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COLLEGE OF HEALTH SCIENCES

DEPARTMENT OF MEDICAL LABORATORY SCIENCES

Knowledge, attitude and practice and associated factors towards method validation/verification among laboratory professionals working in selected health facilities, Addis Ababa, Ethiopia

By: Tegbar Getahun (BSc)

Advisors: Fatuma Hassen (MPH, MA, PHD Candidate)
` Abay Sisay(BSc, MSc,PHD fellow)

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This is to certify that the thesis prepared by; TEGBAR GETAHUN entitled:

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Signed by the Examining Committee:

Examiner_____ Signature _____Date _____

Examiner_____ Signature _____Date _____

Advisors;

Fatuma Hassen (MPH, MA, PHD Candidate) Signature____Date_____

Abay Sisay(BSc, MSc,PHD fellow)Signature _____Date _____

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Contents

List of Abbreviations/Acronyms

AAU- Addis Ababa University

CDC- Center for disease control and prevention

cGMPs- Good manufacturing process

CMLE- Continuous laboratory medical education

EQA- External quality assurance

EQAS- External quality assurance programmers'

EPSA- Ethiopian pharmaceutical supply agency

ISO- International organization for standardization

KAP- knowledge, attitude and practice

LQMS-laboratory quality management system

NGO- Non- government organization

QC- Quality control

SLIPTA- Stepwise laboratory quality improvement process towards accreditation

SLMTA- strengthening laboratory management towards accreditation

SOP- Standard operating procedure

WHO- World health organization

List of tables and figures

List of tables

List of figures

Abstract

Background*:* Method validation and verification are among the requirements to be fulfilled by the laboratories in order to attain quality management system and assessing their own competence. There is paucity of data in Ethiopia regarding the laboratory professional's knowledge, attitude and practice on method validation/verification.

Objective: To assess the knowledge, Attitude and Practice on method validation/verification and associated factors of laboratory professionals in selected health facilities in Addis Ababa, Ethiopia

Methods: Institutional based cross sectional study design using qualitative and quantitative data collection approach was applied in Addis Ababa from 01Dec 2020 to 30March, 2021 on 400 medical laboratory professionals working in selected health facilities. Data was entered and analyzed by SPSS version 23. Descriptive statistics was computed for most of the study variables. Likert scale analysis was used to analyze the attitude level and logistic regression analysis was used to determine associations with dependent and independent variables. Frequency distribution tables were used to describe the findings. P values less than 0.05 was taken as statistically significant when looking for associations between dependent and independent variables.

Result; From a total of 400 participants, 85(21.3%) of them had better knowledge on method validation/verification. Majority of the study participants, 397 (99.3%) had a good attitude on method validation/verification. Regarding their practice on method validation/verification, 344(86.6%) and 324(81%) of the participants did not perform method validation and method verification respectively. Majority of the respondents 326(81.5%) didn't take trainings on method validation/verification. And the associated factor that affects the implementation of method validation/verification were 15(3.8%) due to competent staff turnover, 18(4.5%) work load, 42(10.5%) lack of training.

Conclusion; These study resulted that there is a good attitude but lower knowledge and poor practice on method validation/verification. Absence of adequate training and work experience o the laboratory professionals are the major factors, and continues training, education and motivation is needed to implement laboratory quality management system.

Key words: Method validation, verification, LQMS

1. Introduction

1.1 Background

A quality management system (QMS) is formed by a series of coordinated activities that are carried out on a set of elements to achieve the quality of the products or services offered to the customer or user. In the case of a laboratory, the accuracy, reliability, and timeliness of the analytical results reported define its quality, and all aspects of analytical operations should be controlled (1).

Equipment management is one of the essential elements of a quality management system. Proper management of the equipment in the laboratory is very essential to ensure accurate, reliable and timely testing. The benefits of a good equipment management programme is that it helps to maintain a high level of laboratory performance, reduces variation in test results and improves the technologist's confidence in the accuracy of testing results, lowers repair costs which is as fewer repairs will be needed for a well-maintained instrument lengthens instrument life; reduces interruption of services due to breakdowns and failures, increases safety for workers, and produces greater customer satisfaction (2).

International organization for standardization (ISO) stated that the laboratory shall verify that it can properly perform methods before introducing them by ensuring that it can achieve the required performance. Records of the verification shall be retained. And the laboratory shall validate non-standard methods, laboratory-developed methods and standard methods used outside their intended scope or otherwise modified. The validation shall be as extensive as is necessary to meet the needs of the given application or field of application. Verification is performed on methods that are being used without modification, when evaluating whether or not procedure meets the performance characteristics stated by the manufacturer, and when the manufacturer validation claims. And results of analytical measurements have an extraordinarily great impact on practice. In clinical laboratory, they can definitely, and sometimes even fatally, influence health, quality of life, and even the patient's life (3).

Method validation is the process of defining an analytical requirement, and confirming that the method under consideration has performance capabilities consistent with what the application requires (4). Verification is confirmation that the analytical characteristics data provided by a manufacturer, a laboratory or a reference institution were reached through objective evidence in the given laboratory with the use of a specific measuring system (5).

Knowledge and skills of laboratory personnel are fundamental for the implementation of a laboratory quality management system, and training sessions must be offered. Training emphasized the standard requirements and other basic elements of laboratory safety, method validation, control materials, and quality indicators, with the goal of building and strengthening the foundations of a quality laboratory system (6).

Around 40% of laboratory professionals working in the government hospitals of Ethiopia, There is gap on their knowledge, attitude and practice regarding method validation verification. In general inadequate equipment and supplies leads to provide interrupted service, and these is the reasons for not implementing quality laboratory service and fail to be accredited (7). The main gap is also related to absence of directly related publications done on this title.

1.2 Statement of the Problem

Implementation of laboratory quality management system needs to fulfill the necessary components to provide accurate and precise laboratory results. Some of them are providing a functional and safe laboratory environment, providing trained and competent personnel and maintaining equipment. Despite all laboratory professionals receiving the same training and mentorship, al laboratories were not able to provide laboratory quality system with regard to their difference in understanding and implementation of quality management system in general (8).

In Ethiopia, almost all laboratory heads agreed that poor-quality equipment compromised laboratory service and obstructed the accreditation process. Performance of equipment supplied was in general impossible to validate. The majority of survey done shows that technically poor-quality equipment and absent or poor-quality reagents are the major defects inhibiting the laboratory quality management system. Specifically, some equipment did not meet accreditation standards because of an absence of verification documentation or calibrator materials. It is agreed that challenges related to laboratory equipment's performance and availability of supplies is the main area of interrupting tests. Test interruptions in turn preclude laboratories meeting accreditation requirements. And the reason they said is that facilities of their laboratories were too old or too small to meet the requirements of international organization for standardization (ISO 15189) standards specifically about technical requirements (method validation and verification) (7).

It is known that one of the factors affecting the performance of quality management system is the equipment. That is problems related to the absence of validation and verification. There was a skill gap; and the professionals cannot contribute his/her time, effort, knowledge, and work behaviors by keeping quality due to demotivation. The laboratory management believed that this is due to low salary, no risk payment, no overtime payment; and no good laboratory equipment and no enough training (9).

