



ADDIS ABABA UNIVERSITY

COLLEGE OF HEALTH SCIENCES

DEPARTMENT OF MEDICAL LABORATORY SCIENCES

Evaluation and Professional Perspectives toward Implementation of Six Sigma Metrics in Clinical Chemistry Tests at selected hospitals, Addis Ababa, Ethiopia

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A research thesis to be submitted to the department of Medical Laboratory Sciences, college of Health Sciences, Addis Ababa University, in partial fulfillment of a Master of Science degree in clinical laboratory sciences, clinical Laboratory Management, and Quality Assurance specialty.

June, 2025

Addis Ababa, Ethiopia

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ACKNOWLEDGEMENT

Firstly, I would like to thank the Department of Medical Laboratory sciences, college of health sciences, Addis Ababa University for the opportunity to conduct this research. Secondly, I would like to thank my advisors Dr. Abay Sisay (Assist. Professor), Dr. Fatuma Hassen (Assist. Professor) and Mr. Haile Benti (PhD cand.) for their constant guidance and comments in preparing this thesis paper. I also want to thank Mr. Temsegen, laboratory head at Hospital B and Mr. kassalem , quality officer at Hospital A for granting me access to the necessary laboratory data. I would like to sincerely thank every one of the study participants, as without their willingness and involvement, this would not have been possible

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LIST OF ABBREVIATIONS/ACRONYMS

ALP	Alkaline phosphatase
ALT	Alanine aminotransferase
AST	Aspartate aminotransferase
BD	Direct bilirubin
BT	Total bilirubin
CLIA	Clinical Laboratory Improvement Amendments guideline
CR	Creatinine
CV	Coefficient of variation
DMLS	Department of medical laboratory science
EQAS	External quality assurance service
ERCDMLS	Ethics Review Committee of the department of medical laboratory science
GLU	Glucose
HDL	High density lipoprotein
IQC	Internal quality control
K	Potassium
L1	Level 1
L2	Level 2
Na	Sodium
QC	Quality control
QGI	Quality Goal index
SD	Standard deviation
T.CHOL	Total cholesterol
TEa	Total allowable errors
TG	Triglyceride
UA	Uric acid
USA	United States of America

ABSTRACT

Background: Laboratory errors have potential to cause harm and be fatal so reduction of errors, which is the idea of Six Sigma, is essential. From internal quality control and external quality control data coefficient of variance, bias and total allowable error will be extracted and calculate sigma metrics. There is lack of sufficient knowledge about methodology, process and implementation of Six Sigma.

Objective: The study aim to evaluate and assess professional perspectives toward implementation of Six Sigma metrics in Clinical Chemistry Tests at selected hospitals, Addis Ababa, Ethiopia 2024/2025

Methods: A cross-sectional study was conducted from January to April 2025. A judgmental sampling method was used to select hospitals and laboratory tests were included in the study. In depth interview was used for qualitative method. A self-administered questionnaire was used to collect data regarding the socio-demographic characteristics, knowledge and attitude of the participants. After verifying the completeness, data were coded, entered into SPSS version 25 for analysis. Microsoft Excel record sheet was used to collect daily IQC and recent EQA data for 10 tests and analysis done on excel for quantitative method Descriptive statistics were computed.

Result: sigma metrics was evaluated for 10 tests in Hospital A and 9 tests in Hospital B. Totally 12(60%) at Hospital A and 18(100%) at Hospital B tests had unacceptable/ poor sigma metrics. Cobas 6000 have better sigma metrics than Beckman coulter DXC 700 based on six common tests. A total of 37 staffs was participated. Majority of participants 13(68.4%) at Hospital B and 13(72.2%) at Hospital B have first degree. Only 12(32.4%) of professionals answer above mean. We obtained 18 (48.6%) professionals have positive attitude toward six sigma method.

Conclusion: Continuous process improvement was required for majority of tests. Manager commitment, formal training program, adequate staff with good knowledge and attitude, self-motivation and financial issues were challenges for not implementing of six sigma method.

Keywords: *six sigma, internal quality control, total allowable error, six sigma in healthcare*

1. INTRODUCTION

1.1 Background

In health care services medical errors occur in every department. However it's not always clear how to report a medical error. Errors that get unreported by the laboratory employees is 69.7% (1).

Clinical laboratory is a place where processes that include pre-analytical, analytical, and post-analytic phases take place to produce test results (2). Laboratory results cover about two-thirds of medical decisions related to patients in healthcare service (3). Laboratories should provide accurate and reliable test results on time (4). Laboratory errors led to unnecessary laboratory test repetition and further inappropriate investigation (5). According to the chance of error occurrence the highest percentage is covered by pre-analytical and the lowest percentage of error occurred in analytical phase in the laboratory (6, 7).

For analytical phase quality indicators include proficiency test and machine uptime (8). There are two type of quality controls (QC). The first one is internal quality control (IQC) means performing every morning at machine startup (9, 10). IQC is interpreted by Levy Jennings chart and Westgard rules (11). The other one is external quality assurance service (EQAS) means performing in continuous time interval using control material from external agency (10). EQAS is interpreted by Z-score or standard deviation index (12). IQC indicate imprecision and EQAS shows inaccuracy (13).

The reason behind analytical phase errors are not performing IQC and some others are not within the acceptable range. EQAS results show that not having a good performance (14). Other issue like reagent stock out, unstable electric power, and mix-up samples are also possible factors for error in the analytical phase (15).

There are different statistical methods to ensure that the test laboratory produces accurate and reliable results, such as using Six Sigma metrics.

Six Sigma matrices started around the 19th century when Carl Friedrich Guass develop bell curve (16). Walter Shewhart further explained about Sigma idea in 1920. Three Sigma is the cut point for good performance (17, 18). Six Sigma is created in Motorola in 1980 by Bill Smith who contributed many methods that are used in the current generation and he is called father of Six

Sigma (18, 19). This method has been used in many industrial factories for many years for the aim of reducing defect to almost zero (20). But because of increasing patient need, knowledge about essential of quality service and technology now a days this method became practice in healthcare service (21).

The idea of Six Sigma is to achieve a 99.99966% error-free process. Six Sigma methodology implementation in health care laboratory medicine started in 2000 (22). Result of six sigma indicates that 6 and above world class, 5 excellent, 4 good, 3 marginal and below 3 sigma means poor/ unacceptable (23). There are titles given for personnel based on their training. Champion, Master Black Belts (MBB), Black Belts and Green Belts is from top to bottom level of training and analytical skill they have (24).

There are non-statistical and statistical tools used in six sigma. It computes the sigma by first assessing the outcome of and counting the errors. The foundation of six sigma is DMAIC process (Define, Measure, Analysis, Improve and control) (25-27).

The statistical tool is best for analytical phase. It does not evaluate the outcome but the process of machine producing laboratory result. By using some variable like bias, coefficient of variance (CV) and total error allowable (TEa) (28, 29). There are different TEa target that can be used in routine laboratory. Calculating sigma matrices by using different TEa lead to different sigma matrices value for same test. TEa summarizes both systematic and random error (30, 31).

The reason for calculating sigma rather than just count error is to make sure that result produced in laboratory is really true. The assumption is used based on state of QC, calibration and performance of instrument. so it use by integrating QC (32).

