ADDIS ABABA UNIVERSITY

COLLEGE OF HEALTH SCIENCES, SCHOOL OF ALLIED SCIENCES, DEPARTMENT OF MEDICAL LABORATORY SCIENCES

Evaluation of phlebotomy services in clinical laboratory setting in Addis Ababa public hospitals

By: Wondimeneh Liknaw (BSc)

Advisors:

Aster Tsegaye (MSc. PhD)

Eshetu Lemma (BSc, BA, MSc)

A thesis submitted to the Department of Medical Laboratory Sciences, School of Allied Health Science, College of Health Science, Addis Ababa University in partial fulfillment of the requirements for the degree of masters in clinical laboratory sciences (Clinical Laboratory Management and Quality Assurance Specialty track)

June 2014

Addis Ababa, Ethiopia

ADDIS ABABA UNIVERSITY

COLLEGE OF HEALTH SCIENCES, SCHOOL OF ALLIED SCIENCES, DEPARTMENT OF MEDICAL LABORATORY SCIENCES

Evaluation of phlebotomy services in clinical laboratory setting in Addis Ababa public hospitals

By

Wondimeneh Liknaw (BSc)

Department of Medical Laboratory Sciences, College of Health Science, Addis Ababa University

Approved by the Examining Board

_____	_____
Chairman, Dep. Graduate Committee	Signature
_____	_____
Advisor	Signature
_____	_____
External Examiner	Signature
_____	_____
Internal Examiner	Signature

June 2014

Addis Ababa, Ethiopia

Acknowledgment

First of all, I would like to acknowledgment the department of medical laboratory science for giving this chance and my deepest thanks goes to my advisors Dr Aster Tsegaye and Ato Eshetu Lemma for their unreserved guidance and constructive feedback.

Special thanks go to Yonas Bekele, Befekadu Debebe, Legesse Negash and Tekle Airgecho for their assistant during the proposal preparation and to my classmates Abay Sisay for his unreserved encouragement.

Eventually, I would like to express my sincere appreciation and thanks to my family for their unreserved financial support throughout my career of education.

All study participants (Phlebotomists and patients) are gratefully acknowledged for making this study possible through their kind participation.

Table Contents

List of Tables Page No

List of figures

Abbreviations

AARHB	Addis Ababa Regional Health Bureau
ALERT	All africa leprosy rehabilitation and training center
AST	aspartate aminotransferase
BD	Becton Dickinson
CLSI	Clinical and Laboratory Standards Institute
DRERC	Departmental Research and Ethics Review Committee
EDTA	Ethylenediaminetetraacetic acid
EPI data	Epidemiological research data entry software package version 3.1
ID	Identification
INR	International Normalized Ratio
ISO	International Organization for Standardization
NGO	Non-governmental organization
PATH	Program for Appropriate Technology in Health
PI	Principal Investigator
PT	Prothrombin Time
RBC	Red blood cell
SD	standard devation
SST	serum separator tube
SOPs	Standard operating procedures
SPSS	Statistical package for the social sciences
VBS	Venous blood sampling
VS	versus
WBC	White blood cells
WHO	world health organization

ABSTRACT

Background: Phlebotomy being a critical part of the pre analytical phase of laboratory testing is the most neglected procedure in health care. About 70% of quality of test is affected during phlebotomy and other pre analytical services. However, little is known about the practice of phlebotomy services in developing countries like Ethiopia.

Objectives: To assess the practice of phlebotomists and to identify the major sources of errors during venous blood collection in public hospitals in Addis Ababa.

Methodology: Hospital based, cross sectional study was conducted from April 15 to May 10, 2014. The study followed 40 phlebotomists while each of them were collecting 5 different venous blood collections (giving a total of 200 phlebotomies). Well structured questionnaires and checklists were used to collect data. Data was entred on EPI-Data version 3.1and statistical analysis was performed with SPSS version 20. Descriptive statistics were employed and Chi square test was used for compairing major errors observed.

Result: Almost all laboratory phlebotomy sites had no SOPs available in collection sites and most of collection sites were not well ventilated. The major errors identified were use of single glove for more than one client 139 of 200 (69.5%), inappropreate cleaning practice of vein puncture sites 180 of 200 (90%), collecting blood before the disinfectant alcohol is air dried 139 of 200 (69.5%), incorrect tube collection sequences 107 of 200 (53.5%), unnecessarly applying of tourniquets after blood started flowing in to the collection tubes and syringes 170 of 200 (85.0%) and applying tourniquets before locating and selecting approperate site for venous blood collection 175 of 200 (87.5%).

Conclusion and Recommendation: - Many errors were identified in the phlebotomy practice during the observational study. As the quality of blood specimen influences patient result: emphasis should be given on phlebotomy training to improve the practices for phlebotomists and ensure safety as well as quality during blood collections for laboratory analysis.

Keywords: phlebotomy, venous blood collection, Quality, tourniquet, phlebotomist, preanalytical errors

1 Introduction

1.1 Background

Phlebotomy is the system of drawing blood sample for the use of laboratory testing and for blood transfusion. Professionals who are performing phlebotomy services called phlebotomists and those who are undertaking phlebotomy need to be trained in procedures specific to the types of service they will perform. Training should include venous blood draws and techniques that ensure adequacy of collected specimen, reducing the risk of contamination, avoiding clerical error, avoiding infection and injury and time of transporting samples after collection (1). During the late 1980s and early 1990s, the phlebotomy profession emerged as a result of technology and expansions of laboratory roles. Primarily, only medical technicians and medical technologists were responsible for collecting blood samples, but as technology and the health care industry remarkably advanced in technology, particularly during the last two decades other health professionals and trained phlebotomists share these responsibilities (2).

In recent years, the interest of clinical laboratory has been increasing towards quality improvement and patient safety activities in healthcare (3). Clinical laboratories worldwide are now conforming to certification rules of International Organization for Standardization (ISO) for accreditation programs with standards based on ISO 15189 (4, 5). While the laboratory quality testing process involves three phases: pre analytical, analytical and post analytical phases' (3, 6), a major problem in laboratory quality management is that health care professionals still focus excessive attention on the analytical phase of laboratory testing (4). Accreditation agencies are increasingly requiring laboratories to go beyond analytical quality and take responsibility for the pre- and post-analytical or extra-analytical phases where most errors arise (3, 4).

Phlebotomy, being a vital procedure for obtaining reliable diagnostic blood specimens, is one of the most neglected procedures in healthcare providers and by laboratory managers involved with quality assurance. Because of this, this phase has lack of uniform standards and indicators sufficient to ensure the quality of phlebotomy and often is not supervised by laboratory personnel (2, 4). Venous blood sampling (VBS) is complex and demands both knowledge and skill. It is a routinely practiced

procedure in health care service and it should have been strictly regulated by national and international standards (7). Phlebotomy as a pre analytical process involves different steps and each steps affects the quality of the specimens (1). This phase is the key phase that mostly affects laboratory results (6). About 46–68.2% of total laboratory errors occur in the preanalytic phase (3, 7, 8); of those errors, most errors are produced during blood sample collection (9).

Among factors influencing the outcome of laboratory results during blood collection could be due to problems on phlebotomist education and training, including understanding of anatomy, prevention and control of safety issues during blood collection. Up to 25% of tourniquets contaminated through lack of hand hygiene on the part of the phlebotomist or reuse of contaminated tourniquets (1). Problems on knowing and understanding of standard operating procedures (SOPs) that guide for each step or procedure during collection, incorrectly identifying the patient's through matching with the laboratory request form (1, 10), incorrect use of the recommended blood collection sequence of vacuum tubes and the volume to be filled (4), problems on maintaining good condition of the sample and safe transportation of the blood sample are among the most common errors identified (1, 10).

1.2 Statements of the problem

Several studies have documented most of the errors in the clinical laboratory occur in the pre analytical phase accounting up to 80% (2, 4, 6, 8, 9). The importance of laboratory responsibilities for patient health care and safety is obvious. The pre analytical phase, especially venous blood collection is most critical in influencing patients laboratory results derived from blood specimens. Because phlebotomy is the most regularly practiced but neglected medical process worldwide, it can lead to adverse problems in patient safety and healthy life if not properly regulated. Patient identification problem, usage of incorrect blood collection equipment and improper skin puncturing practices are most problems occurred during phlebotomy service and also laboratory results can be affected during tourniquet application, improper usage of disinfectants (1, 2, 4, 11), improperly using of Vacutainer tube sequence during collection and improper patient identification and instruction before collection (12).

1.3 Significance of the study

In order to have clear view of shortcomings, knowledge gaps on the laboratory phlebotomy practice and the challenges about laboratory phlebotomy services need to be assessed. Studies on evaluation of phlebotomy services in clinical laboratory setting and the factors which influence quality of clinical specimens in Ethiopia have not been documented, as far as our knowlege goes. Therefore, this study was carried out to evaluate phlebotomy services in clinical laboratory and factors affecting the quality of venous blood specimens in Addis Ababa public hospitals. Assessing the status and identifying gaps will help design appropriate intervention.

1.4 Research hypothesis

The phlebotomy practice in Addis Ababa hospitals is below the standard due to either lack of or not properly following standard operating procedures.

2 Literature review

Phlebotomy is one of the most neglected pre analytical activities in healthcare laboratory that shows a high degree of variability in the different work settings. Besides to poor quality of blood sample, as a result of improper vein puncturing practice it leads to serious health risks, mainly needle stick injuries to the operator and casual lesions inflicted to the patient (such as nerve or tendon injury, hemorrhage, vertigo/ syncope, lymph edema). Variability in laboratory testing is introduced by poorly standardized procedures for drawing blood. Due to high personnel turnover rates, lack of understanding about good laboratory practices, and inadequate training, phlebotomists can generate a wide series of errors that compromise specimen integrity, sometimes in ways that laboratory personnel cannot detect during the analytic process (2).

2.1 Evaluation of Phlebotomist Performance

Venipuncture is a collection technique that must be performed exclusively by personnel who have received proper training on how to collect venous blood sample, proper identification of patients, proper handling and transportation of samples and know the general impacts of blood collection on the laboratory results (13). Quality of specimens could be enhanced by giving proper training and education for sample collectors, which can significantly reduce the problems of specimens that will arrive in the laboratory (14). A study conducted by Sultan et al (2013) in India showed that 0.9% pre analytical errors were detected of those 0.4% was due to insufficient samples volume (15).

A study conducted in Brazil by Lima-Oliveira et al in 2012 tried to evaluate the performance of 30 phlebotomists from 10 laboratories and identify the major sources of errors during venous blood sample collection. The performance of each phlebotomist was monitored in 5 different phlebotomies. The result showed that inappropriate request to the patient to tighten his or her fist repeatedly was observed in 83% of the observed phlebotomies (4). This will generate venous stasis and changes the local pH balance, affecting the concentration of ionized calcium, potassium and some protein bound analytes (4, 16). The study also observed that more than 85% of all blood collection practiced excessive rubbing at the venipuncture site (4).

2.2 Evaluation of Tourniquet Application

A tourniquet should be released and removed as soon as possible after the blood begins to flow. The Clinical and Laboratory Standards Institute (CLSI) publication H3A5, USA suggested the tourniquet should be applied approximately 3 to 4 inches (7.5 to 10.0 cm) above the anticipated puncture site, should be tight enough to stop venous blood flow but not to obstruct arterial blood flow, It should be removed as soon as blood flow is established in the collection system, and under any circumstances it should not be left in place for more than 1 min. When more time is required, the tourniquet must be released, so that blood flow can resume and normal skin color returns to the extremities. Evidence showed that venous stasis, as induced by prolonged tourniquet time, might exert considerable influence on the concentration of several analytes in plasma. In particular, hemoconcentration is recognized as a major factor contributing to increased concentration of large molecules, such as proteins and protein-bound substances, cells and coagulation factors (16, 17).

A study conducted in Turkey found that the duration of venous statis during phlebotomy by experienced staff was found significantly shorter (18.9 ± 9.8 sec), whereas non-experts' time was 37.4 ± 11.2 (10). The pattern of change in analytes is mostly dependent on the length of stasis, size and protein binding characteristics of the analytes. A study conducted in Italy in 2005 found that desirable bias, occurred for potassium (1-min stasis, -2.8%; 3-min stasis, -4.8%), calcium (1-min stasis, +1.6%, 3-min stasis, +3.6%,) and albumin (1-min stasis, +3.5%; 3-min stasis, + 8.6%) (17). A Study conducted in 2012, in Brazil found the overall performance of tourniquet application time between public and private laboratories was 84.4 (14.1) seconds, but in Private laboratories tourniquet application time was significantly shorter than public laboratories (69.9 [±10.6] sec versus 98.9 [±17.3] sec. But, only 7% of the total achieved a recommended mean tourniquet time of 60 seconds or less (4). The authors could not justify why private laboratories showed a significantly lower torniquet application time compared to their government counterparts. However, they speculated that the pressure for a fast turnaround time might have a greater influence on procedures in private laboratories (4).