And also 53.3% of factors affecting problems of quality laboratory service are poor equipment quality due to improper validation and verification, In addition documentation system, result verification & reporting system, equipment calibration & maintenance, quality control activities, customer management and laboratory safety were not implemented as per the standards. So poor quality management system directly affects the provision of quality laboratory services as well as patients and health care services at large (10).

Until recently, the majority of Ethiopian public health laboratories delivered suboptimal service and were not in a position to contribute to a quality health system. Many performed poorly, because of limited infrastructures, and poor development and implementation of quality management systems (QMS), including inadequate participation in external quality assessment (EQA) programs. There are many factors which contribute for the failure; these factors were related with personnel, equipment, and supplies (11).

1.3. Significance of the study

The result of this study will primarily benefit the professionals to maximize their knowledge attitude and practice on method validation/verification and its associated factors which are important criteria to be fulfilled before applying to any accreditation process. And also in order to implement laboratory quality management system, the understanding and application of method validation/verification is the necessary components to provide accurate and precise laboratory results.

In addition allocating the associated factors that have direct or indirect effect on the knowledge, attitude and practice on method validation/verification will help to identify monitor the internal and external factors that hinders from providing laboratory quality service. It will also be essential information for lab managers, other health professionals, policy makers and system designers to improve their experience on method validation/verification.

The results obtained from the study may be used to as a baseline data for further studies in other institutions and the country at large.

2. Literature Review

2.1 The KAP level of laboratory professionals on method validation/verification

A study conducted in Lesotho resulted, of the 31 participants; all but one laboratory attained a rating of zero stars, with the exception attaining one star. At the final assessment, after they implement strengthening laboratory management towards accreditation programme, 7 of the 25 laboratories examined at baseline were still at a rating of zero stars, whilst 8 attained one star, 5 attained two stars and 4 attained three stars. None scored above three stars. The highest percentage improvement for any laboratory was 51%, whereas the least improved dropped by 6% when compared to its baseline assessment. Average performances of all laboratories across the 12 sections are measured by the World Health Organization Regional Headquarters for Africa Stepwise Laboratory Quality Improvement Toward Accreditation (WHO–AFRO–SLIPTA) checklist and less than 50% is achieved regarding equipment (10).

A study performed in Tanzania, the departments' external quality assessment performance increased after ISO 15189 implementation. The laboratory also developed procedures to guide staff on how to validate or verify technical methods; the procedures clearly clarified the difference between verification and validation. Verification was defined as, for standard methods that are used without modification, it is a processes that are carried out to prove that the method can provide intended use only when capability data are available. Validation was defined as processes that are carried out to prove that the method is fit for the laboratory intended use when no capability data are available; referring to non-standard laboratory designed methods, which are subjected to some modification. Therefore for method validation, the laboratory has to set criteria to accept or reject the test method (13).

In line with the study by Raniya Abdu Seiyir (2018), In Palestine, the ministry of health (MOH) increased attention on quality improvement in medical laboratory testing's and efficiency, cost-effectiveness, and quality of healthcare are the top priorities. Accurate laboratory tests are required for the diagnosis of diseases and monitoring of treatment. Testing errors can be reduced through quality management and accreditation to ensure reliability and quality results. They also established external quality assurance program (EQAS) with activities include preparation of quality control (QC) samples, distribution of samples to the participating laboratories, collection of the QC samples' results, and finally analyzing the results to evaluate the performance of the affiliated laboratories resulting in a

significant increase in the number of affiliated laboratories from 148 to 435. The program testing panel currently includes the basic laboratory tests in chemistry, haematology and haemostasis. Each laboratory's performance is determined by MOH to all laboratories and for all types of tests to ensure a high quality of the provided laboratory services (14).

On the other hand, another study done in turkey showed that, the "ISO 15189 Standard: Medical Laboratories– Requirements for Quality and Competence" is an internationally accepted accreditation standard based on a series of requirements. However, ISO 15189 accreditation typically requires knowledge and competencies beyond the educational scope. A key to ISO 15189 accreditation is the quality management system. The medical laboratory environment is rapidly changing. In order for effective management, the laboratory directors must be technically and clinically competent in their defined specialty areas, and also have relevant and common managerial, statistical and computer knowledge and skills. . These attributes can be collected under the main topics such as Quality Management (15).

A study done by John N. Nkengasong,et al(2010), although implementing international laboratory standards, such as ISO 15189, has been shown to be possible in developing countries, implementation is not easily scalable in the laboratories of most developing countries. There is need to establish continuous laboratory medical education (CMLE) for clinicians so as to bridge the gap between laboratory testing and uptake for patient management. Regional societies for laboratory medicine or clinical pathology could serve as the appropriate vehicle to meet these critical gaps, including implementing CMLE and certification of training for medical technologists (16).

A special article done by Sheila Woodcock et al (2010) explained that since there is limited published evidence of the benefits of implementing quality management in laboratories, the achievement is minimal. For some of the key components of quality management, e.g., an effective supply chain management system, access to external quality assurance materials, training, and education, laboratories are dependent on governments. Equipment is of no value without a regular supply of quality reagents and controls and regular maintenance. These are frequently lacking in resource-limited countries. Similarly external quality assurance programs are only available in some countries; others are in development or dependent on out-of-country suppliers. Education and training have a more positive short- term outlook because a variety of organizations are bringing workshops and educational tools to Africa and other countries in need (17).

A study done in Ethiopia showed that, wide range of knowledge and skill sets based on ISO/IEC 15189:2012 were shared by the medical consultants regarding validation/verification and uncertainty of measurements. This information was used to prepare standard operating procedures (SOPs), manuals, guidelines and other instructive material to be used in each laboratory. The major challenge to this process has been maintaining continuity of top management commitment to providing the resources and manpower to sustain the project. While this commitment varied from lab to lab, almost all shared a countrywide problem regarding purchasing of reagents/ consumable materials and control materials (certified reference materials). Partial or full proficiency testing has also been a challenge because it is not readily available to all labs seeking accreditation. Getting full validation documentation from the manufacturers and suppliers was also an area of concern (18).

Another study done in Ethiopia stated that by considering the quantitative data, key informants interview were conducted and collected from the quality manager and were health facilities of upper management members using an open-ended in nature and primarily focused factors affecting for the implementation of the quality management system, the involvement of professionals in LQMS implementation, accountability for LQMS system. Most of the participants (6 of 7) agreed as "laboratory quality management is a very important program but because of the erratic reagents, supplies and consumable supply system in the city ,plus there is no equipment service engineer or trained biomedical engineer for resolving our non-functional analyzer's, and there are clear gaps regarding method validation/ verification, performing a root cause analysis, measurement uncertainty and also on metrological traceability among our laboratory professional, despite these there is high alteration rate of trained staffs" (19)

2.2 Associated factors affecting the KAP of laboratory professionals on method validation/verification

A special article performed by Guy-Michel Gershy-Dame et al (2010) stated that in Africa implementation of laboratory standards is verified through the process of accreditation. Laboratory accreditation schemes assess laboratories in accordance with accepted standards, traceable, and reproducible. Accredited medical laboratories must demonstrate a well-functioning quality management system, technical competence, and timely and customer-

focused services that contribute to patient care. Accreditation requires leadership, time, attention, resources, and continuous commitment to evaluation and improvement (20).