Six Sigma is a single number that show the exact error that occurred but cannot be seen by IQC and EQC (33). Quality goal index shows reason for poor performed test or cause of error by describing as inaccurate, imprecise or both (34). Different sigma value could be obtained for level 1(L1) and level 2(L2) from similar instrument caused by difference in method performance at both levels (normal and pathogenic concentration) for single analyte (26). So Six Sigma gives direct vision where the laboratory needs focus for improvement.

1.2 Statement of problem

Healthcare service is teamwork including many different professionals. This characteristic led to high chance of making error and finding solution. This sector makes it difficult to control error like other industries (35). Diagnosis error indicates being unable to give the correct diagnosis at right time. In low and medium income country availability of medical laboratory institute is under a question because of this difficulty the issue of quality is second concern (36). Diagnosis process is under pressure by different situation like diagnosis test resource and limited access to care (37).

Evidence indicate in United States of America (USA) adult outpatient diagnosis error frequency is about 5% and among this half of them may led to severe harm (38). It is not clear that this issue is stable or increased until this year but about 800,000 patients in USA experience misdiagnosis within one year. This number represent most developed countries. This implies medical error is a global burden and quality improvement program should strongly be given attention on medical diagnosis (39). A national survey shows that 54% of the healthcare institutes do not implement Six Sigma. Because of lack of top management involvement, lack of training and resources. Many institutes stop their sigma project for not getting good result within short time (40).

From 1.016 billion laboratory analyses 3.05 million laboratory errors occurs in 2013 in Italy within a year. Continuous quality improvement strategy in clinical laboratory decrease rate of error in to 0.3%. This is the lowest rate compared to other diagnostic disciplines such as radiology, pathology and echography (41). Unsafe health care that include low quality and low effective service cause negative impact on patient health, health finance and trust on health system. In low and middle income countries 134 million case occur in a year and from this 2.6 million patients die (42). Highest number (93%) of incorrect patient results reported by laboratories because of this physicians repeat the test or send it to other laboratory (43).

Because of laboratory error, 6.4%-12% of medical care given are wrong. Most error in laboratory occur in pre analytical phase because this phase involve many non-laboratory participates. In analytical phase out of 100, 16.6% error occurs. This can further explain by half out of 100 is unacceptable EQC(51.4%) and only 14.4 % is IQC failure (44). There is no defined acceptable error in laboratory, no habit of trying new quality improvement methods and above all not having enough information about quality. It's like quality is another duty for staffs additional to their known work so lead to low quality service in laboratory (24).

Most Ethiopian government hospital laboratory buy and use low quality machine even sometimes without calibration and reagents or control. In addition to this training for staff is under question because no training program updates the staff with new knowledge and existing program even does not include all staff. This issue became problem for laboratories to provide quality service (45, 46).

There is a few research done on knowledge related to six sigma (47). Lack of sufficient knowledge about methodology, process, implementation and statistical tool are reasons for not applying six sigma. To solve this gap academic institution and healthcare organization should work together to increase knowledge of six sigma (48).

ISO 15189:2022 under the examination process requires that, IQC must be performed at a frequency that is based on the stability and robustness of the examination method and the risk of harm to the patient from an erroneous result (49).

There is no enough number of research done on knowledge, attitude and practice related to six sigma in laboratory setting in Addis Ababa, Ethiopia. So this study serves as a reference for policymakers and other further researcher to broadly implement the sigma method in Addis Ababa and throughout Ethiopia.

1.3 Significance of study

Now these days the ideas of quality is major priority in medical laboratory. There are different new quality improvement methodology being introduced to modernized laboratory like lean and six sigma. This research calculate sigma values for routine tests at selected hospitals to see their variation. This study will assess the knowledge and attitude of medical laboratory professionals towards six sigma metrics among the two specialized Hospitals. More over the finding of this study could be a baseline data for further large scale similar study.

2. LITERATURE REVIEW

Six Sigma project implement in different industrial sector throughout different countries. Many sigma research is done in India. But mainly focus on manufacture and garment areas (50). Six Sigma also applicable in different healthcare areas mostly in medical laboratory (51). Implementing Six Sigma methodology help to develop knowledge and skill of staff, to improve working environment and overall organizational change (52). Readiness of all staff and organization is important. Skilled personnel that can understand the method and technique used for sigma calculation is mandatory during matrices measurement (53).

2.1 Knowledge and attitude about six sigma

Lack of guideline and need skilled personnel with black belt (54, 55) , need advanced statistical tools (design of sigma project, statistical process control and analysis of variation) and time (18), resource (human, financial and technology), low commitment and lack of training for top menageries are challenge for adopting six sigma method (55, 56). Damage analyzer, temperature variation in laboratory, low analyzer maintenance schedule, water impurity and applying same IQC rule for all anlaytes are challenges for achieving acceptable sigma value (57).

A study conducted in India in 2020 by Deepak Sethi, S. G. Joshi showed knowledge related to six sigma in government and private health care providers. Private health care providers had relatively good knowledge (22%) and 7% had average knowledge compared to government health care providers which was 10% and 8% respectively (58). Another study conducted in India in 2020 showed that knowledge relate to six sigma in health care providers found in low and middle income countries is not a friendly concept (59). According to research done in India in the same year showed that 67.9% hospitals do not have quality department in their laboratory. Only 38% of staff had basic knowledge about sigma and 30% of respondent did not agree on implementing six sigma in their hospital (60).

A comparative study conducted in India showed that 53% of private and only 18% of government health care providers had good attitude toward six sigma method (58). A study conducted in India showed most of health care providers had poor attitude only 4% of government and 8% of private health care providers had good attitude regarded to six sigma method (59).

2.2 Practice of six sigma

A study conducted in U.S.A in 2021 shows that more than 50% of analytes achieved good performance for all three analytes using CLIA guideline. Many of analytes had poor sigma values when Ricos limits applied. Different sigma value could get because using different TEa limits. (61)

A study was conducted in China in 2020 to measure sigma value of 16 analytes using Beckman analyzer. It has two modules A& B and for three electrolytes ion selective electrode module. According to the study 12 analytes, sodium and potassium had $\sigma >3$ and among 12 analytes 5 of them achieved world class (26). Another study conducted in China in same year showed among 26 analytes only 7 tests (26.92%) had poor performance (62).

A retrospective study conducted in India in 2017 found from seven analytes performed by semi-automated analyzer five of them had acceptable performance ($\sigma >3$). When TEa% of single analyte set higher led to higher probability of getting good sigma value (63). Other study in Indian in 2019 analyzed by COBAS 6000 Roche, even if the study had incomplete data for some analytes like urea, total cholesterol, triglyceride and creatinine all analytes had $\sigma >3$ value (64). Another study conducted by Monika Garg, Neera Sharma and Saswati Das in India using Beckman coulter for 14 analytes only 5 analytes had $\sigma >3$ at both L1 and L2 materials (65). In 2024, among 15 routine laboratory test 8 of them had poor performance using EM 200 analyzer (66). In same year in India, σ was calculated after taking quality improvement action show significant positive change like $\sigma <3$ from six analytes decreased to one and $\sigma >6$ from nine analytes increased to 15 for pre and post sigma calculation (67).

A study conducted in Turkey in 2019 found laboratory with routine calibration had 100% acceptable performance (68). Another study done in same year in Turkey, three monthly sigma value was calculated for 28 analytes by using cobas e 601 analyzer for L1 and L2. Three analytes had $\sigma <3$ for either one of quality control level but 8 analytes showed poor performance and the rest 17 analytes had $\sigma >3$ for both levels (69). By Çevlik Tülay and Haklar Goncagül, Out of 17 analytes , 7 analytes had poor performance for at least one quality control level and the major reason was impression (70).

