ADDIS ABABA UNIVERSITY
COLLAGE OF HEALTH SCIENCES
SCHOOL OF ALLIED HEALTH SCIENCES
DEPARTMENT OF MEDICAL LABORATORY SCIENCE

Assessment of Knowledge, Attitude and Practices of Medical laboratory professionals on use of Internal Quality Control (IQC) for Clinical Laboratory Tests among Selected Health Centers in Addis Ababa, Ethiopia

BY: DEREJE MAMUYE

A thesis submitted to Addis Ababa University, College of Health Science, and Department of Medical Laboratory Sciences in partial fulfillment of the requirements for the Degree of Masters of Science in Clinical Laboratory Science (Laboratory Management and Quality Assurance specialty).

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Abbreviations

AAHB	Addis Ababa Health Bureau
AARL	Addis Ababa regional laboratory
CAP	College of American Pathologists
CLIA	Clinical Laboratory Improvement Amendments
CMS‟s	Centers for Medicare and Medicaid Services‟
CTs	closure times
ESR	Erythrocyte Sedimentation Rate
HC	Health center
IQC	Internal quality control
ISO	International standard organization
KAP	Knowledge, altitude and practice
LQM	Laboratory quality management
MLT	Medical Laboratory Technology
NABL	National Accreditation Board for Testing & Calibration Laboratories
NATA	National Association of Testing Authorities
PI	Principal Investigator
QC	Quality control
SLMTA	Strengthen laboratory management towards accreditation
WHO	World Health organization
WHO-AFRO	World Health organization regional office for Africa

Abstract

Background: Internal quality control (IQC) is designed to detect, reduce, and correct deficiencies in a laboratory's internal analytical process prior to the release of patient results, in order to improve the quality of the results reported by the laboratory. As different studies indicated, 5% to 10% of laboratories are deficient in IQC practices, including IQC frequency, use of appropriate material, and statistical processing. Understanding what medical laboratory professionals know about IQC, their thinking about it and their actual practice of what they know will help to design solutions for improving quality of medical laboratory service.

Objective: To assess Knowledge, altitude and practices (KAP) of medical laboratory professionals on the use of IQC for laboratory tests among selected Health centers.

Methods: Cross sectional study design was employed from December 2013 to May, 2014 to assess KAP of IQC for laboratory tests on 175 medical laboratory professionals working in 30 selected health centers in Addis Ababa. The data was entered and analyzed using SPSS version 19.0 soft ware. Descriptive statistics was computed for most of the study variables. Logistic regression analysis was used to determine associations with dependent and independent variables; crude and adjusted odds ratios were used to see the strength of the association and control for confounder‟s effect. P values less than 0.05 were taken as statistically significant.

Result: From a total of 175 study participant majorities (81.7 %) had better Knowledge about preparing in house made IQC and 18.3 % have no knowledge about it.. All in all 98 (68.5%) of the study participants did not face failed result for IQC while 45 (31.5%) had faced failed result. And their decision for failed IQC result was 21(46.6%) immediately reject whereas 24 (53.3 %) of them would repeat the test before rejecting the result. When study participant's feeling was classified as bad, good, very good and excellent, 4 (2.3%) had bad, 79(45.1%) had good, 38 (21.7%) had very good and 54(30.9%) have excellent attitude towards IQC.

About 32 (18.3%) of the study participants had never performed IQC while 143(81.7%) of them declared that they perform IQC. However, only 49.1% had documented their IQC result and the remaining 50.9% have no document. Regarding frequency of IQC, 64 (57.6%) of them perform IQC per batch, 24 (21.6%) daily, 6 (5.4 %) monthly and 17(15.3%) claimed performing IQC weekly. And over all 53(47.8%) of the respondents accepted this frequency.

Major reason for not performing IQC for laboratory tests in this study were work load, difficulty of IQC materials to prepare for some routine tests, cost of IQC materials, lack of supply, lack of staff members. The major factors for good IQC practice in this study were educational level, work experience, participation in SLMTA program. Taking LQM training, however, had no significant association both with Knowledge as well as IQC practice.

Conclusion: The study demonstrates good IQC knowledge and attitude which is not translated into an equivalent practice as demonstrated by poor documentation. Working in a laboratory which participates in SLMTA has a positive association while LQM training has no significant association with IQC knowledge and practice. Hence, practice focused training as well as motivation activities are needed to promote the use IQC and reduce rate of error for laboratory results.

1. INTRODUCTION

1.1 Background

Internal quality control (IQC) is designed to detect, reduce, and correct deficiencies in a laboratory's internal analytical process prior to the release of patient results, in order to improve the quality of the results reported by the laboratory. Internal Quality control is a measure of precision, or how well the measurement system reproduces the same result over time and under varying operating conditions (1).

As defined in the Harmonized Guidelines for Internal Quality Control in Analytical Chemistry Laboratories : „internal quality control (IQC) is a set of procedures undertaken by laboratory staff for the continuous monitoring of operations and the results of measurements in order to decide whether results are reliable enough to be released. Ideally, controls should be assayed with each analytical run and placed randomly through the run to detect analytical imprecision .Controls should also have assay values within clinically significant ranges (2).

Studies of laboratory errors have documented that a higher percentage of errors occur in the pre-analytic and post-analytic processes than in analytic processes. The figures often quoted are 45% for errors in pre-analytic processes, 10% for analytic errors, and 45% for post analytic errors (actual estimates, 45.5%, 7.3%, and 47.2%, respectively). As a consequence of this expected distribution of errors, laboratories are urged to focus their attention on pre analytic and post analytic processes to improve patient safety (3).