A study conducted in Uganda showed that, after conducting a cross-sectional study on selected laboratories, three laboratories assessed met basic facility requirements, had trained personnel, and safety measures in place. Sample reception was properly designed and executed with a well designated chain of custody. All laboratories had sufficient equipment for the nature of work they were involved in. However, we found that standard operating procedures were incomplete in all three laboratories, lack of quality audit schemes by two laboratories and only one laboratory enrolled into external quality assurance schemes. The SLIPTA scores were one star for the research laboratory and no star for both the public and private-for-profit laboratories (21).

A study performed in Ethiopia, The laboratory journey towards accreditation began with a baseline assessment in 2012 using the WHO-AFRO SLIPTA checklist; the baseline audit result was 78 points (0 stars). Major gaps identified at baseline were poor laboratory infrastructure, inconsistent electric power supply, lack of laboratory supplies and knowledge gaps on the standards. In addition, the human power at the laboratory was insufficient to handle the additional workload that resulted from the implementation of the quality management system. This additional work, such as extensive paperwork for adopting laboratory policies, standard operating procedures, manuals, guidelines and other daily task records, was not considered part of the ‘daily tasks’ used to determine the number of laboratory professionals assigned to the health center (22).

A research done in Ethiopia showed that**, t**here is a chance to evaluate the reason behind that the laboratory professional for not exercising the laboratory quality system essentials in their laboratory. Based on the finding, 76% of the respondents disclosed that their facilities have no work plan and budget for laboratory specific purpose and lack of resources accounts 24% which is followed by absence of system in the health system. 105(73.4%) of the participant respond that there is no enough equipment in their laboratory and 115 (79.9%) of the lab equipment did not serviced according to the scheduled in the laboratory because of poor resource allocation and 53.9% the available equipment don't conduct preventive maintenance in the laboratory. According to the participants' response, 91.7% replayed that their laboratory lay out and size was not adequate enough for laboratory operation due to the poor engineering lay out and followed by lack of knowledge and training on laboratory

requirement during building construction. Due to the lack of motivation 27(18.8%) the laboratory didn't communicate regularly with upper management and 54(37.5%) of the laboratory professionals did not conduct their customer satisfaction survey because of poor staff communication and poor recourse allocation (23).

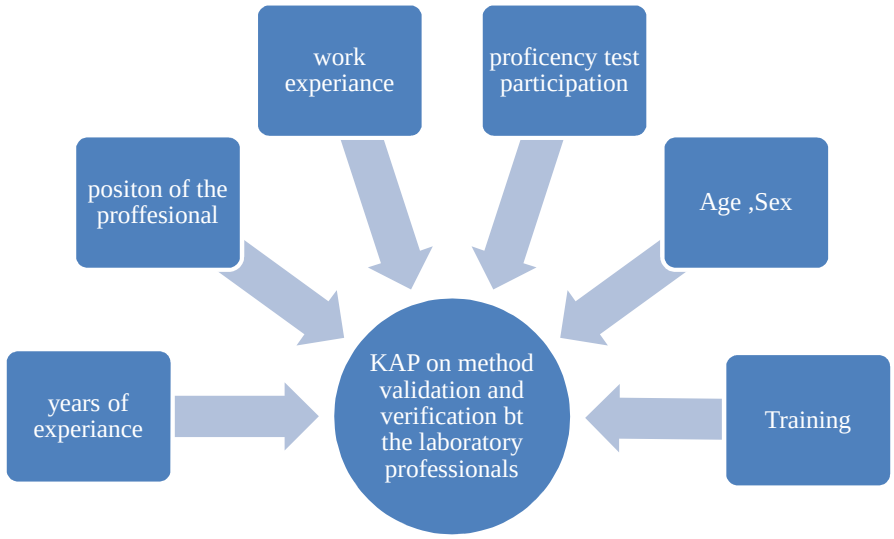

Figure1. Conceptual frame work for the relationship of dependent and independent variables

3. Hypothesis

HO: the laboratory professional's level of knowledge; attitude and practices have no association with method validation and verification in the implementation of LQMS.

4. Objectives

4.1 General Objective

To assess the level of knowledge, attitude and practice and associated factors of method validation/verification among medical laboratory professionals in selected health facilities of Addis Ababa, Ethiopia, 2021

4.2 Specific objectives

- ✓ To assess the KAP level of laboratory professionals on method validation/verification in selected health facilities in Addis Ababa, Ethiopia
- ✓ To identify the associated factors affecting the KAP of laboratory professionals on method validation/ verification in selected health facilities in Addis Ababa, Ethiopia

5. Materials and Methods

5.1 Study Area

This study was conducted in Addis Ababa which is the capital city of Ethiopia. Addis Ababa has a population size of 6.5 million residents and the capital city holds 527 square kilometers of area in Ethiopia. The city has 10 sub-cities with each sub-city has 10-15 woreda comprising 6 - 15 health centers and 0- 2 hospitals (25, 26).

Comment [WU1]:

The study was conducted in selected government and private health facility laboratories that are located in Addis Ababa. Equipment management is one of the elements of laboratory quality management system; training on principles of LQMS was given to all government hospitals. All government hospitals were selected purposively. And from the private hospitals, those private hospitals which implemented LQMS was included in the study. In Addis Ababa there are 8 private facilities who participated in SLMTA program and the study was conducted on those selected facilities.

The government health facilities included in the study were Tikur Anbessa Specialized Hospital, Saint Paul Hospital, Armed Force Hospital, Minilik II Hospital, Police Hospital, Yekatit 12 Hospital, Zewditu hospital, Ras Desta Damtew Hospital, Alert Hospital, Balcha Hospital, Saint Peter Hospital and Addis Ababa Public Health Research and Emergency Management. And from the private facilities, Girum Hospital, Arsho Medical Laboratory, Amin General Hospital, Vision Health Care, Kadisco Hospital, Teklhymanot hospital and Hema Advanced Diagnostic laboratory will be included.

Some information about the study area

Arsho is a brand name of private diagnostic Laboratory practices in Ethiopia. It originated in 1972 in a small individual practice and grows up to internationally accredited big service and name. The Laboratory qualifications comprise a wide variety of areas, including, Clinical Chemistry, Hematology, Histopathology & cytopathology, Microbiology/Virology, Serology and Molecular Diagnosis. (26)

Kadisco Hospital is the sister company of one of the leading paint manufacturing company Kadisco chemical industry, Kadisco group and SMATARA forwarding company. The general hospital was inaugurate on May 1 2007, and commenced to render its services promptly. Its objectives are mainly oriented to secure the societies health through modern

preventive and diagnostic health practices. The hospital building is erected and stretched on a wide flat area in the Gerji region commonly known as 46 mazorya. The hospital is uniquely designed to accommodate a grand entrance with wide reception and corridors, spacious bedrooms and health care units. Wide range of medical equipment units & other facility sections are also available. (27)

Tikur Anbessa Specialized Hospital (TASH) was established in 1972, the hospital became the only site for training Medical Doctors. In 1998, the TASH, the largest referral hospital in the country, with 700 beds, was transferred to the School by the Federal Ministry of Health, and it has since become a University teaching hospital. The Tikur Anbessa Specialized Hospital is now the main teaching hospital for both clinical and preclinical training of most disciplines. It is also an institution where specialized clinical services that are not available in other public or private institutions are rendered to the whole nation. The TASH has 200 doctors, 379 nurses and 115 other health professionals dedicated to providing health care services. The various departments, faculties and residents under specialty training in the School of Medicine provide patient care in the hospital. The hospital also has 950 permanent and contract administrative staff to support the hospital activities. In addition, almost all regional and federal hospitals in Addis Ababa are affiliated to the School of Medicine as clinical services and training sites. (28)

St Paul's Millennium Medical College, as it is known today, was established through a decree of the Council of Ministers in 2010, although the medical school opened in 2007 and the hospital was established in 1968 by the late Emperor Haile Selassie. It is governed by a board under the Federal Ministry of Health. The College initiated Ethiopia's first integrated modular and hybrid problem-based curriculum for its undergraduate medical education, and is currently expanding to postgraduate programs and diversifying its undergraduate program offerings. St Paul's is in the process of building its capacity quickly in a short period of time, growing from 3 to 250 faculty members in the last six years, and expanding teaching facilities. The college has more than 2800 clinical, academic and administrative and support staffs that provide medical specialty services to patients who are referred from all over the country, teaching medicine and nursing students and doing basic and applied researches. While the inpatient capacity is more than 700 beds, The College sees an average of 1200 emergency and outpatient clients daily.