In South Africa 2022, a retrospective study conducted during 12 months periods by comparing three TEa guidelines showed many analytes had poor performance and CLIA guideline had best

sigma value relative to others. The reason for unacceptable value was imprecision. So the laboratory needed improvement on internal quality control and routine calibration (31).

A study conducted in 2023 indicated for overall improvement in laboratory in Ivory Coast. Sigma value was calculated for glucose, creatinine and alanine aminotransferase (ALT). $\sigma < 3$ get for glucose and creatinine because of imprecision but ALT had $\sigma = 7.9$ (71). Another African country Ghana, a pilot study evaluated analytical performance of clinical laboratory and had 100% unacceptable sigma value (72).

A cross-sectional study was conducted in Ethiopia at Dessie specialized hospital in 2020, sigma value was calculated for 14 routine laboratory tests and only Alkaline phosphatase (ALP) had $\sigma = 3.9$ the rest 13 tests had unacceptable performance because of mainly imprecision of IQC (14). In 2019, a retrospective study using COBAS 6000 analyzer measured 21 analytes. The result showed unacceptable sigma value for sodium for L1, total cholesterol for L2, renal function test and chloride for both QC levels. But overall Ethiopian Public Health Institute, clinical chemistry laboratory had good performance (73).

2.2 Comparison between instruments on sigma matrices

Among 14 biochemical analytes processed by Beckman coulter AU680 1 and 2 analyzer in India 11 of them had $\sigma > 3$ even total protein, glucose and urea showed $\sigma > 6$. Calcium, chloride and inorganic iron showed poor performance for both L1 and L2 QC materials. But all 6 analytes processed by RX Imola clinical chemistry analyzer had good performance ($\sigma > 4$) for both QC materials (74). In recent year 2023 in India, sigma value was compared using Cobas 6000 and Cobas C311 by Gadde Ranjeeta and Venkatappa, HM. Out of 21 analytes all analytes had acceptable performance for both analyzer for L1 and L2. Except creatinine had below three in Cobas 6000 for both levels. Cobas C311 had best sigma value compared to Cobas 6000 analyzer (75).

A study conducted in Turkey in 2014 used four different analyzers called Abbot Architect C8000, Beckman coulter Olympus AU2700, Roche Cobas 8000 and Siemens Advia 2400. Highest number of tests achieved world class that performed by Roche cobas 8000 at level (76).

A retrospective, cross-sectional study done in South Africa 2021 by Nareshni Moodley and Verena Gounden showed sigma value achieved acceptable performance for 11 analytes (42%) in four

different laboratory using Siemens Dimension EXLTM 200, Siemens AtellicaVR Solution and Beckman Coulter DxC 880i analyzers. Generally Beckman Coulter DxC 880i had better sigma value compared to other two analyzers. Above 79% of cause for poor performance in all laboratories for all levels was inaccuracy (57).

3. CONCEPTUAL FRAMEWORK OF THE STUDY

The conceptual framework for this study was based on Park’s Six Sigma framework and Furterer Lean Six Sigma framework. According to the Park’s Six Sigma framework commitment (from managers and staff), training schedule and result communication were primary factors to determine six-sigma application. According to Furterer Lean Six Sigma framework suggest resource (time, staff with good knowledge and attitude, technology resource, financial resource), instrument performance (calibration schedule) and advance statically tool were factors for lean six sigma method (77).

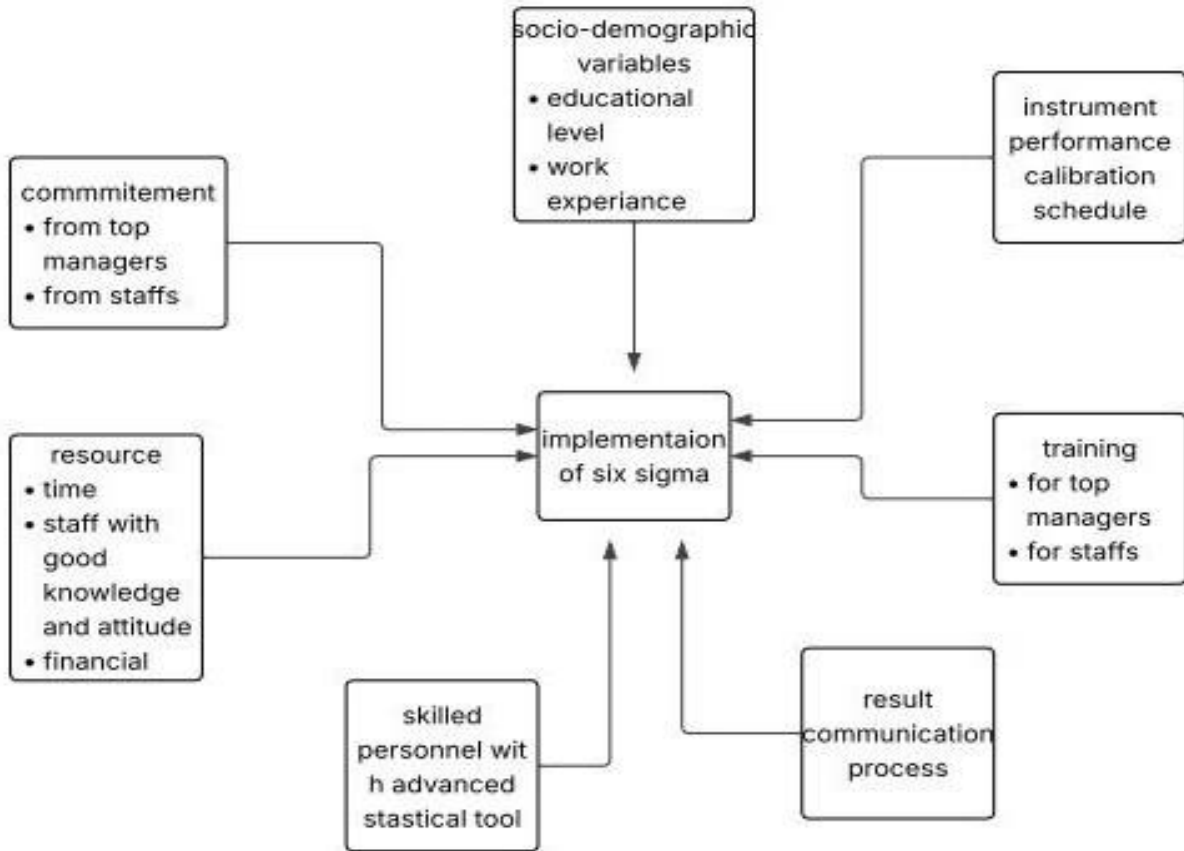


Figure 1 conceptual framework for challenges related to evaluation of Six Sigma metrics in Addis Ababa, Ethiopia, 2024/2025 (77).

4. OBJECTIVE

4.1 General objective

- To evaluate and assess professional perspectives toward implementation of Six Sigma metrics in clinical chemistry tests at selected hospitals, Addis Ababa, Ethiopia 2024/2025

4.2 specific objective

- To calculate six sigma metrics for 10 routine tests in clinical chemistry department at selected hospitals.
- To compare sigma metrics for 6 routine tests between Beckman coulter DXC 700 and Cobas 6000 analyzers at selected hospitals.
- To assess professional perspectives (knowledge and attitude) regarding six sigma methodology among staffs working at selected hospitals.