Another study conducted in Italy compared results obtained from different application time and found meaningful bias for RBC, WBC, hematocrit , hemoglobin, monocytes, and lymphocytes in the

sample collected using either 1- and 3-min stasis in the measurement of numerous hematological parameters (18).

2.3 Order of blood draw

Phlebotomists should use the recommended collection sequence of blood in vacuum tubes in the order of : 1) coagulation; 2) serum with clot activator, with or without gel separator; 3) heparin with or without gel separator; and 4) Ethylenediaminetetraacetic acid (EDTA) with or without gel separator. But, the modification of this sequence has the potential to introduce a source of contamination into primary collection tubes through carrying over of additives (1, 4, 16). A study in Brazil also assess the sequence of collection and found that the lack of compliance with correct tube sequencing was observed in more than 85% of phlebotomies and significant difference was also observed between the results from public (93%) and private laboratories where 80% of them practice erraneous sequence (4). Incorrect sequence was practiced despite phlebotomy trainings in evacuated tubes but the phlebotomists did not consider the tube sequence to be important (4).

2.4 Volume and mixing variation of collected blood

According to CLSI guideline - USA , adequate mixing of blood in tubes containing anticoagulants or additives is essential for the effectiveness of those ingredients, as also adopted by the datasheets from nearly all manufacturers (19). A study in Italy was conducted to compare mixing variation and its results by using K2 EDTA tube whole blood. The results on unmixed specimens showed significant decrease for red blood cell count, hemoglobin, hematocrit and platelets count, whereas the mean platelet volume was significantly increased (20).

CLSI recommended that for plasma based coagulation testing, the proportion of blood to the liquid sodium citrate dehydrate anticoagulant volume is 9:1. Inadequate filling of the collection device will decrease this ratio, and may lead to inaccurate results. As fill volume decreases and the blood to anticoagulant ratio drops below 9:1, clotting times in seconds tend to increase. This effect is not as great when samples are drawn into 3.2% sodium citrate as compared to 3.8%. The effect of fill volume on clotting time results may also be dependent on reagent as well as the size of collection tube and hence 90% fill volume is recommended (19).

An experimental study conducted in south Africa in 2010 by using different volumes of whole blood drawing into tubes containing a fixed volume of 3.2% (0.109M) sodium citrate, concluded that INR values increased as total tube fill volumes decreased (21). In one year study conducted in China a total of 0.19% insufficient sample volumes and improper methods of mixing of the samples were identified. The rate of generation of unqualified samples decreased significantly after the implementation of improvement measures (0.26% in 2009 vs. 0.13% in 2010) (5).

Another study in USA found that volume variation resulted a statistically significant effect on INR results with the mean (+/- SD) INR resulting from sample tube filled 100% (3.2 +/- 1.2), with comparing to 9.9 +/- 4.2 for tubes 50% full and conclude that tube filled < 90% will have a statistically significant effect on INR result (22).

Taken together, the available reports showed effects of torniquet application time, improper sample collection and mixing on test values. In Ethiopia, a study was conducted on a total of 1533 (750 for hematology and 783 for clinical chemistry) samples to determine the frequency and type of pre-analytical errors in Gondar University Hospital. Examination of the samples showed that 0.98%, 2.8% and 0.98% of them were hemolyzed, insufficient for analysis and clotted, respectively (23). Other than such efforts, to our knowledge no published study is available in our country regarding phlebotomy practices like torniquet application, sample volume and mixing, tube order among others.

3 Objectives of the study

3.1 General objective

To assess the practice of phlebotomists and to identify the major sources of errors during venues blood collection in public hospitals in Addis Ababa, Ethiopia.

3.2 Specific objectives

- To assess the performance of phlebotomists' in Public Hospital Laboratories
- To identify the major source of errorrs observed during venous blood specimen collection
- To assess the setup of phlebotomy area and availability of documents

4 Methodology

4.1 Study area

The study was conducted in selected public health facilities in Addis Ababa which is the largest city in Ethiopia. The city has 46 hospitals, 11 are public hospitals, of which 6 are under Addis Ababa Regional Health Bureau (AARHB) and 5 are specialized referral ones (one University Hospital and 4 of them under the Federal Ministry of Health). Three are military hospitals, 4 are NGO's and the rest 28 are private hospitals.

This study focused on 11 public hospitals in the city and surrounding areas which use Vacutainer tube for blood collection. Those were Tikur Anbessa Specialized teaching hospital, St. Peters TB specialized hospital, ALERT center, St.Paul's Hospital Millenium Medical college, Zewditu Memorial hospital, Yekatit 12 hospital, Minilik II hospital, Ras Desta Damtew hospital, Tirunesh Beijing hospital , Emanuel hospital and Ghandi memorial hospitals. One of the hospitals (Emanuel Hospital) selected for piloting by using lottery selection method.

4.2 Study design

Hospital based, observational and interview based cross sectional type study was conducted between April 15-May 10, 2014. In this study both quantitative and qualitative design data collection method was used. Observational follow up study was performed that the practice of phlebotomists were observed while they collect the blood specimen. Phlebotomists were considered for interview about their practice towards phlebotomy services using structured questionnaire. Patients who came for phlebotomy services were interviewed about their demographic and voluntarily participation based on the inclusion criteria. Observational checklist were used to assess the practice of phlebotomists using recommended technique. The performance of each phlebotomist was monitored in 5 different phlebotomies (blood collection practices) and each activity performed during the blood collection time was collected and recorded.

4.3 Study period

Pre testing: Data for pre-test were collected before two weeks of actual data collection started.

Actual data collection time: actual data collection was conducted from April 15-May 10, 2014.

4.4 Source population

The source populations were all phlebotomists who were performing blood collection on out patients in public hospitals, Addis Ababa.

4.5 Study population

All phlebotomists in the selected governmental hospitals in Addis Ababa who were performing venous blood collection using Vacutainer tube system were our study population.

Inclusion Criteria

All voluntary phlebotomists and patients were included and patients who came with atleast two different type of venous blood collection requests (like for hematology, PT/PTT, chemistry and more others) were included.

4.6 Sample size

The required sample size was determined by using single proportion formula considering the following assumptions:

Negative prevalence (1-p)=50%

phlebotomist performance; 50 % was taken due to absence of reliable previous study that show the performance of phlebotomist

Level of significance (p - value)= 0.05 (5%)

Marginal of error (d) = 0.15 (15%) was used to minimize sample size

Non-response rate= 10%

The formula for calculating the sample size (n) was $n = \frac{(Z\alpha/2)^2 P (1-P)}{d^2}$

Where: n= total sample size

n_i - Sample size calculated from infinite population

$Z(\alpha/2)$ = Z-score at 95% confidence interval = 1.96

P= positive prevalence (assuming that 50 % of the phlebotomist were having good performance) (1/2=0.5)

1-P= negative prevalence/proportion (1/2= 0.5)

d= marginal error 0.15 (15%) is used to minimize sample size.

$\Rightarrow n_i = \frac{(1.96)^2 * 0.5(1-0.5)}{(0.15)^2}$

$\Rightarrow n_i = 42.6$

$= \underline{43}$

$\Rightarrow$ by adding 10% non-response rate to n_i = 43 x10% $\Rightarrow \underline{4.3}$

$\Rightarrow$So total sample size = n_i + 10% non-response rate

$\Rightarrow$ n= 43+4.3

= 47 phlebotomists were included from 11 public hospitals

Equal proportion of phlebotomists; here there are

11 hospitals

47 phlebotomists

$\Rightarrow$ 47/11

$\Rightarrow \underline{4.2}$

$\Rightarrow$ 4 **phlebotomists** from each hospital were supposed to be included

If below four phlebotamists were avalaible in some of participating laboratories, the study tried to compenstate by increasing number of study participant in others laboratories which have more than 4 phlebotomists. The study followed phlebotomists when each phlebotomist is collecting 5 different venous blood collections, so the total of 235 (47x 5) venous blood collections were included.

4.7 Sampling procedures

All 11 public hospitals laboratories in Addis Ababa city were included. The total sample size was 47 phlebotomists who were found during the study period and each of them was evaluated in five different phlebotomies. Patients were selected by convenient sampling method as long as the inclusion criteria is fulfilled, after each follow up and observational study for each patient was finished. In addition, to prevent bias and alerting of the phlebotomist of their actual practice, each phlebotomist was interviewed after all follow up and observational study for all phlebotomist practices were finished.

4.8 Data collection method

Structured questionnaires and checklists were used for the interview and observational or follow up techniques. The contents of questionnaire included socio demographic characteristics, education, training, work experience of phlebotomist and the practices during phlebotomy services were assessed.

A number of questions that could address the objective of this study were gathered and adapted. In order to improve the developed questionnaire, valuable comments were incorporated from different sources. The first draft questionnaire was English version and then translated to Amharic Language. The layout of the questionnaire was designed to be easy to read and number of pages were limited, to ensure that the questionnaire could be completed within a reasonable period of time. It was pretested for contents and reliability in phlebotomy context, then correction was done accordingly. The data were collected from the study hospitals by experienced medical laboratory professionals and training were given for data collectors and supervisors about the collection of data until they all well understood the aim and method of collection. Factors that were looked during evaluation of the Phlebotomist performance were:

- Time of tourniquet application
- Proper identification of requests to patients before and after blood draw to check their experience of identification and way of communication with patients
- Excessively aggressive disinfection of the forearm by the phlebotomist, which can produce venous stasis

- The order in which vacuum tubes were used during specimen collection, Proper labeling and adequacy of mixing of blood in primary vacuum tubes that contain anticoagulant or clot-activating additives and other relevant informations.

If the phlebotomists become informed about the study, it might be alert for the phlebotomies and might take special concern during blood collection which would bias the study. To minimize the bias the laboratory managers were the only personnel who were informed about this research; the phlebotomists were unaware why the data are being collected. The performances of the phlebotomists were evaluated only during procedures that involve blood collection in vacuum tubes (i.e. coagulation activator, sodium citrate, ethylene diaminetetra acetic acid [EDTA], heparin, or sodium fluoride). The performance of each phlebotomist was monitored in 5 different collections and after the observation finished phlebotomist were questioned about their practice. Data was collected from April 15-May 10, 2014.

4.9 Study Variables

4.9.1 Dependent variables

Measure phlebotomist veins blood collection practices in the laboratory. That is,

- Proper identification of the right patients before collection,
- Tourniquet application time during collection,
- Cleaning of puncturing sites,
- Order of tube during collection,
- Mixing of collected sample,
- Labeling

4.9.2 Independent variables

- Gender
- Education
- Phlebotomy training

4.10 Data Processing and Analysis

Data entry and statistical analysis were performed using EPI-Data version 3.1, SPSS version 20(Statistical Package for the Social Sciences). Descriptive statistical analysis were used such as percentage, number and data was presented as tables and figures. Majore source of errorrs were compared by using chi square tests. Descriptive statistics and chi square tests were analyzed with SPSS software, version 20. P-values less than 0.05 were considered as statistically significant.

4.11 Data quality assurance

The questionnaire was pre-tested two weeks before the actual data collection. One day training was given for data collector, supervisor and questionnaire was also prepared by local language to facilitate data collection. Data collectors were instructed to check the completeness of each questionnaire at the end of each interview. The supervisor rechecked the completeness of the questionnaire immediately after interview at the spot. The principal investigator also checked the completeness of the data immediately when the data was submitted.

4.12 Ethical considerations

Ethical clearance was obtained from Departmental Research and Ethics Review Committee (DRERC) of Department of Medical Laboratory Sciences, College of Health Science, Addis Abba University, Addis Ababa Health Bureau Research Ethical committee, ALERT/AHRI ethical committee, St Peter TB specialized hospital ethical clearance committee and St Paul's Hospital Millenium Medical college ethical committee. A formal letter of cooperation was requested from Addis Ababa City Administration Health Bureau to all Addis Ababa city hospitals and from Department of Medical Laboratory Sciences, college of Health science, Addis Abba University to the federal hospitals ALERT centre, St Peter TB specialized hospital and St Pouls.

To maintain confidentiality, data collectors asked patients' and phlebotomists to participate in the study before the interview. Then those participants willing to participate were included in the study. Data collectors informed respondents that they have full right to discontinue or refuse to participate in the study at any time. A letter of agreement was attached to the questionnaire to obtain the written consent of each individual.

5 Operational definition

Quality: doing the right thing in the right way at the right time for the right patients.

Hemolysis: Breakdown of red blood cell

Hemoconcentration: A decrease in the fluid content of the blood (plasma) resulting in an increase in concentration of blood cells. Caused by a filtration of plasma into body tissues and often created by dehydration.

Quality assessment: the systematic collection and analysis of information to determine quality of services/care.

Process: the activities that constitute the patient-provider interaction including diagnosis, treatment and prevention activities etc.