St. Paul's Hospital Millennium Medical College provides healthcare and training to its students through its different biomedical and clinical departments, including Anatomy, Physiology, Biochemistry, Pharmacology, Public health, Pathology, General Surgery, Internal Medicine, Obstetrics and Gynecology, Pediatrics and child health, Emergency Medicine, Urology, Neurology, Orthopedics, Psychiatry, Ophthalmology, ENT, Dentistry and Maxillofacial Surgery, Radiology, Anesthesiology, Nursing, ICU (Intensive Care Unit), ART (HIV care), Endoscopy, Physiotherapy, Laboratory and Pharmacy. (29)

5.2 Study design and period

Institutional based cross sectional Study design using qualitative and quantitative data collection was employed to assess Knowledge, attitude and practices and associated factors of Medical laboratory professionals towards on method validation /verification in Addis Ababa, Ethiopia from December 2020 to March 2021.

5.3 Population

5.3.1 Source population

The source population was all medical laboratory professionals working in selected health facilities of Addis Ababa, Ethiopia.

5.3.2 Study population

The study population was all selected and willing laboratory professionals working in selected health facilities of Addis Ababa, Ethiopia.

5.4 Inclusion and exclusion criteria

The laboratory professionals working permanently or at least more than 6 month of experience in the mentioned study area was participated in the study.

5.5 Study variables

5.5.1 Dependent variables

Level of knowledge, attitude and practice towards method validation on verification

5.5.2 Independent variable

- Age
- sex
- Educational status,

- Year of service as a medical laboratory professional,
- Position of the laboratory professionals.
- Training

5.6 Measurements and data collection

5.6.1 Sample size determination

For the best of my literature review due to the absence of similar previous study towards KAP on method validation and verification among laboratory professionals in Addis Ababa Ethiopia, 50% of population proportion was used to determine sample size based on single population proportion and level of significance is 0.05, marginal error (d) is 5%, z-score at 95% CI is 1.96.

$n= (Z\alpha/2)2P (1-P) d 2$

$n= (1.96)2 *0.5*0.5/ (0.05)2 =384$

Where: n =is initial sample size

$Z\alpha/2$ = Z score in a normally distributed curve at 95% confidence interval

P = proportion of the cases

d = maximum allowable error

By adding 10% non-response rate and missing cases the total sample size will be 422.

5.6.2 Sampling method

Mixed sampling techniques were applied to select the health facility laboratories from the total health facilities laboratories based on their implementation of LQMS. The laboratory department head, the quality officer, and the safety officer was selected purposively considering those would have better information about method validation and verification, and the remaining professional was selected based on systematic random sampling.

5.6.3 Data collection procedure

The data was collected by using structured questionnaire and face-to-face interview guide. Quantitative data was collected using structured questionnaire. The questionnaire consisted of four parts; part one: Information about the respondents, part two; knowledge based questions about method validation and verification, part three: attitude based questions on method validation and verification; part four: questions related to practice and associated factors related to method validation/verification. Frame work analysis was used for the qualitative data from laboratory heads, quality officers and safety officer was obtained by face to face

interview and the information was captured by the principal investigator and directly transcribed to a written form. Quantitative data using structured questionnaire and qualitative data was collected by the principal investigator to obtain adequate data.

5.7 Data quality assurance

To ensure the validity of the data pretest was done in AABET hospital before the study period and adequate orientation was given for the professionals to ensure the reliability of their answer and during the data collection period completeness of data will checked by the principal investigator. To protect data manipulation data was stored in a password protected computer and backup was saved by flash and personal email.

5.8 Data analysis and interpretation

After rechecking the completeness of the collected data, data was entered and analyzed, by using statistical package for social science (SPSS version 23) and interpreted accordingly. Likert scale was used to measure respondent's attitude and descriptive statistics was computed for most of the study variables and frame work analysis was used to analyze the qualitative data. 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 associated effect. Frequency distribution tables and graphs was used to describe the findings. P values less than 0.05 was taken as statistically significant when looking for associations between dependent and independent variables.

5.9 Ethical considerations

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 given from the respective health institutions before the data collection process started. The study participants was 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 method validation and verification by laboratory professionals. The study participants was 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.

5.10 Dissemination of result

The final paper of this study will be presented and submitted to Addis Ababa University, College of Health Sciences, and Department of Laboratory science. A copy of this material will be given to those health facilities under the study area and will be used to improve the laboratory's practice by developing guideline. The result will be disseminated through publication in peer reviewed local and international journals and through presenting it in relevant workshop, seminars and scientific conferences.

5.11 Operational definitions

Good KAP level- if the mean is greater than 50%

Poor KAP level- if the mean is less than 50%

Method validation – confirmation that the requirements for specifically intended use or specific applications were met through objective evidence.

Method Verification - confirmation that the analytical characteristics data provided by a manufacturer, a laboratory or a reference institution were reached through objective evidence in the given laboratory with the use of a specific measuring system.

LQMS implementation - the participation of the health facilities on any SLIPTA/SLMTA and/or ISO15189 accreditation process.

7. Result

7.1 Socio-demographic characteristics

A total of 400 laboratory professionals participated in this study from 13 government and 7 private health facilities based on their SLIPTA/SLMTA and/or ISO 15189 implementation in Addis Ababa, with a response rate of 95%. Majority of the respondents age was 21-30 years; 193 (48.3%). Of the respondents 206 (51.5%) were male and 194 (48.5%) were female. The majority of the respondents 250(62.5%) were BSC level. Among the study participants 234(58.5%) worked for 1-5 years, 138(34.5%) for 6-10 years. Regarding the department in the laboratory most of the respondents 94(23.5%) were on haematology and clinical chemistry 56(14%). Of all the study participants 328(80.3%) of them were technical staffs, table 1.

Table 1. Socio-demographic characteristics of laboratory professionals participated in this study, Ababa,Ethiopia,2021

Variable	Frequency	Percent
Age		
21-30	193	48.3
31-40	180	45
41-50	23	5.7
Above 50	4	1.0
Sex		
Male	206	51.1
Female	194	48.5
Educational level		
MSC and above	137	34.3
BSC	244	61.0
Diploma	17	4.3
Certificate	2	0.4
Work experience		
1-5 years	234	58.5
6-10yrs	139	34.8
11-15yrs	20	5
16-20yrs	7	1.7
Above 20yrs	0	0
Department		
Haematology	94	23.5
Clinical chemistry and serology	56	14
Microbiology	33	8.3
Parasitology and urine analysis	46	11.5
Blood bank	33	8.3
All	138	34.4

Position		
Laboratory manager	20	6.6
Quality officer	19	4.8
Safety officer	14	3.5
Section head	19	4.8
Technical staff	328	80.3

7.2 Knowledge, attitude and practice of the laboratory professionals on method validation and verification working in selected health facilities.

