ADDIS ABABA UNIVERSITY

COLLEGE OF HEALTH SCIENCES

DEPARTMENT OF MEDICAL LABORATORY SCIENCES

Assessment of Gram stain competency and associated factors among laboratory professional in clinical laboratories at Mekelle city health facility, Mekelle, Ethiopia

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A thesissubmitted to the Department of Medical Laboratory Sciences, College of Health Science, Addis Ababa University, in partial fulfillment of Master of Science Degree in Clinical Laboratory Sciences (Laboratory management and Quality Assurance Specialty Track)

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Abstract

Background: Gram stains are initially used as a pre-analytical indicator of specimen quality and acceptability for culture. It also gives the clinician preliminary information regarding the nature of potential pathogens present in thepatient specimen and thus serve to guide empirical therapy. This procedure is still considered a high-complexity procedure by the Clinical Laboratory Improvement Amendments (CLIA) program. The manual nature of the staining process and the subjectivity of Gram stain interpretation contribute to the incidence of errors.

Objective: Assessment of Gram stain competency and associated factors among laboratory professional in clinical laboratories at Mekelle city health facility

Methodology: A cross-sectional study was conducted from January 2020 to April 2020 on 77 different health facilities present at Mekelle city. Convenient sampling method was used to collectData from 148participants; of those are 81, 62 and 5 from private, governmental and uniformed health facility respectively.Qualitative data were collected from medical laboratory professional through a structured self-administered questionnaire and panel slide at on-site assessment of their performance. Question and panel slide was used to assess knowledge and skill of laboratory professionals respectively. Panel slides were prepared from American Type Culture Collection(ATCC)by using known bacterial strains and no organism slides were prepared from patient sample.Bloom's cut off point of59 % or below as low, 60-80 % as medium and above 80: as high was used to describe the knowledge and practical skills of the respondents.

Result: Among 155 eligible medical laboratory professionals, 148 (95.5%) of them participatedand most of them were males 78(52.7%). Onehundred twenty seven 127(85.2%), Nineteen 19(12.8%) and 2(1.3%) participants scored low, medium and high skill level respectively. The level of skills and knowledge of medical laboratory professional had significant associated witheducational level, SLIPTA levelof health facility,training, higher institution type and sex had significant association withstudy participant about gram stain ($P < 0.05$).

Conclusion: The present study showed that the majority of medical laboratory professional had low knowledge and skill in gram stain examinations. Attention should be given to develop training strategies that can improve laboratory professional knowledge and skill level. This could be achieved through pre service and in service training and also giving adequate emphasis to gram stain related practical training, continuous followupand Regular competence assessment (supervision).

Key words:

Professional competence, clinical performance, Gram Stain

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List of Abbreviation and Acronym

AAU = Addis Ababa University
ATCC= American Type Culture Collection
ACSH= Ayder Comprehensive Specialized Hospital
CAP = College of American Pathologists
CLIA = Clinical Laboratory Improvement Amendment
CPD = Continuing Professional Development
DRERC= Departmental Research and Ethics Review Committee
LPTP = Laboratory Proficiency Testing Program
PI = Principal Investigator
PT = Proficiency Test
QC = Quality Control
SLMTA = Strengthening Laboratory Management Towards Accreditation
SLIPTA = Stepwise Laboratory Improvement Process Towards Accreditation
U.S = United States

1. Introduction

1.1 Back ground

Clinical laboratory is a laboratory where a tests are carried out on clinical specimens to get information about the health of a patient to help in diagnosis, treatment, and prevention of disease. Clinical Medical laboratories are an example of applied science, as opposed to research laboratories that focus on basic science, such as found in some academic institutions(1).

Laboratory quality can be defined as accuracy, reliability and timeliness of reported test result so, the results must be as accurate as possible, all aspects of the laboratory operations must be reliable, and reporting must be timely,this is important in a clinical or public health setting. When making measurements, there is always some level of inaccuracy. The challenge is to reduce the level of inaccuracy as much as possible, given the limitations of our testing systems. An accuracy level of 99% is acceptable, but the resulting 1% error can become quite large in a system where many events occur, such as laboratory testing. If inaccurate results are provided, there are different consequences those are: unnecessary treatment,treatment complications, failure to provide the proper treatment, delay in correct diagnosis, additional and unnecessary diagnostic testing. So, these consequences result in increased cost in time and personnel effort, and often in poor patient outcomes. (2).

Clinical microbiology laboratory testing plays animportant role in the detection, diagnosis, and treatment of infectious diseases and public health disease surveillance. Microbiology laboratories are often the first lines of defense in the detection of antibiotic resistance and in the identification of outbreaksof, e.g., food-borne infection, and are responsible for reporting certain infectious diseases to public health authorities. Therefore, it iscritical to ensure high-quality testing and results that are accurate and precise (3).

Gram staining is one of the laboratory test methods which is named after the Danish bacteriologist Hans Christian Gram who originally devised it in 1882 and published in 1884 to discriminate between P*neumococci* and *Klebsiellapneumoniae*bacteria in lung tissue.Gram stain is a classic biological protocol that is still actively used to differentiate bacteria into two possible classifications: Gram-positive cells, in which the primary stain is retained and Gram-negative cells, in which the primary stain is lost (4, 5, 6).

Gram stains are initially used as a pre-analytical indicator of specimen quality and acceptability for culture. They also give the clinician preliminary information regarding the nature of potential pathogens present in the patient specimen and thus serve to guide empirical therapy. Although the Gram stain has been the staple of clinical microbiology laboratories for over a century, it is still considered a high-complexity procedure by the Clinical Laboratory Improvement Amendments (CLIA) program. The manual nature of the staining process and the subjectivity of Gram stain interpretation contribute to the incidence of errors (7, 8, 9, 10).Error on specimen sampling,Specimen processing, smear preparation, and prior antibiotictherapy are all factors that can have an adverse impact onGram stain result.

Gram stains remain the cornerstone of diagnostic testing in the microbiology laboratory for the guidance of empirical treatmentbefore to availability of culture results.Misinterpretation of Gram stains may adversely impact patient care, and yet there areno comprehensive studies that have evaluated the reliability of the technique and there are no established standards for performance.In this study, clinical microbiology laboratories at four major tertiary medical care centers evaluated Gram stain errorrates across all non-blood specimen types by using standardized criteria (11).

In Ethiopia, most medical laboratories in health care facilities-cannot perform microbial culture for the diagnosis of microorganisms. Microbial culture for the diagnosis of microorganisms is a limited service. This was due to lack of skilled-man power, infrastructure, or cost of culture diagnostic materials and other issues (12).Hence, Gram stain is a method of choice for the diagnosis of microorganisms in most health care facilities, as microbial culture is impossible or not accessible in most of these facilities.

Competency defines the ability to carry out the total performance responsibilities of the given practitioner’s generic position or competency as the combined knowledge and skill factors necessary to fulfil work obligations adequately. In other words, competency is the ability to carry out a specific task within given parameters of control. The competency required for clinical laboratory personnel reflects performance in many dimensions such as knowledge, intelligence, technical skills, problem solving abilities, interpersonal skills, and skills in oral and written expression (13, 14, 15).

1.2 Statement of the problem

It has been reported that preventable medical errors are responsible for the death of 400,000 Americans annually, the third highest cause of mortality after heart disease and cancer (16). If 60 to 70% of medical decisions are based on laboratory results, it stands to reason that erroneous laboratory results play some role in avoidable patient mortality (17).

The study conducted at USA on four site on gram stain assessment error rate indicates, For sites B and C, the majority of discrepant results (79% and 85%, respectively) were Gram stain negative/culture positive, while for sites A and D, discrepant results were primarily Gram stain positive/culture negative (85% and 61%, respectively) So, Clinical microbiologists face similar obstacles in attempts to characterize the incidence and nature of errors in their laboratories. Many of the tests performed, such as the Gram stain, are prone to variability and differences in interpretation between technologists (11).

In Ethiopia, even though gram stain is the method of choice for diagnosis of microorganisms to guide initial choice of antibiotic therapy as stated above, there was a gap between higher institutions to produce medical laboratory professionals with usable knowledge and practical skills(18), lack of health information resources(19), no evidence of refresher training and supervision on gram stain examination and interpretation, low level but progressive Strengthening Laboratory Management Towards Accreditation (SLMTA) practice(20,21) and lack of continuing professional development(CPD) program. Hence, due to these gaps Gram stain examination and interpretation by medical laboratory professionals is low quality and inconsistent. Lack of proper gram stains examination and interpretation could lead clinicians to miss diagnose and miss treat patients, which could cause drug resistance, resource-wastage, and suffering and possibly death of patients and others (9, 22).

In Ethiopia, a study conducted on 12 hospital laboratories participated on the national PT program from 6 cycles of 2012 and 2013 G.C., Gram stain had high PT failure rates from 20 test parameters. In this study Gram stain failure rate were 88.9% (23).So, this study indicates there is high knowledge and skill gap on gram stain interpretation in Ethiopia including study area in particular.