According to ISO 15189 (International) requirements "The laboratory shall design internal quality control systems that verify the attainment of the intended quality of results." Moreover,
The quality management system shall include, but not be limited to; internal quality control and participation in organized inter laboratory comparisons such as external quality assessment schemes (4).

NATA (National Association of Testing Authorities), AS 4633 (ISO 15189), Australian document state that "The laboratory must have a system of long term monitoring of internal

quality control results to assess method performance." Moreover, "Controls independent of those produced by the manufacturer of the test or analyzer should be used" (5).

According to several regulatory documents including that of CAP (College of American Pathologists), Chemistry and Toxicology Accreditation Checklist, United States document, the laboratory must establish or verify the criteria for acceptability of all control materials. It must perform control procedures at least once each day patient specimens are assayed. Control results must be reviewed before reporting patient/client results. It is implicit in quality control that patient/client test results will not be reported when controls do not yield acceptable results. In general, calibrators should not be used as QC materials (7).

Despite these standard requirements, the few studies conducted regarding knowledge, attitude and practice (KAP) of medical laboratory professionals revealed a significant gap about overall Quality Assurance (QA) as well as specific Quality Control (QC) activities. A study by Azhar et al 2012 assessed the knowledge and attitude of medical laboratory technologists working in laboratories of Lahore and the factors affecting their practices. They identified a deficiency in curriculum and training of B.Sc MLT about implementation of Quality Assurance and Quality Control in Laboratory as well as lack of training facilities in laboratories as main factors affecting KAP of the medical laboratory professionals (14).

1.2. Statement of problem

IQC is a statistical process used to monitor and evaluate the analytical process that produces patient results. When a diagnostic test is performed in the medical laboratory, the outcome of the test is a result .The result may be a patient result or it may be a quality control (IQC) result. The result may be quantitative (a number) or qualitative (positive or negative) or semi-quantitative (limited to a few different values). Ideally, controls should be assayed with each analytical run and placed randomly through the run to detect analytical imprecision. Controls should also have assay values within clinically significant ranges.

The Centers for Medicare and Medicaid Services‟ (CMS‟s) owned data from laboratory inspections show that as many as 5% to 10% of laboratories are deficient in IQC practices, which should raise concerns about the analytic quality achieved (4).

Few studies stated that, there are significant variability in all aspects of IQC practice, including IQC frequency, use of appropriate material, statistical processing and grades of staff involved. Some of the variation in practice may affect the effectiveness of laboratory IQC, and thus the adequacy of a laboratory to monitor system performance. Additionally, a very wide range of staff, including non-state-registered grades were routinely making decisions on when to accept and reject IQC data and continue processing patients‟ samples (10,23).

In general, internal quality control is an integral part of the medical laboratory testing procedures that should be strictly followed as per set guidelines of each laboratory. In Ethiopia, there are some initiatives to prepare selected hospital and Health Center laboratories for accreditation based on the WHO-AFRO check list. This activity is believed to improve the quality of the medical laboratory service. However, to the best of our knowledge, no such studies have been published describing the Knowledge, attitude and practices on use of internal quality control (IQC) for clinical laboratory tests in Ethiopia. The aim of this study was, therefore, to assess knowledge, attitude and practices on use of IQC among selected Health centers in Addis Ababa.

1.3. Significance of the study

- The results obtained in this study may be used as base line data for future studies in other health institution and/or the country at large
- The result may be show what medical laboratory professionals know about IQC and also their actual practices
- It can also indicate factors influencing IQC practice as well as solutions for improving quality.

2. Literature review

According to a data review which is performed at USA on Internal quality control: planning and implementation strategies it is stated that, choosing the statistical criteria or control rules, and the number of control measurements, according to the quality required for the test and the observed performance of the method, are necessary procedures to be considered by any testing laboratory. A general strategy for IQC implementation is recommended that employs a three-stage design in which the first stage provides high error detection, the second stage low false rejection and the third stage prescribes the length of the analytical run, making use of an algorithm involving the average of normal patients' data (8).

A study conducted in Washington University School of Medicine, Department of Pathology showed that expected increase in the number of unacceptable patient results reported during the presence of an undetected out-of-control error condition which is a performance measure that is affected by changes in QC testing frequency. They derived this measure for different out-of-control error conditions and laboratory testing modes and showed that a worst-case expected increase in the number of unacceptable patient results reported can be estimated. The laboratory thus has the ability to design QC strategies that limit the expected number of unacceptable patient results reported (9).

There was an Audit of internal quality control practice and processes in the south-east of England in which 54 laboratories in the region were audited. The result showed that seven sites processing IQC at fixed times of the day (1 at daily set-up/maintenance; 1 at 08:00 h and 16:00 h; 1 at 3 or 4 hourly intervals [day time only] and 1 at 24 h intervals). Nineteen sites indicated that they process IQC at fixed time intervals (range 1–24 h). In addition, 70% of laboratories which responded had no policy detailing IQC practices during on-call/out-of-hours periods, and of these, eight laboratories specifically detailed how IQC practice differs between the routine working day and out-of-hours period (10).

Cost is among the factors influencing the involvement in both internal and external quality control programs. Since many laboratories attribute lack of IQC practices to shortage of resource, several studies tried come up with alternative approaches of using fresh whole blood

samples. As a result, one comprehensive review on Quality control practices in hematology laboratory stated that, a combination of commercial controls (three levels) and retained or fresh patient blood specimens can be used for monitoring of accuracy and precision on a long- and short-term basis. Patient red-cell indices moving average data allow continuous monitoring of instrument performance and should be used as an adjunct to other QC approaches to detecting instrument calibration drift. Correlation of results of related parameters and careful review of blood films remain the two most important and widely used approaches to ensure reliability of results obtained from automated hematology instruments (11).