7.2.1 Knowledge of the laboratory professionals on method validation and verification working in selected health facilities.

The health facilities included in this study were participated in based on their laboratory quality management system implementation (LQMS). The overall mean of the laboratory professionals on having knowledge on method validation/verification was 23%. Among the study participants 386(96.3%) understood the term method validation/verification, but only 85(21.3%) had been involved in method validation/verification. Regarding the work area 29(7.2%) participated on quality control. Majority of the respondents 326(81.5%) didn't take trainings on method validation/verification. To implement the expected quality system 253(63.2%) of them agreed to use the help of external mentor to assist the quality. Among the reasons for not having external mentor 151(37.8%) said due to lack of proper management. Regarding the achievement of expected quality system by the help of external mentors, 376(94%) didn't think they got the expected quality, table 2.

Table 2. Knowledge of the laboratory professionals working in selected health facilities on method validation/verification, Addis Ababa, Ethiopia,2021

Variable	Frequency	Percent
Knowledge on method validation/ verification		
No	14	3.5
Yes	386	96.5
Performance on method validation/verification		
No	308	77
Yes	92	23
Experience on method validation/verification in the laboratory		
None	309	77.3
1-5ys	85	21.3
6-10yrs	4	1.4
Specific area of involvement in the laboratory LQMS implementation		
Method validation	15	3.8
Verification	24	6
Document preparation	24	6

Quality control	29	7.2
None	298	74.5
Other	10	2.5
Having LQMS Training		
No	326	81.5
Yes	74	18.5
Usefulness of external consultant		
I don't know	68	17
Not at all	21	5.3
Small extent	27	6.8
Moderate extent	253	63.2
Large extent	20	5
Very large extent	11	2.8
Reason for not having external consultant		
Lack of competent consultant	87	21.8
Lack of adequate budget	123	30.8
Lack of management	151	37.8
Other	39	9.6
Achievement of quality system by the help of external mentor		
No	376	94
Yes	24	6

7.2.2 Attitude of the laboratory professionals on method validation and verification working in selected health facilities.

The attitude of the laboratory professionals on method validation/verification was good having the overall mean of more than 50%. Majority 397(99.3%) agreed the importance of implementing method validation/verification and 374(80.8%) agreed on the impact of laboratory results on making clinical decisions. Of all the participants 323(80.8%) agreed on performance of verification and 270(67.5%) of them did belief that the laboratory information's from manufacturers should not be used without verification, table 3.

Table 3, Attitude of the laboratory professionals towards method validation/verification working in selected health facilities, Addis Ababa, Ethiopia, 2021

Variable	Frequency	Percent
Importance of implementation method validation/verification		
Disagree	3	0.7
Agree	397	99.3
Purpose of method validation/ verification		
Disagree	26	6.5
Agree	374	93.5
Need of laboratory information for validation/verification		
Disagree	130	32.5
Agree	270	67.5
Importance of modification tests		
Disagree	77	19.3
Agree	323	80.7

Importance of method validation/verification for qualitative and quantitative tests		
Disagree	11	2.7
Agree	389	97.3

7.2.3 Practice of the laboratory professionals on method validation and verification working in selected health facilities.

We also had a chance to ask the participants about their practice on method validation/verification and resulted with poor practice with a mean of 22%. In the case of method validation, 14(3.5%) said that they applied method validation/verification on non-standard methods, 20(5%) on laboratory designed methods, 10(2.5%) on standard methods used outside their intended scope, 15(3.8%) on validated methods subsequently modified and 341(85.3%) said all of the above reasons. On the other hand, the professionals implement verification, 14(3.5%) implemented for methods used without modification, 26(6.5%) said when evaluating whether or not the procedure meets the performance characteristics stated by the manufacturer, 12(3%) said when the manufacturers validation claims. However 344(86.6%) and 324(81%) of the participants did not perform method validation and verification respectively.

313(78%) and 309(77.3%) of the study participants did not define method validation/verification protocol had not compare the test results from different procedures, equipment, method used for the same tests respectively. And of all the professionals included in this study 317(79.3%) had low status on method validation and verification performance. Regarding the associated factors that affect the implementation of method validation verification, 15(3.8%) said it is due to competent staff turnover, 18(4.5%) work load, 42(10.5%) lack of training, 9(2.3%) absence of external mentor, 10(2.5%) lack of equipment full information, and 266(66.5%) agreed on all the above factors, table 4.

Table 4; practice of laboratory professionals on method validation/verification working in selected health facilities, Addis Ababa, Ethiopia,2021

Variable	Frequency	Percent
When do you use method validation		
On non-standard methods	14	3.5
Lab designed methods	20	5
Methods used outside their intended use	10	2.5
Validated methods subsequently modified	15	3.8
In all condition	341	85.2
When do you use method verification		
For methods used without modification	14	3.5
When evaluating manufacturers	26	6.5

performance		
When manufacturer validation claims	12	3
In all conditions	348	87
Method validation performance		
No	344	86
Yes	56	14
Method verification performance		
No	324	81
Yes	76	19
Status on method validation/verification		
No	317	78.3
Yes	83	21.8
Validation/verification performance for all lab methods		
No	309	74.3
Yes	91	25.7
Associated factors		
Competent stuff turnover	15	3.8
Workload	18	4.5
Lack of training	42	10.5
Absence of external mentor	9	2.3
Lack of equipment full information	10	2.5
In all conditions	266	75.5

7.3 Knowledge, attitude and practice of laboratory managers, quality officers and safety officers working in selected health facilities.

It is purposively understood that the laboratory managers, quality officers and safety officers took some training on method validation/verification. In this study there were 20 laboratory managers, 19 quality officers, 14 safety officers. And among them, on the definition of method validation/verification, 14(26.4%) said that it is 'a process of checking the test that the result meets its specification.' On the importance of validation,' 28(54.7%) of the participants said that it 'is important to test the suitability of the method' and regarding the implantation of method validation/verification, majority 26(49.1%) 'analysed the data component by developing protocol.' 39(73.6%) of the participants didn't have a good experience on external mentor, and for the factors affecting the implementation of method validation/verification, they said 26(49.1%) was lack of training, At last they took some measures in order to improve method validation/verification, that is, 27(50.9%)reported to the responsible management, table 5.

Table 5; KAP analysis and associated factors of laboratory managers, quality officers and safety officers on method validation/verification, Addis Ababa, Ethiopia, 2021.

