for comparison of medians between males and females*.

Regarding the RBC parameters, except MCV and MCH where there was no statistically significant difference, in all the other RBC parameters females were having significantly lower values than males. The 95% RI for RBC was 4.25-5.46 $x10^{12}$/L versus 4.70-6.09, HGB 12.40-15.53 versus 13.90-17.85 gm/dL, HCT 38.01-48.0 versus 41.55-53.23 for females and males respectively. The respective values for MCV, MCH, MCHC were 81.32-93.70 fl, 26.50-31.40pg, 31.1-35.00% (Table 4).

Table 4 Calculated RBC parameters RI for adult populations Mekelle City, Tigray Region, northern Ethiopia, 2019 (N= 275)

Parameters	Sex	No	Mean	Median	95%CI for the mean	2.5^{th}-97.5^{th} RI	2.5^{th} 90%CI	97.5^{th} 90%CI	P-value (sex)
RBC $X10^{12}$	C	275	5.15	5.12	5.10-5.20	4.40-6.00	4.24-4.46	5.93 - 6.07	0.001*
	F	138	4.85	4.88	4.80-4.90	4.25-5.46	4.1-4.39	5.34-5.56	
	M	137	5.45	5.49	5.39-5.51	4.70-6.09	4.462-4.83	5.99-6.16	
Hgb (g/dl)	C	275	15.0	14.80	14.85-15.14	12.70-17.40	11.76-12.8	17.1-17.87	0.001*
	F	138	14.08	14.15	13.96-14.21	12.40-15.53	11.42-12.67	15.2-15.68	
	M	137	15.88	16.0	15.72-16.04	13.90-17.85	13.25-14.24	17.4-18.33	
Hct (%)	C	275	45.44	45.05	45.03-45.85	39.24-52.02	36.16-39.38	51.51-53.40	0.001*
	F	138	43.08	43.40	42.69-43.48	38.01-48.0	37.75-39	46.56-49.72	
	M	137	47.70	47.70	47.23-48.17	41.55-53.23	41.33-43.52	52-55.04	
MCV (fl)	C	275	88.06	88.20	87.69-88.43	81.32-93.70	80.5-82	93.21-95.07	0.07
	F	138	88.55	88.70	88.06-89.03	82.16-93.75	71.47-83.44	93.15-95.02	
	M	137	87.57	87.45	87.01-88.13	80.85-94.25	79.62-82.08	93.98-95.46	
MCH (pg)	C	275	29.05	29.10	28.90-29.20	26.50-31.40	23.47-26.48	30.8-31.76	0.092
	F	138	28.94	28.90	28.73-29.15	26.45-31.60	25.6-26.52	31-32.3	
	M	137	29.15	29.30	28.96-29.38	26.4-31.40	25.05-26.72	31.2 - 31.75	

MCHC (g/dL)	C	275	32.93	32.90	32.82-33.05	31.1-35.00	30.69-31.4	34.81-35.6	0.001*
	F	138	32.65	32.60	32.50-32.82	30.85-34.50	30.24-31	34.28-34.89	
	M	137	33.22	33.20	32.50-32.8	31.40-35.25	30.6-31.6	35.06-36.01	
RDW (%)	C	275	13.95	13.7	13.75-14.07	12.6-15.9	12.4-12.8	15.2-17.9	0.111
	F	138	14.07	13.6	13.6-14	12.6-16.4	12.4-12.8	15.2-19.02	
	M	137	14.0		13.7-14.3	12.7-29.73	12.41-12.8	15-29.73	

*RI: reference interval, CI: confidence interval; RBC: red blood cell; Hgb: hemoglobin; Hct: hematocrit; MCV: mean corpuscular volume; MCH: mean corpuscular hemoglobin; MCHC: mean corpuscular hemoglobin concentration; RDW: red cell distribution width; C: combined M: male; F: female; N: number of participants. *P < 0.05 by (Mann–Whitney U test) for comparison of medians between males and females.*

Table 5 displays the 95% RI for platelets. The sex specific interval was 158.3-399.5 x 109/L for females and 142-345.1 x 109/L for males. The combined mean platelet volume (MPV) RI was 8.89-12.9 fl.

Table 5 Calculated hematological parameters (platelet parameters) RI for the screened adult population Mekelle City, Tigray Region, northern Ethiopia, 2019 (N= 276)

Parameters	Sex	No	Mean	Median	95% CI for the mean	95% range	2.5th 90%CI	97.5th 90%CI	P-value (sex)
Plt x 10^9/L	C	276	256.08	248.0	249.0-263.2	149.5-385.3	141- 158	366.2-399.6	0.001*
	F	140	272.90	248.0	262.5-283.3	158.3-400	126-174.7	381.7 – 412	
	M	136	238.76	237.5	229.9-247.6	142-345.1	140-153.16	328.8-383	
MPV (fl)	C	276	10.7	10.6	10.65-10.92	8.89-12.9	8.6-9	12.7-14.12	0.475
	F	140	10.72	10.6	10.54-10.9	8.75-12.89	8.6-9.1	12.6-13.7	
	M	136	10.8	10.6	10.6-11.05	8.84-13.7	8.61-9	12.7-17.2	
PDW	C	276	13.6	13.3	13.48-13.86	10.5-18.4	9.8-11.35	16.6-19.7	0.527
	F	140	13.57	13.3	13.2-13.92	10.46-18.34	9.65-11.2	16.35-19.4	
	M	136	13.68	13.4	13.3-14.01	10.5-18.45	9.8-11.35	16.6-19.7	

*Plt: platelet; MPV: platelet mean cell volume, PDW: platelet cell width distributions; C: combined M: male; F: female; N: number of participants. *P < 0.05 by (Mann–Whitney U test) for comparison of medians between males and females.*

6.3 Comparison of hematological parameters by sex

The differences between sexes were evaluated using Mann–Whitney U test. There was a significant difference in the RBC count ($p < 0.001$); Hemoglobin ($p < 0.001$); Lym (%) ($p>0.033$), Hematocrit ($p < 0.001$); MCHC ($p < 0.001$), and differential mixed percentage ($p < 0.00$) and platelet count ($p <0.001$) between the two sexes. There was no significant difference

between male and females in WBC ($p > 0.43$), Neut (%) ($p>0.971$), MCV ($p>0.07$) and MCH ($p>0.092$) (Tables 3-5)

6.4 Misclassification of study participant by RI of Sysmex KX-21

The study tries to calculate the rate of misclassifications as a result of using company derived RIs which were mainly based on Caucasians. Accordingly, 6% and 1% of the study participants were classified as having leucopenia and leukocytosis by the instrument (Sysmex KX-21) as compared to the established RI in this study. From the total study participants 4.2%, and 1.4% who had Lymphocytopenia and 2.5% and 4.9% who had a lymphocytosis considered as a healthy individual by the instrument for the females and males respectively. From the total study participants 24.6% were healthy by the established RI in this study, But the instrument considered as Neutropenia, and 3.5% of the study participants were had a neutrophilia but classified as healthy individual by the company derived values.

Regarding RBC parameters, 1%,10.2%,2.2%,7%,2.9%, and 8.7% of females and males study participants who had low RBC, Hgb, Hct for females and males study participants were miss classified as healthy individuals by RI established by the manufacture, and 16.4%, 8%,6.9%,6.9%,11.3%, 1% of females and males study participants who were healthy individuals by RI established in this study, But RI established by instrument were classified as having high RBC, Hgb, and, Hct, respectively.