A study conducted on the use of retained patient specimens for hematology quality control showed that, patient blood specimens constitute ideal quality control material in many respects. Although stability is a problem, patient specimens are sufficiently stable to allow their use in the control of short-term systematic error. The principal challenges involve the design of a system which combines excellent performance characteristics (probability of error detection and probability of false rejection) with a minimum of extra work (12).

On the other hand, another study done at Italy on use of fresh blood for quality control of erythrocyte sedimentation rate (ESR) showed that the data obtained by calculating the mean daily value for routinely collected specimens over time and the corresponding SDs and hence reporting these data on a traditional quality control chart. The individual daily means ranged around the average mean (26.57 ± 3.81) and were always within ± 2 SDs. While The storage of 1,140 whole blood samples at 4°C for 24 hours caused a decrease in ESR values obtained by 2 different TEST1 EC analyzers with respect to the initial value: the mean differences were 2.86 (95% CI, 2.41-3.31) and 2.28 (95% CI, 1.90-2.65), respectively. This can be translated into mean percentage decreases of 9% and 11%, respectively, from one day to the next (13).

A study performed in the United States to assess the analytic quality of laboratory testing revealed that from laboratory inspections as many as 5% to 10% of laboratories are deficient in QC practices, which should raise concerns about the analytic quality achieved. These results showed that analytic quality is still a major issue when evaluated (4).

Study conducted in Pakistan to assess the knowledge, attitude and practice of Medical Laboratory Technologists (MLTs) working in laboratories of Lahore, Pakistan, regarding quality assurance and associated factors showed that 14 % MLTs had poor, 76% had average, while only 10% MLTs had good knowledge about implementation of QC in Laboratory. The study also indicated that, 16% MLTs had poor, 40% had average and 44% MLTs had good attitude towards implementation procedures of QC in Laboratory. Although more than 80% of the MLTs had at least average knowledge and attitude towards quality assurance, the majority (66%) had poor 32% had average and only 6% showed good practice of implementation procedures of QC in Laboratory (14). The data indicated that having average knowledge and attitude have great negative impact on their performance.

Quality of test result depends on ensuring quality at all the three phases of the laboratory work flow. The high rate of pre analytic errors (accounting for more than 60% errors in the laboratory) coupled with the reported (14) gaps in knowledge, attitude and practice of medical laboratory professionals regarding QA/QC would greatly affect the quality of results generated by laboratories and hence clinical management of patients. For example, a study undertaken in Egypt to assess the quality of work in Clinical Pathology Department, Alexandria Main University Hospital, considers one of the major preanalytic error attributors, sample quality. The study showed that average number of sample rejection due to different causes was evaluated before and after implementing College of American Pathologists (CAP) recommendations; these causes include hemolysis , clotted serum, quantity not sufficient, and lost samples. The percentage of rejected samples before implementing CAP recommendations was 15.8% due to hemolysis, 1.81% due to clotting, 0.70% due to insufficient quantity, and 0.51% due to loss of samples, while after implementing CAP recommendations rate of rejection was significantly reduced to 7%, 0.77%, 0.08%, and 0.05%, respectively (15).

In line with a study by Azhar et 2012 (10), Dargahi and ,Rezaiian (2007) identified KAP gaps regarding QA. Their results showed that knowledge, attitude and performance of the employees for implementation and observation of QA system and its indicators were more increased and positive with increased level of the laboratorians academic degrees (16).

In Ethiopia, although KAP studies are lacking regarding QA/QC an external quality assessment was conducted among hospital based medical laboratories in west Amhara region. In this study, a total of 324 test results were to be reported from all participant laboratories. The result showed that none of the study laboratories could deliver all the six tests for estimation of both liver and renal functions simultaneously during the study period. Only 213 values from the expected 324 values were reported and about 65 % of the 213 values reported fell outside of the allowable limits of errors for the chemistry tests, which indicated that there were lack of accuracy and precision in chemistry measurements. (17).

3. OBJECTIVES

3.1. General Objective:

To assess Knowledge, attitude and practices of Medical laboratory professionals towards use of Internal Quality Control (IQC) for Clinical Laboratory Tests among Selected Health Centers in Addis Ababa, Ethiopia.

3.2. Specific objectives:

- To assess Knowledge of Medical laboratory professionals towards using internal quality control (IQC)
- To assess attitude and practice of Medical laboratory professionals towards using internal quality control (IQC)
- To determine associated factors towards using internal quality control (IQC)

3.3 Hypothesis

There are poor knowledge attitude and practice on use of IQC for clinical laboratory tests among laboratory professionals in Addis Ababa and will vary depending on socio demographic factors like age, education, experience, and training and SLMTA participation.

4. MATERIALS AND METHODS

4.1 study Area:

The study was conducted in Addis Ababa which is the capital city of Ethiopia. Addis Ababa has a population size of 2,738,248 million with annual growth rate of 2.1 (18). The city divided into ten sub-cities and 99 kebeles (Lowest level administrative unit in the city). The city has 58 Health centers during the study period which are found in 10 sub cities and 25 are old and the rest are new Health Centers. All old health centers were participated in strengthening laboratory management towards accreditation (SLMTA) which was facilitated by Addis Ababa Regional Laboratory (AARL) and Addis Ababa Health Bureau (AAHB) in 2011/12 GC.