Variable	Frequency	Percent
Definition of method validation/verification		
Process of establishing performance	14	26.4
Assures the necessity of the equipment	8	15.1
Assessment weather a procedure can be used	30	56.6
Determining the degree of validity	1	1.9
Importance of validation/verification		
To test suitability of the method	28	54.7
Reliability of analytical data	15	28.3
Component of quality management system	3	5.7
Accuracy of the result	5	9.4
Error minimization	1	1.9
Implementation of validation/verification		
By developing protocol	26	49.1
By preparing sample for verification	10	18.9
By using ISO standards	16	30.2
By manufacturer claim	1	1.8
Experience on external mentor		
No	39	73.6
Yes	14	26.4
Factor affecting validation/verification		
Lack of training	26	79.1
Lack of equipment	6	11.3
Workload	4	7.5
Lack of management support	16	0.2
Lac of resource implementation	1	1.9
Measure taken to improve validation/verification		
Report to responsible management	27	50.9
Trying to create awareness	17	32.1
Arrange trainings	9	17

7.4 Factors associated with KAP on method validation/verification

Regression analysis was done to observe the association between knowledge of the laboratory professionals and the associated factors, as a result from the socio-demographic characterise age is found to had significant association with the knowledge on method validation/verification. Participants aged between 21-30 years had better knowledge on method validation/verification when compared with those above 50 years of age (AOR=24.652, CI=95% 1.181-560.4). In addition position of the study participants is another variable that is found to be statically significant and the laboratory head had a better knowledge regarding method validation verification compared to the technical staffs (AOR=10.121, CI=95% 3.301-31.194). Training is final variable that is significant, those participants who didn't took the training on method validation/verification are less likely to have a better knowledge than those who took the training, (AOR=18.535, CI 95%=8.682-39.429). However there were no significant relation between gender, work experience, educational level, proficiency test participation and knowledge on method validation verification, table 6.

In order to observe the relationship between practice of the laboratory professional and associated factors towards method validation/verification, regression analysis was also applied. Work experience, position and training were significant and sex, age, educational level and proficiency test participation were not statistically significant. Those study participants having 1-5years and 6-10 years of experience are more likely to had a better practice on method validation/verification comparing to those who had 16-20years of experience (AOR=85.574 CI 95%=3.650-2053.613 and AOR=38.027 CI 95%CI=1.685-858.318 respectively). Furthermore, comparing to the technical staffs, the section heads and safety officers are more likely to had a practice on method validation/verification (AOR=4.56, CI95% =1.485-14.059 and AOR= 4.322, CI95% =1.485-14.059). For the case of training, those without training are less likely to had practiced method validation/verification than those with the training, (AOR=14.914 CI 95%=7.015-31.709), table 7.

Table 6; knowledge and associated factor of laboratory professionals on method validation/verification, Addis Ababa, Ethiopia, 2021

Knowledge and associated factor on method validation/verification					
	Yes	No			
Variable			COR(95%CI)	AOR(95%CI)	P-Value
Sex					
Male	151	55	1.136(0.591-2.185)	0.880(0.458-1.693)	0.617
Female	157	37	1	1	
Age					
21-30	160	33	0.041(0.002-0.886)	24.652(1.128-538.659) *	0.003
31-40	132	48	0.100(0.005-2.059)	9.999(0.486-205.505)	0.136
41-50	14	9	0.180(0.012-2.757)	5.571(0.363-85.582)	0.218
Above 50	2	2	1	1	
Educational level					
Certificate	2	1	0.541(0.017-16.834)	1.850(0.059-57.602)	0.643
Diploma	10	4	0.936(0.207-4.235)	1.068(0.236-4.834)	0.931
BSC	194	51	1.382(0.668-2.858)	0.724(0.350-1.497)	0.383
MSC	102	6	1	1	
Work experience					
1-5	187	47	1.703(0.118-24.626)	0.587(0.041-8.490)	0.440
6-10	104	35	1.267(0.088-18.210)	0.789(0.055-11.336)	0.789
11-15	14	6	1.337(0.111-16.126)	0.748(0.062-9.025)	0.748
16-20	3	4	1	1	
Position					
Technical staff	269	36	0.099(0.032-0.304)	10.121(3.288-31.154) *	0.000
Section head	20	14	0.240(0.060-0.965)	4.167(1.036-16.767)	0.044
Safety officer	5	9	0.519(0.090-2.996)	1.926(0.334-11.141)	0.464
Quality officer	6	14	0.595(0.118-3.007)	1.681(0.333-8.501)	0.530
Department head	8	19	1	1	
Training					
No	291	17	0.054(0.025-0.115)	18.535(8.684-39.559) *	0.000
Yes	35	57	1		

*- statistically significant

Table 7. practice and associated factor on the laboratory professionals on method validation/verification, Addis Ababa, Ethiopia,2021

Practice and associated factors on method validation/verification					
	Yes	No			
Variable			COR(95%CI)	AOR(95%CI)	P-Value
Sex					
Male	151	55	1.406(0.748-2.664)	0.711(0.378-1.337)	0.290
Female	157	37	1	1	
Age					
21-30	160	33	1.308(0.044-38.560)	0.764(0.026-22.527)	0.876
31-40	132	48	1.075(0.038-30.535)	0.930(0.033-26.430)	0.966
41-50	14	9	0.395(0.018-8.732)	2.530(0.115-55.912)	0.517
Above 50	2	2	1	1	
Educational level					
Certificate	2	1	0.579(0.006-58.378)	1.727(0.017-174.164)	0.816
Diploma	10	4	0.238(0.054-1.052)	4.201(0.951-18.568)	0.058
BSC	194	51	0.547(0.283-1.057)	1.828(0.946-3.532)	0.073
MSC	102	6	1	1	
Work experience					
1-5	187	47	0.012(0.000-0.274)	86.574(3.650-2053.619)*****	0.006
6-10	104	35	0.026(0.001-0.594)	38.027(1.685-858.318)*****	0.022
11-15	14	6	0.191(0.012-3.632)	4.868(0.946-3.532)	0.280
16-20	3	4	1	1	
Position					
Technical staff	269	36	0.240(0.079-0.730)	4.173(1.370-12.713)*****	0.012
Section head	20	14	0.287(0.072-1.144)	3.487(0.874-13.890)	0.077
Safety officer	5	9	0.575(0.104-3.189)	1.738(0.314-9.632)	0.527
Quality officer	6	14	0.417(0.093-1.878)	2.399(0.533-10.808)	0.254
Department head	8	19	1	1	
Training					
No	291	17	0.067(0.032-0.143)	14.914(7.015-31.709)*****	0.000
Yes	35	57	1		
Proficiency test participation					
No	84	28	1.580(0.796-3.133)	0.633(0.319-1.256)	0.191
Yes	224	64	1		

*- statistically significant

8. Discussion

Laboratory quality management system is one of the most important tools in order to achieve the quality of the products or services offered to the customer or user and method validation/verification is one of the factors needed to the implementation of LQMS. There is still a gap in the improving of laboratory services and system, such as poor laboratory infrastructure and lack of laboratory equipment or their maintenance (30). Method validation/verification is part of the equipment management and proper management of the equipment in the laboratory is very essential to ensure accurate, reliable and timely testing. The overall factors affecting the implementations were lack of trainings, and the laboratory professionals had poor knowledge and practice towards method validation/verification.

This study is designed to assess the level of knowledge, attitude and practice (KAP) of the laboratory professionals towards method validation/verification and the associated factors affecting the implementation of method validation/verification.