Additive – in a specimen collection tube, any ingredient that is placed in a collection container to facilitate an intended function (e.g. to prevent the blood from clotting or to prevent glycolysis)

Anticoagulant – an agent that prevents coagulation of blood or blood products

Capillary blood – blood obtained by skin puncture or incision that contains a mixture of undetermined proportions of blood from arterioles, venues and interstitial and intracellular fluids

Clot activator – material used to initiate the clotting mechanism

Collection sequence: order of vacuum tube usage during blood collection using Vacutainer needle or during distancing collected blood from syringe

Client- any one who comes in to laboratory to get any laboratory service

Recommended collection order: collection or adding of blood samples in to test tube in the order of SST/ PLAIN tube first and EDTA tube secondly

Error– any incorrorect works from the recommended one

Order of draw – standardized sequence used during the blood collection process for the filling of the blood collection tubes to minimize carryover of tube additives from tube to tube.

Specimen – the discrete portion of a body fluid or tissue taken for examination, study or analysis of one or more quantities or characteristics to determine the character of the whole

Tourniquet: In regards to Venipuncture a constrictive band placed over an extremity to distend veins for the purpose of blood aspiration or intravenous injections. Materials used may be rubber, latex, or other synthetic elastic material. A blood pressure cuff may also be used.

Recommended Tourniquet: A latex or plastic strip with a Velcro closing used to cause blood to pool in the area and to enlarge the veins, making them easier to palpate

Phlebotomy: is the act or practice of opening a vein by incision or puncture by needle to collect blood.

Phlebotomist: A person who performs phlebotomy has the title "Phlebotomist", and can be laboratory professionals, doctors, nurses or trained persons.

Evacuate: create a vacuum in or removing of air from the tube

Performances: ability to do the assigned works

Patient preparation: Identifying and checking of state of condition of patients before blood collection that will affect / mislead quality of test results

Critically ill: Patents who are unable to walk, speak

Trained: Anyone who is taking training on phlebotomy or blood collection

Experienced: Anyone who is working three years and above in phlebotomy and laboratory service

Good volume: volume of blood filled more than ¾ of blood tube volume

Recommended mixing: times (5-8 times) of mixing for blood collected with additives like for SST, EDTA tubes

Identification of patients: checking of the right patients by confirming with hospital card, by asking patients to state their name and checking with requests they hold

Good labeling: labeling of blood collection test tubes with unique ID, patient name/ initial, collection date and time, collectors name/initial, address of requesters' and requester name/ initial and signature

appropriate cleaning : is cleaning of puncture site should be cleaned by starting from the centre of the venipuncture site and work outwards by covering an area of 2 cm diameter slowly

6 Results

6.1 General information

A total of 40 phlebotomists and 200 patients from ten public hospitals of Addis Ababa were involved in the study. Piloting was done in one hospital selected by using lottery method. Phlebotomists were evaluated when they were collecting venous blood samples from five different clients who were coming for getting laboratory service.

6.1.1 Base line information about the hospital phlebotomy area

The study assessed the phlebotomy area of each hospital. Nine of the ten hospitals have clear sign of direction. Eighty percent (8 of 10) of phlebotomy area had clean waiting area and in70% (7 of 10) had patients waiting area outside of blood collection area. Seventy percent (7 of 10) of the blood collection area had sufficient space to precede their works and had separate cleaning area but 50% (5 of 10) of the phlebotomy areas had no clean water access to keep hygiene (Table 1). Ninety percent (9 of 10) of them had cleanable surface and blood drawing table but 70% (7 of 10) of phlebotomy areas were not ventilated. Phlebotomy areas were not appropriate to secure patients' confidentiality as other patients were around when patients are giving blood specimen in 30% (3 of 10) of phlebotomy sites (Table 1). As shown in Table 1, ninety percent (9 of 10) of phlebotomy sites had no any SOPs found during the study time but 50% (5 of 10) of them posted job aids which directs how to collect and process blood and other specimens. All laboratories have requests which had space for writing and recording of results and necessary information like patient's socio demographic information, requesting date, time, signature and clinical information. Blood collection materials were accessible and available for blood collection in all laboratory specimen collection areas (Table 1).

Table 1: Base line information about the hospital phlebotomy area in public hospitals in Addis Ababa, May 2014.

Base line information	Frequency	Percentage
Sign or direction indicator of the laboratory		
Yes	9	90.0
No	1	10.0
Have clean waiting area		
Yes	8	80.0
No	2	20.0
Patients waiting outside collection area		
Yes	7	70.0
No	3	30.0
Sufficient size phlebotomy room		
Yes	7	70.0
No	3	30.0
Phlebotomy separate cleaning area		
Yes	7	70.0
No	3	30.0
Clean water for washing		
Yes	5	50.0
No	5	50.0
Phlebotomy table surface cleanable		
Yes	9	90.0
No	1	10.0
Adequate number of chairs		
Yes	7	70.0
No	3	30.0
Clean drawing table		
Yes	9	90.0
No	1	10.0
Ventilated collection room		
Yes	3	30.0
No	7	70.0

Room confidentiality for patients		
Yes	7	70.0
No	3	30.0
SOPs availability and accessibility		
Yes	1	10.0
No	9	90.0
Availability of Job aids		
Yes	5	50.0
No	5	50.0
Requests' form containing pts full name, age, sex, ID, physician sign, sign of tester, date and other information space		
Yes	10	100.0
No	0	0.0
Availability of tourniquets (elastic and recommended)		
Yes	9	90.0
No	1	10.0
Availability of cottons and gauze, alcohol, collection materials, waste and sharp containers		
Yes	10	100.0
No	0	0.0

6.1.2 Socio Demographic Characteristics

Out of the 40 phlebotomist 25(62.5%) were females and 15(37.5%) were males and of the 200 participated clients on whom phlebotomists practice was followed, 107(53.5%) were females and 93(46.5%) were males. The average (±SD) age of patients were 31.68 (± 17.54) years (ranges from 2-74 years), whereas the mean (±SD) age of phlebotomists were 31.65 (± 9.7) and they were found in the age group of 20-29 (52.5%), 30-39 (25%), 40-49 (15%) and 50-59 (7.5 %) (Figure1). Nineteen (47.5%) of the phlebotomist had monthly income within range of 1001-1500. Twenty-one (52.5%), 8 (20%), 6 (15.0%), and 12.5% (5 of 40) of the phlebotomists were educated diploma in laboratory, degree and above, certificate, and ≤12 grade, respectively (Table 2).

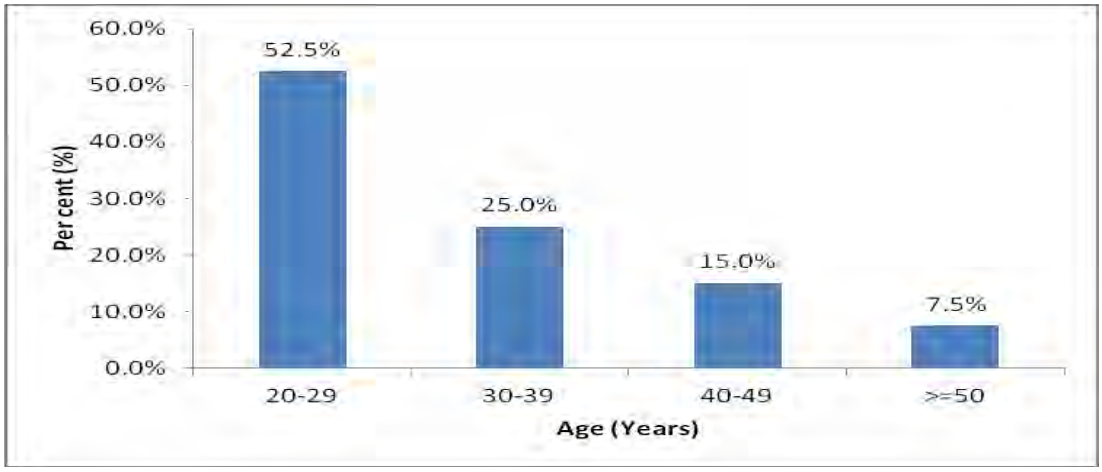

Figure 1: Age (in Years) distributions of phlebotomists in public hospitals in Addis Ababa, May 2014

Table 2: Socio-demographic characteristics of phlebotomist in public hospitals in Addis Ababa, May 2014 (N=40)

Category	Frequency	Percent (%)
Sex		
Male	15	37.5
Female	25	62.5
Marital Status		
Single	18	45.0
Married	22	55.0
Divorced	0	0
Widowed	0	0
Education		
≤12	5	12.5
Phlebotomy Certificate	6	15.0
Diploma	21	52.5
Degree and above	8	20.0
Work experience		
≥3 years	28	70.0
<3 years	12	30.0
Monthly income		
501-1000	8	20.0
1001-1500	19	47.5
1501-2000	4	10.0
2001-2500	4	10.0
>2501	5	12.5
Vaccinated (like HBV)		
Yes	14	35
No	26	65

6.1.3 Knowledge of the phlebotomist about general phlebotomy service

About 55% (22 of 40) phlebotomists had no idea about the recommended tourniquet application time whereas only 37.5 % (15 of 40) knew too long application would have impacts on laboratory test results. Ten percent (4 of 40) of phlebotomists allow patients to go immediately before blood was stopped bleeding (Table 3). Majority of them 60% (24 of 40) of phlebotomist said they were using collection sequences as EDTA tube firstly and SST/ plane (dry tube) second. While 85% (34 of 40) of them were thinking that SST tube with additive does not need mixing, 40% (16 of 40) said collected blood with EDTA tube were mixed or inverted 1-4x times. Moreover, 92.5 % (37of 40) of phlebotomist reported that they are using the recommended elastic tourniquets during phlebotomy (Table 3). Around half [52.5% (21of 40)] of them said identification's of patents done by asking to state their full name and checking by comparing name with the request they bring and also with hospital cards.

All (100%) Phlebotomists agreed that recapping of needle are performed by using one hand principle and disposed used sharps with sharp containers. Regarding hand hygiene, 70% (28 of 40) of phlebotomist said that they have performed hand hygiene before and after blood collection and after removal of gloves. While 75% (30 of 40) of phlebotomists said they do not know for how many minutes to let the tourniquet applied during venous blood collection, 62.5 % (25 of 40) even did not know the impacts of applying tourniquets too long on laboratory results. But 67.5% (33 of 40) of them agreed as they have general knowledge about phlebotomy service. After sample collection, 32 of 40 (80%) of phlebotomists said they let the patients to stay until the bleeding is stopped and all of them said they use new gloves for each new patients who come for getting phlebotomy service. Regarding labeling, 57.5% (23 of 40) of phlebotomists reported that they always label the time of blood collection, however, only 3 (7.5%) reported correct time for labeling (that is after collection and before the patient leaves). Majority, 97.5% (39 of 40) of them know the recommended volume to be filled in vacuumed tube (Table 3).

Table 3: General knowledge of phlebotomists on standard procedures during blood collection in public hospitals in Addis Ababa, May 2014 (N=40)

Phlebotomy procedures	Frequency	Percent %
Sequence of blood collection tube		
SST / plane tube 1st (recommended)	16	40
EDTA tube 1st (non recommended)	24	60
Number of time of tube mixing after collection		
SST tube (5-8 times)		
Acceptable	6	**15.0**
Unacceptable	34	**85.0**
EDTA tube (5-8 times)		
Acceptable	24	60.0
Unacceptable	16	40.0
Type of tourniquets they prefer to use		
Recommended type	18	45.0
Not recommended (like gloves, IV set, …)	22	55.0
Way of patient identification		
Acceptable (Ask patients to state full name & check with request)	40	100.0
Unacceptable	0	0
General knowledge had on phlebotomy		
Adequate	33	**82.5**
Inadequate	7	**17.5**
Allow patients to stay after collection		
Will let them out immediately after blood collection	4	10.0
Let them stay until blood stopped	32	80.0
depends according to patients' condition	4	10.0
Frequency of mixing blood tube with aditives		
I always mix	25	62.5
I always mix except when I am busy	15	37.5
When do you performing hand hygiene		
before collection only	4	10.0
after blood collection and removal of gloves only	8	20.0
before collection and end of blood collection and removal of each	28	70.0

gloves		
When do you change and use new glove		
I change for every new patients coming for the service	40	100.0
Labeling of time of blood collection		
Yes	23	57.5
No	17	42.5
Knowledge of recommended volume to be filled		
Yes	39	97.5
No	1	2.5
Knowledge of minutes left to stay tourniquet on patients during blood collection		
≤1 minutes	10	25.0
Not know exactly how much minutes to apply	30	75.0
Knowledge on impact of too long time of tourniquet application on laboratory results		
Yes	15	37.5
No	25	62.5
Labeling of test tube		
Before I approach the patients (before checking to whom the request is)	17	42.5
Before collection after checking the request	20	50.0
Alongside after collection and before the patients goes out	3	7.5

6.1.4 Observational findings on patient preparation and handling during venous blood collection

Forty phlebotomists were followed while each of them performs 5 phlebotomy procedures on a total of 200 patients during observational study. The results are summarized in Table 4. Accordingly, phlebotomists were not easily identifiable for 108 of 200 (54%) of patients (like they do not introduce their name or do not put badge which could identify themselves for clients). And 126 of 200 (63%) of patients were not asked any permission from phlebotomists before blood collection (Table 4). Phlebotomists did not change new gloves for 134 of 200 (67%) of patients. They apply tourniquets without observing the presence of good vein visually for 175 of 200 (87.5%) of blood collection procedures; they just ask patients to extend their arm, apply a tourniquets and then start to locate the vein. Cleaning of blood collection site were performed for 195 of 200 (97.5%) of patients

by using 70% alcohol but for 5 of 200 (2.5%) of patients no cleaning procedure was performed (Table 4).