This study focused on 30 selected HC"s based on their convenience and SLMTA participation status. The health centers were Addis Ketema HC, Worda 7 HC, Semen HC, Arada HC , Kebena HC, worda 02 HC, Afenchober HC, Beata HC, Bole 17 HC,Meri HC, Amoraw HC**,** Janmeda HC, Addishiwot HC, Adisu gebeya HC, Hedasie HC, Shuromeda HC, Shegole HC, Selam HC, Meshoalekia HC, Kirkos HC, Kolfe HC, Saris HC, Akaki HC, T/haimanot HC, Lideta HC , Beletishachew HC, Yeka HC, Kotebe HC.

4.2. Study design:

Cross sectional Study design was employed to assess Knowledge, attitude and practices of Medical laboratory professionals towards use of Internal Quality Control (IQC) for Clinical Laboratory Tests among Selected Health Centers in Addis Ababa, Ethiopia from December 2013 to May, 2014.

4.3 Population

4.3.1 Source population

The source population was all medical laboratory professionals working in Health centers in Addis Ababa.

4.3.2 Study population:

The study population was all laboratory professionals who are working in the selected health centers and willing to participate in the study, during the study period.

4.4 Inclusion criteria

All laboratory professionals who are working in the respective health centers and willing to participate were included in the study.

4.5 Variables:

4.5.1 Dependent variable

Knowledge, attitude, practices towards IQC

4.5.2 Independent variables

Age, sex , educational status, year of service as a medical laboratory professional, frequency of IQC, types of tests for which IQC is performed, documentation of IQC results, reason for not performing IQC

4.6. Sample size determination and sampling technique:

Since no study was available towards KAP on use of IQC among laboratory professionals in Ethiopia, 50% of population proportion was used to determine sample size based on single population proportion and the finite population proportion formula, the level of precision (d) is (0.05).

The samples size was calculated by the formula :- (30)

$Nf = n_o / (1+n_o/N)$

384/ (1+384/348)

Nf= 182

Where nf=finite population sample size

$n_{o=}$ is the sample size determined from single population formula

$$\text{no} = \frac{Z^2(P(1-P))}{D^2}$$

$$n_o = 1.96^2(0.5(1-0.5))/0.05^2$$

$$n_o = 384$$

Where: n_o = number of the study subjects

Z= is standardized normal distribution curve /value for the 95% confidence interval (1.96)

p =proportion of population (50%).

d = the margin of error taken (0.05 taken

N=number of laboratory professionals working in all health centers in Addis Ababa (58 *6=348) (18).

4.7. Sampling procedures:

Convenient sampling method was used to select 30 laboratories from the 10 sub cities. Among these 30 selected health centers, 15 of them were selected from health centers which are participated on SLMTA 2011/2012 and the rest 15 were selected from those, which are not participating on SLMTA.

4. 8.Data collection procedures

The data was collected by using structured questioners and circulated through all selected Health Centers. Structured questionnaires were originally developed in English because the study participants were medical laboratory professionals. The data collectors were also experienced medical laboratory professionals.

4.9. Data Quality assurance

To maintain the quality of the data, questionnaire was pretested and appropriate modifications have been made. The data collectors were oriented by the principal investigator on the objectives of the study and how to interview, fill the questionnaire, observe some documents and handle questions while asking the participants. During the data collection process each questionnaire was checked daily in the morning by the principal investigator for its completeness.

4. 11. Data Analysis:

Data was entered and analyzed using SPSS version 19.0 soft ware. Descriptive statistics was computed for most of the study variables. Logistic regression analysis was used to determine associations with dependent and independent variables; crude and adjusted ratios were used to see the strength of the association and control for confounder‟s effect. Frequency distribution tables and graphs were used to describe the findings. P values less than 0.05 were taken as statistically significant when looking for associations between dependent and independent variables.

4.12. Ethical consideration:

Ethical clearance and permission was obtained from Departmental Research and Ethics Review committee (DRERC) of Department of Medical Laboratory Sciences, Addis Abba University and Addis Ababa Health Bureau and permission was sought from the respective health institutions before the data collection process started.

The study participants were informed about the purpose of the study and the importance of their participation in the study by contributing information that may help in assessing the Knowledge, attitude and practices regarding internal quality control for laboratory tests. The study

participants were also informed that they can skip a question or questions that they did not want to answer fully or partly and also to stop the interviewing process at any time if they want to do so. Then after assuring the confidential nature of responses and obtaining informed consent from the study participants interviewing was proceeded with strict privacy. Confidentiality of the data was maintained throughout the study by keeping hard copies in lockers and electronic files pass word protected.

4.13. Dissemination of results:

After conducting the research, the results of the study will be submitted to Department of Medical Laboratory Sciences (DMLS) Addis Ababa University (AAU). Oral presentation of the thesis will be made. Reports will also be submitted to Addis Ababa Health Bureau. In addition the finding will also be presented on annual conferences of professional societies. Since it is said that scientific work is incomplete until published, the manuscript will be submitted to peer reviewed journals for publication.

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5. Result

5.2 Socio-demographic characteristics of respondents

A total of 175 laboratory professionals participated in this study, the median age of the respondents was 26 years. The majority (54.9%) of the participants were found between 26 - 30 years age group. Most of the respondents 97(55.4%) were male and regarding education, the majority of the respondents (58.8%) were at diploma level.

Regarding their responsibilities in the department, the majority 122 (69.7 %) were staff members involved in routine laboratory activities. Among the study participants, more than half 104 (59.4%) of participants were working at SLMTA participated laboratory. The majority 103(58.9%) of the respondents had taken LQM (Table1).