5. HYPOTHESIS

HO: There are no three and above three sigma metrics at selected hospitals, Addis Ababa, Ethiopia

6. METHODS AND MATERIAL

6.1 Study area

The study was conducted in Addis Ababa, the capital city of Ethiopia. Addis Ababa was established by Emperor Menelik II (1889-1913), covers an area of 364.5 sq. km (78). According to minster of health Ethiopia report in 2022/2023, Addis Ababa has an estimated population of 3,938,772. Over all there is 142,412 health professionals and about 6,710 medical laboratory professionals and 13 hospitals are found in the city (79). Hospital B found in Addis Ababa city, it is the largest referral teaching hospital starting from 1972. The study was conducted in, Hospital B has 200 doctors, 379 nurses, 115 other health professionals with 700 beds (80). Hospital A is teaching institution started in 2007 found at Addis Ababa, established in 1968 by Emperor Haile Selassie. The college has more than 700 beds more than 2800 clinical and support staffs. The college provide medical services for 1200 emergency and outpatient clients daily (81). These two hospitals are selected because both are teaching hospitals and the biggest ones in the city, providing the majority of medical services using Beckman coulter DXC 700 and Cobas 6000 instrument in the laboratory.

6.2 Study design and study period

A retrospective and prospective study, cross-sectional study was used for quantitative data and phenomenology study design for qualitative data was conducted from January 22 – April 8 2025 at selected hospitals.

6.3 population

6.3.1 Source tests and professionals

- All IQC and recent EQC data from the Clinical Chemistry laboratory at selected hospitals were included in the study
- All medical laboratory professionals working at selected hospitals were included in the study

6.3.2 Study tests and professionals

- All daily 180 IQC and recent EQC data for ten routine tests at Hospital A and nine tests at Hospital B from the Clinical Chemistry laboratory.
- Medical laboratory professionals working at selected hospitals for quantitative study.

- Quality officers and laboratory heads working at selected hospitals for qualitative study.

6.4 inclusion and exclusion criteria

6.4.1 Inclusion criteria

- All daily IQC and recent EQC data for 10 routine tests from the Clinical Chemistry laboratory during the specified study period were included. Because those tests were the most frequently ordered every day.
- All medical laboratory professionals working at selected hospitals who were available at data collection period.
- Key personnel quality officers and laboratory heads working at selected hospitals. Because considering those would have better information about six sigma metrics.

6.4.2 Exclusion criteria

- Incomplete IQC and EQC data from 10 routine tests from the Clinical Chemistry laboratory
- Medical laboratory professional who refuse to participate in the study
- Medical laboratory professionals who work at microbiology department and others who don't shift into clinical chemistry department
- Medical laboratory professionals who had attended any seminar or workshop and already have certificate on six sigma. Because these peoples may already have certain knowledge or may be more interested on six sigma. This does not represent overall knowledge and attitude within a hospital.

6.5 Study variables

6.5.1 Dependent variable

- Six sigma implementation

6.5.2 Independent variables

- Socio-demographic variables (educational level, experience)
- Training for top managers
- Commitment (from managers and staff)
- Resource (time, staff with good knowledge and attitude, financial resource)
- Skilled personnel with advanced statistical tool
- Result Communication skill

- Instrument performance (calibration schedule)

6.6 Sample size and sampling technique

6.6.1 Sample size

Six months daily internal quality control data and recent external quality control data and all laboratory professionals' working at selected hospitals who were available at the time of data collection based on inclusion criteria were included for quantitative data.

Two quality officers and two laboratory heads working at selected hospitals were included for qualitative data.

6.6.2 Sampling technique

Judgmental sampling method was used to select hospitals and laboratory tests to be included in the study. Because the hospitals were selected using non probable sampling technique and selection was based on justification. From these hospital number of health professionals to be included in the study were allocated by Census method for quantitative data.

Purposive sampling method was used to select key personnel's for qualitative data.

6.7 Data collection tool and procedure

6.7.1 Data collection tool

A record formats and checklist of 10 routine test on Microsoft Excel was prepared to collect daily IQC. The most recent EQC was taken to record formant. The Self-administered questionnaire developed from different literatures were used to collect data from participants. The questionnaire to assess knowledge consisted of 12 questions while the part for attitude consisted of 18 questions and challenge related 16 questions to assess different factors. Given that all laboratory professionals have educational backgrounds of at least a diploma, the final data collection tool was in the English language.

Five questions for in-depth interview were chosen from different literatures for qualitative data.

6.7.2 Data collection procedure

Data was collected by graduate laboratory professional who was not currently working at selected hospitals facilities with the necessary proper supervision from the principal investigator. The data collector was given one day training about research methodology, data collection technique and ethical issues. The principal investigator was recheck the completeness of the questionnaire and record format daily upon receiving the filled questionnaires.

Qualitative data from laboratory heads and quality officers were obtained by face to face interview and the information was captured by the principal investigator and directly transcribed into a written form.

6.8 Data collection tool quality assurance

The questioner was pre tested on 5% of laboratory professionals working at the same hospitals before collecting the actual data to undertake and ensure clarity and easy understandability for each respondent. After analyzing the pre-tested result, the refined questionnaire was used to collect the actual data. Completeness, accuracy and consistency of the collected data was checked on daily bases during data collection by the principal investigator. Further Cronbach's alpha was calculated using SPSS software to verify the tool's validity and reliability. Cronbach's alpha values of 0.67 for knowledge question , 0.76 for attitude questions and 0.905 for challenges related questions confirmed the tool's reliability (82).

6.9 Data analysis and interpretation

The QC data was taken from Beckman coulter DXC 700 and Cobas 6000 (German, Japan Cobas 6000 series of Roche) instrument. Both normal and pathological levels of QC was analyzed daily in the morning before start testing patient sample. The analytes were glucose, alanine aminotransferase (ALT), aspartate aminotransferase (AST), alkaline phosphatase (ALP), Bilirubin direct, Bilirubin total, Creatinine, Total cholesterol, Triglyceride, High Density Lipoprotein (HDL), uric acid, sodium and potassium. The final result was interpreted like $\sigma < 3$ as unacceptable (poor sigma), $\sigma = 3$ as margin, $\sigma = 4$ as good, $\sigma = 5$ as excellent and $\sigma > 6$ as world class.

The formula used for six sigma calculation

$$\text{Six sigma} = \frac{TEa\% - bias\%}{CV\%}$$

Total allowable error (TEa)

Total allowable (analytical) total error was known value, means acceptable limit for a single result to be correct but if exceed the limit will be error because that result cause medically significant difference result. TEa get from Clinical Laboratory Improvement Amendments guideline (CLIA) (32, 83).

Bias

Bias was systematic error which means difference between our laboratory result and acceptable result that get from other laboratories performance using same instrument. Finally use absolute value of bias for sigma calculation. The sign express the direction of variation (32).

$$\text{Bias\%} = \frac{\text{Mean of our laboratory} - \text{mean of other laboratories using same instrumen}}{\text{Mean of other laboratories using sameinstrument}} \times 100\%$$

Coefficient of variation

CV was random error, variation of repeated result and method from over all internal quality control. After calculating laboratory mean and standard deviation,

$$\text{CV\%} = \frac{\text{Standard deviation}}{\text{Mean of our laboratory}} \times 100\%$$

Quality Goal index (QGI)

QGI calculate for poor performed analytes sigma value below 3, and describe the reason for unacceptable sigma value. The result will interpret like <0.8 mean imprecision, between 0.8 and 1.2 means both imprecision and inaccuracy and if > 1.2 means because of inaccuracy (84).

$$\text{QGI} = \frac{\text{Bias\%}}{1.5} \times \text{CV\%}$$

Data was entered and analyzed using Microsoft excel. Descriptive statistics was used to present our finding using (table and charts) was used to determine results of six sigma metrics. Self-administered questioner data was entered and analyzed on SPSS version 25. For qualitative data from in-depth interviews was organized, categorized and summarized.