The better one had prior knowledge on the subject matter, the better he/she understands it. In this case among the study participants, only 85(21.3%) had better knowledge on method validation/verification. This result is in line with a study done by Rusanganwa V et al, Uganda, 2019 and Desalegn DM et al, Ethiopia 2019, which resulted inadequate resource optimization, where insufficient knowledge in Laboratory Quality Management System (LQMS) contributed to low-quality performance and Even though a remarkable quality performance improvement was observed over the entire process, inadequate skilled personnel was the major challenge identified in the road towards implementation of LQMS respectively, (31,22).

Training is needed to enhance skills, capabilities and knowledge's, however minority of the participants 74(18.5%) had the chance. These has some similarities with a research done by Sisay A et al, Ethiopia, 2015 which stated that one of the reasons for not fully implementing LQMS in the laboratory is inadequate trainings (23). And in addition to trainings, external mentors help to improve the implementation of LQMS. In this study, 253(63.2%) moderately agreed on having external mentor and 151(37.8%) of the participants said lack of good management is the main reason for not using the external mentors properly. this result has some similarities with a research done by Aslan D, 2018, that shows one of the challenging issue is that it is not possible to find a university or teaching hospital that has sufficient trainers who have all required knowledge and skills. One of the solutions may be the training

courses organized, competency-based in the concepts of “case-based”, “entrustable professional activities” and task-based (15).

One of the important components on the implementation of laboratory quality management system is equipment management, and method validation/verification is part of these. We are living in resource limited environment and these has its own impact on the result we found only 39(9.8%) had involved on method validation/verification specifically. And when we observe the performance of the participants on method validation/verification, 308(77%) of them had poor performance on the study subject. These result has some similarities with Taramawa IM et al, Uganda, 2017 that resulted in Participating laboratories had equipment’s desired for the nature of work being done. However, there was poor adherence to equipment protocol as they all lacked labels and maintenance records which leads to failure to meet base line quality standards (21).

Practice on method validation/verification is also one of the objectives. Having a good work experience is essential to provide reliable and quality service but the reverse is true here, those with lower work experience had a good practice on method validation/verification. 309(77.3%) had poor practice on method validation/verification. Among the minority of the participants that had good practice in the case of method validation, 14(3.5%) said that they applied method validation/verification on non-standard methods, 20(5%) on laboratory designed methods, 10(2.5%) on standard methods used outside their intended scope, 15(3.8%) on validated methods subsequently modified and 341(85.3%) said all of the above reasons. On the other hand, the professionals implement verification, 14(3.5%) implemented for methods used without modification, 26(6.5%) said when evaluating whether or not the procedure meets the performance characteristics stated by the manufacturer, 12(3%) said when the manufacturers validation claims, which is similar to a research that implied as it clearly defines validation and verification, that is , Verification was defined as processes that are done to prove that the method can provide intended use only. And validation is defined as processes that are carried out to prove that the method is fit for the laboratory intended use to non-standard laboratory designed methods, which are subjected to subsequent modification. It is done by Beyanga M et al, Tanzaniya, 2018, (13).

The laboratory professionals on the study also define how they behave towards method validation/ verification. Majority 397(99.3%) agreed the importance of implementing method validation/verification and 374(80.8%) had good attitude on the impact of laboratory results

on making clinical decisions. Of all the participants 323(80.8%) had a good thought on performance of verification and 270(67.5%) of them did belief that the laboratory information's from manufacturers should not be used without verification.

Focused individual discussion is done with the laboratory head, safety officer and quality officer because of the highest probability of getting training on the subject matter. Of all the study participants that answered the open ended questions, majority of them defines and understands the importance of method validation/verification but there is still a big gap on the implementation of it. This clearly shows that continual trainings and updates is needed and competent external mentors should help the laboratories frequently.

There are associated factors that affect KAP of laboratory professionals on method validation/verification. Age is one factor and the categories between 21-30years of age are the one with good knowledge and attitude. In fact there are no similar studies done here to compare the result with. In addition position of the laboratory professionals is significantly associated with their KAP on method validation/verification and the managerial positions that are laboratory head, safety officer and quality officer are more likely to have a good knowledge and attitude than the technical staffs. This is probably because of those are the groups that are prone to trainings.

Training, work experience and position of the laboratory professionals are other factors that are found statically significant with their practice on method validation/verification. Majority of the participants 326(81.6%) didn't take trainings which brings a gap on the implementation of LQMS, and the longer experience the have the lower performance. This might be due to work load, lack of competence, and inadequate training. This result goes in line with the research done by Sisay A et al, Ethiopia, 2015. However age, sex, educational level and importance of proficiency participation are not significantly associated with practice of method validation/verification. These result is discordant with a research done by Hyile EL et al, Ethiopia, 2014 and the reason might be that proficiency testing is more of directly related to accreditation than method validation/verification, (18).

9. Strength and Limitation

9.1 Strength

- Key informant interviews were used to deeply explore facts on method validation/verification and to get the root of the factors that directly or indirectly affecting it.
- All data results was collected with the principal investigator

9.2 limitation

- There is scarcity on directly related research's done, thus this makes it difficult to compare results with.
- Due to the world wide pandemic, some of the research activates were hindered at different levels majorly at data collection stage.

10. Conclusion and recommendation

10.1 Conclusion

According to the finding of the study, the following conclusion can be stated;

In this study the participants had a good attitude but poor knowledge and practice towards method validation/verification. Understanding and performing the subject matter should be considered mainly because those are the main criteria's that needs to be fulfilled first. Achieving laboratory quality management system is directly affected and having good attitude doesn't mean having good knowledge and practice.

The major factors that affect the knowledge and attitude of the participants are their age, training on LQMS and position of the professionals on the laboratory. So that continues trainings to all responsible professionals are needed besides their position. In addition competent external mentors should be assigned regularly to enhance and increase the capabilities of the professionals.

Practice of the laboratory professionals on method validation/verification is also altered by absence of adequate training, and work experience of the professionals. These in turn emphasized more on arranging LQMS trainings and assigning the professionals on a lot of educational and motivational activities.

10.2 Recommendation

According to the finding of this study, the following recommendation is given by the principal investigator in order to improve the KAP level of laboratory professionals on method validation/verification;

To health facilities and upper managements

- By communicating to Addis Ababa Health Bureau and Minister of Health Should arrange continual trainings for external mentors and the laboratory professionals
- prepare continuous educational and motivational activities
- Should supply and control equipment's with their full information's
- Have to give attention to human resource management and development and give consideration on identification of required qualification, skills and competency during hiring or delegation and on job follow-up.
- allow the professionals to participate to different kind of LQMS trainings

- Should give full guarantee to the equipment's
- Should arrange meetings regularly to communicate about the equipment's used in their facilities

To the laboratory professionals

- Must have internal motivation and team sprit
- Should protect and use the equipment carefully
- Should update themselves to become confident and competent in their job

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ANNEXES

Annex I : English Versions of Participant Information sheet and consent form

Participant Information Sheet

Laboratory Department

You are invited to participate in a study to be conducted in selected health facilities by Tegbar Getahun a Master's student of Addis Ababa University at the Department of Medical Laboratory Sciences. Please read the following statements and ask any unclear points before you agree to participate.

Introduction

The topic of the study is "assessing the knowledge, attitude and practice on method validation and verification by laboratory professionals in selected health facilities in Addis Ababa, Ethiopia. Participation in this study is exclusively voluntarily and you can withdraw anytime from the study.

If you are not interested to participate, there will be no consequences. If you decide to participate, we will use the leftover sample.

What is expected from me as participant of the study?