In Africa including in Ethiopia there were also limited accessible studies in the scientific literature that reported competency of medical laboratory professionals on gram stain examination and interpretation. This indicates that the area was not enough examined by both researchers and responsible bodies for continuing professional development and quality medical laboratory services. Therefore, there was lack of scientific evidence on competency of medical laboratory professionals on Gram stain examination and interpretation in Ethiopia and in the study area in particular.

1.3 Significance of the study

Competency assessment it is a part of problem analysis and becomes a key tool in identifying errors through quality assurance process and also preventing from recurring. Competency assessment procedures can help to identify problemsoccurring in the technical aspects of laboratory practice and assess performance deficiencies before they develop into major problems. Competency assessment is also an opportunity to provide continuing education and performance feedback to employees and to document valuable objective information for performance evaluations. It should and can be used as a positive experience that helps to ensure that employees and employers can perform assigned tasks.The result of this study will contribute in provision of concrete data about the Gram stain competency assessment and associated factorson clinical laboratories in the study area.It will also enable to design strategies for enhancing patient safety and reduce laboratory error because of significant laboratory errors have an impact on patient outcome, in some cases leading to erroneous medical interventions. In addition to this result will be useful for employee to evaluate own strength and weakness to perform required tasks, and also encourages employees to read and review carefully of laboratory policies and procedures.

2. Literature review

A cross sectional study conducted at USA in 2014 by Goodyear N.on gram stain competency assessment, out of 278 laboratory staff from 40 laboratories that are participate on the study, from 40 multiple questions for assessment of knowledge the mean score is 88%(range 63% - 98%), skill level of laboratory professional, mean of identification of host cells is 93%, other cells like yeast cells, 92%, gram positive 90 % and gram negative 88%. Mean of categorized by type of interpretation, a laboratory professional who identify by structure like bacterial morphology feature 91% and identify by Name genus and species 87% (22).

In Ontario, Canada, a study conducted on competency assessment practices on 112 licensed ontario microbiology laboratories those are participated in EQA (proficiency testing). Out Of the 111 responding laboratories, 6(5.4%) indicated they did not have a formal evaluation program since they perform only limited bacteriology testing. Of the remaining 105 respondents, 87% perform evaluations at least annually or every 2 years, and 61% include any test or task performed, whereas 16% and 10% focus only on problem areas and high-volume complex tasks, respectively. A survey respondents indicated that the most common competency issue requiring remediation was associated with Gram staining and interpretation (30).

The cross sectional studyconducted by Samuel et al, at USA in 2016 focused on several factors that primarily contributeto errors in the process of Gram stain, including poor specimen quality, smear preparation, and interpretation of the smears. The number of specimens during the evaluation period ranged from 976 to 1,864 specimens per site, and there were a total of 6,115 specimens. Gram stain results were discrepant from culture for 5% of all specimens. Fifty-eight percent of discrepant results were specimens with no organisms reported on Gram stain but significant growth on culture, while 42% of discrepant results had reported organisms on Gram stain that were not recovered in culture. Upon review of available slides, 24% (63/263) of discrepant results were due to reader error, which varied significantly based on site (9% to 45%) (24).

In the U.S., a cross sectional study conducted in 1996, a study surveyed a total of 552 institutions and, showed that 89.2% of institutions had a written competency plan and of those, 90.3% used their plan for microbiology. The study reported that approximately 98% of institutions review employee competency at least annually. Of all laboratories surveyed,

87.5% perform direct supervision, 77.4%review test or QC results, 60% review instrument preventive maintenance, 52.2% conduct written testing, and 20.8% perform other methods of assessment as a competency tool. For this study, measuring of adherence to the laboratory's own competency plan found that 89.7% assessed using direct observation, 85.8% assessed by reviewing QC and patient test results, 78% assessed by reviewing instrument records, and 74% assessed using written testing; 90.4% of new employees were assessed as indicated per policy, and 90% of employees were found to have responded satisfactorily to a written competency assessment regarding specimen processing. In these institutions failure to comply with the laboratory's own competency plan ranged from 1 to 6.4%, and employees who failed competency assessment were not allowed to continue their usual work in 8.6% of institutions (25).

An assessment of medical laboratory professionals was done in the U.S. by using sets of direct Gram stained smears for which the culture results were known. For this study accuracy of identification of Pseudomonas aeruginosa was 60% for the first survey conducted in 1987 but improved progressively to over 80% in 1988 and 1989 until a decline was observed in 1990. According to this study, this was correlated with an increase in the number of untrained personnel and indicated a greater need for in-service education in interpretation of gram-stained smears (26).

Another study was conducted in the U.S., by reviewing major errors in Gram stain reports from positive blood cultures during a 23-month period. The study reported that blood cultures were misread for 57 (0.7%) of 8,253 patients. Of 5,885 read as gram-positive cocci, 6 (0.1%) had only gram-negative organisms by culture, 3 of which were Acinetobacter species. Of 1,959 read as gram-negative bacilli, 25 (1.3%) had only gram positive organisms by culture. Of these, 9 were *Bacillus* and 2 were *Clostridium* species. Non recognition of mixed Gram stains accounted for 28 errors that most often were associated with a reading of gram-positive cocci (9).

In other study in the U.S., gram stain results were discrepant from culture for 5% of all specimens. Fifty-eight percent of discrepant results were specimens with no organisms reported on Gram stain but significant growth on culture while 42% of discrepant results had reported organisms on Gram stain that were not recovered in culture. Upon review of available slides, 24% (63/263) of discrepant results were due to reader error, which varied

significantly based on site (9%-45%). The Gram stain error rate also varied among sites, ranging from 0.4% to 2.7% (11).

Cross sectional study conducted in Ethiopia in 2017 they used both knowledge and skill tests to assess competence of medical laboratory professionals on gram stain examination and interpretation. Out of 190 study participants that are administered 15 theory knowledge test questions, the minimum and maximum score results were 3(20%) and 13(86.7%) respectively and also 55(28.9%), 131(68.9%) and 4(2.1%) participants scored with low, medium and high knowledge level respectively. Fromall 1140 observations for skill of medical laboratory professionals on gram stain examination and interpretation, they found, 44 observations (4%) with major errors and 321 observations (28%) with very major errors. Of all observations, 321(28.2%) reported without grading, 39 (3.4%) reported gram positive bacteria as gram negative bacteria and 15(1.4%) reported gram negative bacteria as gram positive bacteria. One hundred forty eight observations (12.9%) also reported without grading with gram positive bacteria reported as gram negative bacteria while 43 observations (3.7%) reported without grading with gram negative bacteria reported as gram positive bacteria (27).

Therefore this study will provide valuable information on gram stain competency on laboratory professional in mekelle city health facility.

In Ethiopia, there are limited literatures related to our study. Therefore this study will provide baseline information on gram stain competency of laboratory professional in Mekelle city health facilities.

3. Objective

3.1. General objective:

To assess gram stain competency and associated factor among laboratory professional in clinical laboratories at Mekelle city health facility

3.2. Specific objectives:

- To assess the knowledge of Medical Laboratory Professionals on gram stain examination at Mekelle city health facility
- To assess the skill of Medical Laboratory Professionals on gram stain examination at Mekelle city health facility
- To identify factors associated with competency of medical laboratory professionals on gram stain at Mekelle city health facilities

4. Materials and methods

4.1. Study Area

The study was conducted at Mekelle city, Tigray, north Ethiopia. Mekelle formerly the capital of Enderta awraja in Tigray, is currently the capital city of Tigray National Regional State. It is located around 780 kilometres north of the Ethiopian capital Addis Ababa, with an elevation of 2,254 meters (7,395 ft) above sea level. Administratively, Mekelle is considered a Special Zone, which is divided into seven sub-cities. Mekelle is the economic, cultural, and political hub of northern Ethiopia. Based on the 2007 Census conducted by the Central Statistical Agency of Ethiopia (CSA), this town has a total population of 215,914 people (104,925 men and 110,989 women).According to Tigray regional health biro, This city has 77 health facility, fromthose 62 are private health facility(4 primary hospitals, 4 lower,20 medium, 34 higher/specialty clinic), one uniformed hospital and 14 are governmental health facility those are 9 health center (Quiha health center, Aynalem health center, Kasech health center, Mekelle health center, Adishendehun health center, Adi ha health center, Semen health center, Serawat and Lachi health center), Two primary hospital (HEWO and Adihaki), Two general hospital (Mekelle and Quiha) and one Federal hospital (Ayder comprehensive specialized hospital). All health facilities that are present at this city were included in the study.There was lack of scientific evidence on competency of medical laboratory professionals on Gram stain examination and interpretation in Ethiopia and in the study area in particular.

4.2. Study Design and Period

A cross-sectional study design was conducted from January 2020 to April 2020.

4.3 Population

4.3.1 Source population

All Medical Laboratory Professionals who were working in Medical Laboratories of health facilities at Mekelle city, Ethiopia.

4.3.2 Study population

All Medical Laboratory Professionals who were working Medical Laboratories of Health facility in Mekelle city and fulfilled the eligibilitycriteria.