6.10 Operational definitions

Professional Perspectives: The attitudes, knowledge, and beliefs of laboratory staff regarding Six Sigma methodology, which may impact their willingness and ability to implement it effectively.

Evaluation: calculating the sigma metrics for 10 routine tests using mathematical equation.

Knowledge of Six Sigma-refers to the understanding of Six Sigma principles, tools, and methodology, on key Six Sigma concepts, such as DMAIC, defect per million opportunities (DPMO), and the role of Six Sigma in quality improvement.

Good Knowledge: respondents with score ≤ 4 were classified as poor knowledge, while those with score > 4.14 were considered good knowledge

Attitude toward Six Sigma-represents the respondent's overall disposition and feelings regarding the value and feasibility of implementing Six Sigma within their laboratory.

Positive Attitude: respondents with score ≤ 63 were classified as negative attitude, while those with score > 63.62 were considered positive attitude.

Key personnel: - staff members those could have better information about six sigma metrics include quality officer and laboratory head.

6.11 Ethical consideration

The study was conducted after an ethical clearance letter is obtained from the Research and Ethics Review Committee of the department of medical laboratory science (ERCDMLS), letter number DRERC/792/24/MLS, college of health science, Addis Ababa University. Then, **permission letter from selected hospitals managers was communicated to diagnostic director and section heads** before the commencement of the data collection process. Additionally, each study participant was received a clear explanation of the study's purpose and benefits, and their written informed consent was obtained. To ensure confidentiality, all study participants' results and information's were kept confidential, and personal identifiers was removed and analyzed anonymously. Participation in the study was entirely voluntary.

6.12 Dissemination of the result

The result of this study will be presented to the department of medical laboratory sciences, college of health sciences, Addis Ababa University. Additionally, a copy of the results will be provided to selected hospitals to identify areas for improvement in implementing six sigma method. Furthermore, the findings will be disseminated through publication in reputable journals, allowing for wider access to the results.

7. Results

7.1. Quantitative Result

7.1.1 Six sigma metrics

In this study sigma metrics was evaluated for 10 tests in Hospital A and 9 tests in Hospital B. Table 1 showed that 12(60%) and 18(100%) of tests had unacceptable/ poor sigma metrics at Hospital A and Hospital B respectively. None of tests at Hospital B and three Hospital B at of all tests that evaluate sigma metrics got acceptable value. The percentage represent both tests on L1 and L2. Sigma value is interpret as <3= unacceptable/poor sigma, 3= margin, 4= good, 5= excellent and >6= world class.

$$\% \text{ of sigma level} = \frac{\text{number of tests for both controls}}{\text{total tests for both controls at each hospital}} \times 100\%$$

Table 1 sigma metrics at selected hospitals

Sigma value	Hospital B			Hospital A		
	L1	L2	Frequency (percent)	L1	L2	Frequency (percent)
Poor	9	9	18(100 %)	7	5	12(60%)
Margin	0	0	0(0%)	2	0	2(10%)
Good	0	0	0(0%)	0	1	1(5%)
excellent	0	0	0(0%)	0	2	2(10%)
World class	0	0	0(0%)	1	2	3(15%)

L1= level one, L2= level two

Hospital A sigma metrics for ten tests

Sigma metrics was evaluated for ten tests for both controls. Table 2 and 3 summarizes the CV% calculated form IQC data, Mean of our laboratory and other laboratory results were taken from recent EQA data. Bias was calculated from the percentage difference of mean of our laboratory and others divided by mean of others laboratory. TEa% was used from updated 2025 CLIA. 3 tests ALT, BT and HDL for level 1 and 5 tests AST, ALT, BT, TG and HDL for level 2 achieve acceptable sigma. level two have better sigma metrics than level one based on achieving world class (>6). TEa and bias of two tests (NA and K) was express by number so we use standard deviation instead of CV %.

Table 2 sigma metrics of ten tests for level one at Hospital A

Test name	CV %	TEa%	Our laboratory mean	Others laboratory mean	BIAS%	Absolute bias	SIGMA
CR	2.66	10	3.33	3.641	-8.592	8.592	0.53
AST	4.57	15	227.16	244.8	-7.206	7.206	1.71
ALT	3.96	15	210.24	212.4	-1.008	1.008	3.53
BT	3.6	20	2.714	2.898	-6.335	6.335	3.8
BD	8.2	20	1.029	1.177	-12.579	12.579	0.91
TCHO	5.98	10	173.76	175.4	-0.924	0.924	1.52
TG	3.43	15	139.40	148.6	-6.178	6.178	2.57
HDL	1.44	20	60.10	67.3	-10.645	10.645	6.5
NA	2.14	4	132.20	139.4	-7.180	7.18	-1.49
K	0.12	0.3	3.84	4.00	-0.156	0.156	1.2

TEa= total allowable error, CV=coefficient of variance

Table 3 sigma metrics of ten tests for level two at Hospital A

Test name	CV %	TEa%	Our laboratory mean	Others laboratory mean	BIAS%	Absolute bias	sigma
CR	2.37	10	3.33	3.641	-8.592	8.592	0.59
AST	1.11	15	227.16	244.8	-7.206	7.206	7.04
ALT	3.28	15	210.24	212.4	-1.008	1.008	4.26
BT	2.05	20	2.714	2.898	-6.335	6.335	6.65
BD	6.12	20	1.029	1.177	-12.579	12.579	1.21
TCHO	3.3	10	173.76	175.4	-0.924	0.924	2.75
TG	1.54	15	139.40	148.6	-6.178	6.178	5.71
HDL	1.62	20	60.10	67.3	-10.645	10.645	5.79

NA	2.17	4	132.20	139.4	-7.180	7.18	-1.47
K	0.09	0.3	3.84	4.00	-0.156	0.156	1.64

TEA= total allowable error, CV=coefficient of variance

Hospital B sigma metrics for nine tests

Sigma metrics was evaluated for nine tests for both level (level one and level two). All tests have unacceptable/poor sigma value. IQC data used for this study was result of AMP MULTIITOL 1 for level 1 and AMP MULTIITOL 2 for level 2. This controls were not Beckman manufacture controls. The negative sigma value showed that our laboratory bias was greater. Table 4 and table 5 summarizes CV%, bias%, TEa% and sigma.