As a participant of this study, it is expected from the participants to address all questions appropriately.

Potential benefits to participant and/or to the society

Based on the results obtained, guidelines will be prepared and continued improvmrnt process will be implemented.

Compensation for participation

You will receive some pocket money for participation in this research study.

Confidentiality

Your name and identity on the request paper will be changed to confidentiality code for the purpose of this study. Information given by the participants will serve only for this research not for any other purpose

Person to contact

Please direct any questions you may encounter during this study to the principal investigator.

Tegbar Getahun

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

Cell phone - +251910620523

Email – tege0000@gmail.com

Annex2 consent form

Consent form

This page contains an agreement signature to participate in the study entitled “assessing the knowledge, attitude and practice on method validation and verification by laboratory professionals in selected health facilities in Addis Ababa, Ethiopia”. So, please read the following points and sign your signature at the end in the space provided.

1. I understand the objective of the study is to asses assessing the knowledge, attitude and practice on method validation and verification by laboratory professionals in selected health facilities
2. I understand that, all the information and the results are confidential.
3. I understand that I will not get any money for my participation.
4. All the information is explained by the Principal investigator
5. I understand that my participation is voluntary and can withdraw anytime from the study and this will not affect the service I am getting from the hospital.

Therefore, with full understanding of the situations I agree the information I give can be used for this study.

Signature of the participant: _____

Address of the participant: _____

Date: _____

Annex 3: Data collection tool

I am a post graduate student at Addis Ababa University pursuing a Master of Laboratory Management and Quality Assurance. For my final thesis, assessing the knowledge, attitude and practice on method validation and verification by laboratory professionals in selected health facilities in Addis Ababa, Ethiopia. I believe the findings of this study will have great benefit to your laboratory and other organizations seeking not only this particular accreditation but supporting the program and others as well. If you choose to participate in this research, please answer all questions as honestly as possible. Participation is strictly voluntary and you may refuse to participate at any time. There is no compensation for responding or any known risk. The data collected will be for research purposes only

The questioners are divided into four parts

Part 1 information about yourself

Part 2 knowledge related questions about method validation and verification

Part 3 attitude related questions about method validation and verification

Part 4 practice related and associated factors affecting method validation and verification.

Hospital code----------(to be filled by the researcher)

Part 1 information about yourself

1. Sex 1. Male 2. Female

2. Age (in years)----------

3. Educational level 1. MSc and above 2. BSc 3.Diploma 4. Certificate

4. How long have you worked in your organization/hospital----------

5. In which unit/department are you working?

1. Hematology 2. Clinical chemistry 3. Microbiology 4. Serology 5. Parasitology 6. Urinalysis 7. ---------- (Other specify)

6. Which of the following describes your position in your organization?

1. Section Head 2. Lab Manager (head) 3. Lab Quality manager 4. Safety officer 5. Technical staff 6. Other specify--------

Part two knowledge related questions

The following questions relate to your knowledge of you on method validation and verification. Answer the questions below by **encircling** below the appropriate item.

1. Are you aware of the term method validation and verification?

1. Yes 2. No

2. If your answer in the question above is Yes, have you been involved in method validation and verification process.

1. Yes 2. No

3. If your answer for question number 2 is Yes, how long have you been involved in the process?---------- (specify)

4. If your answer for question 2 is Yes in which way(s) have you been involved in the process?

1. Method validation. 2. Verification. 3. Document Preparation. 4. Quality control preparation. 7. Other (specify)---------

5. Have you ever taken training related to method validation and verification?

1. Yes 2. No

6. Did you know that your organization use external consultants/mentors to assist with quality system implementation?

0. I don't know 1. Not at all 2. Very small extent 3. Moderate extent 4. Large extent. 5. Very large extent

7. If your answer for question 6 is not at all and very small extent, what is the reasons?

1. Lack of competent consultants 2. lack of adequate budget for external consultants 3. Lack of management support 4. Other----------specify

8. If your answer for question 6 is at large extent and very large extent, have you got the expected quality assistance?

1. Yes 2. No

Part 3 attitude related questions

The following questions are related to attitude/belief of the laboratory professionals about method validation and verification.

1. Method validation and verification are important tools to implement laboratory quality management system.
   1. Agree 2. Disagree

2. All tests are validated according to the clinical test purpose/intended use/ impact of the result on the clinical decision.

   1. Agree 2. Disagree

3. All tests used without modification are verified using performance information data available from the manufacturer.

   1. Agree 2. Disagree

4. For quantitative testes, the laboratory must verify or estabilish the method performance specifications that are applicable and clinically significant.

1. Agree 2. Disagree

5. Laboratories may use information's from manufactures, publications literatures, or studies performed in other laboratories without verification.

1. Agree 2. Disagree

Part four-practice related and associated factors affecting method validation and verification

1. For what cases do you use validation?
    1. on non-standard methods
    2. Laboratory designed or developed methods
    3. Standard methods used outside their intended scope
    4. Validated methods subsequently modified.
    5. All

2. When do you use verification?

    1. Performed on methods that are being used without any modifications
    2. When evaluating of whether or not the procedure meets the performance characteristics stated by the manufacturer
    3. When the manufacturer validation claims.
    4. All

3. Have you ever performed equipment / method validation?

    1. Yes 2. No

4. Have you ever performed equipment verification?

    1. Yes 2. No

5. Can you define method validation /verification protocol specific for each procedures at the same time of validation and verification?

    1. Yes 2. No

6. Can you compare the results from the different procedure, equipment, methods used for the same tests?

    1. Yes 2. No

7. Are all equipment and methods validated/verified on-site upon installation and before use and is documented evidence available?

    1. Yes 2. No

1. Is validation performed for all laboratories designed or developed methods, standard methods used outside their intended scope and validated methods that are subsequently modified?
   1. Yes 2. No

2. Has validation information been obtained from the manufacturer/method developer as part of the verification?
   1. Yes 2. No

3. Have the verification/validation results/reports been reviewed and approved by an authorized person?
   1. Yes 2. No
4. What do you think is associated factors affection implementation of method validation and verification in your laboratory?
   1. Competent staff turn over
   2. Workload
   3. Lack of training on method validation and verification
   4. Absence of external mentor
   5. Lack of equipment full information
   6. Other specify----------
5. Have your organization participated in any proficiency testing program?
   1.yes 2.no

Open ended questions for laboratory head, quality officer and safety officer for focused group discussion

1. What is method validation and verification?
2. What is the importance of method validation and verification?
3. How did you implement the method validation and verification in your laboratory?
4. What is the experience of your laboratory regarding mentors by external bodies?
5. What do you think is associated factors affection implementation of method validation and verification in your laboratory?
6. What measurers have you taken when you encounter problems related to method validation and verification?

Declaration

I, the undersigned agree to accept responsibility for the scientific ethical and technical conduct of the research project and for provision of required progress reports as per terms and conditions of the research publications office.

M.Sc. candidate: **Tegba Getahun(B.Sc.)**

Signature: _____

Date of submission: _____

This thesis has been submitted with our approval as advisors.

Advisor: **Fatumma Hassen (BSc, MSc)**

Signature: _____

Date: _____

Place: Addis Ababa, Ethiopia.

Advisor: **Abay Sisay (BSc, MSc)**

Signature: _____

Date: _____

Place: Addis Ababa, Ethiopia.