As to platelets, 4% of female and 1.8 male participants who had low platelet by the RI established by this study, but misclassified by RI established by the instrument as healthy individuals. 1.4% of female participants who had low platelet misclassified as healthy individuals and 5.4% of the male participants were having high platelet count but considered as normal by the instrument values (Table 6).

Table 6 Misclassification of study participants by the instrument of Sysmex KX-21; Mekelle, Tigrai, northern Ethiopia, 2019

Parameters	Sex	Current Study	Instrument	lower limit		Upper limit	
				Frequency	Percent	Frequency	Percent
WBC ($x10^9$ /L)	C	3.0- 10.08	3.7-10.4	17	6	3	1
Lymphocyte Count/L*	C		0.7-4.7				
	F	1.30-3.40	-	12	4.2	7	2.5
	M	1.15-3.10	-	4	1.4	14	4.9
Mixed Count/L*	C		0.04-1.14				
	F	0.20-1.20		5	1.8	9	3.2
	M	0.30-1.50		14	4.9	9	3.2
Neutrophil count /L	C	0.90-6.00	2.0-8.7	70	24.6	10	3.5
RBC ($x10^{12}$ /L)	F	4.25-5.46	4.0-5.2	3	1.0	45	16.4
	M	4.70-6.09	4.5-5.8	28	10.2	22	8
Hgb (g/dl)	F	12.40-15.53	11.8-15.1	6	2.2	19	6.9
	M	13.90-17.85	13.6-16.7	20	7	19	6.9
Hct (%)	F	38.01-48.0	36-40	8	2.9	31	11.3
	M	41.55-53.23	41-50	24	8.7	3	1
Platelet ($x10^9$ /L) *	Combined		140-385				
	F	158-400		11	4	4	1.4
	M	142-345		5	1.8	15	5.4

*WBC; white blood cells RBC: red blood cell; Hgb: hemoglobin; Hct: hematocrit; M: male; F: female, * the current studies indicate there was difference among gender, but reported results by the instruments were similar among those sexes.*

Finally, the study tried to compare the current RIs determined for Mekelle city adults with other selected studies in Ethiopia and elsewhere. As summarized in Tables 7 to 9, variations were noted among the various studies. The WBC count RI intervals are consistent in the various Ethiopian and in general African studies except the study from Mali which reported a higher upper limit particularly in females. Particularly in the differential count the lower limit for neutrophils was higher and that of lymphocytes was lower in the company derived values. The neutrophil count was also lower than that derived from Morocco (Table 7).

Comparison of RBC RIs revealed that the lower limit defined in the current study is higher than most of the studies in Ethiopia and others. The same for hemoglobin value and hematocrit values except one study in Ethiopia and Eritrea which reported consistent finding like the present study (Table 8). The platelet count RI is consistent with most of the studies except that two studies from Ethiopia and one study from Ghana reported a remarkable lower limit for platelet counts (Table 9).

Table 7 Comparison of the obtained WBC parameters RI Mekelle City, Tigray Region, northern Ethiopia with other parts of Ethiopia and other countries

Parameters	Sex	Present study	Instrument(36)	Gondor (31)	Amhara(15)	Ethiopia (9)	Eritrea (18)	Mali (28)	Ghana (37)	Morocco (30)	Different African countries (27)	China(23)	France (1)
WBC X109/L	C	3.0- 10.08	3.7-10.4	3.2–8.8	3–11.2	3.0–10	3.4–9.0		3.4–9.2				
	F	3.09-10.70					3.3–8.9	3.80-12.50	3.4–9.3	4.1-10.7	4.55-6.45	3.69 - 9.16	3.9–10.9
	M	3.0-9.70					3.7–9.3	3.08-11.13	3.5–9.2	4.1-10.8	4.15-5.85	3.97- 9.15	4.1–10.8
Lym (%)	C	19.60-57.60		22–55	9.8–57.4	17–59	22–59.2		25.2–57.7			18.6–48.7	
	F	21.02-56.79					22.3–58.2		26.9–58.3	28.1x	43x		
	M	18.00-58.45					22–59.9		24.0–57.2	26.2x	41x		
Neut (%)	C	24.91-70.29		36–69	27.2–71.9							41.5–73.8	
	F	26.06-70.0						26-67		58.7x	50.2 x		56% x
	M	22.03-71.77						26-66		57.3%	48.2		54.5 %x
Mixed (%)	C	4.98-23.63		6–13	5.2–26.4								
	F	3.49-20.78								15.4x	6.8		
	M	5.40-25.55								15.1x	10.8		
Lym count	C	1.20-3.30	0.7-4.7							1.2-3.8			
	F	1.30-3.40				1.098–3.487		1.4-4.6					1.3–3.6
	M	1.15-3.10				0.95–3.47		1.2-2.8					1.3–3.8
Neut count	C	0.90-6.00	2.0-8.7					-	-	1.8-7	-	-	
	F	1.00-6.54						1.2-7.4					
	M	0.85-5.90						1.0-4.4					
Mixed count	C	0.30-1.33	0.04-1.14										
	F	0.20-1.20											
	M	0.30-1.50											

WBC: white blood cell; Lym: lymphocyte, Neut: neutrophil; C: combined M: male; F: female, x: median

Table 8 Comparison of the obtained RBC and RBC indices RI with other parts Ethiopia and other countries

Parameters	Sex	Present study	Instrument (36)	Gondor (31)	Amhara(15)	Ethiopia (9)	Eritrea (18)	Mali (28)	Ghana(37)	Morocco (30)	Different African countries (27)	China(23)	France(1)
RBC X 1012	C	4.40-6.00											
	F	4.25-5.46	4.0-5.2	3.45–6.25	3.5–5.6	3.7–5.2	4–5.7	3.88-5.75	3.09–5.30	3.86-5.20	4.025-4.48	3.68 - 5.13	
	M	4.70-6.09	4.5-5.8	3.53–6.93	4.0–6.0	4.3–5.9	4.2–6.07	4.16-6.23	3.79–5.96	4.37-5.96	4.64-5.24	4.09 - 5.74	
Hgb (g/dl)	C	12.70-17.40											
	F	12.40-15.53	11.8-15.1	11.0–16.7	10.7–17.5	12.2–16.6	12.5–17.6	12.0-14.9	8.8–14.4	11-14.8	11.8-13.2	11.5–15.2	11.7–15.0
	M	13.90-17.85	13.6-16.7	11.5–18.0	12–18.9	13.9–18.3	12.6–17.8	12.4-17.6	11.3–16.4	13-17.1	13.75-15.05	13.3–17.5	13.4–16.7
Hct (%)	C	39.24-52.02											
	F	38.01-48.0	36-40	32.1–56.6	32.2–50.1	35.3–48.8	37.9–52	26.8-52.5	26.4–45.0	33.5-43.9	35-39	35–46	
	M	41.55-53.23	41-50	36.2–58.6	35.7–55.3	41.6–55.1	40.5–55	33.2-54.6	33.2–50.5	38.3-50	39.5-44.5	40-51	
MCV (fl)	C	81.32-93.70		85–100	81–100		85.8–100		72–97				
	F	82.16-93.75	82-99				85.5–100	92-118.0	-	75.1-94.7	80.25-86.75	82.3–99.2	78.4–95.3
	M	80.85-94.25	82-99				85.7–100	72.3-97.7		77.4-94.2	83.75-89.25		
MCH (pg)	C	26.50-31.40	27-32		25.3–34.6		27.4 –32.8		22.6–33.5			27.0–33.7	-
	F	26.45-31.60	27-32	5.8–32.8				23.1-34.8		24-32.3	29-30.8		26.1–32.5
	M	26.4-31.40	27-32	26.6–33.3			25.2-32.3	29.95-31.25		27.2–32.8			
MCHC (g/dL)	C	31.1-35.00			28.8–36.9				31.6–35.4				
	F	30.85-34.50	32-36	28.5–34.4			31.2-36	32.45-33.95		31.9–35.8			
	M	31.40-35.25	32-36	29.5–34.4			31.7-36	33.2-34.6		32.4–36.3			