Table 4 sigma metrics of nine tests for level one at Hospital B

Test name	CV %	TEa%	Our laboratory mean	Others laborator y mean	BIAS%	Absolut bias	sigma
GLU	3.21	8	88	88.9	-0.97	0.97	2.19
CR	9.51	10	3.7	3.250	13.85	13.85	-0.4
ALT	10.32	15	189	182.2	3.62	3.62	1.09
ALP	11.08	20.00	244	150.7	62.18	62.18	-3.81
BT	15.24	20	2.8	2.987	-5.59	5.59	0.95
BD	10.36	20	.99	1.130	-12.00	12	0.77
TCHO	5.98	10	178	162.7	9.42	9.42	0.1
TG	8.03	15	126	134.8	-6.39	6.39	1.07
UA	6.87	10	5.5	83.01	-93.33	93.33	-12.13

TEa= total allowable error, CV=coefficient of variance

Table 5 sigma metrics of nine tests for level two at Hospital B

Test name	CV %	TEa%	Our laboratory mean	Others laborator y mean	BIAS%	Absolut bias	sigma
GLU	6.09	8	88	88.9	-0.97	0.97	1.15

CR	20.83	10	3.7	3.250	13.85	13.85	-0.18
ALT	6.24	15	189	182.2	3.62	3.62	1.82
ALP	9.57	20	244	150.7	62.18	62.18	-4.41
BT	15.52	20	2.8	2.987	-5.59	5.59	0.93
BD	6.81	20	.99	1.130	-12.00	12	1.17
TCHO	9.02	10	178	162.7	9.42	9.42	0.06
TG	7.9	15	126	134.8	-6.39	6.39	1.09
UA	4.06	10	5.5	83.01	-93.33	93.33	-20.53

TEA= total allowable error, CV=coefficient of variance

Figure 2 showed 12(60%) of tests were <3 sigma. According to the result CR, AST, BD, TC, TG, NA and K with level one and CR, BD, TC, NA and K with level two were unacceptable sigma values. We obtained 3(15%) world class for HDL with level one and AST and BT with level two and the remaining 5(25%) of test achieve acceptable sigma at Hospital A

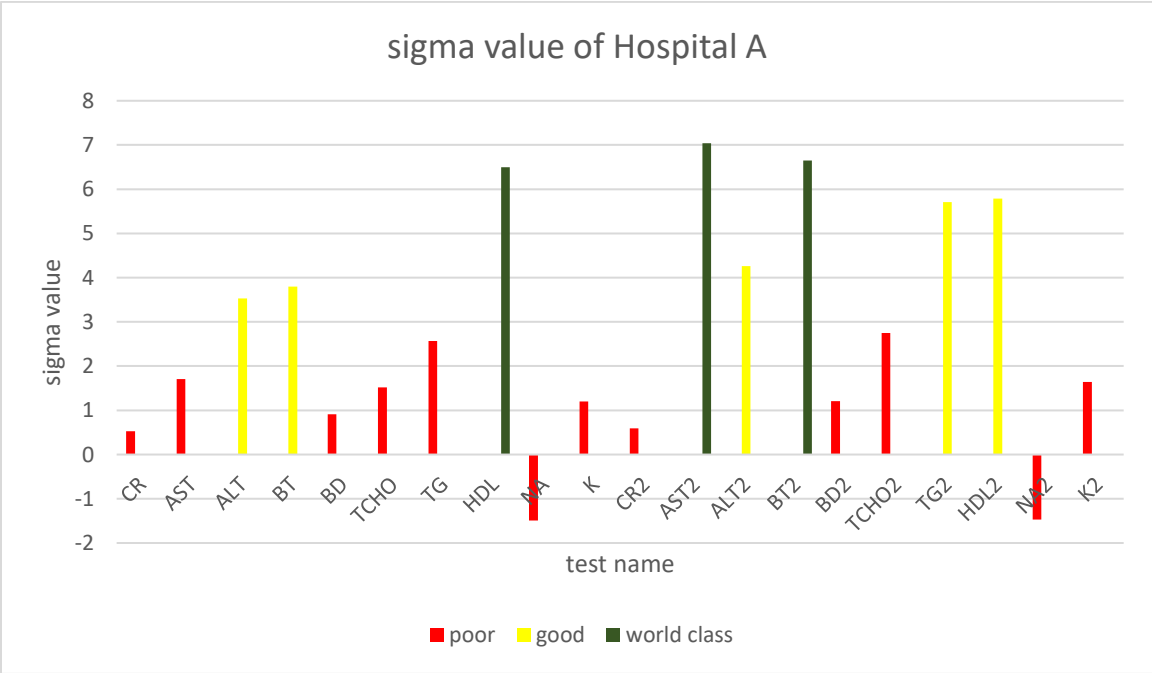


Figure 2 graph showing sigma metrics at Hospital A

Figure 3 showed 18(100%) of tests were <3 sigma. According to the result GLU, CR, ALT, ALP, BT, BD, TCHOL, TG and UA with both level one and two were unacceptable sigma values. The high value in CV% lead to lower sigma value based on mathematical equation. Sigma describe low variation between IQC data which represented by CV% and minimum difference among peer laboratories which represented by bias%. And also bias% should not be exceeded from TEA%. We obtained none of tests were acceptable sigma values for both level one and two.

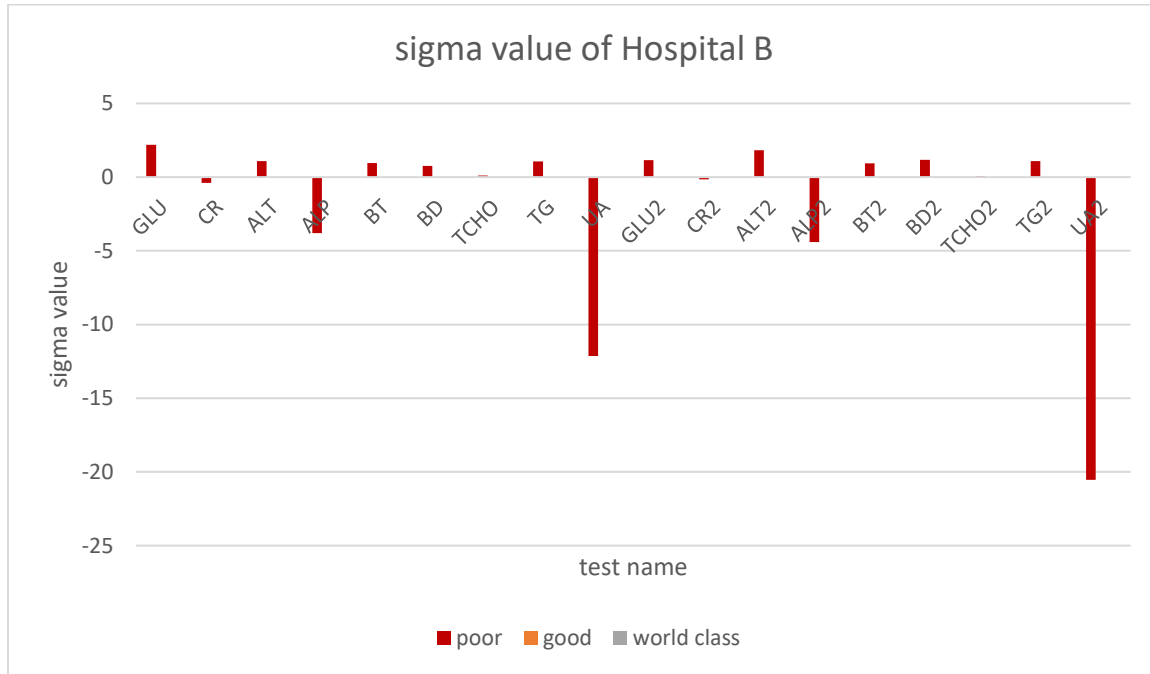


Figure 3 graph showing sigma metrics at Hospital B

2.3 Quality goal index (QGI)

QGI was calculated for tests those sigma metrics was below acceptable value to interpret the possible cause for poor performance. The last result was interpreted <0.8 as imprecision, 0.8-1.2 as both imprecision and inaccuracy and >1.2 as inaccuracy. Among 7 tests that was unacceptable sigma value the most identified reason for the evaluated tests were inaccuracy of the EQC at Hospital A. However, the result of QGI for potassium showed that because of imprecision at Hospital A. Accordingly, to our finding nine evaluated tests failed to achieve acceptable sigma the only reason was inaccuracy at Hospital B. Table 6 and 7