4.4. Eligibility criteria

All laboratory professionals working permanently in Mekelle city health facility during study period was eligible for the study.

4.5. Study variables

4.5.1. Dependent variables:

Competency level of Medical Laboratory Professionals

4.5.2. Independent variables:

- Sex
- Age
- Qualification
- Experience
- Previous training
- Health institution type
- Higher Institutions(private,governmental)
- competency assessment(supervision)
- Health information Resource
- Type of Microscope

4.6 Sample Size Determination and Sampling Techniques

4.6.1 Sample Size Determination

The totalnumber of medical laboratory professional who was working at governmental and private health facility wasaround 140 and 62 respectively. This makes a total of 202 professionals.Of those 17, 16, 7 and 7 laboratory, this makes 47 professional was excluded due to those are on education, break, training and also part time workerduring the study period respectively, so total number of medical laboratory professional that are working permanently at government and private health facility during the study period was155, those are included in the study to increase the reliability and accuracy of the study result. Preliminary assessment was done to know about the number of medical laboratory professionals in each health facility before data collection. After preliminary assessment there were 155 laboratory professional present at the whole health facility that are present at Mekelle city. Among those 95.5% (148) of themfully participated. The remaining 4.5% were not willingto participate and lack of time was the most frequent reason given not to participate.Of those 80, 63 and 5 medical laboratory professional who are from private, governmental and uniformed health facility respectively.

4.6.2 Sampling Techniques

All laboratory professional who are working permanently at Mekelle health facility was included using Convenience Sampling technique.

4.7. Measurement and Data collection

4.7.1Data collection tools and procedure

Data on Socio demographic characteristics and 25 knowledge assessment question of study subject were collected byself-administered structured questioner. Thequestionnaire wasdeveloped based on reviewing different literatures.7 panel slides were prepared to assess skill of laboratory professionals.Stainedand graded slide were provided to each participant and then each participant was graded when interpreting one stained slide within five minutes. Participants were provided 25 structured knowledge questions with background questionnaire to fill their response within 30 minutes and also monitored the participant while filling the questionnaire so as to not use reading material and discuss with their friends.Functionality of microscope was checked by senior laboratory professional by using control slide that are prepared from ATCC.The data from gram stained slide identification and 25 structured knowledge questions with background questionnaire from each study participant were collected by the researcher. Generally, Gram stains reporting criteria per oil immersion:

Grade	Description	Cells	Bacteria
1+	Rare	<1	<1
2+	Few	1–5	2–10
3+	Moderate	6–10	11–50
4+	Many	>10	>50

Based on the reading of more than 10 fields (29).

4.7.2 Panel Slide Preparation and Distribution

Senior microbiologists that are present at Ayder comprehensive specialized hospital and the principal investigator prepared and validated the gram stained panel slides.Patient sample for no microorganisms with cell and samples from known bacterial strains known as American Type Culture Collection (ATCC) were used for preparation of gram stained panel slides.The known bacterial strain was sub cultured on blood agar. From growth on blood agar, gram stained panel slides was prepared. All slides were stained by gram staining procedure. Senior microbiologist interpret the prepared gram stain smears using investigative criteria for the presence or absence of gram stain findings (bacteria, yeasts and cells) and also quantification of findings (few, moderate and many). Senior microbiologist were validated the gram stain interpretation agreement with the culture growth on blood agar. For this study, seven gram stained panel slide types were used and the composition of test panels prepared in Microbiology Laboratory Department and those panel slides have Gram positive cocci in cluster (S.aureus), Gram positive cocci in chain(S.pyogenes), Gram negative(N.gonorrhoeae)and Gram positive(S.pnemonia) diplococcic and Gram positive (bacillus) and gram negative (E.coli) rods from ACSH, and no microorganisms with many pus cells from patient sample. Panel of slides were graded as few, moderate and many with different interpretation. Next to preparation, the slides and reporting format was arranged, packed and distributed to the participant by the researcher.

4.8 Data management and Data Quality Assurance:

The following precautions were considered so as to assure the quality of the data. The data were collected by the researcher. By using standard data collection material, preparing of quality control from ATCC for checking of Microscope functionality before assessing the performance of laboratory personnel and pre testing of the questioner's data at wukro general hospital, checking the completeness of questionnaires. Based on the findings of the pre-test, some questions were modified. Furthermore data were checked during entry into the computer before analysis. After preparation of panel slide from ATCC, all slides were stained by gram staining procedureThen Senior microbiologist were validated the gram stain interpretation agreement with the culture growth on blood agar and alsointerpreted the prepared gram stain smears using investigative criteria for the presence or absence of gram stain findings (bacteria, yeasts and cells) and also quantification of findings (few, moderate and many).

4.9Data analysis and presentation:

Data obtained was checked for completeness and Qualitative data from the questionnaires coded and entered into SPSS version 23 data analysis. Descriptive statistics were used to summarize socio demographic characteristics of study participant.The univariate analysis such as percentage and frequency distribution of different characteristics of the questionnaire was analyzed. Bivariate analysis was used to see the association of independent with the dependent variable but there were no difference with multivariate analysis.A chi square model was employed to determine associations with dependent and independent variables. Percent of correct response to a set of 25 knowledge questions were graded as follows: 59 % or below (14.7/25) as low, 60-80 % (15-20/25) as medium and above 80 % (>20/25): as high knowledge level. Similarly, percent of correct responses to a set of 7 skill related questions were graded as follows: those who perform correctly in 59% or below (4.13/7) as low, 60-80 % (4.2-5.6/7) as medium and above 80 % (>5.6/7) as high skill level(28). Major error, minor error, very major error, maximum score, minimum score were analyzed for skill tests and also participants grouped in to low, medium and high skill level. For 25 knowledge questions the analyses were performed for maximum score and minimum score of questioner answers and also classify participants to low, medium and high knowledge level.*P*Valueof <0.05 was considered statistical significant. Participants' knowledge about gram stain was assessed using 25questions. Define gram stain, difference between cell structure of gram positive and gram negative bacteria, important of decolourization in gram staining, Why is the gram stain considered a differential stain and important of knowing gram positive or gram negative bacteria. Those questions had a coded in spss (minimum correct response coded by 'yes' and wrong or don't know response had a code of 'No'). The rest had single answers, so giving a value as a choice question.

4.10 Operational Definitions:

Competency:is the ability of personnel to apply their skill, knowledge, and experience to perform their laboratory duties correctly.

Uniformed Hospitals: Armed Force Referral and Teaching Hospital and Police Hospital

High knowledge and Skill:when Percent of correct response> 80 %. (28)

Medium knowledge and Skill:when the percent of correct response 60 – 80 %.(28)

Low knowledge and Skill: when the percent of correct response ≤ 59 %. (28)

Gram stain interpretation minor error: report the presence of polymorph when not present (29).

Gram stain interpretation major error: report the presence of an organism not present or failure to report the presence of 1+ to 2+ polymorphs (29).

Gram stain interpretation very major error: failure to report the presence of an organism and failure to report the presence of 3+ to 4+ polymorphs (29).

4.11 Ethical considerations

This study was ethically approved by the “departmental research and ethical review committee” (DRERC) of the department of medical laboratory science. Permission letter was written fromTigray regional health biro. All the collected data was kept confidentially by using codes instead of any personal identifiers. It is also cleared that participation fully based on the willingness of participants using written consent.

4.12 Dissemination of the result

The result of this study will be disseminated or communicated to Addis AbebaUniversity College of Health Science, department of medical laboratory science and also governmental and private health institution and other concerned bodies that are present atmekelle city through reports and publication on an appropriate journal or by presentations of the findings in appropriate scientific conferences.

5. Result

5.1 Socio-demographic characteristics of the studyparticipant

During study time, there were 77 health facilities; of them 62 were private, 14 governmental and also one uniformed health facility. Among 62 health facilities, 58 of them was clinics, the rest one was primary hospitals and also among 14 governmental health facility, 9 was health center, one specialized hospital, two primary hospitals and two referral hospitals.