Table1. Socio demographic characteristics of medical laboratory professionals working in selected Health Centers in Addis Ababa, 2014(n=175)

Variables	Frequency	Percent
Age		
20-25	61	34.8
26-30	96	54.9
31-35	13	7.4
>=36	5	2.9
Sex		
F	78	44.6
M	97	55.4
Educational level		
Diploma	103	58.8
Degree	64	36.6
Postgraduate	8	4.6

Work experience		
<1 yr	15	8.6
1-3 yr	78	44.6
3-5 yr	36	20.6
>5 yr	46	26.3
Responsibility		
Dept. head	28	16.0
Quality	15	8.6
Safety	10	5.7
Staff	122	69.7
SLMTA participated		
No	71	40.6
Yes	104	59.4
LQM training		
No	72	41.1
Yes	103	58.9

5.3 Knowledge of Internal Quality Control (IQC) of medical laboratory professionals working in selected Health Centers in Addis Ababa, 2014

Among the 175 study participants, majorities (81.7 %) had better Knowledge about preparing in house made IQC. A total of 45 (31.5%) of the study participants have faced failed result. Of them, according to 21(46.7%) of the study participants, their decision was immediately rejecting the result, while 24 (53.3 %) responded to repeat the test before rejecting the result. Regarding acceptability of IQC frequency for the various tests they perform 47.8% (53/111) think it is acceptable. Their main reason for this was cost (30.2%) workload (5.6%), difficulty to perform IQC for some tests (3.8%), accuracy of test within the same batch is similar (49.0%) (Table 2).

Table2. Knowledge on internal quality control (IQC) of medical laboratory professionals working in selected Health Centers in Addis Ababa, 2014 (n=175)

Knowledge on IQC	Frequency	Percent
Possibility of Preparing in-house IQC		
No	32	18.3
Yes	143	81.7
Acceptability of IQC Frequency (n=111)		
No	58	52.2
Yes	53	47.8
Reason to accept frequency		
Cost	16	30.2
Difficult	2	3.8
Enough	6	11.3
Similar[@]	26	49.0
Workload	3	5.6
Failed result (n=143)		
No	98	68.5
Yes	45	31.5
Decision for failed results (n=45)*		
Reject	21	46.7
Repeat	24	53.3

*Those who reported that they have faced failed result

[@] once run, accuracy of tests within same batch are similar

5.4 Attitude on internal quality control (IQC) of medical laboratory professionals working in selected Health Centers in AA, 2014

The study participant's feeling about performing IQC for each test was categorized as bad, good, very good and excellent. Based on this category, except 4 (2.3%) surprising responses of bad feeling , all declared good feeling towards IQC, of which 54 (30.9%) had excellent feeling. And the majority 170 (97.1%) believe that performing internal quality control is necessary (Table 3).

Table. 3 Attitudes on internal quality control (IQC) of medical laboratory professionals working in selected Health Centers in Addis Ababa, 2014

Attitude	Frequency	Percent
Feeling about performing IQC		
Bad	4	2.3
Good	79	45.1
very good	38	21.7
Excellent	54	30.9
Necessity of IQC		
No	5	2.9
Yes	170	97.1

5. 5 Internal quality control (IQC) Practice of laboratory professionals working in selected Health Centers in AA, 2014

The majority 143(81.7%) of the participants responded that they are performing IQC. However, only 86 (49.1%) documented their result for IQC. Regarding frequency of running IQC for the total of tests, 64 (57.6%) was running in batch or with every test depending on test type, the remaining 24 (21.6%) are running daily, 6 (5.4 %) were monthly, 17(15.3%) weekly (Table 4).

Table 4 Internal Quality Control (IQC) Practice of medical laboratory professionals working in selected Health Centers in Addis Ababa, 2014

Practice	Frequency	Percent
Perform IQC (n=175)		
No	32	18.3
Yes	143	81.7
In house (n=143)		
No	76	53.1
Yes	67	46.8
Failed result (n=143)		
No	98	68.5
Yes	45	31.5
Documentation (n=175)		
No	89	50.9
Yes	86	49.1
Average frequency of IQC (n=111)		
Every Batch	64	57.6
Daily	24	21.6
Weekly	17	15.3
Monthly	6	5.4

5.6 Reasons for not running Internal Quality Control with test items

Participants were also asked about the reason for not using IQC for those laboratory test items for which they did not perform IQC, Of the 175 respondents, 22.9 % indicated due to work load, 14.9 % difficulty to prepare IQC materials for some tests, 28.6 % IQC materials are expensive, 13.7 % due to lack of supply, 6.3 % we don't have enough time to do IQC and patient sample, 10.3 % lack of staff members and the rest 3.4 % mentioned different reason (Figure 1).