RBC: red blood cell; Hgb: hemoglobin; Hct: hematocrit; MCV: mean corpuscular volume; MCH: mean corpuscular hemoglobin; MCHC: mean corpuscular hemoglobin concentration; C: combined M: male; F: female

Table 9 Comparison of the obtained platelet parameters RI Mekelle City, Tigray Region, northern Ethiopia with other parts Ethiopia and other countries

Parameters	Sex	Present study	Instrument (36)	Gondar (31)	Amhara (15)	Ethiopia (9)	Eritrea(18)	Mali (28)	Ghana (37)	Morocco (30)	Different Africa countries(27)	China (23)	France (1)
Plt x109/L	C		140-385		90–399	98–337	134–344.2				188-280	127–350	
	F	158.2-400		150–436			145.4- 351.6	151-532	89–403	150-378			186-440
	M	142-345		120–443			128.4–318.4	133-460	88–352	145-338			171–397

Plt: platelet; C: combined; F: female; M: male

7. Discussion

Hematological parameters are the most commonly ordered laboratory tests. Those parameters give additional information to the diagnosis, treatment and follow up of various diseases. The blood indices differ by several factors including ethnic, age, sex, attitude, and nutrition. So local hematological parameters RI should be established (10-12).

The results were obtained to represent hematological parameters RI for apparently healthy adult populations in Mekelle, northern Ethiopia. The result obtained was different from the similar studies conducted in other places.

The RI derived in this study was different from other studies conducted in another part of Ethiopia Amara region(15) , Gondar (31), and Ethiopia(9) African countries (18, 28, 30, 37), and western and Asian countries(24, 25).

As indicated in the present study the lower limit of WBC RI is less than other reported studies in Eritrea (18), different African countries (27), China(23), France(1) and from the instrument that was used to analyzing (36) the blood. But it was similar with studies conducted in Amhara region and a specific study in Gondar town, and Akaki town in Ethiopia (9, 18, 31). The lymphocyte percentage RI was similar with other previously conducted researches in other parts of Ethiopia (15, 31), other African counties (28, 30) and western (1) and Asian (23, 25) for both sexes. The lower limit of neutrophil percentage RI was lower than other studies in Ethiopia (31) and China and the median was also lower than from France populations(1). But the neutrophil percentage RI was similar with a reported result from Amara(15). Of 95 % of mixed percentage, RI was higher than as compared to a result reported from Gondar (31), but similar with the report from Amara(15). The median was lower than Morocco(30) and higher than research conducted in different African countries (27). The main cause for these lower values is still unknown and therefore further research is essential. However, other studies documented that these lower values might be due to the diet, genetic factors or other environmental factors(26).The observed inconsistent differences within Ethiopia as well as other studies underscore the need for locally established RI.

There was no significant difference based on sex for WBC, neutrophil and lymphocyte count and this was similar with other studies (9, 15, 18, 31, 37) but the mixed count was statistically significant among gender difference similar with a reported study in Morocco(30), and with a study which recruited participants from different African countries(27). However, a study conducted in Erzurum, Turkey(24) showed a statistically significant sex-related difference for WBC counts. Those variations may due to the type and method of the analyzer used, ethnicity nutrition, parasitic infection. The WBC parameters are reduced by parasitic infections(38, 39), but the study conducted in different African countries did not test for parasites (27). That the total WBC and neutrophil count of black peoples are lower than the white peoples. The hypothesis of an excess of marginated neutrophils pool is often proposed but a recent study did not confirm it (29).

The 95 percentile lower limit of RBC of both genders was higher than other studies conduct in (15, 18, 23, 28, 31). But it was similar with a reported studies in different African countries (27). Whereas the upper limit was less than a reports in other parts of Ethiopia(31) and Mali(28) but it was higher than reported studies from Ghana (37), Morocco(30) , different African countries (27). It was similar with the findings from Amhara regional state in Ethiopia(15) and Eritrea(18). The lower limit of Hgb RI of both genders was higher than in similar studies in other parts of Ethiopia(15, 31), Mali(28), France(1)and China(23) but lower limit of females was similar to Eritrea(18). On the other hand, the lower limit of males was similar to findings from a study involving different countries(27). The upper limit is lower than previous studies in other parts Ethiopia(15), Eritrea(18) and higher than other African countries (27, 30), but comparable with western countries and Asian (1, 23).

The lower limit of Hct RI for both genders was higher than reported results in other parts of Ethiopia(1, 15) and other African countries (28, 30, 37), and China(23) but it was similar with the findings from Eritrea. The upper limit was higher than African counties (30, 37)and lower than Gondar (Ethiopia)(31), Mali(28), Eritrea(18).

The lower limits of combined MCV RI for sexes were higher than Ghana(37) and lower than Eritrea (18), but similar with (15). The upper limit was lower than in different Africa countries (27), other parts of Ethiopia(15, 31), Eritrea (18) and Ghana(37). The lower and upper limits of

MCH and MCHC for both sexes was similar with other studies reported on the parts of Ethiopia (15, 31), other African countries (18, 28, 30, 37) and Caucasian peoples(1, 23).

The differences among RI of RBC parameters with hose reported studies from this study might be due to geographical variation (altitude), environment, diet, ethnic background, method and instrument used for analysis (7, 9-11, 21). The high altitude has an effect of tissue hypoxia. This causes to reduce the plasma volume and increase the red blood cell, hemoglobin, and hematocrit. These differences appear to be the result of both increased erythropoiesis which is secondary to the hypoxic stimulus and the decrease in plasma volume that occurs at high altitudes(40, 41).

The platelet RI lower limit for both sexes was higher than previously conducted studies of Eritrea(18), Mali(28) and Ghana(37) and lower than France(1). The upper limits of females were higher than Eritrea(18) and Morocco(30) and lower than Mali (28)and France(1), but similar with Amhara regional state (Ethiopia)(15) and Ghana(37). The upper limits of males were higher than Eritrea(18) and lower than Mali(28) and France(1), but similar to Morocco ,and Ghana (30, 37). Such variations imply that each locality establish appropriate RIs to be used by each health facility.

Hematological parameters RI by sex

Higher RBC 4.70-6.09 versus 4.25-5.46 $x10^{12}$ /L, hemoglobin 13.90-17.85 versus 12.40-15.53 g/dL, hematocrit 41.55-53.23% versus 38.01-48.0 % than females. This finding agreed with many other studies (15, 18, 26, 27, 37). The observed gender differences have been attributed to a range of well-established factors including menstruation, hormonal influences of androgen, estrogens, and testosterone on erythropoiesis, and the relatively high prevalence of iron deficiency anemia in women(42, 43).