Of 155 medical laboratory professionals, 95.5% (148) of them fully participated. The remaining 4.5% were not willingto participate and lack of time was the most frequent reason given not to participate.Out Of148 respondents 78(52.7%) were males. regarding education, 67(45.3%),73(49.3) and 8(5.4) were degree, diploma and masters holder respectively.Fifty-nine (39.9%)of the respondents were in the age group of 26-30 years.The present study indicates Most of the study participants 107(72.3%) had work experienceof ≤ 9 years.Nearly half, 81(54.7%) participants were from private health facility andseventy-two (46.2%) respondents were who graduate from Government University.Most 109(73.6%) of respondent did not participate in EQA and among study participants most of them 106(71.6%) did not get regular competency assessment (supervision). Of respondent 142 (95.9%) were not get training related to gram stain. During the study time, 109(73.6%) respondents were from health facilities that are not participating on accreditation program.(Table 1)

Table 1:Socio demographic characteristics of medical Laboratory professionals in Mekelle city health facility,Tigray, Ethiopia 2020(N=148)

Variable characteristics		**Number**	**percent**
Sex	Male	78	52.7
	Female	*70*	47.3
Age in years	≤ 25	27	18.2
	26-30	59	39.9
	31-35	36	24.3
	≥36	26	17.6
Experience in years	0-9	107	72.3
	10-19	35	23.6
	≥20	6	4.1
Educational level	Diploma	73	49.3
	Degree	67	45.3
	Masters	8	5.4
Health facility type	Government	62	41.9
	private	81	54.7
	uniformed	5	3.4
EQA	Yes	39	26.4
	No	109	73.6
Current SLIPTA level	Not participated	109	73.6
	Star 0	4	2.7
	Star 1	5	3.4
	Star 2	11	7.4
	Star 4	19	12.8
Training related to gram stain	Yes	6	4.1
	No	142	95.9
Competency assessment(supervision)	Yes	42	28.4
	No	106	71.6
Licence provider institution type	Government college	59	39.9
	Government university	72	48.6
	Private college	17	11.5
Over all total		148	100

5.2 Resource access of study participants

Out of all study participants, there was 102(68.9%) laboratory professional who has health information resource in their laboratory section. Among all respondents, 53(35.8%) of study participants used Olympus microscope. (Table 2)

Table 2: Resource access of study participants at Mekelle city health facility, Tigray, Ethiopia 2020

Variable characteristics		**Number**	**percent**
Health information resource	Yes	102	68.9
	No	46	31.1
	Total	148	100
Types of microscope	Olympus	53	35.8
	Novel	40	27.0
	primo star	21	14.2
	Gemmy and heuer	19	12.8
	Other	15	10.1
	Total	148	100

5.3Knowledge of medical laboratory professional

For the 25 theoretical knowledge questions administered to 148 participants, the minimum score was 0(0%) and the maximum score was 24(96%).A number of medical laboratory professionals who score 0 of 25 knowledge assessment questionswere 7(4.7%). Among participants, the knowledge score was low for 95 (64.2%), medium for 49(33.1 %) and high for 4 (2.7 %).From study respondents with low knowledge levels, most of the respondents 59(62.1%) with low knowledge levels were those who had diploma. Analyses were carried out to examine the association between different factors and knowledge of study participants on gram stain examination. Education level, SLIPTA level of health facility, Licence provider institution type and sex had statistically significant association with knowledge level of study participants (p value <0.005).Out of148study participant four respondents had high knowledge level, among those two of them had degree holder and one haddiploma and masters holder.(Table 3)

Out of four study participants who had high knowledge level, three of them were from health facility that had star 4 level of SLIPTA, the rest one was from a health facilities that are not participating on accreditation. About 79(83.2%) of respondentswho had low knowledge level was from health facility that are not participating on accreditation.Of respondents with high knowledge level (4), 3(75%) of them were respondents who graduate from government university and also all respondents who graduates in private college had low knowledge level. As the present study indicates among low and high knowledge level participants, 55(57.9%) and 3(75%) were Female and Male respectively.(Table 3)

Age, microscope type, health facility type, health information resources, EQA participation,training, competency assessment and experience had no significant association with knowledge level of medical laboratory professionals on Gram stain examination.(Table 3)

Table 3: Knowledge of medical laboratory professional related to background characteristics in mekelle city health facility, Tigray, Ethiopia, 2020 (n=148)

Variable characteristics		Knowledge level			Total	X^2	P-value
		Low No(%)	Medium No (%)	High No (%)			
Age	<25	26(17.6%)	1(0.7%)	0(0%)	27(18.2%)	5.359	0.499
	26-30	47(31.8%)	11(7.4%)	1(0.7%)	59(39.9%)		
	31-35	31(20.9%)	4(2.7%)	1(0.7)	36(24.3%)		
	≥36	23(15.5%)	3(2%)	0(0%)	26(17.6%)		
Sex	Male	40(27%)	35(23.6%)	3(2%)	78(52.7%)	11.971	0.003
	Female	55(37.2%)	14(9.5%)	1(0.7%)	70(47.3%)		
Health facility type	Government	33(53.2%)	27(43.5%)	3(2%)	62(41.9%)	5.827	0.212
	Private	58(71.6)	21(25.9)	1(1.2%)	80(54.1%)		
	Uniformed	4(80%)	1(20%)	0	5(3.4)		
Licence provider institution type	Government college	43(29.1%)	15(10.1%)	1(0.7%)	59(39.9%)	19.078	0.001
	Government university	35(23.6%)	34(22.9%)	3(2%)	72(48.6%)		
	Private college	17(11.5%)	0(0%)	0(0%)	17(11.5%)		
Experience in years	0-9	73(49.3%)	32(21.6%)	2(1.4%)	107(72.3%)	3.957	0.412
	10-19	19(12.8%)	14(9.5%)	2(1.4%)	35(23.6%)		
	≥20	3(2%)	3(2%)	0(0%)	6(4.1%)		
Educational level	Diploma	59(39.9%)	13(8.8%)	1(0.7%)	73(49.3%)	27.169	0.000
	Degree	36(24.3%)	29(19.6%)	2(1.4%)	67(45.3%)		
	Masters	0(0%)	7(4.7%)	1(0.7%)	8(5.4%)		
EQA participation	Yes	22(14.9%)	16(10.8%)	1(0.7%)	39(26.4%)	1.506	0.471
	No	73(49.3%)	33(22.3%)	3(2%)	109(73.6%)		
Current SLIPTAlevel	Not participated	79(53.4)	28(18.9%)	1(0.7%)	108	22.381	0.004
	Star 0	2(1.4%)	2(1.4%)	0	4(2.7%)		
	Star 1	4(2.7%)	1(0.7%)	0	5(3.4%)		
	Star 2	6(4.1%)	5(3.4%)	0	11(7.4%)		
	Star 4	4(2.7%)	13(8.8%)	3(2%)	20(13.5%)		
Training	Yes	2(1.4%)	3(2%)	1(0.7%)	6(4.1%)	5.978	0.050
	No	93(62.8%)	46(31.1%)	3(2%)	142(95.9%)		
Competency assessment	Yes	28(18.9%)	13(8.8%)	1(0.7%)	42(28.4%)	0.161	0.923
	No	67(45.3%)	36(24.3%)	3(2%)	106(71.6%)		
Health information resource	Yes	59(39.9%)	39(26.4%)	4(2.7%)	102(68.9%)	6.469	0.039
	No	36(24.3%)	10(6.8%)	0	46(31.1%)		
Types of microscope	Olympus	33(22.3%)	18(12.2%)	2(1.4%)	53(35.8%)	11.624	0.071
	Novel	26(17.6%)	13(8.8%)	1(0.7%)	40(27%)		
	Primo star	8(5.4%)	12(8.1%)	1(0.7%)	21(14.2%)		
	Gemmy and heuer	15(10.1%)	4(2.7%)	0(0%)	19(12.8%)		
	Other	13(8.8%)	2(1.4%)	0(0%)	15(10.1%)		
Over all total		95(64.2%)	49(33.1%)	4(2.7%)	148(100%)		

5.4Response of medical laboratory professional on each theoretical knowledge question about Gram stain

Out of all participants, 110(74.3%) respondents score correct answer on question of what is a primary stain in gram stain technique, and also 124(83.8%) respondents score incorrect answer on the question of what would happen if iodine were missed during gram staining procedure.(Table 4)

Table 4: Participants' knowledge about Gram stain among medical laboratory professionals at Mekelle city, Tigray, Ethiopia, 2020 (n= 148)

No	Item	Yes(Correct)	No(Incorrect)
1	Define gram stain	67(45.3%)	81(54.7%)
2	One gram positive bacteria	79(53.4%)	69(46.6%)
3	The difference between cell structure of gram positive and gram negative bacteria	28(18.9%)	120(81.1%)
4	Important of decolourization in gram staining	39(26.4%)	109(73.6%)
5	Possible cause of false gram reaction results	108(73%)	30(27%)
6	Appearance of Gram positive bacteria	41(27.7%)	107(72.3%)
7	Appearance of Gram negative bacteria	88(59.5%)	60(40.5%)
8	bacteria'sdecolorized by Acetone alcohol & contain a counter stain colour	90(60.8%)	58(39.2%)
9	Bacteria resist decolourization& retain the colour of the primary stain	90(60.8%)	58(39.2%)
10	A counter stain in Gram stain technique	106(71.6%)	42(28.4%)
11	A primary stain in Gram stain technique	110(74.3%)	38(25.7%)
12	one possible morphologies of bacteria	77(52%)	71(48%)
13	Consequence of if iodine were missed during gram staining	24(16.2%)	124(83.8%)
14	The order of reagents used in the Gram stain	82(55.4%)	66(44.6%)
15	Use of heat fixative after smearing the sample before we use reagent to stain bacteria	80(54.1%)	68(45.9%)
16	Typical morphology of staphylococcus aures	51(34.5%)	97(65.5%)
17	The gram stain considered a differential stain	12(8.1%)	136(91.9%)
18	Gram positive cocci in pairs mean(suggestion/interpretation)	57(38.5%)	91(61.5%)
19	Gram positive cocci in cluster mean(suggestion/interpretation)	51(34.5%)	97(65.5%)
20	Important of knowing gram positive or gram negative bacteria	68(45.9%)	80(54.1%)
21	A counter stain other than safranin be used in gram staining	21(14.2%)	127(85.8%)
22	A primary stain other than crystal violet be used in gram staining	20(13.5%)	128(86.5%)
23	Consequence of if you reverse crystal violet and safranin stains	28(18.9%)	120(81.1%)
24	Safranin basic or Acidic dye	77(52%)	71(48%)
25	One gram negative bacteria	59(39.9%)	41(60.1%)