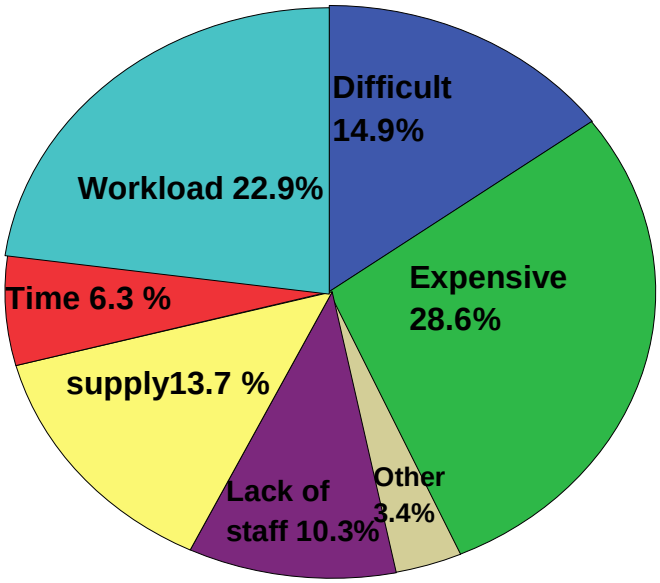

Figure.1 Reasons for not running Internal Quality Control with test items

5.7. Associated factors and Knowledge towards IQC

Regression analysis was carried out to see the association between different factors with Knowledge, of study participants towards IQC. The analysis was made between socio demographic characteristics of laboratory professionals and the outcome variables. The finding revealed that age has significant association with knowledge of study participants. Those participants whose age was 26-30 years have better knowledge about preparing in house made IQC (AOR=3.429, 95% CI =1.127-10.431). Furthermore study subjects who have degree have better knowledge about preparing in house made IQC compared to those who have diploma (AOR= 5.726, 95% CI =1.029-31.879).In addition participants who are working at laboratories which have participated in SLMTA have better knowledge about preparing in house made IQC compared to participants who are working at laboratories which did not participate in SLMTA (AOR =3.547, 95%CI =1.093-11.513). However, there was no significant association between knowledge of preparing in house controls and taking laboratory quality management (LQM) training and experience (Table 3).

Table 5. Knowledge about Internal Quality Control (IQC) and associated factors of medical laboratory professionals working in selected Health Centers in Addis Ababa, 2014

Variables	Knowledge towards preparing in house made IQC		COR	AOR
	No	Yes		
Age				
20-25	22(12.6%)	39(22.3%)	1	1
26-30	9(5.1%)	87(49.7%)	5.453(2.301-12.920)*	3.429(1.127-10.431)*
31-36	1(0.6%)	12(6.9%)	6.769(.824-55.604)	6.223(.577-67.122)
>=36	0	5(2.9%)	9E+008(.000)	4E+008(.000)
Sex				
Female	21(12%)	57(32.6%)	1	1
Male	11(6.3)	86(49.1%)	2.880(1.291-6.427)*	3.380(1.165-9.809)*
Educational level				
Diploma	28(16%)	75(42.9%)	1	1
Degree	4(2.3%)	60(3.4%)	5.600(1.862-16.845)*	5.726(1.029-31.879)*
Postgraduate	0	8(4.6%)	6E+008(.000)	3E+008(.000)
Work experience				
<1year	6(3.4%)	9(5.1%)	1	1
1-3year	14(8%)	64(36.6%)	3.000(0.918-9.805)	1.117(.227-5.497)
3-5year	7(4%)	29(16.6%)	2.762(.736-10.362)	.937(.166-5.281)
>=5year	5(2.9%)	41(23.4%)	5.600(1.397-22.441)*	.207(.024-1.796)
Responsibility				
Staff	30(17.1%)	92(52.6%)	1	1
Safety officer	0	10(5.7%)	5E+008(.000)	1E+008(.000)
Quality officer	0	15(8.6%)	5E+008(.000)	2E+008(.000)
Dpt. head	2(1.1%)	26(14.9%)	4.239(.950-18.924)*	2.393(.305-18.788)

SLMTA participated				
No	25(14.3%)	46(26.3%)	1	1
Yes	7(4%)	97(55.4%)	7.531(3.036-18.683)*	3.547(1.093-11.513)*
LQM Training				
No	13(7.4%)	59(33.7%)	1	1
Yes	19(10.9%)	84(48%)	0.974(.447-2.125)	.463(.171-1.255)

SLMTA=strengthen laboratory management towards accreditation
LQM = Laboratory quality management, Reference categories are indicated by 1; Significant Associations are indicated by *

5.8 Associated factors and Practice towards IQC

When regression analysis was done between socio-demographic factors and performing IQC through participants‟ experience, the finding indicated that educational level, work experience and participating in SLMTA, were found to be significantly associated. However, there were no significant associations of age, sex, responsibility and taking LQM training of the respondents.

As shown in Table 6, those who have degree have better practice compared to diploma level. (AOR=20.696, 95% CI=2.331-183.731) Similarly, it was found that the respondents who are working at SLMTA participated laboratory have practices towards IQC better than participants who are working non participating laboratory. (AOR=21.854, 95 % CI =3.774-12.541) (Table 6).

Table 6. Internal Quality Control (IQC) Practice and associated factors of medical laboratory professionals working in selected Health Centers in Addis Ababa, 2014.

Variables	Perform IQC		COR	AOR
	No	Yes		
Age				
20-25 years	7(4%)	54(30.9%)	1	1
26-30 years	22(12.57%)	74(42.3%)	0.436(0.174-1.094)	0.042(.008-1.220)
31-36 yrars	2(1.1%)	11(6.3%)	.713(.130-3.903)	.259(.019-3.549)
>=36years	1(0.5%)	4(2.3%)	.519(.051-5.321)	.033(.001-1.004)
Sex				
Female	18(10.3%)	60(34.3 %)	1	1
Male	14(8%)	83(47.4 %)	1.779(0.821-3.854)	2.798(.813-9.628)
Educational level				
Diploma	3(1.7%)	61(34.9%)	1	1
Degree	27(15.4%)	76(43.4%)	.138(2.092-24.949)*	20.696(2.331-183.731)*
Postgraduate	2(1.1%)	6(3.4%)	.147(0.203-5.602)*	.473(.015-15.036)
Work experience				
<1year	9(5.1%)	6(3.4%)	1	1
1-3year	20(11.4%)	58(33.1%)	4.275(1.351-13.525)*	.404(.064-2.556)
3-5year	0	36(20.6%)	2E+009(0.000-)	5E+008(.000)
>=5year	3(17.1%)	43(24.6%)	21.500(4.621-104.736)*	1.206(.061-24.006)
Responsibility				
Staff	28(16%)	94(53.7)	1	1
Safety officer	0	10(5.7%)	5E+008(0.000)	2E+008(.000)
Quality officer	0	15(8.6%)	5E+008(0.000)	2E+008(.000)
Dept head	4(2.2%)	24(13.7%)	1.787(0.572-5.586)	.860(.082-9.063)