On the other hand, the platelet count was significantly higher in females 158.3-399.5 versus 142-345.1$x10^{9}$ /L other than males. This finding was consistent to other studies (26, 27, 37). This may be as a result of the differences in hormone types and concentrations in the different sexes and the consequence of Thrombopoietin release in response to regular menstruation cross-stimulating thrombopoiesis (44, 45).

Finally, the study checked how much misclassification could have happened as a result of utilizing company derived RIs, which is widely being practiced in our country as in most resource limited settings. The reported result showed such misclassification is noted in managements of the hematological parameters by the RI established by manufacturer of the instrument Sysmex KX21as compared to the RI established by this study. This may be due to nutritional difference, climate, parasitic and viral infections, ethnic background differences between the current study population and the population used for the company derived values, mostly Caucasians. So, it is better to use this established RI for the Mekelle populations.

8. Strength and Limitation of the study

8.1 Strength

The study was the first community-based study in Mekelle and the sample was collected at morning this may minimize the diurnal variation. Wet mount, concentration (formol-ether), Kato Katz and modified acid-fast technique were performed to exclude participants who are infected with intestinal parasites. Besides this, blood films were done and well-prepared questionnaire to check individual's current or previous apparently healthy status.

8.2 Limitation

We did not perform WBC five differentials because the reagents for Sysmex XT-4000i were stock out. The findings in this study will be limited to be used in the 3 Diff analyzer until validated.

9. Conclusion and Recommendation

9.1 Conclusion

The hematological parameters reference interval for apparently healthy adult individuals in Mekelle, Tigrai, Ethiopia established in this study almost differs from those established for other parts of Ethiopia, African countries, and western countries, though some consistency was noted for some either in the lower or upper limit. The values of RBC, MCHC, Hgb, Hct, and mixed percentage were statistically significantly higher in males than females. However, platelet counts were statistically significantly higher in females than males.

9.2. Recommendation

Based on the findings this study recommends:

- To Mekelle health bureau to use this local hematological parameter RI for adult population residing in the city
- Further transferability studies for a wider use of the established RIs in other facilities which have different equipment than the one used in the current study
- To researchers to conduct further researches in all around Tigrai regional state, Ethiopian and other places.

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Annex

Annex I: Participants' information sheet

A. English version

Title of the project: Determining reference intervals for hematological parameters among apparently healthy adult individuals in Mekelle city, Tigrai, Northern Ethiopia from December 2018 to May 2019: a cros sectional study.

Principal investigator: Gebreyohannes Teklehaimanot (BSc, MSc candidate)

Introduction

Dear study participants you are invited to participate in the study on Determining reference intervals for hematological parameters among apparently healthy adult individuals in Mekelle city, Tigrai, North Ethiopia. This study is approved by the Addis Ababa University Department of Medical Laboratory Science research ethics committee. You are voluntarily participating in this study and you have a full right to stop participation if you have something uncomfortable.

Purpose of the study: The main objective of the study is to Determining reference intervals for hematological parameters among apparently healthy adult individuals in Mekelle city, Tigrai, Northern Ethiopia.

Duration: The duration of this study depends on the availability of study subjects and it may take not more than 24hrs.

The associated risk with the study: during sample collection from your vein, there is minor pain or discomfort. The sample is collected by the experienced laboratory personnel and the risk is minimizing as well.

The procedure of the study

If you are agreed to participate in this study, you will give about 4ml venous blood for hematological analysis.

Confidentiality: The confidentiality of your information and laboratory results are respected strictly. A unique identification number is given to you and your name will not be written in the form and the result of laboratory tests could only be accessed by the researcher.

Agreement: Dear participant, you have read all the information described above and you will request to put your signature to indicate your agreement to participate in the study.

Participant name _____

Date _____ sign_____

Contact information

If you have any questions about this study you can contact the following principal investigators and advisors for further information.

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B. Amharic version

ለተሳታፊዎች መረጃ መስጫ ሰነድ

የጥናቱ ርእስ፡ በትግራይ ክልል በመቐለ ከተማ በሚነሩ ጤናማ ጎልማሳ ሕብረተሰብ ውስጥ የክሊኒካል ኬሚስትሪ ምርመራ ሪፈረንስ ኢንተርቫል ማጥናት፡፡

የአጥኚው ስም: ገብረዮሃንስ ተ/ሃይማኖት ገብሩ

የተቋሙ ስም: አዲስ አበባ ዩኒቨርሲቲ የህክምና ና ጤና ሳይንስ ኮሌጅ የህክምና ላቦራቶሪ ትምህርት ክፍል

መግቢያ: የተከበሩ የጥናቱ ተሳታፊ በትግራይ ክልል በመቐለ ከተማ በሚነሩ ጤናማ በሚመስሉ ጎልማሳ ሕብረተሰብ ውስጥ የሄማቶሎጂ ምርመራ ሪፈረንስ ኢንተርቫል በሚደረገዉ ጥናት ለመሳተፍ ተጋብዛል ።ይህ ጥናት በ አዲስ አበባ ዩኒቨርሲቲ ላቦራቶሪ ትምህርት ክፍል የጥናትና የሰነምግባር ኬሚቴ የጸደቀዉ ጥናት መሆኑን መገለጸ እንወዳለን ። በዚህ ጥናት መሳተፍ ሙሉ በሙሉ በእርስዎ ፍቃደኝነት የተመሰረተ በመሆኑ በማንኛውም ሰአትና ቦታ የማቋረጥ ሙሉ መብትዎን የተጠበቀ ነው።

የጥናቱ ዋና አላማ፡- በትግራይ ክልል በመቐለ ከተማ በሚነሩ ጤናማ ጎልማሳ ሕብረተሰብ ውስጥ የሄማቶሎጂ ምርመራ ምርመራ ሪፈረንስ ኢንተርቫል ማጥናት፡፡

የጥናቱ ጊዜ፡ የጥናቱ ግዜ 24 ሰዓት ሊወስድ ይችላል፡፡

ከጥናቱ ጋር ተያይዞ የሚመጣ ጉዳት: የደም ናሙና በሚሰጥበት ወቅት ምንም አይነት የከፋ ችግር አያጋጥምዎትም ። ነገር ግን ደም ሲወስድ መጠነኛ የህመም ስሜት ልያስከትል ይችላል ። ሆኖም ግን ናሙናዉን ለመሰብሰብ ልምድ ባላቸዉ ባለሞያ ስለሚመደብና አስፈላጊውን ጥንቃቄ ና እርምጃ ስለሚወስድ የህመም ስሜት አይኖርም።

ከጥናቱ የሚያገኙት ጥቅም ፡ያለ ምንም ክፍያ የጉበት ና ኩላልት ምርመራ ያደርጋሉ።ችግር ካለ በፍጥነት ህክምና ይሰጣችዋል።

ከርስዎ የምናገኘዉ መረጃ እና ሚስጥራዊነቱ: የእርሶ ስም በዚህ መጠይቅ ላይ አይጠቀስም፡፡ በተጨማሪም የሚሰጡት መረጃ እና በሰጡትም ደም ላይ የሚደረገው የምርመራ ውጤት ከተባለለት ጉዳይ ውጭ እንደማይውል እና ሚስጥራዊነቱ የተጠበቀ እንደሚሆን አረጋግጣለሁኝ፡፡