5.5The level of the skills of the medical laboratory professional on gram stain examination

Among all respondents assessed for skills in gram stain examination, one hundred twenty-seven 127(85.2%), Nineteen 19(12.8%) and 2(1.3%)participants scored low, medium and high skill level respectively.The level of skills of medical laboratory professionals variedaccording to educational level, SLIPTA levelandtraining ($P < 0.05$). (Table 5)

During study time, regarding to educational levelamong respondents with low skill levels, most of the respondents were diploma and degree level71(55.9%) and 52(40.9%) respectively.Of respondents who had low skill levels, 101(79.5%)was from health facility that are not participating on accreditations. Inaddition to theseparticipants from SLIPTA level of stare 0 and 1 health facility had no high skill level but respondents with high skill level were those are from SLIPTA level 2 and 4 health facility. (Table 5)

Out of high skill level participants, all 2(100%) had a gram stain training certificate whereas of all participants with low knowledge level,almost all of them 124(97.6%) had no training on gram stain. Among all study participants, 83.8% had no training certificate on gram stain and had low knowledge level.Of respondents with low knowledge levels were a respondents who get one 2(33.3%) and two 1(16.7%) gram stain training certificates.(Table 6)

Table 5: Skill of medical laboratory professional on each slides about Gram stain

Among all respondents, 120(81.1%) participants incorrectly report gram stain slide 6 (gram positive cocci) as gram negative bacteria and also 87(58.8%) participants correctly report gram stain slide 5 (gram negative rod). (table 5)

Item	Correct	In correct
Gss 1	66(44.6%)	82(55.4%)
Gss 2	49(33.1%)	99(66.9%)
Gss 3	70(47.3%)	78(52.7%)
Gss 4	52(35.1%)	96(64.5%)
Gss 5	87(58.8%)	61(41.2%)
Gss 6	28(18.9%)	120(81.1%)
Gss 7	64(43.2%)	84(56.8%)

Table 6: The level of the skills of the medical laboratory professional on gram stain examination in Mekelle city health facility,Tigray, Ethiopia, 2020

Variable characteristics		Skill level			Total	X^2	p-value
		Low No (%)	Medium No (%)	High No (%)			
Age	<25	26(17.6%)	1(0.7%)	0(0%)	27(18.2%)	5.359	0.499
	26-30	47(31.8%)	11(7.4%)	1(0.7%)	59(39.9%)		
	31-35	31(20.9%)	4(2.7%)	1(0.7%)	36(24.3%)		
	≥36	23(15.5%)	3(2%)	0(0%)	26(17.6%)		
Sex	Male	62(41.9%)	14(9.5%)	2(1.4%)	78(52.7%)	5.919	0.052
	Female	65(43.9%)	5(3.4%)	0(0%)	70(47.3%)		
Health facility type	Government	50(79.4%)	11(17.5%)	2(3.2%)	63(42.6%)	4.438	0.232
	Private	73(91.2%)	7(8.8%)	0(0%)	80(54.1%)		
	Uniformed	4(80%)	1(20%)	0(0%)	5(3.4%)		
Licence provider institution type	Government college	56(37.8%)	3(2%)	0(0%)	59(39.9%)	13.945	0.007
	Government university	54(36.5%)	16(10.8%)	2(1.4%)	72(48.6%)		
	Private college	17(11.5%)	0(0%)	0(0%)	17(11.5%)		
Experience in years	0-9	92(62.2%)	14(9.5%)	1(0.7%)	107(72.3%)	0.938	0.919
	10-19	30(20.3%)	4(3.1%)	1(0.7%)	35(23.6%)		
	≥20	5(3.4%)	1(0.7%)	0(0%)	6(4.1%)		
Educational level	Diploma	71(55.9%)	2(10.5%)	0(0%)	73(49.3%)	21.907	0.000
	Degree	52(40.9%)	13(68.4%)	2(2.9%)	67(45.3%)		
	Masters	4(3.1%)	4(3.1%)	0(0%)	8(5.4%)		
EQA participation	Yes	31(20.9%)	7(4.7%)	1(0.7%)	39(26.4%)	1.901	0.387
	No	96(64.9%)	12(8.1%)	1(0.7%)	109(73.6%)		
Current SLIPTA level	Not participated	101(79.5%)	8(5.4%)	0(0%)	109(73.6%)	28.191	0.000
	Star 0	4(3.1%)	0(0%)	0(0%)	4(3.1%)		
	Star 1	4(3.1%)	1(0.7%)	0(0%)	5(3.4%)		
	Star 2	8(5.4%)	2(1.4%)	1(0.7%)	11(7.4%)		
	Star 4	10(6.8%)	8(5.4%)	1(0.7%)	19(12.8%)		
Training	Yes	3(2%)	1(0.7%)	2(1.4%)	6(4.1%)	48.339	0.000
	No	124(83.8%)	18(94.7%)	0(0%)	142(95.9%)		
If yes, How many times/certificate	One	2(1.4%%)	0(0%)	1(0.7%)	3(2%)		
	Two	1(0.7%)	0(0%)	1(0.7%)	2(1.4%)		
	Four	0(0%)	1(0.7%)	0(0%)	1(0.7%)		
	Total	3(2%)	1(0.7%)	2(1.4%)	6(4.1%)		
Competency assessment(super vision)	Yes	36(24.3%)	5(3.4%)	1(0.7%)	42(28.4%)	0.500	0.779
	No	91(61.5%)	14(9.5%)	1(0.7%)	106(71.6%)		
Health information resource	Yes	83(56.1%)	17(11.5%)	2(1.4%)	102(68.9%)	5.403	0.067
	No	44(29.7%)	2(1.4%)	0(0%)	46(31.1%)		
	Total	127(85.8%)	19(12.8%)	2(1.4%)	148(100%)		
Types of microscope	Olympus	43(29.1)	8(5.4%)	2(1.4%)	53(35.8%)	7.763	0.256
	Novel	37(25%)	3(2%)	0(0%)	40(27%)		
	Primo star	16(10.8%)	5(3.4%)	0(0%)	21(14.2%)		
	Gemmy and heuer	18(12.2%)	1(0.7%)	0(0%)	19(12.8%)		
	Other	13(8.8%)	2(1.4%)	0(0%)	15(10.1%)		
Over all total		127(85.8%)	19(12.8%)	2(1.4%)	148(100%)		

5.6Errors of Medical Laboratory Professionals on gram stain examination

During the study time, results from a total of (148 x 7=1036) observation, 437(42.2%)observation with major error and 308 (29.7%) observation with very major error. 249 observations (24%) reported gram positive bacteria as gram negative bacteria and 106 observations (10.2 %) reported gram negative bacteria as gram positive bacteria.(Table 7)

About 55.4 % of laboratory professionals have reported negative slides (slide 1) as false positive (gram positive and gram negative). 49(33.1%) of the participants correctly reported the bacteria of slide 2. Slide 3 contains Gram positive rod (many), 70(47.3%)of the participants correctly reported the bacteria. Similarly 52(35.1%) of the participants correctly reported the bacteria of slide 4. Out of respondents87(58.8%),28(18.9%), and 64(43.2%)correctly reported bacteria of slide 5, 6 and 7 respectively. (Table 7)

Table 7: The Skill level of Medical Laboratory Professionals on gram stain examination at Mekelle city health facility, Tigray, Ethiopia 2020

	Characteristics								Error type		
Slide number	Gram reaction				Total	No. of participants correctly report Morphology of bacteria	No. of participants correctly report Density of bacteria	Other cells(PMNS)	Minor	Major	V.major
	No	posneg		both							
GSS 1	66	48	34	0	148	-	-	11	-	82	137
GSS 2	25	49	73	1	148	64	54	1	1	73	25
GSS 3	28	70	47	3	148	75	64	0	0	47	28
GSS 4	37	59	52	0	148	38	28	0	0	59	37
GSS 5	14	47	87	0	148	79	19	1	1	47	14
GSS 6	26	28	92	2	148	57	44	1	1	92	26
GSS 7	41	64	37	6	148	35	21	1	1	37	41
Total	237	365	422	12	1036				4	437	308

Notice: Gss 1: no gram rxn with many PMNCs, Gss 2: gram +vecocci (s.aures), Gss 3: gram +ve rod, Gss 4: gram –ve diplococcic, Gss 5: gram –ve rod, Gss 6: gram +vecocci(s.pyogens), Gss 7: gram +vediplococci

6. Discussions

The goal of competency assessment is to improve the laboratory's performance by identifying areas requiring education and/or training of the staff and thus ensuring patient safety. Ongoing competency assessment outside initial training is not as universally implemented and, in some cases where it exists, may be limited in scope and intensity. Performing competency assessment as the need arises is a reactive rather than a proactive approach. The goal should be to detect problems before they happen. Ongoing assessment needs to be incorporated into a laboratory's quality management system. Quality laboratorytesting is an essential building block of the clinical diagnosis scheme, infectious disease surveillance, and the development of public health policy. Following good laboratory practices leads to reliable and accurate test results, which in turn fosters good patient care and promotes a positive attitude toward testing from providers' and patients' perspectives.