Table 4: Observational findings on patient preparation and handling during venous blood collection in public hospitals in Addis Ababa, May 2014

Procedures	Frequency	Percent
Phlebotomist introducing/ easily identifiable for patients		
Yes	92	46.0
No	108	54.0
Ask minor permission before collection		
Yes	74	37.0
No	126	63.0
Phlebotomist wear new gloves for each patients		
not wear glove	5	2.5
Yes	61	30.5
No	134	67.0
Locate good vein without applying tourniquet		
Yes	25	12.5
No	175	87.5
Cleaning blood collection site with 70% alcohol swabs		
Yes	195	97.5
No	5	2.5
Cleaning site with gentle pressure		
not clean at all	5	2.5
Yes	15	7.5
No	180	90.0
Collecting blood after cleaning alcohol dried from blood collection site		
Yes	61	30.5
No	139	69.5
Use elastic tourniquet		
Yes	132	66.0
No	68	34.0
Inappropriate requesting to clenching fist during collection		
Yes	101	50.5
No	99	49.5
Touching of cleaned site		
Yes	66	33.0
No	134	67.0
Repeat cleaning of touched cleaned collection site		
Yes	28	14.0
No	38	19.0
Not applicable	134	67.0

6.1.5 Observation during venous blood collection

Only 35% of the phlebotomists use vacutainer tubes with vacutainer needle to collect blood sample, while most of the use syringe and transfer blood to vacationer tube; 60.5% (121) of blood collected were transferred by removing the needle from syringes and by opening vacuum tube. Regarding sequence of blood draw, 53.5 % (107 of 200) of the phlebotomies were performed following unrecompensed order of tube collection sequences. Of the collected blood with additive, 60.5% were mixed gently to prevent hemolysis. During 85% (170) of the collections, tourniquets were not released after blood starts to flow in to the syringes and tubes (Table 5). Labeling of test tubes was performed before blood collection and before checking of the patients in 51 % (102) of blood collections. Phlebotomists used hospital card number for labeling in 90% of collection tubes. Except few hospital phlebotomies which were using labeling by using barcode and for one hospital laboratory which have great concern on specimen quality and quality results which used labeling by using hospital ID, date of collection, time of collection, collectors initials, address of requesting units and patents name or initials, more than 57.5 % of tubes containing specimens were not easily identifiable to minimize the preanalytical errors and for performing repetitions of testing required (Table 5).

Table 5: Observational finding during venous blood collection in public hospitals in Addis Ababa, May 2014

Procedures	Frequancy	Percentage
Collection materials used for vacuum tube		
Vacutainer with needle	70	35.0
Syringe	130	65.0
Transferring blood without removing the needle		
Yes	9	4.5
not applicable (use vacationers needle)	70	35.0
no (remove the needle)	121	60.5
Transferring blood by opening vacuum tube		
Yes	121	60.5
No	79	39.5
SST/ Plain/ EDTA tube collection order/ sequence		
SST/plain tube 1st (recommended)	93	46.5
EDTA tube 1st (unrecommended)	107	53.5
Removing tourniquet after blood flow starts		
Yes	30	15.0
No	170	85.0
Recommended tube volume filling		
Yes	105	52.5
No	95	47.5
Gently mixing to prevent hemolysis		
Yes	121	60.5
No	79	39.5
Labeling of tube		
Alongside the patiets after collection and before the patients' go out	20	10.0
Before blood collection and after confirming the patients'	78	39.0
Before blood collection and before checking the patients'	102	51.0
Tubes labeled with date		
Yes	85	42.5

No	115	57.5
Tubes labeled with Time		
Yes	85	42.5
No	115	57.5
Tubes labeled with patients hospital number		
Yes	180	90.0
No	20	10.0
Tubes labeled with patients initial		
Yes	40	20.0
No	160	80.0
Tubes labeled with clinic address		
Yes	69	34.5
No	131	65.5
Tubes labeled with phlebotomists initial		
Yes	50	25.0
No	150	75.0
Labeled by lab number		
Yes	35	17.5
No	165	82.5

6.1.6 Observational finding after venous blood collection

All of the phlebotomists were applying cottons in collected sites that were used for cleaning skin site for blood collection and when they were asked why they use these dirty swabs for stopping blood, most of them have no reason. Phlebotomists were recapping needles in about 89 % of collections by using one hand principle which was very helpful to minimize needle stick injury; for that reasons most of the phlebotomists said that they have never exposed to needle stick injury. Most phlebotomists were putting blood samples on test tube rack immediately after blood collections but 78.5% (157) of the collections were not mixed or unacceptable mixing time was practiced after collection (Table 6). Of note, during the study time hand hygiene were not performed in all the studied phlebotomy service by phlebotomists

Table 6: Observational finding on practices after venous blood collection in public hospitals in Addis Ababa, May 2014

Observational finding	Frequency	Percentage
Apply new gauze after blood collection		
No	200	100.0
Yes	0	00.00
Recapping of needles after blood collection		
No	7	3.5
Yes	193	96.5
Way of recapping needle after blood collection		
not recapped	7	3.5
by using one hand	178	89.0
by using two hand	15	7.5
Storing collected sample		
give it to patients	2	1.0
laying on table	27	13.5
put on racks	171	85.5
EDTA tube blood mixing times		
Acceptable (5-8x)	122	61.0
Unacceptable	78	39.0
SST tube with additives blood mixing times		
Unacceptable	157	78.5
Acceptable	43	21.5

Among the major errors committed, we selected some and compared against the socio demographic factors. Table 7 shows the major errors distributions based on phlebotomist sex distribution (male=15 and female= 25). Significant difference between genders were found regarding not using new gloves for every patient, where males demonstrated better use (p=0.024). But no significant finding was found for the other selected errorrs..

Table 7: Major Source of errors observed during phlebotomies by sex distributions in public hospitals in Addis Ababa, May 2014

Error distributions	**N (%) Of phlebotomies** All (200 phlebotomies by 40 phlebotomists)			P value*
	N=200[#]	Phlebotomies by Male N=75[#]	Phlebotomies by Female N=125[#]	
Not using of new gloves for each new patient	139 (69.5%)	45(60%)	94(75.2%)	0.027
Inappropriate cleaning procedure of venipuncture site	180 (90.0%)	68(90.7%)	112(89.6%)	1.000
Collecting blood before cleaning alcohol dry	139(69.5%)	47(62.7%)	92(73.6%)	0.115
Incorrect tube collection sequences	107(53.5%)	39(52%)	68(54.4%)	0.771
Wrongly using of tourniquets after blood flow starts in to the tube/ syringes	170(85.0%)	64(85.3%)	106(84.8%)	1.000
Applying tourniquet before locating good sites and vein	175(87.5%)	64 (85.3%)	111 (88.8%)	0.512

*chi square test used (Statistically significant, $p<0.05$)

[#]Number of phlebotomies

Table 8 summarizes common source of errors observed during phlebotomies by educational status of the phlebotomists (Below diploma = 11 and Diploma and above= 29). As shown in the table, statistically significant finding was observed on not using new gloves for new patients (p=0.00), wrong tourniquets application after blood flow into the tube or syringes (p=0.000), incorrect tube collection sequences(p=0.00) and wrongly applying tourniquets before locating good vein (p=0.007). In all cases those below diploma level peform better.

Table 8: Major Source of errors observed during phlebotomies by educational status in public hospitals in Addis Ababa, May 2014

Error distributions	**N (%) Of phlebotomies** All (200 phlebotomies by 40 phlebotomists)			P value*
	All (n=200) #	Below diploma (n=55) #	Diploma and above (n=145) #	
Not using of new gloves for each new patient	139 (69.5%)	25(45.5%)	114 (78.6%)	0.000
Inappropriate cleaning procedure of venipuncture site	180 (90.0%)	53(96.4%)	127(87.6%)	0.070
Collecting blood before cleaning alcohol dry	139 (69.5)	37(67.3%)	102(70.3%)	0.732
Incorrect tube collection sequences	107(53.5)	18(32.7%)	89(61.4%)	0.000
Wrongly using of tourniquets after blood flow starts in to the tube/ syringes	170 (85.0%)	33(60.0%)	137(94.5%)	0.000
Applying tourniquet before locating good sits and vein	175 (87.5%)	42(76.4%)	133(91.6%)	0.007
*chi square test used (Statistically significant, p<0.05) #Number of phlebotomies				

Table 9 summarizes common source of errors observed during phlebotomies based on phlebotomy training distributions (trained = 16 and untrained = 24). As shown in the table, statistically significant differences were observed on not uising of new gloves for new patients (p=0.00), incorrect tube collection sequnces (p=0.002) and wrongly applying tourniquets before locating good vein (p=0.048), in which those taking phlebotomy training peform better than those who did not.

Table 9: Major Source of errors observed during phlebotomies based on phlebotomy training distributions in public hospitals in Addis Ababa, May 2014

Error distributions	**N (%) Of phlebotomies** All (200 phlebotomies by 40 phlebotomists)			P value*
	All (n=200) #	trained (n=80) #	untrained (n=120) #	
Not using of new gloves for each new patient	139(69.5%)	43(53.8%)	96(80%)	0.000
Inappropriate cleaning procedure of venipuncture site	180 (90%)	71(88.8%)	109(90.8 %)	0.638
Collecting blood before cleaning alcohol dry	139(69.5%)	54 (67.5%)	85(70.8%)	0.641
Incorrect tube collection sequences	107(53.5%)	32(40%)	75(62.5%)	0.002
Wrongly using of tourniquets after blood flow starts in to the tube/ syringes	170(85%)	64(80%)	106(88.3 %)	0.111
Applying tourniquet before locating good sits and vain	175(87.5%)	65(81.2%)	110(91.7 %)	0.048

*chi square test used (Statistically significant i.e $p<0.05$)

#Number of phlebotomies

Tourniquet application time was recorded for the 40 phlebotomists and is depicted in Figure 2. The final grand mean (SD) was 51.57 seconds (±12.514). Our finding indicates that appropriate tourniquet time was utilized in 148 of 200 (74%) patients based on CLSI where as 52 of 200 (26%) where collected with greater than maximum recommendation time (60 second) by CLSI recommendation. Only 5 of 200 (2.5%) collections were collected below 30 seconds which is very acceptable.

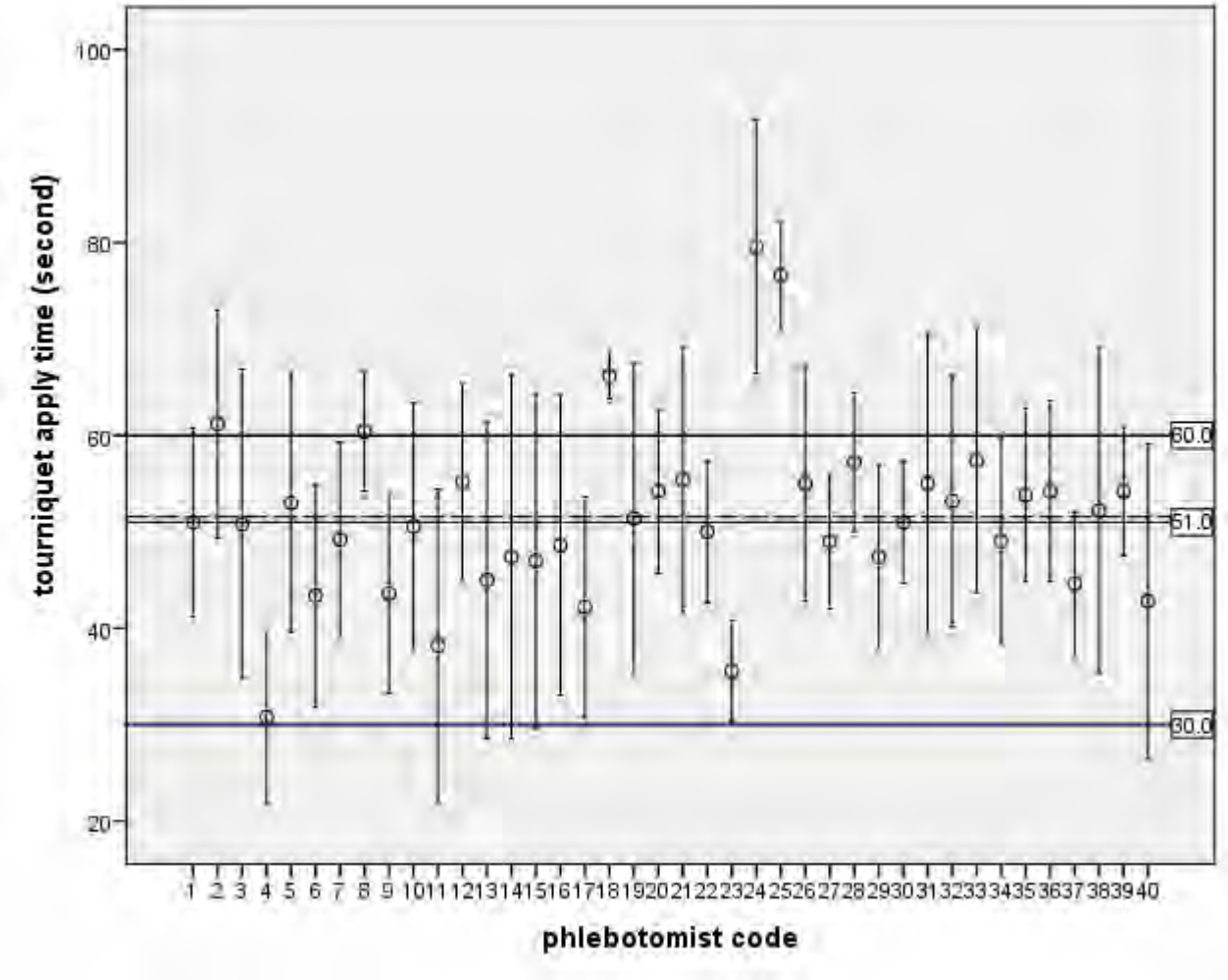

Figure 2. Tourniquet application time in seconds during phlebotomy in public hospitals in Addis Ababa, May 2014