በዚህ ጥናት ላይ ያለዎትን ጥያቄ በሚከተሉት ኣድራሻ በማንኛውም መጠቀም ይችላሉ።

የኣጥኚው ስም: ገብረዮሃንስ ተ/ሃይማኖት ገብሩ ሞባይል፡0972-175160 ኢሜል: gebret29@gmail.com

ኣማካሪ ፡ ዶ/ር አስቴር ፀጋዬ ሞባይል፡0911-696085 ኢሜል: tsegayeaster@yahoo.com

C. Tigrigna version

ናይ መፅናዓይ ሽም: ገብረዮሃንስ ተ/ሃይማኖት ገብሩ

ናይ ትካል ሽም: ኣዲስ ኣበባ ዩኒቨርሲቲ ጥዕናን ሕክምና ሳይንስን ኮሌጅ ናይ ሕክምና ላቦራቶሪ ትምህርቲ ክፍሊ

ናይቲ መፅናዕቲ ርእሲ፡- ኣብ ክልል ትግራይ ኣብ ከተማ መቐለ ኣብ ዝነብሩ ጥዕኖኣም ኣብ ዝተሓለወ ዓበይቲ ሕብረተሰብ ዝካየድ ናይ ሄማቶሎጂ ምርመራ ሪፈረንስ ኢንተርቫል ምፅናዕ

መእተዊ: ዝተከበሩ(ራ) ናይዚ ጽንዓት ተሳታፊ/ት ኣነ ናይ ኣዲስ ኣበባ ዩኒቨርስቲ ጥዕናን ሕክምናን ሳይንስ ኮሌጅ ናይ ሕክምና ላቦራቶሪ ትምህርቲ ክፍሊ ብማስተርስ ድግሪ ተምሃራይ እየ። ንሶም ወይ ንሰን ኣብ ክልል ትግራይ ኣብ ከተማ መቐለ ኣብ ዝነብሩ ጥዕኖኣም ኣብ ዝተሓለወ ሕብረተሰብ ዝካየድ ናይ ሄማቶሎጂ ምርመራ ሪፈረንስ ኢንተርቫል ምፅናዕ ኣብ ዝብል ናይ መመረቂ መፅናዕቲ ፅሑፍ ተሳታፊ ንክኾኑ/ና ተዓድሞም/ዲመን አለዉ/ዋ።

ናይቲ መፅናዕቲ ዋና ዓላማ፡- ኣብ ክልል ትግራይ ኣብ ከተማ መቐለ ኣብ ዝነብሩ ጥዕኖኣም ዝተሓለወ ዓበይቲ ሕብረተሰብ ዝካየድናይ ሄማቶሎጂ ምርመራ ሪፈረንስ ኢንተርቫል ምፅናዕን ምፍላጥን።

እቲ ጽንዓት ዝካየደሉ እዋን ፡ ናይቲ ጽንዓት እዋን ካብ 24 ሰዓት ከወስድ ይክእል እዩ።

ቐደም ስዒብ እቲ ጽንዓት፡ ዝተከበሩ(ራ) ናይዚ ጽንዓት ተሳታፊ/ት እዞም ዝስዕቡ ናይዚ ጽንኣት ምስ ተረድኡ/ኣ እና ፍቃደኛ እንድሕር ኮይኖም/ነን ነዚ ጽንዓት ዝከዉን ካብ 4 ሚ.ሊ ዝከዉን ደም ክንወስደሎም/ለን ኢና።

ምስቲ መፅናዕቲ ተታሒዙ ዝመፅእ ሳዕቤን፡- ንምርመራ ዝከዉን ደም ኣብ ዝህብሉ እዋን ምንም ዓይነት ዝኸፍአ ፀገም አየጋጥሞምን። ነገር ግን ደም ኣብ ዝውሰደሉ እዋን ዝተወሰነ ናይ ምሕማም ስሚዕት ክህሉ ይኽእል እዩ። ይኹን ዳኣምበር ደም ንምስብሳብ ልምዲ ብዘለዎም በዓል ሞያታት ስለ ዝምደቡን አድላይ ዝኾነ ጥንቃቐን ስለዝውሰድ ናይ ምሕማም ስምዕት አይህሉን።

ናይ ሕክምና መረዳእታ ብምሸጥር ምሕላዉ ዝምልከት ፡ ኣብዚ ጽንዓት ስለ ናቶም ወይ ናተን ንእክቦ ዝኮነ ዓይነት መረዳእታ ብሚስጥር ክም ንሕዘለኩም ነፍልጥ። ነዚ መጽናዕቲ ኢልና ዘሎ ናቶም/ተን መንነት ዝገልጽ ኩሉ መረዳእታ ናብ ሚሽጥር ክንቐይሮ ኢና።ብተወሳኺ እቲ ትህቡና ደም ኮነ መረዳእታ ካብቲ ጽንዓት ወጻኢ ኣይንጥቀመሉን።

ካብቲ መፅናዕቲ ስለምቁራፅ: - ኣብቲ መፅናዕቲ ምስታፍ ብናቶም/ተን ፍቓደኝነት ዝተመስረተ ኮይኑ ኣብ ማእከል ምቑራፅን ዘይደለይዎ ሕቶ ዘይምምላስ ይኽእሉ/ላ እዮም/የን። ኣብዚ መፅናዕቲ ዘለዎም/ወን ሕቶን/ ርኢቶን ኣብ ዝኾነ ይኹን ግዜ ክሓቱ/ታ ይኽእሉ/ላ።

ንተወሳኺ ሓበሬታ ነዞም ዝስዕቡ ኣድራሻ ይጠቀሙ።

ናይ መፅናዓይ ሽም: ገብረዮሃንስ ተ/ሃይማኖት ሞባይል፡0972-175160 ኢሜል: gebret29@gmail.com

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Annex II : Consent Form

A. English version

Principal investigator: Gebreyohannes Teklehaimanot (BSc, MSc candidate)

Research title: Determining reference intervals for hematological parameters among apparently healthy adult individuals in Mekelle city, Tigrai, Northern Ethiopia from December 2018 to May 2019: a cros sectional study.

I have read, or have had this document read to me in a language that I understand, and I understand the purposes, procedures and risks of this research project as described within it. I understand that at any time I may withdraw from this study without giving a reason. I know that no special payment for being participating in the study. I freely agree to participate in this study, as described. I understand that I was given a signed copy of this document to keep.