In this study, we used both knowledge and skill tests to assess competence of medical laboratory professionals and associated factors on gram stain examination.This study showed Among 148 participants, the knowledge score was low for 95 (63.8%), medium for 49(32.9 %)and high for 4 (2.7 %) and also the skill score was low for 127(85.2%)%, medium for 19(12.8%) and high for 2(1.4%) so, this finding revealed that participants with lowknowledge level were higher than the study conducted at Adis Abeba, regrading to skill level, as study at Adis Abeba revealed that participants with high skill level was 33.7% , so this indicate the knowledge and skill level of participants was better than our studies this may be due to all participants was from hospitals(27) but in both studies,the participants with high knowledge level were very few. This may be due to lack of regular competency assessment, training and also lack of attention from the responsible body. When we seethe skill test of our study,out of all participants 13.4% and 21.4%of respondents correctly identify gram negative and gram positive respectively this may be due to lack of proper funding, adequate training for laboratory workers and systematic management of work. A study in the U.S showed that participants score of gram negative(88%) and gram positive (90%),which was higher than our study (22) so, this finding was it may be due to adequate training, supervision,high infrastructure of laboratory facility and also advanced technology.

Our study indicate that from 25 knowledge assessment questions the mean score was 44.3% (range 0% - 96%), mean score was lower than the finding in USA in 2014 by Goodyear

N(22). This may be due to continuous training, concerning body giving an attention on this, enough funding budget to improve quality and also advanced set up.

Analyses were carried out to examine the association between different factors and knowledge of study participants on gram stain examination. So our study found Sex, Licence provider institution type, Education level and SLIPTA level of health facility had statistically significant association with knowledge level of study participants.Level of knowledge of participants regarding to educational level was low for diploma holder than degree and master's holder. So concerning body should give education opportunity to medical laboratory professional in order to upgrade themselves. From study respondents with low knowledge level, most of the respondents 59(62.1%) with low knowledge level were those who had diploma, this number was higher than the study conducted at Adis Abeba (27). This may be due to most study participants were diploma level or it may be due to most participants was from private health facility. Of respondents with high knowledge level (4), all of them were respondents who graduate from government institution this was similar with the study conducted at Adis Abeba (27). Both study results indicate may be due to responsible body not give attention on private higher institution. When we compare government institution (university and college), 3(75%) of them was from government university this may be due to responsible body gives attention on government university rather than college. In addition to this when we compare Government College and private college, all respondents who graduates in private college had low knowledge and skill level but not participants from Government College, which had medium and high knowledge level and also medium skill level.This may be due to lack of attention of responsible body on private higher institution.

This study showed that Out of four study participants who had high knowledge level, three of them were from health facility that had star 4 level of SLIPTA, the rest one was from a heath facility that are not participate on accreditation and also of the low level respondents about 79(73.1%) of respondents who had low knowledge level was from health facility that are not participate on accreditation but only 4(4.2%) respondents who were from health facility that had star 4 on SLIPTA level so, this indicates participation on accreditation has an impact on knowledge of medical laboratory professional.

Among 148 respondents assessed for skills in gram stain examination, one hundred twenty seven 127(85.2%), Nineteen 19(12.8%) and 2(1.3%) participants scored low, medium and high skill level respectively in addition to this high and low score for skill was 6(85.7%) and

0(0%) from all 7 skill tests. The level of skills of medical laboratory professional varied according to educational level, accreditation status and training.During study time, regarding to educational level among respondents with low skill level, most of the respondents were diploma and degree level 71(55.9%) and 52(40.9%) respectively. Participants who were diploma and masters level had no high skill level. Of respondents who had low skill level, 101(79.5%) and also no high skill level was from a health facility that are not participating on accreditations in addition to this SLIPTA level of stare 0, 1 had no high skill level. From study participants with high skill level (2), all respondents 2(100%) were those were from SLIPTA level star 2 and 4 health facility. Although related literature was not accessed, our study showed that participation in accreditation and also increase step of SLIPTA level had an impact on the skill of medical laboratory professionals.

This study showed that among all study participants, 83.8% had no training on gram stain and had low knowledge level. From all study participants with high skill levels (2), all of them had gram stain training certificate. Of respondents who get training certificates with low skill levels were respondents who get one 2(1.4%) and two 1(0.7%) training certificates. Participants who get four training certificate had no low skill on gram stain examination. The study done in US by using gram stained smear of known culture result, accuracy of identification of Pseudomonas aeruginosa was 60% but after 1-2 years of in service training it improved progressively to over 80% (26). So this study indicates if there is continuous training it can be improve our skill level. Generally, our study showed that this area had a lack of attention from the concerning body. Doing competency assessment definitely improves the quality of the laboratory services provided using gram staining methods.

7. Limitation

Too little literature was available And Shortage of recently conducted studies are some of the limitation.

8. Conclusion

Among participants, the knowledge score was low for 95 (64.2%) and one hundred twenty seven 127(85.2%) for skill score, So this showed that the majority of medical laboratory professional had low knowledge and skill in gram stain examinations this may be due to most participants had no get training, were from heath facility that are not participate on accreditation, diploma level and also it may be due to the professionals focus on other laboratory technique.

As the present study indicates, License provider institution type, sex, SLIPTA level of health facility and educational level affect knowledge level of medical laboratory professional on gram stain examination. Educational level, SLIPTA level of health facility and trainingwere affect skill level of medical laboratory professional on gram stain examination.As our study showed most participant with low skill level were working without training this may affect on gram stain examination. Even though this study did not show association of microscope type with skill level, the study conducted at Adis Abeba indicates microscope type correlated with skill of medical laboratory professionals on gram-stain examination.

9. Recommendation

- Training and education is needed to reduce error rate of gram stain examination, those are not only used to improve knowledge and skill level of medical laboratory professionals or the quality of test results, but also clinicians trust in the laboratory so, Concerning body like Tigray regional health biro should give education and training opportunity to medical laboratory professional in order to upgrade themselves
- It requires to give attention by Concerning body like Tigray regional laboratory preparing of training on gram stain.
- The WHO AFRO has established a 5-step accreditation process structured around its core standards for laboratories, which will allow laboratories to gradually receive credit for improvement and eventually attain accreditation; So Heath facility should require participation on accreditation.

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11. Annexes

Annex I: Information Sheet (English Version)

Title of the project: Assessment of Gram stain competency and associated factors in clinical laboratories in Mekelle City health institute, Ethiopia

Name of Principal Investigator: Fikadu Miruts

Organization: Addis Ababa University

Name of sponsor: Mekelle University

This information sheet was prepared for Medical laboratory professionals who will be involved in project entitled above. I was tell them about the whole processes that have been undertaken in the study and requesting them to participate voluntarily.

Description and Purpose of the study

The Gram stain is a classic biological protocol that is still actively used to differentiate bacteria into two possible classifications: Gram-positive cells, in which the stain is primary retained and Gram-negative cells, in which the primary stain is lost. Gram stain is one of the most frequently performed laboratory diagnostic procedures. Gram stain interpretation gives immediate information regarding the presence or absence of bacterial infection. This can be ground for hospitalization and initiation of treatment and also initial choice of antibiotic therapy. However, the competency of clinical laboratories is not well known in this study area. Therefore, this study willdesigned to determine the gram stain competency and associated factors in clinical laboratories in Mekelle. This study will be identified the gap on laboratory professional as well as laboratory department on Gram stain examination and interpretation and provide scientific evidence to responsible bodies for continues professional and laboratory improvement.

Procedures: In order to undertake the above-mentioned study, theoretical examination questions related with the topic; socio demographic characteristics, seven Gram stained panel slides examination and interpretation will be taken from each study participants for analysis. Written consent wills obtain from each study participants and they will be kindly asked to give required information related with the study. The analysis of the data will be done by principalinvestigator.

Time Allowed: You should grade and interpret one slide within five minutes. You will be also provided 15 structured knowledge questions and background questionnaires to be answered and filled within 30 minutes.

Risks and discomforts: There will have not any possible risks during examination and interpretation of panel slides and answering of exam questions. It might be a possibility of discomfort during examination and interpretation of panel slides and answering of exam questions. Please feel free to ask which is not comfortable to you.