Note: Identical symbols show that the mean (SD) tourniquet time of each phlebotomist. The double line indicates that the overall mean of tourniquet application time. The solid line on 60- seconds

mark shows that the maximum recommended time and the line at 30 seconds mark indicates mean time of tourniquet application time according to clinical and laboratory standards' institute (CLSI) publication H3-A5 (16).

Figure 3 showed that tourniquet application time between experienced mean(SD) 52.28±13.1 and non experienced phlebotomists mean(SD) 49.9±10.9 and here the mean time of application were slightly higher than non experience (P>0.05).

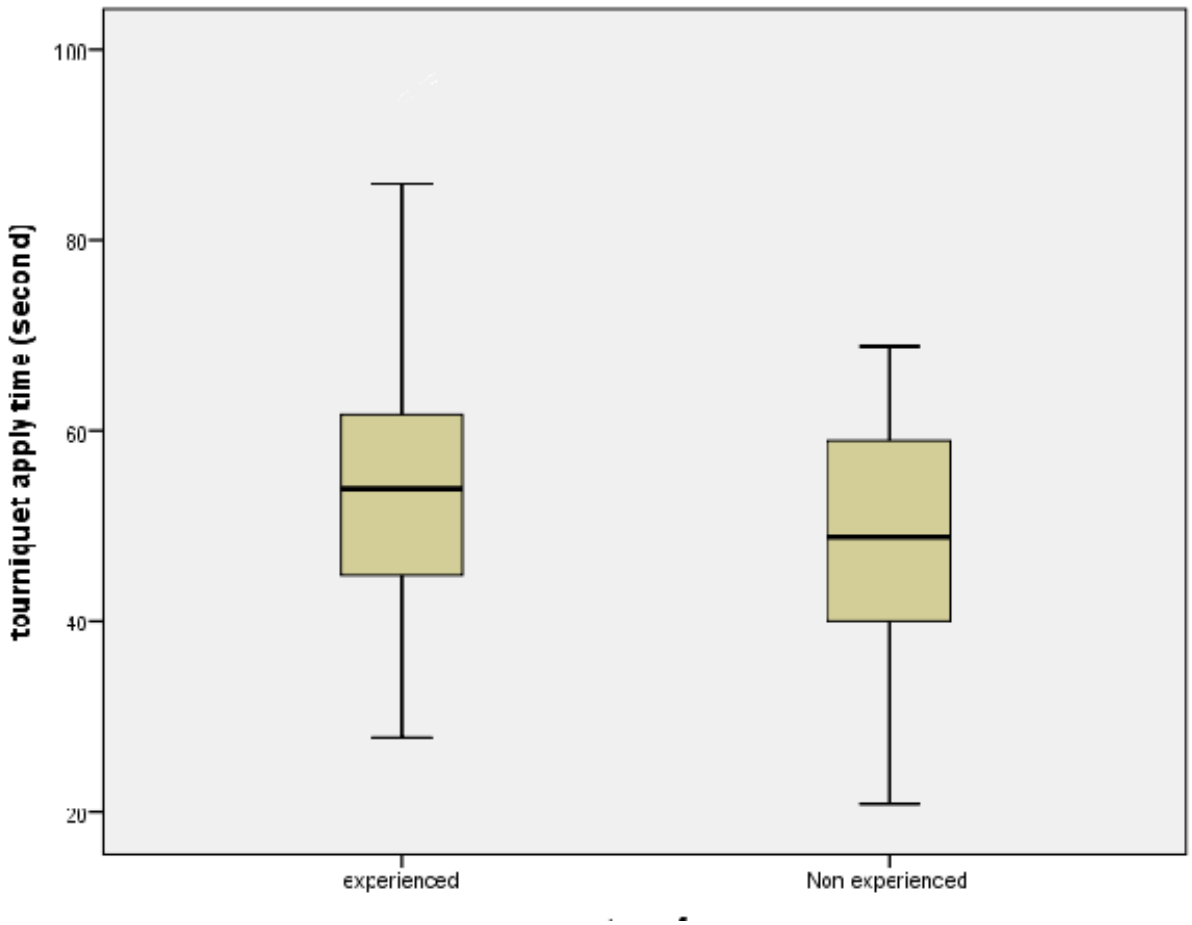

Figure3. Tourniquet applying time based on phlebotomists experience in public hospitals in Addis Ababa, May 2014

Figure 4 showed that tourniquet application time comparison based on experience and training. From this picture we observed that there is no difference between experienced and trained for tourniquet usage, even experienced were delaying more than the mean application time but non experienced perform lower than the total mean time.

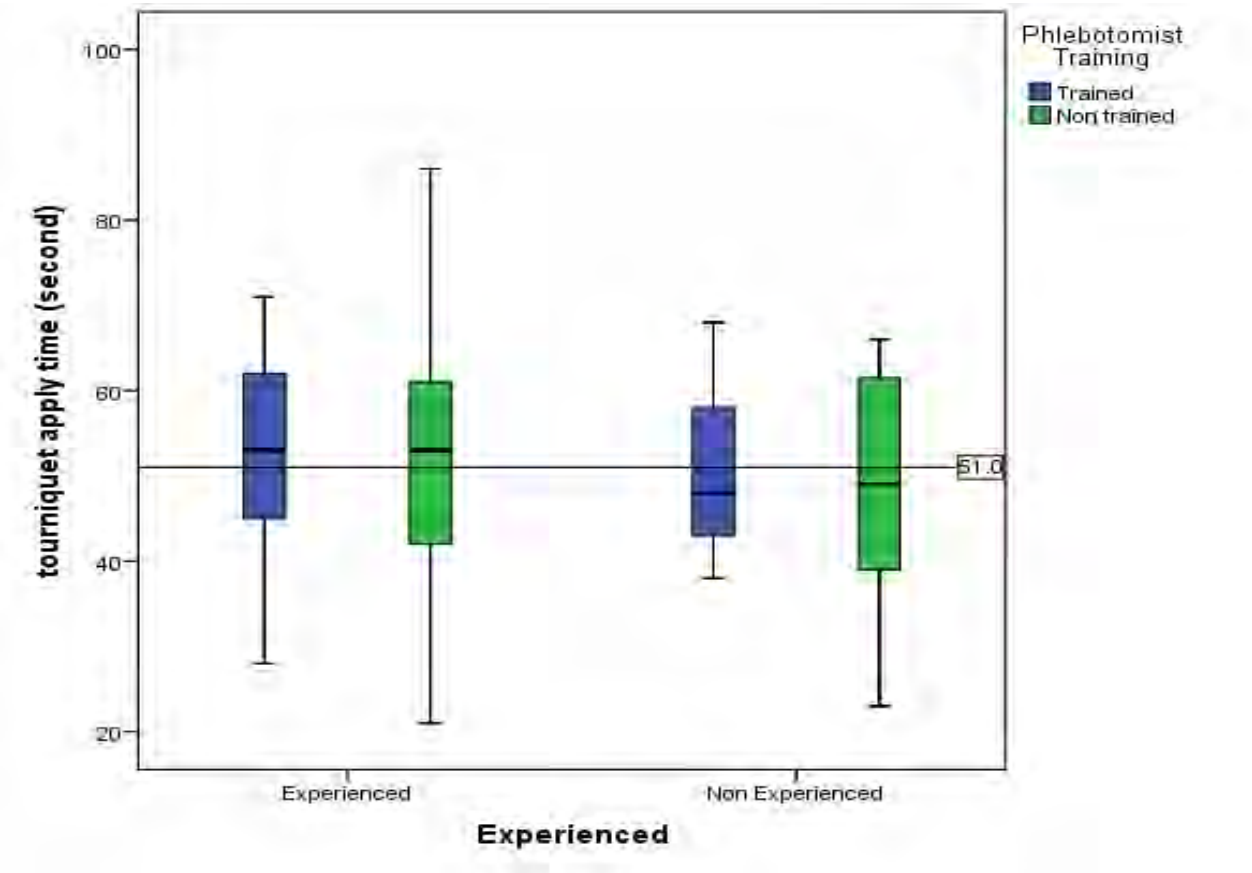

Figure4. Tourniquet application time based on phlebotomists experience and training in public hospitals in Addis Ababa, May 2014.

Note: Experienced and trained were n= 11, experienced and non trained n= 17, non-experienced and trained n=5 and non experienced and not trained n=7 with adjusted ratio(OR) = 0.9.

7 Discussion

Several studies have documented most of the errors in the clinical laboratory occur in the pre analytical phase accounting up to 80% (2, 4, 6, 8, 9). Phlebotomy is most neglected but regularly practiced medical process worldwide. It can lead to adverse problems in patient safety and healthy life if not properly regulated (1, 2, 4, 11). This study aimed to assess the practice of phlebotomists and to identify the major sources of errors during venous blood collection in public hospitals in Addis Ababa, Ethiopia.

Primarily, laboratories should have clear sign and direction that will direct clients' where the laboratory sample collection area found and which prevent patients from killing their time by searching blood collection area(1). During blood collection, other patients should be waiting outside of the collection area for the sake of confidentiality of the patients. Specimen collection area should have sufficient space and clean washing water access to perform washing hands and to wash if any accident happened (1). In this study, 80% of the phlebotomy areas were found that have clear sign that directs easily where the collection area is found and 70% had sufficient space to perform daily works and this agrees with the recommended WHO 2010 phlebotomy guideline, although 20-30% of the phlebotomy sites have to still fulfill this (1).

Each laboratory should have their own standard operating procedure (SOP) (1), which instructs the phlebotomists how to collect, handle, and manage phlebotomy service starting from patients identification up to providing of specimens for laboratory testing without affecting the quality of specimens. Nevertheless, only one phlebotomy site was found that have SOPs, in the rest 90 % of the phlebotomy areas no SOPs were found available in the collection area during the study time, whereas half of them have posted short job aids.

Phlebotomy service is a very direct intractable area with the patients (1, 10) as patients only need to get service by any means. Before starting the work, all materials which is required for collection should be available (1), but in this study we found that all of them have availed enough collection materials for their work which fullfill the recommendations of WHO blood drawing guide line.

Quality of care is one of the essential services of laboratory; it benefits both the laboratory work and the patient when clear information or permission (it could be verbal or written) is available for each patient who came for phlebotomy (1). Phlebotomist should be easily identifiable to the patient which increase the patient confidence and increase smooth communication between patients and collectors (1). But, in this study more than half of the phlebotomists were not easily identifiable and more than sixty present of patients were not asked permission befor starting blood collection which contradicates WHO blood drawing guide line (1).

Safety is the major issues of the laboratory as the most infectious specimens are proceed in the laboratory(1). Infection prevention should be implemented throughout all steps of laboratory works and Special care is required for patients during blood collections (1, 10) but in our study new glove were used only for 30.5 % of phlebotomies , which is not recommended by WHO blood drawing guide line. Around 60 % of phlebotomists disclosed that they get trained on infection prevention but not vacinated (65% {26 of 40}) and not follwed WHO recommendations that phlebotomists should be vacinated(1). According to WHO blood drawing guide line and Bowen et al, the puncture site should be clean properly in circular manner from the puncture site out wards slowly but in our study cleaning of collection site was performed by rubbing vigorously and irregularly; sometimes in zigzag and repeating the cleaned site with dirty swab for 180 (90%) of collections which was almost similar with the study conducted in Brazil (85%) (4), but in contrary with WHO blood drawing guide line (1).