Name of participant_____ Age____ Address_____ Signature____ Date_____

Interviewer's name_____Signature_____

Principal investigator Name_____ Signature_____

B. Amharic version

የፍቃደኝነት ማረጋገጫ ቅጽ

የጥናቱ ርእስ፡ በትግራይ ክልል በመቐለ ከተማ በሚነሩ ጤናማ ጎልማሳ ሕብረተሰብ ውስጥ የማቶሎጂ ምርመራ ሪፈረንስ ኢንተርቫል ማጥናት፡፡

የአጥኝው ስም: ገብረዮሃንስ ተ/ሃይማኖት ገብሩ

የተቋሙ ስም: አዲስ አበባ ዩኒቨርሲቲ የህክምና ና ጤና ሳይንስ ኮሌጅ የሕክምና ላቦራቶሪ ትምህርት ክፍል

እኔ ከዚህ በታች የተገለጸዉ በዚህ ጥናት ተሳታፊ ለመሆን ስወሰን የጥናቱ ዓላማዎች ኣሳራሮችና ቾድመ ሁኔታዎች በግልጽ በመረዳትና እንዲሁም ከጥናቱ ተሳታፋይነት ፈቃደኝነቴን በማነኛዉም ግዜ የመውጣት መብቴን በማረጋገጥ ነዉ።

ሰለዚህ በጥናቱ ተሳታፊ መሆኔን በፈርማየ እየራጋገጥኩ ይህንን ስውስን በጥናቱ ሊከሰቱ የሚችሉ ስጋቶችን በሚገባ የተረዳሁና ከጥናቱ በማነኛዉም ግዜ ራሴን ለምግለል ብወስን ተገቢ የሆኑ ህክምናዎችና እገዛዎች ሁሉ እንደማትነፈጉኝ በማመን ነው። እነዚህ መረጃዎች ሁሉ በሚገባ በምረዳዉ ቋንቋ የተገለጸልኝ መሆኑን በፈርማየ ኣጋግጣለሁ።

የተሳታፊው ስም……ፊርማ…… ቀን ……

የቃለ መጠይቅ ያስመላ ስም ……ፊርማ ……ቀን ……

ስለ ትብብርዎ አመሰግናለሁ!

C. Tigrigna version

ናይ መፅናዒይ ሽም: ገብረዮሃንስ ተ/ሃይማኖት ገብሩ

ናይ ትካል ሽም: ኣዲስ ኣበባ ዩኒቨርሲቲ ጥዕናን ሕክምና ሳይንስን ኮሌጅ ናይ ሕክምና ላቦራቶሪ ትምህርቲ ክፍሊ

ናይቲ መፅናዕቲ ርእሲ:- ኣብ ክልል ትግራይ ኣብ ከተማ መቐለ ኣብ ዝነብሩ ጥዕኖኣም ኣብ ዝተሓለወ ዓበይቲ ሕብረተሰብ ዝካየድ ናይ ክሊኒካል ኬሚስትሪ ምርመራ ሪፈረንስ ኢንተርቫል ምፅናዕ:

ኣነ ኣብዚ ተገሊጹ ዝኣሆ መጽናዕቲ ተሳታፋይ ንምኳን እንትወሰን እንተለኩ ናይዚ ጽንዓት ዘድልዩ ነገራት ብምርዳእ እና ካብዚ ጽንዓት እዚ ምስታፍ ኣብ ዝኮነ ይኩን እዋን ከም ዘግልል ብምርግጋጸይ እዩ።ስለዚ ኣብዚ ጸንዓት ተሳታፋይ ምኳነይ በፈረማይ የራጋግጽ።እዞም ኩሎም መረደእታታት ብዝግባእ ብዝሩድኡኒ ቋንቋ ዝተገለጹለይ ምኳኖም በፈረማይ የራጋግጽ።

ናይ ተሳታፊ/ፊት መለለዪ ቑፅሪ ---------- ፊርማ ---------- ዕለት----------

ሓበሬታ ዝኣከበ በዓል ሞያ ሽም ---------- ፊርማ ----------ዕለት----------

ስለ ዝተሓባበሩኒ የቐንየለይ!

Annex III: Questionnaire

A. English version

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? _____

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

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) 5. College diploma/degree and above

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
	Part IV: HEALTH STATUS	
12	Did you take any type of drug for any illness for the last three months?	1. 1.Yes 2. No
13	If yes to Q12, 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	
14	History of diabetes	1.Yes 2. No
15	History of Hypertension	1.Yes 2. No
16	History of Blood transfusion for the last 1 year	1.Yes 2. No
17	Any history of donation of blood previously 3 months	1.Yes 2. No
18	History of Hospital Admission for the last 1 year	1.Yes 2. No
19	History of Surgical procedure for the last three years?	1.Yes 2. No
20	History of chronic gastritis	1.Yes 2. No
21	History of Malaria for the last 6 months	1.Yes 2. No
22	History of TB for the last two years	1.Yes 2. No
23	History of Cancer	1.Yes 2. No
24	History of Cardiac illness	1.Yes 2. No
25	History of Bleeding disorders	1.Yes 2. No
26	History of allergy	1.Yes 2. No
27	History of Wheezing	1.Yes 2. No

How frequently do you consume/use the following (put a √ mark)							
		Once/day (Regular)	More than once/day	2-3 times/week	Once a week	Occasionally (holiday, special ceremony)	Never
28	Alcohol						
29	Khat						
30	Cigarettes						

	Part VI. Anthropometric measurement	
31	Height (in cm)	_____
32	Weight (in kg)	_____
33	MUAC	_____in cm
34	Blood pressure (mm Hg)	_____

NB. Questions 12 and questions from 14-27 answer yes, taking Khat and cigarettes, and if blood pressure was out of 90-120/69-90 mmHg, the study participants were excluded.

❖ We thank you for your cooperation!

Interview Date: _____

Interviewer's Name_____ Signature_____

B. Amharic version (ቃለ መጠይቅ)

በጤና ባለሞያዎች የሚሞላ ቃለ መጠይቅ

ክፍል 1. አጠቃላይ መረጃ

ኮድ_____ ክልል _____ ዞን_____

ወረዳ _____ ከተማ/ክፍለከተማ _____ቀበሌ _____

ክፍል 2. የግል መረጃ

1. እድሜ _____
2. ጾታ_____
3. የትውልድ ቦታ_____
4. በትውልድ ቦታዎ ለምን ያህል ጊዜ ኖረዋል? _____
5. አሁን ያሉበት ቦታ ለምን ያህል ጊዜ ኖረዋል? (ከትውልድ ቦታዎ የተለየ ከሆነ) _____ዓመት

ቁጥር.	ጥያቄ	ምላሽ
	ክፍል 3. ማህበራዊ ና ኢኮኖሚያዊ መረጃ	
6.	የትምህርት ደረጃ	ነ. ያልተማሩ 2.ማንበብ ና መፃፍ 3.አንደኛ ደረጃ (1-8) 4.ሁለተኛ ደረጃ (9-12) 5.ኮሌጅ ዲፕሎማ/ዲግሪ እና ከዚያ በላይ
7.	ሥራ	ነ.ተማሪ 2.የቤት እመቤት 3.የመንግስት ሠራተኛ 4.የግል ተቀጣሪ 5.ገበሬ 6.ሌላ ካለ ይግለፁ _____
8.	የጋብቻ ሁኔታ	ነ.ያላገቡ 2.ያገቡ 3.የተፋቱ 4.ባል/ሚስት የሞተባቸው 5.አይመለከታቸውም (ህፃናት)
9.	ሃይማኖት	ነ.ኦርቶዶክስ ክርስቲያን 2.ሙስሊም