SLMTA participated				
No	24(13.7%)	47(26.8%)	1	1
Yes	8	96(54.85%)	6.128(2.56-14.669)*	21.854(3.774-12.541)*
LQM Training				
No	15(8.6%)	57(32.6%)	1	1
Yes	17(9.7%)	86(49.1%)	1.331(0.616-2.878)	.577(.187-1.776)

SLMTA=strengthen laboratory management towards accreditation
LQM = Laboratory quality management, Reference categories are indicated by 1; Significant Associations are indicated by *

6. Discussion

Internal quality control (IQC) is a set of procedures undertaken by laboratory staff for the continuous monitoring of operations and the results of measurements in order to decide whether results are reliable enough to be released. Above all, IQC is a control of the precision of your analytical process with the aim of assuring a long-term constancy of the results. It can also be a control of trueness depending of the control material used. The main objective is to ensure the constancy of the results day-to-day and their conformity with defined criteria (20-24).

This study aims to assess the knowledge, attitude and practice (KAP) of medical laboratory professionals working in selected health centers in Addis Ababa.

Even though no similar studies were published to compare the findings, the majority (81.7 %) had Knowledge about possibility of preparing in house made IQA. When it comes to practice more than half of them responded negatively although use of in house control has been proven to be a good substitute for the commercial control especially in developing countries like Ethiopia. This is because its preparation is easy, does not need for reconstitution for example in the case of plasma and serum and has lower cost as well (25).

About 45 (31.5%) of the study participants had faced failed result and their decision was immediately reject the result in 21(46.7%) of them, while repeating the test before rejecting the result was stated by 24 (53.3%) of them. This is knowledge gap despite recommendations to take troubleshooting actions before immediate rejections (26). General knowledge gaps related to IQC/QA have been reported from India (14, 16).

In this study, about 79(45.1%) have good, attitude towards IQA. The majority, (81.7%) of the study participant perform IQC through their experience. However only 86 (49.1%) were documented their result. But different guidelines state that "The laboratory shall document its quality control results in detail, including the levels of quality control materials run each day, frequency of performing QC, types of QC materials and the QC acceptance criteria customized for each examination procedure based on that procedure"s capabilities."(22).

In laboratory operations, control samples are analyzed during each analytical run to evaluate method performance (23). Even though no such kinds of studies are published in Ethiopia, in this study the finding showed that the highest proportion of average frequencies for all tests that the study participants done was every batch 64 (57.6 %). The major reason for this was cost, workload, difficult to perform, lack of staff, and the belief that accuracy of test within the same batch is similar and others. This is against guidelines which recommend that the level of QC applied in the laboratory varies according to the number of analytical runs and the specimens analyzed per day. For example for less than 50 tests per day - apply at least one level QC once a day whereas if more than 100 tests per day - apply two level QCs at least twice a day for such analytes (26)

According to this study, age have significant association with knowledge of the study participants. Those study participants whose age is 26-30 have better knowledge about IQC. Further more study subjects who have degree had better knowledge about IQC compared to those who have diploma. Although we cannot explain the observed gender differences, in a related study Dargahi H and Rezaiian M (2007) showed that knowledge, attitude and performance of the employees for implementation and observation of QA system and its indicators are more increased and positive with increased level of their academic degrees (16).

However, neither work experience nor laboratory quality management (LQM) training were associated with knowledge related to IQC. rather, participants who are working at laboratories which have participated in SLMTA have better knowledge about IQC compared to participants who are working at laboratories which were not participating in SLMTA, According to SLMTA program "performing IQC is one requirement to meet quality laboratory and achieves stars (20).

IQC better practice was also significantly associated with educational level, work experience, and participation in SLMTA (than those who did not participate), where those with degree better than those having diploma, longer years showed better IQC practice. However, there were no significant associations of age, sex and taking LQM training and responsibility with IQC practice in this study.

The finding that taking LQM training has no association both with Knowledge as well as practice is surprising and needs due attention regarding the training methodology. A WHO document on the implementation of quality standard for Thailand identified and states training of medical laboratory professionals in practical kills as fundamental means to Success (27). Strengthening the pre service trainings have also been suggested as a feasible strategy in resource-limited settings, since it help ensuring local capacity, country ownership and sustainability (28).

And also those participant who are work at SLMTA participated laboratory have better practices towards IQC than participant who are work at not SLMTA participated laboratory. Several advantages of participation in SLMTA have been documented in developing countries. It was observed that staff members were empowered to improve their own laboratories by using existing resources, communicate with clinicians and hospital administrators, and advocate for system strengthening. SLMTA yielded observable, measurable results in the laboratories (29). Our study also substantiates this general observation in a specific area of use of IQC in routine testing.

In general, designing and implementing an internal quality control systems that verify the attainment of the intended quality of results is mandatory (31), and addressing the identified gaps in knowledge, attitude and skill towards IQC in this study needs further follow up.

7. Limitations

1. Very limited studies have been published, thus it was difficult to compare the result with other study; however, the existing guidelines were consulted to discuss the finding
2. The results mostly depended on the responses of the participants, here there is a high Chance of recall bias
3. Because of some variables have 0 frequency, there were difficult to calculate COR and AOR

8. Conclusion

Based on the findings of this study, the following conclusions can be drawn**:**
In this study despite the study participants have better Knowledge and attitude about IQC and claimed practice , majority have poor documentation of IQC result This may affect negatively to attain the objectives of quality laboratory and also it may clarify that better Knowledge and attitude does not always leads to good IQC practice.