WHO blood collection guide recommends after blood is collected, the punctured site should be pressed to stop bleeding by using new gauze (1,13), but in our study, it was found that all phlebotomists were practicing to stop bleeding by applying alcohol swabs which were used for cleaning of punctured sites but inconterary with WHO and PATH recommendations and infection privantions should be in place as recommended by WHO and Lai X et al (1,5).

Our finding showed that a large proportion, 130 of 200 (65%), of phlebotomies were performed by using syringe and needle and most of them transfer blood by opening the vacuum tube which violets CLSI and Beckton Dickinson (BD) recommendations (13, 14) but only 35 % were using a vacutainer needle suggesting for a critical need for a targeted practical oriented training requirements by BD (14).

Phlebotomists were requesting clients to clench unnecessarily his/her fist repeatedly during the study time for 50.5 % (101) of collections , which is incomparable with the study of Lima-Oliveira G et al 2012 that reported 83% of observed patients were unnecessarily requested to clench fists repeatedly but those practices would lead to change in the PH of local skin, affect electrolyte concentration like potassium, calcium and protein analyses (4).

According to PATH publications, BD lab notes, CLSI H3-A5 and other publications, sequence of blood collection with vacuum tube should be in the order of 1st coagulation (citrated tube), 2nd serum tube with clot activator, 3rd heparinated tube and 4th EDTA (Ethylenediaminetetraacetic acid) (8,10,13,14,16). If this order is modified the possibility of contamination through carryover with additives will be potentially high; but, in our study 53.5%(107 of 200) phlebotomies were collected by modifying SST with additive and EDTA tubes collection order but lower than similar problems observed (87%) by Lima-Oliveira G et al 2012 findings (5).

Blood collected with additive tube should be mixed by inverting gently for effective homogeneity of additive with the blood within the tube as recommended by most manufacturers(13, 14). But in our study 60% of collections were not mixed as recommended by manufacturers, which was smaller than Lima-Oliveira G et al 2012 findings 83% (4). Mixing blood collected with additives like SST tubes, clot activators facilitates a dense rapid and complete clotting for clear separation of serum by centrifugation (19, 25).

According to CLSI H3-A5 and WHO guideline, blood collection materials should be labeled after confirming of patients and after insuring of enough blood collection for laboratory testing and before the patients leaving from collection area, and collected tube should be labeled at least with patient's first and last names, identification number, date and time of collection, identification of the person collecting the specimen and address from where the test is requested. The specimen by itself should be identifiable without the need of requests (1,16, 19). However, in our study only 10% of the phlebotomists labeled the tube after blood collection and before patients leave the collection area while the other labeled the tube before blood collection (use prelabeled tubes), which is not followed the CLSI and WHO guideline (1, 16). Our study found that bellow 40 % of the collections were fulfilled the recommended labeling on blood collection tube by different publications(1,5,13).

Generally, six major sources of errors were observed in the 10 public laboratories. Those errors were selected based on CLSI descriptions, BD lab notes and PATH publications (13, 14, and 16). During blood collection, Phlebotomists should wear well-fitting gloves, and should also carry out hand hygiene before and after each patient procedure, before putting on gloves and after removing the gloves (1, 13). But during our study 139 (69.5%) phlebotomies were performing without changing gloves for different patients, which lead to the infection of blood borne and skin microorganisms that cause disease in human and contradicate with WHO blood collection guideline (1).

It is acceptable to use tourniquets to increase vein visibility during blood collection (1, 2,4). However, there is a recommended time to apply tourniquet during venous blood collection (4,13, 16). CLSI indicates that optimum tourniquet application time should be 30 seconds and not to exceed more than 60 seconds (16, 25) as increasing the time of tourniquet more than 60 seconds could significantly affect the result of laboratory tests (17). we observed that applying before checking visibility of vein were for 175(87.5%) collections, which is not follow the WHO and Lai X et al recommendations(1,5).

We observed more than 80% of phlebotomists were found wrongly applying the tourniquets even when the blood was starting to flow and even few of them were not immediately removing it after blood collection is finished. But different literatures and guideline indicated prolonged tourniquet application will increase the hemoconcentrations of non filterable elements (like proteins) and increase hydrostatic pressure for causing some water and filterable elements to leave the extracellular space and enter the venous blood and have significant effect for abnormal increment of result for total protein, aspartate aminotransferase (AST), total lipids, cholesterol, and iron and affects packed cell volume and other cellular elements (1,4,10,12,13,16, 17). For that reason we found time of applying of tourniquets includes with in recommended time (51.6±12.5). However, this result was different with the study showed by Serdar et al as average time of less than 30 seconds (12); but, our finding disproof the finding of Lina-oliver G. et al that the overall mean (SD) application time of 84.4± 14.1(4).

Strengths and limitations of the study

Strengths

- ✓ This study assessed different aspects of laboratory phlebotomy service; it shades light what the laboratory phlebotomy service practices of public hospitals in Addis Ababa look like.
- ✓ The study is new in its kind that no other similar study has been done in the country yet. Thus, it will be a valuable base line data for planning and implementation for increasing laboratory quality service and to increase patient's healthy life.
- ✓ In this study both observational follow-up and interview type of methods were used

Limitation

- ❖ Interviewed results were dependent on phlebotomist response so biased information might be given as data were collected during their daily working time. However, the observational data helps to minimize this bias.
- ❖ The study covers only phlebotomists that are found during the study period, so those who are not in working site during the study time were not included.
- ❖ The study only observe vein blood collection practice, we did not included other specimen collection and all specimen handling up to result delivering.

8 Conclusion and Recommendations

Conclusion:

According to our study findings the following conclusions could be obtained;

- Most phlebotomy areas were having clear sign of location, clean patients waiting area and requests contains space to record informations of the patients
- Almost all laboratory phlebotomy site have no SOPs that directs how to collect, process and handle laboratory specimens but few have job aids
- Most of phlebotomy area were not well ventilated and could be cause of infection for phlebotomist and patients
- Most of the phlebotomist were not getting phlebotomy training and even those who have training and who responded as they have enough knowledge on phlebotomy service were not well practicing phlebotomy.
- The main errors were using of a single gloves for different patient, vigorously and inappropriately cleaning of vein collection site, collection of blood specimens before disinfectant alcohol dry, incorrectly using of collection tube sequence, collecting with syringe and transerring to vacutainer tubes some even by opening the tubes with additives, applying of tourniquets even after blood flow started in to the tube or syringe and tourniquet application before examination of appropriate collection site
- Average tourniquet application time of phlebotomists were with in range of CLSI recommendations but have little knowledge of its usage and it's impact if applied too long.

Recommendations:

Based on the finding of the result about phlebotomy service and phlebotomy practice the following recommendations are forwarded:

1. Laboratories should have clear sign and direction that will direct clients' where the laboratory sample collection is found (some in this study do not have signs).

2. Phlebotomy area should be ventilated.

3. In our study phlebotomy trainings were given within laboratories for their phlebotomy use only but training providers should design and provide especial and organized specimen collection training for phlebotomists following WHO, CLSI guidelines and manufacturers instructions.

4. Based on our findings phlebotomist who were educated below diploma were assigned specifically on phlebotomy service and perform relatively better than those who were diploma and above but were assigned additionally to laboratory testing, so organizations should be promoted to assign workers for phlebotomy service only

5. No specimen collection SOPs found in almost all phlebotomy area; so general phlebotomy SOPs should be provided and available in collection areas. The situation might even be worst in patient venous blood collections, thus, SOPs should be available with appropriate training in all collection sites.

6. Laboratory managers, supervisors or quality officers at each facility should take responsibility to ensure quality of laboratory specimen

7. Phlebotomists are performing their daily work with infectious and possibility of injury conditions so phlebotomists should be vaccinated.

9 Reference

1. WHO Guidelines on Drawing Blood: Best Practices in Phlebotomy. Geneva; 2010.

2. Lippi G, Salvagno GL, Montagnana M, Franchini M, Guidi GC. Phlebotomy issues and qualit improvement in results of laboratory testing. Clinical laboratory. 2006;52(5-6):217-230.

3. Hawkins R. Managing the pre-and post-analytical phases of the total testing process. Ann Lab Med. 2012;32(1):5-16.

4. Lima-Oliveira G, Guidi GC, Salvagno GL, Montagnana M, Rego FG, Lippi G, et al. Is Phlebotomy Part of the Dark Side in the Clinical Laboratory Struggle for Quality? Lab Med. 2012;43(5):172-176.

5. Lai X, Yang P, Zhang Y, Cao J, Zhang L. Analysis of Factors Influencing the Generation of Unqualified Clinical Samples and Measures to Prevent this Generation. Ann Lab Med. 2012;32(3):216-219.

6. Mäkitalo O, Liikanen E. Improving Quality at the Preanalytical Phase of Blood Sampling: Literature Review.International Journal of Biomedical Laboratory Science (JIBS).2013;2(1):7-16.

7. Bolenius K, Brulin C, Grankvist K, Lindkvist M, Soderberg J. A content validated questionnaire for assessment of self reported venous blood sampling practices. BMC Res Notes. 2012;5:39. 1

8. Saurav Patra M, Mukherjee B, Das AK. Pre-analytical errors in the clinical laboratory and how to minimize them. Int. J. Bioassays. 2013;2(3):551-553.

9. Söderberg J, Wallin O, Grankvist K, Brulin C. Is the test result correct? A questionnaire study of blood collection practices in primary health care. J Eval Clin Pract. 2010;16(4):707-711.

10. Bowen RA, Hortin GL, Csako G, Otanez OH, Remaley AT. Impact of blood collection devices on clinical chemistry assays. Clin Biochem. 2010;43(1-2):4-25.

11. Lippi G, Becan-McBride K, Behúlová D, Bowen RA, Church S, Delanghe J, et al. Preanalytical quality improvement: in quality we trust. Clin Chem Lab Med. 2013; 51(1): 229–241.

12. Serdar MA, Kenar L, Hasimi A, Kocu L, Turkmen YH, Kurt I, et al. Tourniquet application time during phlebotomy and the influence on clinical chemistry testing; is it negligible. Turk J Biochem. 2008;33:85-88.

13. Program for Appropriate Technology in Health (PATH). RBP-EIA: Collecting, Processing, and Handling Venous, Capillary, and Blood Spot Samples.PATHPublications.2005. [http://www.path.org (accsessed date 16 september 2013)]

14. Bush V, Mangan L. The Hemolyzed Specimen: Causes, Effects, and Reduction. BD LabNotes. 2003;13(1).[http://www.bd.com/vacutainer (accessed date 12 september 2013)]

15. Sultan J, Afzal T, Jabeen K. Identification of the Types of Pre-analytical Errors in the Clinical Chemistry Laboratory from Jan-2012 to Dec-2012 at Jinnah Hospital, Pathology Department. A.P.M.C . 2013; 7:1 (accsessed date 1 september 2013)]

16. Clinical and Laboratory Standards Institute (CLSI). Procedures for the collection of diagnostic blood specimens by venipuncture. Document H3-A5. 2003;23(32):17.

17. Lippi G, Salvagno GL, Montagnana M, Brocco G, Guidi GC. Influence of short-term venous

stasis on clinical chemistry testing. Clin Chem Lab Med. 2005;43(8):869-75.

18. Lippi G, Salvagno G, Montagnana M, Franchini M, Guidi G. Venous stasis and routine hematologic testing. Clinical & Laboratory Haematology. 2006;28(5):332-7.

19. Clinical and Laboratory Standards Institute (CLSI). Collection, Transport, and Processing of Blood Specimens for Testing Plasma-Based Coagulation Assays and Molecular Homeostasis Assays. CLSI H21-A5. 5th ed. Wayne, PA: Clinical and Laboratory Standards Institute; 2008.

20. Lippi G, Salvagno GL, Montagnana M, Banfi G, Guidi GC. Evaluation of different mixing procedures for K2 EDTA primary samples on hematological testing. Lab Medicine. 2007;38(12):723-5.

21. Potgieter J, Pool R, Prinsloo A, Botha E, Olorunju S. The impact of collection tube fill volume on international normalized ratio. Medical Technology SA. 2011;24(1):6 .

22. Chuang J, Sadler MA, Witt DM. Impact of evacuated collection tube fill volume and mixing on routine coagulation testing using 2.5-ml (pediatric) tubes. CHEST Journal. 2004;126(4):1262-6.

23. Addis Z, Birhan W, Mathewos B, Alemu A. Frequency and type of pre-analytical errors in Gondar University Hospital, presented at the 18th annual conference of the Ethiopian Medical Laboratory Association (EMLA), 8-9, June 2013, Addis Ababa, Ethiopia Abstract 07.