		3.ፕሮቴስታንት 4.ካቶሊክ 5.ሌላ ካለ ይግለፁ _____
10.	ብሄር	_____ድብልቅ ከሆኑ ይግለፁ
11.	የመኖሪያ ቦታ	1. ገጠር 2. ከተማ
	ክፍል 4. የጤና መረጃ	
12.	ባፉት ሶስት ወራት ለማንኛውም ዓይነት ህመም ማንኛውንም ዓይነት መድሃኒት ወስደኋል?	1. አዎን 2. የለም
13.	ለተራ ቁጥር 12 መልስዎ ወስጃለሁ ከሆነ የትኛውን ዓይነት መድሃኒት ነው ወሰዱት? (ከአንድ በላይ መልስ ይቻላል)	ነ.ፀረ-ፕሮቶዞአ 2.ፀረ-ሄልሚንትስ 3.ፀረ-አለርጂ 4.የወሊድ መከላከያ ኪኒን 5.ፀረ-ባክቴሪያ 6.ፀረ-ቲቢ 7.ሌላ ካለ ይግለፁ _____
	የሚከተሉትን የህመም ዓይነቶች አሞዎት ያውቃል?	
14.	የስኳር ህመም?	1. አዎን 2. የለም
15.	የደም ግፊት ከፍ ማለት?	1. አዎን 2. የለም
16.	ባለፈው 1 ዓመት ደም ተሰጥቶዎ ያውቃል?	1. አዎን 2. የለም
17.	ባለፈው 3 ወር ደም ሰጥተው ያውቃሉ?	1. አዎን 2. የለም
18.	ባለፈው ዓመት ሆስፒታል ተኝተው ያውቃሉ?	1. አዎን 2. የለም
19.	ባለፉት 3 ዓመታት የቀዶ ህክምና ተደርጎልዎ ያውቃል?	1. አዎን 2. የለም
20.	የቆየ የጨጓራ ህመም አለብዎት?	1. አዎን 2. የለም
21.	ባፉት 6 ወራት የወባ ህመም አጋጥሞዎት ያውቃል?	1. አዎን 2. የለም
22.	ባለፉት 2 ዓመታት የቲቢ ህመም ኖሮዎት ያውቃል?	1. አዎን 2. የለም
23.	ካንሰር ህመም	1. አዎን 2. የለም
24.	የልብ ህመም	1. አዎን 2. የለም
25.	የመድማት ችግር/ህመም	1. አዎን 2. የለም
26.	አለርጂ (የሰውነት መቆጣት)	1. አዎን 2. የለም
27.	የመተንፈስ ችግር (ሲተነፍሱ ሲር ሲር የሚል ድምፅ)	1. አዎን 2. የለም

የሚከተሉትን ምን ያህል ይበላሉ/ይጠቀማሉ (√ ይህን ምልክት ያስቀምጡ)							
		በቀን አንድ ጊዜ (ሁልጊዜ)	በቀን ከ1 ጊዜ በላይ	በሳምንት ከ 2 እስከ 3 ጊዜ	በሳምንት 1 ቀን	አልፎ አልፎ (ለምሳሌ፣ ለበዓል፣ ልዩ ዝግጅቶች ሲኖሩ)	ተጠቅሜ አላውቅም
28.	አልኮል						
29.	ጫት						
30.	ሲጋራ						

	ክፍል 6. ክብደት፣ ቁመት፣ የክንድና የደም ግፊት ልኬት	
31.	ቁመት	_____ሴንቲ ሜትር
32.	ክብደት	_____ኪሎ ግራም
33.	የክንድ መሃለኛው ክፍል ዙሪያው (MUAC)	_____ሴንቲ ሜትር
34.	የደም ግፊት (በሚሊሜትር ሜርኩሪ)	_____ (mm Hg)

NB. ጥያቄ ቁ. 12 ና ከ 12-27 አዎ ከሆነ፣ ጫት ና ሲጋራ የሚትከሙ ከሆነ፣ደም ግፊት ከ90-120/69-90 mmHg ከሆነ ከጥናቱ ውጭ ይሆናሉ።

ስለትብብርዎ እናመሰግናለን!

ቃለ መጠይቅ የተደረገበት ቀን: _____

ቃለ መጠይቁን ያካሄደው ስም_____ ፊርማ_____

C. Tigrigna version (ቃለ -መሕተት)

<u>ክፍሊ 1. ኣጠቓላሊ መረዳእታ</u>

ኮድ_____ ክልል <u>ትግራይ</u> ዞባ <u>መቐለ</u>

ክፍለ ከተማ _____ጣብያ _____

<u>ክፍሊ 2. ናይ ዉልቀ መረዳእታ</u>

1. ዕድመ (ብዓመት) _____
2. ፆታ_____
3. ናይ ትዉልዲ ቦታ_____
4. ኣብ ትዉልዲ ቦቶኣም ንኽንደይ ጊዜ ነቢሮም_____
5. ኣብ ሕዚ ዘለዉዎ ቦታ ንኽንደይ ጊዜ ነቢሮም? (ካብ ትዉልዲ ቦታ ዝተፈለየ እንተኾይኑ) _____ዓመት

ክፍሊ 3. ናይ ማሕበራውን ኢኮኖሚያውን መረዳእታ

6. ናይ ትምህርቲ ደረጃ

   6. ዘይተመሃረ 2. ምንባብን ምፅሓፍን 3. ቀዳማይ ብርኪ (1-8) 4. ካልኣይ ብርኪ (9-12)

   5. ናይ ኮሌጅ ዲፕሎማ/ዲግርን ልዕሊኡን

7. ስራሕ

   7. ተመሃራይ/ት 2. ናይ ገዛ እመቤት 3. ናይ መንግስቲ ሰራሕተኛ 4. ናይ ግሊ ተቐፃሪ

   5 ሓረስታይ 6. ካሊእ እንተሃልዩ ይገለፅ_____

8. ኩነታት ሓዳር

   1. ሓዳር ዘይገበረ/ት 2. ሓዳር ዝገበረ/ት 3. ዝተፋተሐ/ት 4. በዓልቲ ገዝኡ/ኣ ዝሞተቶ/ታ

   5. ኣይምልከቶምን (ህፃዉንቲ)

9. ሃይማኖት

   1. ኦርቶዶክስ 2. ሙስሊም 3. ፕሮቴስታንት 4. ካቶሊክ 5. ካሊእ እንተሃልዩ ይገለጽ _____

10. ብሄር 1. _____ 2. ሕዋስ እንተሃልዩ ይገለፅ_____

11. መንበሪ ኣድራሻ 1. ገጠር 2. ከተማ

ክፍሊ 4. ናይ ጥዕና መረዳእታ

12. ኣብ ዝሓለፉ ሰለስተ ወርሒ ዝኾነ ዓይነት መድሓኒት ንዝኾነ ዓይነት ሕማም ወሲዶም ዶ ይፈልጡ ?

   1. እወ 2. ኣይፋሉን

13. ንታራ ቁፅሪ 12 መልሶም እወ እንተኾይኑ ኣየናይ ዓይነት መድሓኒት እዮም ወሲዶም ? (ካብ ሓደ ንላዕሊ መልሲ ምምላስ ይካኣል እዩ)

   ነ. ፀረ-ፕሮቶዝዋ 2. ፀረ- ሓሰኻ 3. ፀረ-ኣለርጂ 4. ናይ ወሊድ መከላኸሊ ክኒና

   5 ፀረ-ባክቴሪያ 6. ፀረ-ቲቢ 7. ካለእ ተሃልዩ ይገለፅ _____

ናይ ዝስዕቡ ናይ ሕማም ዓይነት ሓሚሞም ይፈልጡ ዶ?