Benefits and Compensation: Participants in this study will be got 100 birr for lunch.

Confidentiality: The information obtained during this study will be remained confidential. Disclosure of any of the data to third parties other than those allowed in the informed consent will not permit. Records will remain confidential. To maintain confidentiality, the investigator will keep records in locked cabinets and the results will be coded to prevent identification of the volunteers. However, you can find out the competence results of your own.

Right to refuse or withdraw: I assure them that, they will be free to withdraw from the study at any time and that they will be not discriminated in any form for education or other services.

Whom to Contact: The following contact addresses will be given to contact investigators at any time.

Name of investigator: **FikaduMirut**sPhone No: +**251914210892**

Email: **fikadumiruts0892@gmail.com**

Department of Medical Laboratory Sciences, CHS, AAU, Tel. 0112 75 51 70

Sponsor Address**: Mekelle University**

Name of advisors: **FatumaHassen (BA, MPH, PhD Candidate, AAU)**

HabtamuMolla(Bsc, MSc,PhD Candidate, AAU)

Annex II: Informed Consent form (English Version)

I am informed fully in the language I understand about the aim of above mentioned research. I understood the purpose of the study entitled with "assessment of Gram Stain competency and associated factors in clinical laboratories health facility in Mekelle City, Ethiopia**"**. I have been informed that I will be done examination and interpretation of gram stain and also written examination. In addition I have been told all the information collected throughout the research process will be kept confidential. I understood my current and future medical services and others will not be affected if I refused to participate or with draw from the study.

Agree_____ Not agree_____

Therefore I give my consent freely for my participation in this study.

Code of participant: _____

Signature:_____ Date_____

Name of researcher:_____Signature:_____

Date_____

Annex III: Data collection tool for assessment of gram stain competency and associated factors among laboratory personnel in clinical laboratory at Mekelle city health facility.

Part 1: socio demographic data

1. Participant Code ----------

2. Health facility type: 1. Government 2. Private 3.Uniformed

Socio demographic characteristics		
NO	Question	Response
1	Age	
2	Gender	1. Male 2. Female
3	Educational level	1. Certificate 2. Diploma 3. First Degree 4. Masters
4	Where did you graduate?	1. Government collage 2. Government university 3. Private collage 4. Private university 5. Other specify
5	Type of microscope	
6	Employment status (full time , part time)	
7	Service year as clinical laboratory professional	
8	Are you participate in EQA program(proficiency testing) related to gram stain	1. Yes 2. No
9	Current accreditation status of your health facility (not participate, `0` star , `1` star , `2` star ,`3` star, `4` star, `5` star)	
10	Did you get trainingcertificate related to gram stain?	2. Yes 2. No
	If Yes on Q10, how many?	
11	Did you get regular competency assessment in your laboratory related to gram stain	1. Yes 2. No
12	Are there health information resources available in your work area	1. Yes 2. No

Part 2: Gram stained panel slides report form for gram stain competency assessment

Participant Code: ----------

To be filled by Laboratory personnel					To be filled by Principal Investigator		
Result					Expected Result	Error Type	Remark
Slide Number	Gram rxn	Morphology	No. of bacteria	Other cells			
GSS……..1							
GSS……..2							
GSS……..3							
GSS……..4							
GSS……..5							
GSS……..6							
GSS……..7							

Part 3: Competence assessment for theoretical bases in Gram staining for medical laboratory professionals working in Mekell city health institute, Mekelle, Ethiopia

Q 1. What is Gram stain :

Q 2. Write one gram positive bacteria

Q 3. What is the difference between cell structure of gram positive and gram negative bacteria

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Q 4. Why is the decolourization important in gram staining?

Q 5.Write one possible cause of false gram reaction results?

Q 6. Using gram staining method, what is the appearance of Gram positive bacteria?

Q 7. Using gram staining method, what is the appearance of Gram negative bacteria :

Q 8. Which bacterias are decolorized by Acetone alcohol & containa counter stain colour

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Q 9. which bacteria resist decolourization& retain the color of the primary stain (Crystal violet)?……..

Q 10. What is acounter stain in Gram stain technique? .....

Q 11. What is a primary stain in Gram stain technique?.....

Q 12. Write one possible morphologies of bacteria: …….....

Q 13. what would happen if iodine were missed during gram staining ?

Q 14. What is the order of reagents used in the Gram stain?

Q.15. Why we use heat fixative after smearing the sample before we use reagent to stain bacteria?

Q.16. Write typical morphology of staphylococcus aures ?

Q.17.Why is the gram stain considered a differential stain?

Q.18.What does gram positive cocci in pairs mean(suggestion/interpretation)?

Q.19.What does gram positive cocci in cluster mean?

Q.20.Why is it important to know gram positive or gram negative ?

Q. 21 Write a counter stain other than safranin be used in gram staining……

Q. 22 Write a primary stain other than crystal violet be used in gram staining…….....

Q. 23 What happens if you reverse crystal violet and safranin stains ?

Q. 24 Is safranin basic or Acidic dye ?

Q. 25 Write one gram negative bacteria ?

Annex IV: Media preparation for blood agar

Purpose: Blood Agar (BA) is**enriched medium** used to culture those bacteria or microbes that do not grow easily. Such bacteria are called "fastidious" as they demand a special, enriched nutritional environment as compared to the routine bacteria. Blood Agar is used to grow a wide range of pathogens particularly those that are more difficult to grow such as Haemophilus influenza*,* Streptococcus pneumoniaandNeisseria species. It is also required to detect and differentiate haemolytic bacteria, especially Streptococcus species. It is also a differential media in allowing the detection of hemolysis (destroying the RBC) by cytolytic toxins secreted by some bacteria, such as certain strains of Bacillus,Streptococcus, Enterococcus, Staphylococcus, and Aerococcus.

Principle: Several species of Gram-positive cocci produce exotoxins called hemolysins able to destroy red blood cells (RBCs) and haemoglobin. Blood agar, which is a mixture of tryptic soy agar and sheep blood, allows differentiation of bacteria based on their ability to hemolyze RBCs.

Procedure

1. Add 40 gm Blood agar powder in 1000 ml of distilled water
3. Heat until completely dissolved on the water boil
4. Autoclave at 121 0c for 15 minutes
6. Cool until 45-50 0c
7. Aseptically add sheep blood 5% (7%) and mix well
8. Dispense 15-20 ml of the ready media on to the petridish
9. Wait until solidify or Dry
10. Check sterility at 37 0c incubators for 24 hours with positive control
11. Inoculate or subculture
12. Check growth within 24 -48 hours

Annex V: Gram stain smear preparation procedure

1. Labelling slides: - Every slide must be labelled clearly with codes by a lead pencil
2. Smears should be spread evenly covering an area of about 15–20 mm diameter on a slide.
3. After making a smear, leave the slide in a safe place for the smear to air-dry, protected from dust, flies, ants, and direct sunlight.
4. To fix the smear, rapidly pass the slide; smear uppermost, three times through the flame of a spirit lamp or pilot flame of a Bunsen burner.
5. Allow the smear to cool before staining it.

Note: our study used six slides prepared from known bacterial strains (ATCC) and one slide prepared from patient sample. The ATCC was first took from Deep freezer and allow to room temperature until become warm. Then it was subculture on blood agar and after 24 hours, the smear was done from growth culture after dilution. To get different grading smear, tenfold serial dilution by normal saline could be conducted. I took one colony from subcultured blood agar by using sterile wire loop then add the colony in 50ml normal saline containing test tube(tube 1) and then vortex in order to emulsify. We do not know the number of bacteria that are present in test tube one ,so I prepared additional 5 test tube that are contain 450ml of normal saline in order to conduct 10 fold serial dilutionthenTo prepare slide smear with few number of bacteria by using micro pipette transfer 1 ul from test tube 2 or 3, for moderate from test tube 4 and for few from test tube 5 this grade was confirmed by Experts those are present at ayder comprehensive specialized hospital microbiology department. Slides coded as GSS (Gram Stain Slide) 1, GSS 2, GSS 3, GSS 4, GSS 5, GSS 6 and GSS 7. GSS 1 prepared frompus patient sample with no microorganism and many pus cells,GSS 2 prepared from *S.aurous*, GSS 3 prepared from bacillus,GSS 4 prepared from *N. gonorrhoeae*, GSS 5 slides prepared from E.*coli*. , GSS 6 prepared from *S.pyogen* and GSS 7 prepared from S, pneumonia.

Annex VI: Gram Stain Procedure

Principle

The Gram stain, a differential stain was developed by Hans Christian Gram, a Danish physician, in 1884. Gram staining classifies bacteria into 2 major groups, Gram positive and Gram negative bacteria. The Gram stain reaction is based on the difference in the chemical and physical composition of bacterial cell wall. Gram positive cells have a thick peptidoglycan layer, whereas peptidoglycan layer in Gram negative cells is much thinner and surrounded by outer lipid containing layer.