$$QGI = \frac{Bias\%}{1.5} \times CV\%$$

Table 6 QGI of all tests in Hospital A

Test name	Control level	CV%	Absolute Bias%	sigma	QGI	problem
CR	L1	2.66	8.592	0.53	15.24	inaccuracy
	L2	2.37	8.592	0.59	13.58	inaccuracy
AST	L1	4.57	7.206	1.71	21.95	inaccuracy
TG	L1	3.43	6.178	2.57	14.13	inaccuracy
BD	L1	8.2	12.579	0.91	68.77	inaccuracy
	L2	6.12	12.579	1.21	51.32	inaccuracy
T.CHOL	L1	5.98	0.924	1.52	3.68	inaccuracy
	L2	3.3	0.924	2.75	2.03	inaccuracy
NA	L1	2.14	7.18	-1.49	10.24	inaccuracy
	L2	2.17	7.18	-1.47	10.39	inaccuracy
K	L1	0.12	0.156	1.2	0.01	imprecision
	L2	0.09	0.156	1.64	0.01	imprecision

l1= level one, l2= level two, QGI= Quality Goal index

Table 7 QGI of all tests in Hospital B

Test name	Control level	CV%	Absolute Bias%	sigma	QGI	problem
GLU	L1	3.21	0.97	2.19	2.08	inaccuracy
	L2	6.09	0.97	1.15	3.94	inaccuracy
CR	L1	9.51	13.22	-0.4	83.81	inaccuracy
	L2	20.83	13.22	-0.15	183.58	inaccuracy
ALT	L1	10.32	3.62	1.09	24.91	inaccuracy
	L2	6.24	3.62	1.82	15.06	inaccuracy
ALP	L1	11.08	62.18	-3.81	459.3	inaccuracy
	L2	9.57	62.18	-4.41	396.71	inaccuracy
BT	L1	15.24	5.59	0.95	56.79	inaccuracy
	L2	15.52	5.59	0.93	57.84	inaccuracy
BD	L1	10.36	12	0.77	82.88	inaccuracy
	L2	6.81	12	1.17	54.48	inaccuracy
TCHOL	L1	5.98	9.42	0.1	37.55	inaccuracy
	L2	9.02	9.42	0.06	56.65	inaccuracy
TG	L1	8.03	6.39	1.07	34.21	inaccuracy
	L2	7.9	6.39	1.09	33.65	inaccuracy
UA	L1	6.87	93.33	-12.13	427.45	inaccuracy
	L2	4.06	93.33	-20.53	252.61	inaccuracy

l1= level one, l2= level two, QGI= Quality Goal index

7.1.2. Comparison of sigma metrics among different analyzer

The main analyzers used in the two hospitals were Beckman coulter DXC 700 and Cobas 6000. Beckman coulter DXC 700 is manufactured by United States which can process about 400 tests per hour and sample could be Serum, Plasma, and urine and Amniotic fluid. Cobas 6000 manufactured by Roche company which is used for Clinical chemistry, ISE (K, Na, Cl) and HbA1c test. The capacity for test performance is 1000 test per hour. Among all laboratory tests that performed their sigma metrics only six tests are mutual or common in Beckman coulter DXC 700

and Cobas 6000. From six tests all of them have poor sigma metrics using Beckman coulter DX 700. Two tests (ALT and BT) have acceptable sigma metrics at level one and three tests (ALT and TG have above acceptable sigma value and BT achieved world class sigma value) for level two control using Cobas 6000. Cobas 6000 have better sigma metrics than Beckman coulter DXC 700. table8

Table 8 comparison of sigma metrics between analyzers

TEST	SIGMA VALUE			
	Beckman coulter DXC 700		Cobas 6000	
	L1	L2	L1	L2
CR	-0.4	-0.15	0.53	0.59
ALT	1.09	1.82	3.53	4.26
BT	0.95	0.93	3.8	6.65
BD	0.77	1.17	0.91	1.21
TCHOL	0.1	0.06	1.52	2.75
TG	1.07	1.09	2.57	5.71

l1=level one, l2=level two

7.1.3. Socio-demographic characteristic of employee

In this study 37 staffs was participated, among these, the majority of participants 13(72.2%) and 13(68.4%) have first degree educational level at Hospital A and Hospital B respectively. Higher population 6(31.6%) in the study based on work experience is juniors (0-3) at Hospital B but junior (0-3) and seniors (>11 years) are proportional at Hospital A table 9.

Table 9 Socio-demographic characteristic

		Hospital A	Hospital B
Educational level	diploma	1(5.6%)	1(5.3%)
	first degree	13(72.2%)	13(68.4%)
	second degree	4(22.2%)	5(26.3%)
work experience	0-3	5(27.8%)	6(31.6%)
	4-6	4(22.2%)	5(26.3%)
	7-10	4(22.2%)	3(15.8%)

	>11	5(27.8%)	5(26.3%)
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7.1.4. Professionals' perspective

In this study, we enrolled 37 medical laboratory professionals from two different tertiary hospitals in order to get their perspective on the six sigma method on clinical laboratory professionals. Participants who scored mean and above were considered to have good knowledge mean = 4.14, Figure 4 showed that 25(67.6%) of Participants were answered below mean. Only 12(32.4%) of professionals achieve above mean and majority of them is Hospital B staffs.