14. ናይ ሽኮር ሕማም? 1. እወ 2. ኣይፋሉን

15. ናይ ደም ድፍኢት ልዕል ምባል? 1.እወ 2. ኣይፋሉን

16. ኣብ ዝሓለፈ 1 ዓመት ደም ሂቦም ይፈልጡ ዶ? 1.እወ 2. ኣይፋሉን

17. ኣብ ዝኾነ ጊዜ ደም ተዋሂብዎም ይፈልጡ ዶ? 1.እወ 2. ኣይፋሉን

18. ኣብ ዝሓለፈ 1 ዓመት ሆስፒታል ሃሪሶም ይፈልጡ ዶ? 1.እወ 2. ኣይፋሉን

19. ኣብ ዝሓለፈ 3 ዓመታት ናይ መጥባሕቲ ህክምና ተገይርሎም ይፈልጡ ዶ? 1.እወ 2. ኣይፋሉን

20. ዝፀንሐ ናይ ጨነራ ሕማም ኣለዎም ዶ? 1.እወ 2. ኣይፋሉን

21. ኣብ ዝሓለፈ 6 ኣዋርሕ ናይ ሕማም ዓሶ ኣጋጢምዎም ነይሩ ዶ? 1.እወ 2. ኣይፋሉን

22. ኣብ ዝሓለፈ 2 ዓመት ናይ ቲቢ ሕማም ሒዝዎም ይፈልጥ ዶ ? 1.እወ 2. ኣይፋሉን

23. ናይ ካንሰር ሕማም 1. እወ 2. ኣይፋሉን

24. ናይ ልቢ ሕማም 1.እወ 2. ኣይፋሉን

25. ናይ ምድማይ ፀገም /ሕማም ኣጋጢምዎም ነይሩ ዶ? 1.እወ 2. ኣይፋሉን

26. አለርጂ (ናይ ሰውነት ቁጠዐ) ኣጋጢምዎም ነይሩ ዶ? 1.እወ 2. ኣይፋሉን

27. ናይ ምትንፋስ ችግር ኣጋጢምዎም ነይሩ ዶ? 1.እወ 2. ኣይፋሉን

ካብዞም ዝስዕቡ ክንደይ ግዘ ይጥቀሙ/ይበልዑ (√ እዚ ምልክት የቕምጡ)							
		ብመዓልቲ ሓደ ግዜ	ብመዓልቲ ካብ ሓደ ግዜ ንላዕሊ	ብሰሙን ካብ 2 ክሳብ 3 ግዜ	ብሰሙን ካብ 1 ንላዕሊ	ሓልሓሊፉ (ንኣብነት በዓል፣ፍሉይ ምደላው ከህሉ ከሎ)	ተጠቒመ ኣይፈልጥን
28.	አልኮል						
29.	ጫት						
30.	ሽጋራ						

	ክፍሊ 5. ክብደት፣ ቁመት፣ ጭዋዳን ናይ ደም ድፍኢትን	
31	ቁመት (ሴንቲ ሜትር)	_____
32	ክብደት (ኪሎ ግራም)	_____ኪሎ ግራም
33	ናይ ጭዋዳ ማእዝላይ ክፍሊ ዙሪያ (MUAC)	_____ሴንቲ ሜትር
34	ናይ ደም ድፍኢት (በሚሊሜትር ሜርኩሪ)	_____

NB. መልሶም ን 12ን 14-27ን እወ እንተኮይኑ፤ ጫትን ሲጋራን ዝጥቀሙ እንተኮኖም መጠን ድፍኢት ደም 90-120/69-90 mmHg እንተኮይኑ ኣብ መናዕቲ ኣይካተቱን።

❖ ስለ ምትሕብባሮም ነምስግን!!!

ቃለ መሕተት ዝተገበረሉ መዓልቲ: _____

ቃለ መሕተት ዘካየደ ሽም_____ ፊርማ_____

Annex IV Standard operating procedures

SOP for blood collection

Equipment

- 21-gauge needle for each participant with closed vacutainer system
- Blood collection tubes for each participant
    - Tourniquet
    - Box of nitrile /vinyl gloves (Do not use latex gloves due to allergies/sensitivities.)
    - 70% Alcohol wipes
    - Cotton balls/swabs
    - Bandages
    - Pillow/pad for raising an arm to comfortable elevation
    - Apple/orange juice and snacks for fasting participants
    - Disposable, single-use materials or equipment are to be used whenever possible
    - Any reusable materials or equipment must be cleaned and disinfected with alcohol-based sanitizers before use with another participant

Safeguards /safety procedures

- A new pair of disposable latex/vinyl gloves is used with each participant.
- Gloves are to be for single-procedure use only. Gloves should always be removed using a glove-to-glove or skin-to-skin technique which will prevent contaminating the hands.
- The use of gloves does not replace the need for hand hygiene. Hands should be properly washed before the gloves are put on and after the gloves are removed. Hand hygiene is also needed before and after the replacement of gloves during a procedure or in between tasks.
- Participants are reminded to do no heavy lifting for 24 hours.

Procedure for drawing blood

Steps 1; Assemble equipment

Collect all the equipment needed for the procedure and place it within safe and easy reach on a flat surface table ensuring that all the items are visible.

Step 2; Identify and prepare the participants and allow to sit comfortably preferably b stretching his/her arm

Step 3; Perform hand hygiene and put on gloves

Step 4; Select the site of injection

Step 5; apply the tourniquet

Step 6; prepare the arm by swabbing the antecubital fossa with a gauze pad or cotton moistened with 70% alcohol.

Step 7; insert the needle properly into the vein

Step 8; draw the required amount of blood

Step 9; Fill the laboratory sample tubes and mix properly

Step 10; Draw samples in the correct order and label the sample using a unique code of participants

Step 11; clean contaminated surfaces and complete patient procedure

Step 12; Prepare samples for transportation

Step 13; Clean up spills of blood

SOP for haematology analyser SYSMEX KX-21

The Sysmex KX-21 is an automatic multi-parameter blood cell counter for in vitro diagnostic use in clinical laboratories. The KX-21 processes approximately 60 samples an hour and displays on

the LCD screen the particle distribution curves of WBC, RBC, and platelets, along with data of 18 parameters, as the analysis results.

Reagent: Diluent: CELLPACK; WBC/HGB lyse reagent: STROMATOLYSER-WH

Detergent: CELLCLEAN
Consumption of reagent (per sample): Diluent (CELLPACK): Approx. 30 mL: WBC/HGB lyse reagent (STROMATOLYSER-WH): Approx. 1.0 mL
Throughput: Approx. 60 samples/hour
Analysis principle: WBC and RBC: DC detection method; HGB: Non-cyanide hemoglobin analysis method

Quality Control: This product is supplied with three control levels; at least two levels should be run every 8 hours of operation or in accordance to regulations applicable to your laboratory.

Parameters: WBC, Lym %, Mixed %, Neut %, Lym count, Mixed count, Neut count, Hgb, Hct, MCV, MCH, MCHC, RDW, Plt, MPV.

Specimen Type/Stability/Storage

Specimens should be stored at room temperature of 18 - 26ºC or in the refrigerator of 2 - 8ºC. If stored in a refrigerator, samples should be returned to room temperature, for approximately 30 minutes, before analysis. Otherwise correct results may not be obtained.

Procedure

Samples are processed in the following steps:

1. Collecting and preparing samples

2. Selecting whole blood mode

3. Inputting sample No.

4. Analyzing samples

5. Display and printing of analysis results

Declaration

Assurance of Principal Investigator

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.

Name **of the student: Gebreyohannes Teklehaimanot**

Date _____ Signature _____

Approval of Advisor:

Aster Tsegaye, MSc, PhD. Associated professor

Date_____ Signature _____