24. Clinical and Laboratory Standards Institute (CLSI). Collection, Transport, and Processing of Blood Specimens for Testing Plasma-Based Coagulation Assays and Molecular Homeostasis Assays. CLSI H01-A6. 5th ed. Wayne, PA: Clinical and Laboratory Standards Institute; 2010.

25. Clinical and Laboratory Standards Institute (CLSI). Collection, Transport, and Processing of

Assays. CLSI documents GP 34-A. 5th ed. Wayne, PA: Clinical and Laboratory Standards Institute; 2010.

10 Annexes

10.1 Annex I: English Version Questionnaire and checklist

ADDIS ABABA UNIVERSITY DEPARTMENT OF MEDICAL LABORATORY SCIENCES

Questionnaire for data collection on the evaluation of the performance of phlebotomists and for identify the major sources of errors during venous blood collection in Addis Ababa hospitals.

General about the hospital

Name of facility_____

Institution code _____ Address: sub city_____ Kebele _____

For selected patient

Hello, how are you? My name is…… I am currently a student of Addis Ababa University, School of Medical laboratory Sciences going to conduct a survey. I would like to ask your willingness to follow you during your venous blood collection time. The objective of this study is to evaluate the performance of phlebotomists and to identify the major sources of errors during venous blood collection in public hospitals in Addis Ababa. This will be important to improve quality of laboratory phlebotomy practice in over all laboratory works towards quality patient care. Your cooperation and willingness for the study during your blood collection time will be very helpful in identifying the problems related to the issue. Your name will not be written in the form and I assure you all the information obtaine will be kept strictly confidential. Your participation is voluntary and you are not obliged to participate in the study. If you are not comfortable you can stop from participation any time you like. Do I have your permission to continue?
A. yes B. no

If yes, continue to the next page for the interview

If no, continue to the next patient

Consent form for patient selection

I have heard the information above and clearly understood the purpose and expected benefit of the research. I hereby need to assure with my signature below that I, without any forceful act by the research team, have decided to willingly participate on this research to contribute my part for the improvement of laboratory quality service.

Institution code _____ Interviewer's name_____

Signature of the patient_____ Signature_____

Date_____ Date of interview _____Time _____

Supervisor's Name_____ Signature_____

If you have any questions about this research , you can contact the principal investigator

Wondimeneh Liknaw Tel. +251911305040

Email- wondimenehliknaw@gmail.com

I thank you for your cooperation

patient interview				
1	Age			
2	Sex			
3	if "female" are you pregnant?			
Observation Base line information				
Part 1: About general location of the hospital laboratory				
No	Questions	yes	no	Comment
101	Does this facility have clear sign for lab units, location of lab specimen collection services?			
102	Are the receptions and waiting areas of the laboratory clean ?			

103	Is Waiting areas outside the collection area?			
104	Is the phlebotomy room have	yes	no	
	sufficient size for efficient operations?			
	with separate areas for cleaning and dirty processes?			
	with clean running water and with proper hand washing?			
	surfaces cleanable (not be carpeted) by disinfectants?			
	any other comment?			
104	Is there an adequate number of chairs for the number of patients present at waiting area?			
105	Is the blood drawing area clean including table?			
106	Is the blood drawing area ventilated?			
107	Are the chairs for the phlebotomy service appropriate? (The chair should have arms to provide support and prevent falls if the patient loses consciousness)			
108	is phlebotomy sit comfortable for privacy of the patient ? (no other patients with in the collection room)			
109	how many phlebotomist involved per day?			
Part 2: About general Phlebotomy and available items				
		Yes	no	Comment
201	Does this facility have SOPs for sample collection and monitoring phlebotomy service?			
202	written standard operating procedures available and accessible?			
203	Does any job aids available on the site of collection for quick referring during collection ?			
	Dose the requisition form fulfill the necessary things like	Yes	no	
	patient full name			

204	Age			
	Sex			
	Hospital ID			
	Name and signature of requesting clinician			
	Date of requested			
	Clinical information of the patients			
	Address of sender/ requesters'			
205	Are every equipments which are necessary for blood collection available and accessible in collection site?	Yes	no	
	Tourniquet			
	70% alcohol swabs for skin disinfection			
	gauze or cotton-wool ball to be applied over puncture site			
	laboratory specimen labeling equipment			
	Sharp container (leak-proof containers and that could be sealed after use)			
	Test tubes(vacuum or non vacuum)			
	Vacutainer needle			
	Syringe			
206	which type of tourniquets available			
	manufactured for the purpose of blood collection with plastic clip			
	they use disposable			
	Inelastic and laboratory made (like IV set)			

Part 3: Observation during phlebotomist Identify and preparing of the patient

301	Is phlebotomist introducing themselves to the patient or			

	easily identifiable to patients? (badge or posted name avail ?)			
302	Is phlebotomist asked the patient to sit and state their full name before collection?			
303	Do they Check that the laboratory form matches with the patient's identity? (i.e. match the patient's details with the laboratory form, to ensure accurate identification)?			
304	Do they ask whether the patient has allergies, phobias or has ever fainted during previous injections or blood draws?			
305	Do they ask the patient for intake of food before some tests which will be affected by food intake (e.g. fasting tests)?			
305	Are phlebotomist carrying out a minor, verbal or written permission or consent before collection from the patient during blood sampling?			
Part 4: During Selecting the site for blood collection and Disinfection of the site				
401	Do they ask the patient's Extend arm and inspect the appropriate sit of collection?			
402	Are wear well-fit gloves for each procedure			
403	Are they able to locate a vein of a good size that is visible, straight and clear? (The vein should be visible without applying the tourniquet)			
404	Do they clean the site with a 70% alcohol swab approximately for 30 seconds ?			
405	Are phlebotomists perform cleaning by applying firm but gentle pressure, Start from the centre of the venipuncture site and work downward and outwards to cover an area of about 2 cm or in circular motion from the center to the periphery ?			
406	Do they allow the area to dry (≈ 30 sec) before collection ?			
407	Do they use Clean elastic tourniquet			
408	Do they apply the tourniquet about 3 to 4 inches (7.5 to 10.0 cm) above the venipuncture site and re-examine the			

	vein ?			
409	Record Tourniquet application time from tourniquet application up to removal of tourniquet during phlebotomy	Time		
	Starting time			
	Ending time			
410	Do phlebotomists inappropriately request the patient to clench his or her fist repeatedly during collection ?			
411	Do they touch the cleaned site before collection ?			
412	If the site is touched after cleaning, do they repeat the disinfection?			
Part 5: Observation during blood collection				
501	Do they use Vacutainer needle or syringe			
	What are the gage number (16-18 or 21 or 22 or 23)			
	If they use syringe, do they remove the needle and use safe transfer device for inserting vacuum tube in it			
	Are they open the vacuum tube and add the syringe sample in the tube?			
	using number , record which tube is first and the next (rank order) collected during collection	Use 1st, 2nd ,...		
	Coagulation			
	Serum with clot activator, with or without gel separator			
	Heparin with or without gel separator			
	Ethylenediaminetetraacetic acid (EDTA) with or without gel separator			
	Glycolytic inhibitor			
		Yes	no	
502	Do they release and remove the tourniquet as soon as possible after the blood begins to flow?			

503	Are collected sample fill >˜3/4 th of the total volume ?			
504	How much time do they mix the tube containing additives after collection?	write in number like 2x, 3x..		
	Serum with clot activator, with or without gel separator			
	Heparin with or without gel separator			
	Ethylenediaminetetraacetic acid (EDTA)			
	Glycolytic inhibitor			
505	way of mixing the contents of vacuum tubes	Yes	no	
	by inverting gently and slowly to prevent any heamolysis			
	by shaking the tube vigorously			
506	When do they label the test tube?	Yes	No	
	Before blood collection and before checking the patient			
	Before blood collection after confirming the patient			
	Alongside the patient after collection and before the patient go out			
	Somebody else labels the test tube after sampling			
	Somebody else has labeled the test tube in advance any time			
	At a later occasion when finishing collection and after patient go out			
507	Does the tube labeled with (can be more than one answer)			
	Collection date			
	Patient id			
	Patient name(initial)			
	Address of the clinic where they come from			
	Name(initial) of collectors			

508	Are they apply new gauze at the end of collection on the puncture site ? if not, specify ?			
509	Do they recap after blood collecting?			
510	How they recap the needle? (One-hand or both hand)			
511	Do they perform Hand hygiene Before and after each patient contact, as well as between procedures on the same patient			

10.2 Annex II. Interviewing Questionnaires for phlebotomist

ADDIS ABABA UNIVERSITY

DEPARTMENT OF MEDICAL LABORATORY SCIENCES

Hello, how are you? My name is…… I am currently collecting data for a student of Addis Ababa University, Department of Medical laboratory Sciences .I would like to ask your willingness to answer to some general questions about phlebotomy or venous blood collection. The objective of this study is to assess the general knowledge of phlebotomists about the phlebotomy they performed. This will be important to improve quality of laboratory phlebotomy practice in over all laboratory works towards quality patient care. Your cooperation and willingness for interview will be very helpful in identifying the problems related to the phlebotomy knowledge gaps. Your name will not be written in the form and I assure you all the information you give will be kept strictly confidential. Your participation is voluntary and you are not obliged to answer any questions that you do not want to answer. If you are not comfortable you can stop a participation any time you like. Do I have your permission to continue? A. yes B. no

If yes, continue to the next page for the interview, if no, continue to the next phlebotomist

Interviewing Questionnaires for phlebotomist
Part 6: Interviewing for phlebotomist

No	Questions			Comment
601	Age			
602	Sex	male	female	
603	Marital status	yes	no	
	Single			
	Married			
	Divorced			
	Widowed			
604	Education			
	≤12			
	Certificate on			
	Diploma			
	Degree and above			
605	Experience			
	≤1			
	2-5			
	6-9			
	≥10			
606	How much do you get(Birr) per month ?			
	≤500			
	501-1000			
	1001-1500			
	1501-2000			

	≥2501			
		yes	no	
607	Have you take phlebotomy training ?			
608	Have you vaccinated (like HBV) ?			
609	Have you ever exposed for needle stick injury during blood collection?			
610	If Yes, Have you taken PEP? how many times			
611	have you take any safety training before ?			
612	How and how often do you check the identity of a patient when collecting venous blood sampling?	yes	no	
	I ask the patient to state his/her full name and confirm with the request			
	I already know the patient			
	I ask the patients relatives			
	I check the patient s hospital ID-card			
	I call patients name (Are you ...?)			
613	If the patient has a skin lesion at the intended tourniquet location of both hands, what should you do ?			
	I use alternate drawing site			
	Apply the tourniquet over the patient's gown			
	Use a piece of gauze pad or paper tissue			
614	During labeling, which unique labeling do you use to prevent miss labeling on test tube at the same time?			
615	Do you label the collection time on test tube ?			
	if yes, for "615" how often do you mark the sampling time on the test request and test tube ?			
	Always In all both tube and request			

	Always in test tube only			
	Not always but sometimes			
	No , not marking time of collection			
616		Yes	no	
617	Is there any other tube labeled with the collection time (observationally check it) ?			
	If you see stasis(hematoma) when performing venous blood sampling, what did you do?			
	I stop before the first tube collection			
	I stop any time during sampling			
618	I stop after the sampling is finished			
619	Do you know the recommended minimum volume to be filled in the tube ?			
620	if no for the above "618" question , how do you collect and fill the tube ?			
621	What type of tourniquet do you use?			
622	If you are not use standard or recommended tourniquet , what is the reason for not using the standard one ?			
623	Do you know that applying the tourniquet have recommended time?			
624	How many minutes do you allow to stay the applied tourniquets on patient hand?			
625	Do you know applying too long the tourniquet have impact on laboratory results?			
	When do you label the test tube?			
	Before I approach the patient (before checking to whom the request is)			
	Alongside the before collection			

626	Alongside the patient after collection and before the patient goes out			
	At a later occasion when I finish collection and after patient goes out			
	Somebody else has labeled the test tube in advance any time			
	Somebody else labels the test tube after sampling			
		yes	No	
627	To what extent do you agree in the following statements? you have adequate knowledge			
	on phlebotomy			
	in Proper collection and handling of sample			
	on impact of phlebotomy in quality of laboratory results and quality of patient life			
628	How long do you usually allow your patient to rest after blood collection?(min)			
629	How often do you carry out inversion or mixing the test tube has an additive?			
	I always mix			
	I always mix except when I am busy			
630	if you mix the collected blood with tube additive, how much time do you mix the tube?	Like 1x, 2x,...		
	coagulation			
	serum with clot activator, with or without gel separator			
	heparin			
	(EDTA) ethylenediaminetetraacetic acid			
	coagulation			
631	What do you do when you are not sure how a sample should be collected?			