In Gram negative, the higher amount of lipid in the formation of large pores thus facilitating the leakage of crystal violet-iodine complex and resulting in the decolonization of the bacterium which later takes this complex counter stain. In contrast, the Gram positive cell wall are thick and composed mainly of proteins and cross linked mucopeptide, when treated with alcohol it causes dehydration and closure of the cell wall pores thereby not allowing the loss of complex and cell retains primary stain.

1. Fix the dried smear.

2 Cover the fixed smear with crystal violet stain for 30–60 seconds.

3 Rapidly wash off the stain with clean water.

Note: When the tap water is not clean, use filtered water or clean boiled rainwater.

4 Tip of all the water, and cover the smear with Gram's iodine for 30–60 seconds.

5 Wash off the iodine with clean water.

6. Decolorize rapidly (15 -30s) with acetone–alcohol. Wash immediately with clean water.

7. Cover the smear with Safranin for 30 sec to 1 min.

8. Wash off the stain with clean water.

9. Wipe the back of the slide clean, and place it in a draining rack for the smear to air-dry.

10 Examine the smear microscopically, first with the 40 × objective to check the staining and to See the distribution of material, and then with the oil immersion objective to report the bacteria and cells.

አባሪ(Annex) VII : የስምምነት ቅጽ(Consent form) የአማርኛው ቅጂ(Amharic version)

ሙለለሙለ በምረዳው ቋንቋ ከፍ ብሎ ስለተመለከተው ጥናታዊ ስራ አላማ መረጃዎች ተሰጥቶኛል፡፡ርእሱ "በመቐለኢትዮጵያበሚገኙየህክምናተቋማትውስጥየሚሰሩየህክምናላብራቶሪባለሙያዎችናየላቦራቶሪክፍልበግራምእ ስቴይንምርመራላይያላቸውብቃትመመዘን"የተሰኘውንጥናትአላማተረድቼዋለሁ፡፡ምርመራእናስለክፍሉአንዳንድመረ ጃእንደሚደረግተነግሮኛልእንዳሁምየጹሁፍምርመራምእንደሚደረግተነግሮኛል፡፡በተጨማሪምበጥናትሂደትውስጥበ ሙለየተሰበሰቡመረጃዎችንሁሉሚስጥራዊበመሆንእንደሚጠበቁተነግሮኛል፡፡የወቅቱእናየወድፊትየህክምናአገሌግልቶ ችከጥናቱበወጣወይምበመሳተፍፍላጎቱባይኖረኝተጽኖእንደማይደርስብኝተረደቻለሁ፡፡

እስማማለሁ _____ አልስማማም _____

ስለዚህበዚህጥናትላይእንድሳተፍበነጻነትፍቃድንሰጥቻለሁ፡፡

የተሳታፊውኮድ፡ _____

ፊርማ፡ _____ ቀን፡ _____

የተመራማሪውስም፡ _____ ፊርማ፡ _____

ቀን፡ _____

አባሪ(Annex)VIII: የመረጃ ቅጽ(Information Sheet) የአማርኛው ቅጂ(Amharic Version)

የፕሮጀክቱርእስ፡በመቐለኢትዮጵያበሚገኙየህክምናተቋማትውስጥየሚሰሩየህክምናሊብራቶሪባለሙያዎችናየላቦራቶሪ ክፍልበግራምእስቴይንምርመራላይያላቸውብቃትመመዘን"

የዋነኛ ተመራማሪው ስም፡ፍቃዱ ሙሩፅ ተስማ

ተቋም፡አዱስ አበባ ዩኒቨርስቲ

የእስፖንሰሩ ስም፡መቐለ ዩኒቨርስቲ

ይሄየመረጃቅጽከፍብሎበርእሱበተመለከተውፕሮጀክትውስጥተሳታፊለሚሆኑየህክምናሊብራቶሪባለሙያዎችየተዘጋጀ ነው፡፡በበጎፍቃደኝነትእንዲሳተፉበመጠየቅእናበጥናቱስለተከናወነውሙለሂደትየምንነግራችሁይሆናሌ፡፡

መግለጫ እና የጥናቱ አላማ

ግራምስቴይንባክቴሪያንበሁለትክፍልችለመለያየትአሁንምበከፍተኛሁኔታበንቃትጥቅምላይእየዋለያለክላሲክባይልጂካ ሌአካሄዴነው፡ግራምፖዘቲቭሴሎችቀለምበዋነኛነትተይዞባቸውየሚቆይሲሆንግራምኔጌቲቭሴሎችዋነኛቀለማቸውየጠ ፉናቸው፡፡ግራምስቴይንአንደበተዮጋጋሚሁኔታየሚከናወንየሊብራቶሪምርመራበቅደምተከተልነው፡፡የግረምስቴይንት ርጓሜየባክቴሪያቁስሆትንመኖርወይምአሆመኖርበተመሆከተእናበቁስሆትሂዮትሊይተሳታፊየሆኑየባክቴሪያሞርኮታ ይፕስሊይፈጣንየሆነመረጃንይሰጣሌ፡፡ይሄምወደሆስፒታልገብቶለመታከምእናህክምናለማስጀመርእንደመሰረትሆኖ ሊያገለግልየሚችልሲሆንእንዱሁምየአንቲባዮቲክህክምናንየመነሻምርጫሉሆንይችላል፡፡ይሁንእናበዚህየጥናትአካባቢየ ህክምናላብራቶሪባለሙያዎችብቃትበሚገባአይታወቅም፡፡በመቐለኢትዮጵያበሚገኙየህክምናተቋማትውስጥየሚሰሩየ ህክምናሊብራቶሪባለሙያዎችናየላቦራቶሪክፍልበግራምእስቴይንምርመራላይያላቸውብቃትለመወሰንየተነደፈነው፡፡

የአካሄድ ቅደም ተከተል

ከፍብሎየተመለከተውንጥናትለማከናወንከርእሱጋርተጓዳኝየሆኑየተወሰኑየምርመራጥያቄዎች፣ሶሾዱሞግራፊከባህሪያ ቶች፣ባለፓኔልእስላይድምርመራእናትርጓሜለምርመራከእያንዲንዱየጥናትተሳታፊዎችየሚወሰድይሆናል፡፡የጹሁፍስም ምነትከእያንዲንደየጥናቱተሳታፊዎችተወስድተገቢውንከጥናቱጋርየተገናኙመረጃዎችእንዱሰጡይጠየቃለ፡፡የመረጃው ትንተናበተመራማሪውየሚደረግይሆናል፡፡

አደጋዎችእናተግዲሮቶች፡በምርመራውወቅትእናበፓኔልእስላይዶቹትግበራወቅትእንዱሁምየምርመራጥያቄዎችመልስ በሚሰጡወቅትምንምአይነትአደጋዎችወይምተግዲሮቶችየማይኖሩይሆናል፡፡

ሚስጥራዊነት፡በዚህጥናትወቅትየተገኙመረጃዎችሚስጥራዊእንደሆኑይቀጥላሉ፡፡መረጃከተሰጠበትስምምነትውስጥከ ተፈቀደላቸውአካላትበስተቀርለማናቸውምሶስተኛወገኖችመረጃይፋማዴረግአይፈቀድም፡፡ሪከርድችሚስጥራዊእንደሆ ኑይቀጥላሉ፡፡ሚስጥራዊነትንለመጠበቅተመራማሪውሪከርድቹንበሚቆለፉመደርደሪያዎችውስጥየሚያስቀምጣቸውሲ ሆንውጤቶችምበበጎፍቃደኞችመለየትእንዲይችለበኮድምልክትይደረግባቸዋል፡፡የሚተዉመብቶች፡ለእነርሱከጥናቱበ ማንኛውምጊዜመውጣትእንደሚችሉነጻነቱእንዳላቸውእንዱሁምለትምህርትወይምለሌላአገልግሎቶችመገለልእንደማ ይደረግባቸውአረጋግጩሊቸዋለሁ፡፡

ማንንማግኘትይፍልጋሉ፡፡የሚከተለትየግንኙነትአዴራሻዎችበማንኛውምጊዜተመራማሪውንማግኘትይችላሉ፡፡

የተመራማሪው ስም፡ፍቃዱ ሙሩዕ ተስማ ስሌክቁጥር ፡09 14 21 08 92

ኢሜይሌ፡ fikadumiruts0892@gmail.com

የአማካሪው ስም፡ፋቱማ ሃሰን (ቢኤስሲ፣ኤምኤስሲ፣ፒኤችዱእጩ፣አአዩ)

ሃብታሙሞላ(ቢኤስሲ፣ኤምኤስሲ፣ፒኤችዱ;እጩአአዩ)

Annex IX: Declaration

Title of Project: Assessment Gram stain Competency and associated factor in Clinical Laboratories in Mekelle city health institute, 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: **Fikadu Miruts**

Address: Department of Medical Laboratory Sciences, AAU

Signature: _____ Date: _____

Advisors: **FatumaHassen (BA,BSc, MPH, PhD Candidate)**

HabtamuMolla(BSc,MSc, phD Candidate)

Address: Department of Medical Laboratory Sciences, AAU

Signature: _____ Date: _____