The major factors for good IQC practice in this study shows educational level, work experience, participation in SLMTA program, but not LQM training., Hence a lot of educational and motivation activities and improvement of IQC practice are needed to promote the use IQC and reduce rate of error for laboratory results.

Similarly the major reason for not performing IQC for laboratory tests in this study indicates that work load, difficulty of IQC materials to prepare for some routine tests, cost of IQC materials , lack of supply, lack of staff members and others are included.
In addition to this professionals who are working in non SLMTA participated laboratory have low level of knowledge and practice as indicated in this study.

9. Recommendations

- Practical focused training and motivation activities and improvement of IQC practice are needed to promote the use IQC and reduce rate of error for laboratory results.
- All laboratories should be encouraged to participate in SLMTA and other accreditation programs.
- All necessary IQC Supplies should be fulfilled by the concerned bodies
- Further studies should be done to supplement this study

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8. Appendices

Assessment of Knowledge, Attitude and Practices of Medical laboratory professionals on use of Internal Quality Control (IQC) for Clinical Laboratory Tests among Selected Health Centers in Addis Ababa, Ethiopia

Annex-I Confidentiality and verbal Consent

My name is _____I am working as data collector in study conducted by Addis Ababa University college of Health science school of allied health sciences department of Medical Laboratory Science on Assessment of Knowledge, Attitude and Practices on use of IQC for laboratory tests among selected Health Centers. We would very much appreciate your participation in this survey. I would like to ask you some questions and it will take about 15-20 minutes. Your answers will remain confidential, and we will not be taking down your name or address, so your answers will be anonymous.

Participation in this survey is voluntary and you can choose not to answer any individual question or all of the questions. However, we hope that you will participate in this survey since your views are important.

Are you willing to disclose your work and participate in our study?

Yes ☐ No ☐

Start time____: _ End time____: Date_____/____/_____

Annex -II Questionnaire

No	Questions	Response
100	**Socio demographic characteristics**	
101	Age	…….
102	Sex	1. Male 2. Female
103	Education level	1. Certificate 4. Diploma 5. Degree 6. postgraduate
104	For how long are you working in this laboratory?	1. <1yr 2. 1-3yr 3. 3-5yr 4. >5yr
105	What are your responsibilities in this laboratory?	1. Dpt. head 2. Quality officer 3.Safety officer 4. Staff member 5.Phlebotomist
106	Did you take laboratory quality management training?	1. Yes 2. No
107	Was your laboratory participating in SLMPTA?	1. Yes 2. No
108	If yes, what was the result?	1. Star 0 2. Star 1 3. Star 2 4.Star 3 5. Star 4 6. star 5
109	Where is your work station (you can answer more than one)?	1. Parasitology 2. Hematology 3.Bacteriology 4. Serology 5.urinanalysis 6. Sample collection 7. Other specify……
200	**Questions on attitude**	
201	What is your feeling about IQC?	1. Bad 2. Good 3. Very good 5. excellent
202	Do you think performing IQC is necessary?	1. Yes 2. No
203	If yes, what is your reason?	

300. Questions on practices

301. Which type of test items are performed, have IQC done and frequency of IQC in your laboratory? (Please tick √)

No	Test items	Items which are included in your test menu	Items which are tested for IQC	Items which are not tested for IQC	Frequency of IQC
1	AFB				
2	Urine stripe test				
3	Stool exam.				
4	BF				
5	Hematocrite/Hgb				
6	Blood group				
7	HCG				
8	Widal weil flex				
9	H.pylori				
10	HBsAg				
11	HCV				
12	Gram stain				
13	RPR				
14	CBC				
15	RF				
16	Diff.				
17	WBC				
18	ASO				
19	KOH				
20	HIV				
21	Chemistry				
22	Uric Acid				
23	FBS/RBS				
24	CD4				
	Others				

Hint: Frequency can be -Every hour, daily, every 25 samples, every batch, every week, every month etc

No	Question	Response
302	For items for which IQC was not run, what was the reason?	1. QC material is too expensive 2. QC is too difficult to perform 3. there is no enough staff to perform patient testing and do QC 4. I don't have enough time to do everything required for QC 5. because of high workload 6. other specify _____
303	Did you perform IQC?	1. Yes 2. No
304	Did you document your IQC results?	1. Yes 2. No
305	If yes, did results reviewed by the responsible person?	1. Yes 2. No
400	**Questions on Knowledge**	
401	Do you think the above frequencies are enough?	1.Yes 2.No
402	If yes, what is your reason?	
403	What type of IQC material do you use?	1. House made 2. in built
404	Do you think preparing in house made IQC material is possible?	1. Yes 2. No
405	If No, what is your reason?	
406	Have you ever seen failed result?	1. Yes 2. No
407	If yes, what was your decision**?**	

408	Why do you prefer such kind of decision**?**	

Annex III: Declaration

Title of Project: Assessment of Knowledge, Attitude and Practices of Medical laboratory professionals on use of Internal Quality Control (IQC) for Clinical Laboratory Tests among Selected Health Centers in Addis Ababa, Ethiopia

I, the undersigned, declare that this MSc research project is my original work. It has not been presented for a degree in any other University. False statements could be cause for invalidating this research project and may lead to other administrative or legal action.

Principal investigator:

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Address: Department of Medical Laboratory Sciences, AAU

Signature: _____ Date: _____

Advisor:

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Signature: _____ Date: _____