	How do you store the test tubes immediately after sampling?			
	Lying on a workbench			
	I will give to the patient to hold			
	In a test-tube stand rack			
632	any where that I get access to put the test tube			
	When do you carry out hand hygiene ?			
	before collection only			
633	after blood collection and removal of gloves only			
	before collection and end of blood collection and removal of glove			
	when do you change the glove ?			
	for every new patient coming			
634	as needed to change any time			
	after finishing all collection			
635	Do you use sterile, single-use blood-sampling devices for each collection?			
636	Do you discard the used device (a needle and syringe as a single unit) immediately after blood collection?			
	how do you dispose sharps materials ?			
	in sharp containers			
637	any containers which is provided in collection area			
638	During recapping of a needle, how do you do the recapping technique ?			
639	when do you disinfect collection surfaces and chairs?			
640	When do you Clean and Disinfect the tourniquets?			

10.3 English Consent form

I have heard the interview from the information sheet above and clearly understood the purpose and expected benefit of the research. I hereby need to assure with my signature below that I, without any forceful act by the research team, have decided to willingly participate on this research to contribute my part for the improvement of laboratory quality service and I assure that the above data is a true data that I give for the data collators during their visits for data collection on phlebotomy service.

Institution code _____ Interviewer's name_____

Signature of phlebotomist _____ Signature_____ _____

Supervisor's Name_____ Signature_____

I thank you for your cooperation

10.4 Annex III: Amharic version questionnaire

አዲስ አበባ ዩኒቨርሲቲ ላቦራቶሪ ትምህርት ቤት

እንዴት ነዎት፤ሥሜ----------ይባላል አሁን የምሰበስበው መረጃ ለአ.አ. ዩንቨርስቲ ሕክምና ላቦራቶሪ ተማሪ ለማስተርስ ዲግሪ መመረቂያ የሚሆን ጥናት ነው፡፡ በመጀመሪያ እርስዎ ስለሚቀዱት ሥራ ያለዎትን እዉቀት ለመዳሰስ ለማቀርብልዎት ጥያቄ መልስ ለመሠጠት ፍቃድኝነት እጠይቃለሁ፡፡ ጥናቱ የላበራቶሪ ጥራትን ለመጠበቅ ለሚደረገዉ ጥረት ጠቃሚ ስለሚሆን ይህም ታካሚዎችን ከአለስፈላጊ ሕመምና እንግልት ለማዳን ለሚደረገዉ ጥረት የእርስዎ መሳተፍ ያሉትን ችገሮች ለማወቅና ለችግሮች መፍትሄ ለመስጠት ጠቀሜታዉ ብዙ ነዉ፡፡በምንም መልኩ የእርስዎ ስምም ሆነ ማንነት የሚገልፅ በፍፁም አይኖርም የእርስዎ ተሳትፎ በእርስዎ ፍቃደኝነት ላይ ብቻ የተመሰረተ ብቻ ነዉ፡፡

ለመሳተፍ ፍቃደኛ ነዎት ? 1 አዎ 2 አይደለም

አመሰግናለሁ ::

ከተስማሙ መጠይቁን እንቀጥል

ለታካሚዎች መጠይቅ				
1	ዕድሜ			
2	ፆታ			
3	ሴት ከሆኑ አርግዘዋል?			
4	በጣም ወፍራም ናቸዉ ?			
5	ያለማንም እገዛ መንቀሳቀስ ይችላሉ?			
የደም ቀጅዎች ቃለመጠይቅ				
ክፍል 6: ለደም ቀጅዎች መጠይቅ				
ተ.ቁ	መጠይቅ	አዎ/ በቁጥር	አይደለም	አስተያየት
601	ዕድሜ			
602	ፆታ	ሴት	ወንድ	
	የጋብቻ ሁኔታ	አዎ	አይደለም	

603	ያላገባ			
	ያገባ			
	የፈታ			
	የሞተበት			
604	የትምህርት ሁኔታ			
	≤12			
	ሰርተፍኬት			
	ዲፕሎማ			
	ዲግሪ ና ከዛም በላይ			
605	የስራ ልምድ			
	≤1			
	2-5			
	6-9			
	≥10			
606	በወር ሥንት ያገኛሉ?			
	≤500			
	501-1000			
	1001-1500			
	1501-2000			
	≥2501			
607	የደም መቅዳት ሥልጠና ወስደዋል?			
608	የሄፓታይተስ ቢ ክትባት ወሥደዋል ?			
609	በመርፊ የመወጋት አደጋ ኢጋጥሞዎት ያዉቃል?			

610	ፕሮፍላክሲስ ወስደዋል? ምን ያህል ጊዜ ወስደዉ ያዉቃሉ?			
611	የሴፍቲ ሥልጠና ወስደዉ ያዉቃሉ ?			
612	ደም ሲቀዱ እንዴትና መቼ የታካሚዉን ማንነት ያረጋግጣሉ?			
	ሥማቸዉን እንዲናገሩ በማድረግና ያመጡትን የላበራቶሪ ትዕዛዝን በአንድ ላይ ማመሳከር			
	ማንነታቸዉን ቀድሜ አዉቃለሁ			
	የታካሚዉን ዘመድ እጠይቃለሁ			
	ስማቸዉን እጠራለሁ			
	የታካሚን ካርድ እጠይቃለሁ			
613	ምነአልባት የታካሚዉ ደም የሚቀዳበት ቦታ ላይ ጠባሳ ቢኖር እንዴት ይቀዳሉ?			
	ሌላ አማራጭ መርጣለሁ			
	ቶረንኬቱን በልብሱ ላይ አስራለሁ			
	ጎዝ ወይም ጨርቅ በመጠቀም ቶርነኬቱን አስራለሁ			
614	መለያ በሚሰጡበት ጊዜ ምን ምን በመጠቀም መለያ ይሠጣሉ?			
615	የቀዱበት ሰዓት መቅጃዉ ላይ ይመዘግባሉ??			
616	"አዎ", ለ "615" ከሆነ እንዴትና መቼ ይመዘግባሉ?			
	ሁሌም መቀጃዉ ላይ እና በላብራቶሪ መጠየቂያዉ ላይ			
	ሁሌም መቅጃዉ ላይ ብቻ			
	አልፎ አልፎ ብቻ			
	መቼም መዝግቤ አላወቀም			
617	ሌላ መቅጃ ላይ እንዳሉት መመዝገቡን ያረጋግጣሉ?			
	ደም ሲቀዱ እጃቸዉ ቢጠቁር (hematoma) ቢፈጠር ምን ያድረጋሉ?			
	መጀመሪያዉኑ መቅዳቴን አቋርጣለሁ			
	በማንኛዉም ሰዓት አቋርጣለሁ			

618	መቅዳቴን ስጨርስ ብቻ አቋርጣለሁ			
619	መቅጃዉን እቃ ዝቅተኛ መሞላት ያለበትን መጠን ያዉቃሉ?			
620	ለ "619" "የለም" ከሆነ ጥያቄ እነዴት ታድያ ይቀዳሉ?			
621	ምን አይነት ቶርኒኬት ይጠቀማሉ?			
622	እስታንዳርድ ቶርኒኬት ካልሆነ የሚጠቀሙት ምክንያቱ ምንድን ነዉ?			
623	ቶረንኬት ለምን ያህል ደቂቃ ታስሮ መቆየት እንዳለበት ያዉቃሉ?			
624	ለረጅም ጊዜ ቶረነኬቱን አስሮ መቆየት ላብራቶሪ ዉጤት ተፅዕኖ እንዳለዉ			
625	ምን ያህል ደቂቃ ቶርነኬቱን ታካሚዉ አስረዉ ይቆያሉ?			
626	መቅጃዉን መቼ መለያ ይሰጣሉ ?			
	የበሸተኛዉን ማንነት ከማረጋገቴ በፊት			
	Alongside the በሸተኛዉ እያለ ከመቅዳቴ በፊት			
	በሸተኛዉ አያለ ከቀዳሁ በኃላ			
	ከጨረስኩና በሸተኛዉ ከሔደ በኃላ			
	ሌላ ሰዉ ከጨረሰኩ በኃላ በማንኛዉም ጊዜ			
	በሌላ ሰዉ እኔ ቀድቼ እንደጨረስኩ			
627	ከታች ላሉ ነገሮች ምን ያህል ይስማማሉ? እኔ በቂ እዉቀት አለኝ ?			
	በደም መቅዳት			
	በጥሩ ሁኔታ ደም መቅዳትና በጥንቃቄ መያዝን			
	ደም መቅዳት በላብራቶሪ ዉጤት ላይ እደሚያመጣ ያዉቃሉ			
628	ታካሚዉን ከቀዱ በኃላ ለምን ያህል ደቂቃ እንዲያርፍ የደርጉታል ?			
	መቼ መቼ ደም ከቀዱ በኃላ በጥንቃቄ ያቀላቅሉታል ?			
	ሁሌም			
	አልፎ አልፎ			

629	አላደርግም			
630	በጥንቃቄ የቀዱትን ደም የሚያቀላቅሉ ከሆነ ምን ያህል ጊዜ እንደሚያቀላቅሉት በቁጥር ይግለጡ ?	1x, 2x,...	እንዴት አወቁት ምክንያቱ ይገለጥ	
	ኮአጉሌሽን ትዩበን			
	ደም እነዲረጋ የሚያደርግ ኬሚካል ያለዉና ጄል ያለዉን/ የሌለዉን			
	ሄፓረን ትዩበን			
	ኤዲቴ ትዩበን			
631	ምን ያደርጋሉ ምን አልባት እነዴት ደም መቅዳት ቢቸግርዎት?			
632	ደም እነደቀዱ ወዲያዉኑ እንዴት ያስቀምጡታል?			
	ጠረንጴዛ ላይ አጋድማለሁ			
	ታካሚዉ እነደይዘዉ እሰጠዋለሁ			
	በማስቀመጫ ቦታ ላይ አቁሜ አስቀምጣለሁ			
	በማንኛዉም ባገኘሁት ቦታ ላይ አስቀምጣለሁ			
633	እጅዎን መቼ ይታጠባሉ ?			
	ከመቅዳቴ በፊት ብቻ			
	ከቀዳሁና ጓንት ካወለኩ በኃላ			
	ሁሉንም ቀድቼ ከጨረስኩ በኃላ			
	ከመቅዳቴ በፊትና ከቀዳሁ በሁአላ			
634	ጓንት መቼ የቀይራሉ?			
	አዲስ ታካሚ በመጣ ቁጥር			
	እንደ አስፈላጊነቱ በማንኛዉም ሰዓት			
	ሁሉንም ቀድቼ እንደጨረስኩ			
635	ጥራቱን የጠበቀ እና ለ አንድ ጊዜ የሚያገለግል መቅጃ ለእያነዳነዱ ሰዉ ይጠቀማሉ?			
636	የተጠቀሙበትን እቃ ወዲያዉኑ ያስወግዳሉ?			

637	ስለታምና ሹል መሳሪያዎችን እንዴት ያስወግዳሉ?			
	ስለታምና ሹል መጣያ እቃ ዉስጥ			
	በማንኛዉም እቃ ላይ			
638	እንደግና መርፌን መክደን ሲያስፈልግዎ እንዴት ይጠቀማሉ?			
639	ጠረጵዛ እና ወንበሩን መቼ መቼ ያጸዱታል?			
640	ቶርኒኬቱን መቼ መቼ ያጸዱታል?			

10.5 Annex IV: Amharic Consent form

የስምምነት ማረጋግጫ፡፡

ከላይ የተዘረዘሩዉትን በትክክል ሰምቻለሁ፤አላማዉንም በትክክል ሰምቻለሁ፤አላማዉንም ተገንዘቤለሁ ጥቅሙም የላብራቶሪን ጥራት ለመጠበቅ እጅግ አንደሚጠቅም ተረድቻለሁ፡፡ ስለዚህ በምርመሩ ለመሳተፍ ፍቃደኛ በመሆኔ ከላይ ላለው መጠይቅ ትክክለኛና ከኔ የተሰበሰበ መሆኑን በፊርማዬ አረጋግጠለሁ፡፡

የሆስፒታል መለያ ቁጥር ---------- የጠያቂዉ ሥም----------

የተጠያቂዉ ፊርማ----------ቀን---------- የጠያቂዉ ፊርማ ----------ቀን----------

ሰለጥናቱ ጥያቄ ካለዎት ዋና አጥኝውን ማናገር ይችላሉ

ወንድሜነህ ልቅናው በስልክ ቁጥር 0911305040 ወይም

በ ኢሜል wondimenehliknaw@gmail.com ወይም likewonde@yahoo.com ላይ መጠቀም ይችላሉ፡፡ለትብብርዎ በጣም አመሰግናለሁ !

ASSURANCE OF PRINCIPAL INVESTIGATOR

I, the undersigned, declare that this thesis is my original work in partial fulfillment of the requirement for the degree of Master of in clinical laboratory sciences (clinical laboratory management and quality assurance specialty track).

Name of the student: Wondimeneh Liknaw

Signature: _____

Date: _____

Place of Submission: Department of medical laboratory science, school of allied sciences, college of health science, Addis Ababa University

Date of Submission_____

This thesis work has been submitted for examination with my approval as University advisor.

Name of the primary advisor: Aster Tsegaye (MSc, PhD)

Signature: _____

Date: _____