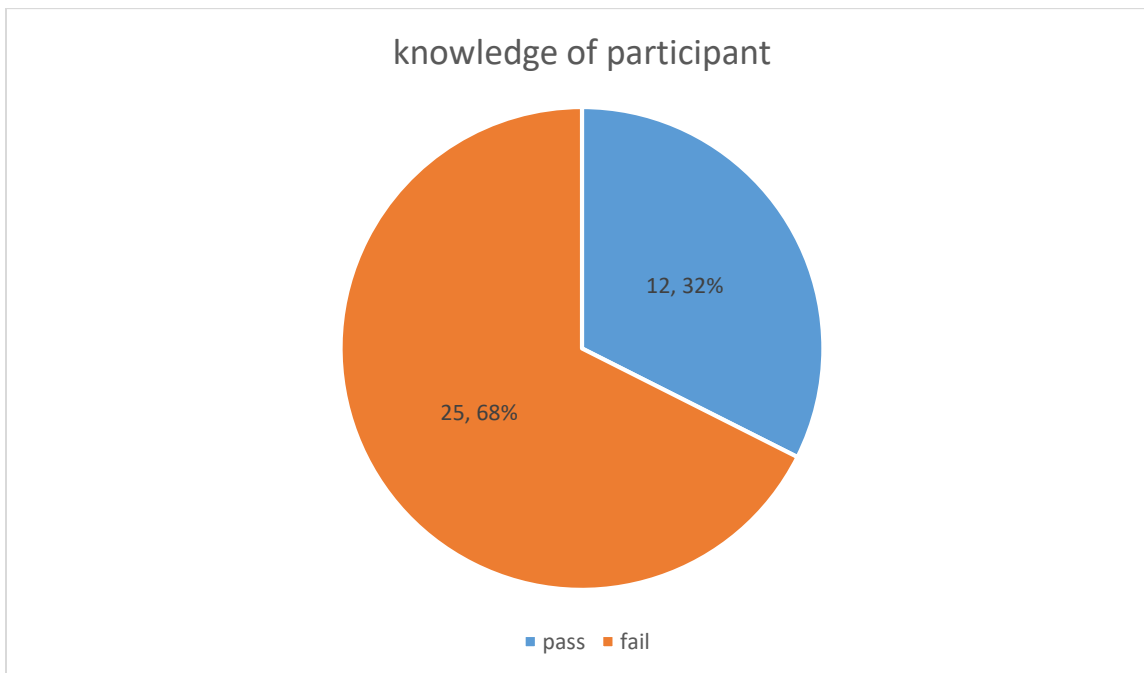


Figure 4 professional's knowledge at the two hospitals

In this study, 37 laboratory professionals were participated and those who score mean and above mean which is mean = 63.62 concluded as positive attitude. Figure 5 showed score of attitude questions for all 37 participant response. We obtained positive attitude 18 (48.6%) of professionals about six sigma method and this professionals are relatively equal proportion between the two hospitals.

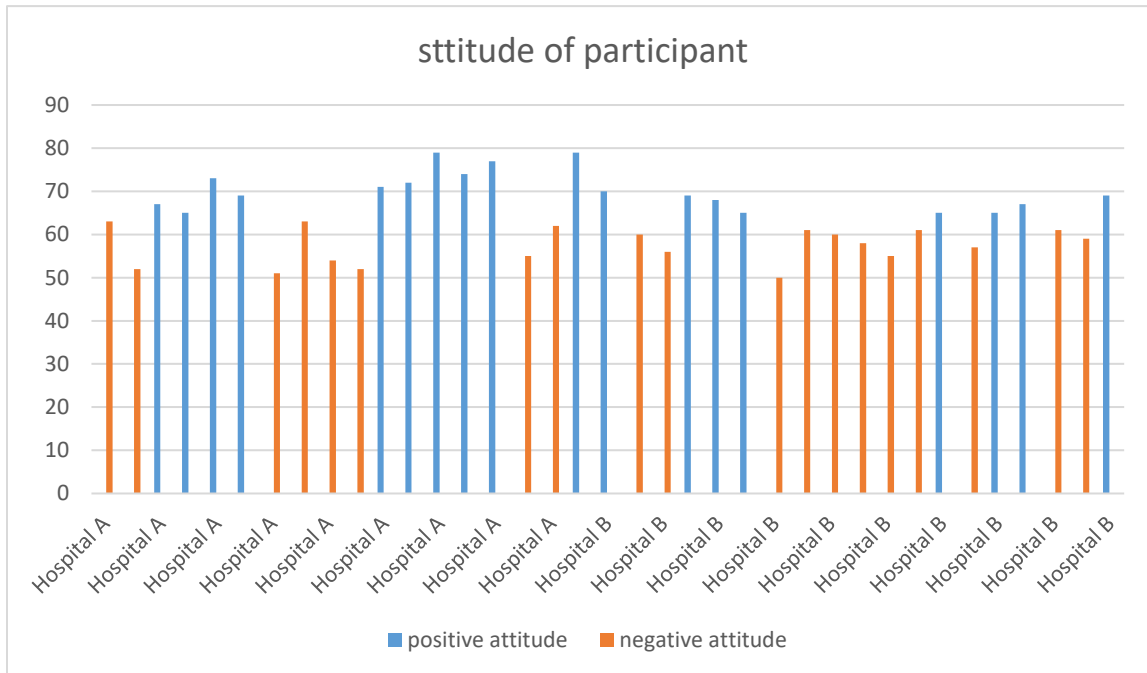


Figure 5 professionals attitude at the two hospitals

7.2. Qualitative result

Theme one: - six sigma method

Is latest statistical tools, it combine different variable like bias, total allowable error, coefficient of variation. That describe accepting only 4 error in million laboratory results.

A participant said”By combining these methods and calculating the numbers, we get the result. One of the methods that we ensure quality is internal quality control, and we work not only by looking at this method, but also by doing it with another additional method, external quality control. Sigma Four and above means that there is good performance. Sigma below Four means that the root cause needs to be investigated....”

Another participant also said” I did not participate in training related to six sigma methodology so I don’t know anything”

A second participant said” Six Sigma method is a general process. It is a method to improve the quality of a process.... Sigma metric also shows us whether we have improved our service from the problems we had or not... Six Sigma means six standard divisions. So it means expanding the standard division to six.... Any organization can apply at all three levels. But when we bring it to the laboratory, we mostly apply it in the analytical process...”

The third participant said” The Six Sigma method shows the quality level (status) of our laboratory. It works by choosing one of the two rules, namely the LJ chart or the multi rules. It also uses both controls, namely internal quality control and external quality control. Six Sigma is an improved and modern way of both rules. When we look at it from the past to the present, the LJ chart, then the multiple rules, then Six Sigma are arranged in a chronological order from the past to the present. So this method identifies the gap between quality and accuracy in our laboratory”

Theme two: - purpose of six sigma methodology

Any benefit that we gain because of implementing the method in the laboratory.

A participant who took training program before three years ago said” ... to confirm the quality of the laboratory and, the accuracy of the tests performed in the laboratory. In other words, it shows how much a laboratory is providing quality services compared to other large hospitals. Sigma at different times ensures consistency and continuous quality. It also makes it competitive”

A participant who don't get a chance for training said” To reduce or eliminate errors... it is useful to bring the error to zero and provide a completely 100% accurate error-free service... The benefit is to control quality and reduce errors”

A participant who took training program in this year said” To identify errors, to obtain accurate and reliable laboratory results, it covers both systematic and random errors”

Theme three: - challenges for not implementing six sigma method

Any obstacle that cause or lead to difficulty for not practicing six sigma method in the laboratory.

Lack of adequate IQC data

The first participant said” Lack of consistent internal control data Due to lack of reagent supply, there is interrupted data for the required time. Not working on a single device (machine) for the required time. This means that tests are performed on different devices, so internal quality control data is not sufficient for one analyzer.

Lack of knowledge

Lack of sufficient knowledge among employees and managers. Therefore, it becomes a new idea when trying to implement. There is no person who is prepared or assigned to implement this method. There is no one who is technically and statistically qualified. There is no one who is qualified to do the mathematical calculation. There is no additional person (expert) to do or implement this work (method) other than the regular laboratory worker. The existing laboratory worker has a workload and does not have the knowledge or time to implement this complex method

The third participant said” Mainly it is a lack of awareness. Quality does not improve only because of one or a few people. Everyone (employee) should have an understanding of quality control

methods. Also, everyone should participate. On the other hand, thinking that it is very difficult. Thinking that it will not be for Ethiopia because it has not been widely implemented in this country before”

Lack of training program

A second participant said” Lack of training program means there is no adequate training program about Six Sigma: what it means, its benefits, how to implement it. Since it is a complex method, it is necessary to work using custom software or a mathematical formula. This means that it is laborious and time-consuming to get the final result”

A third participant said” Another is the lack of a training program. If everyone had this opportunity, it would understand its simplicity and importance. I think it is easy to implement this method”

Lack of commitment

The last participant said” Lack of commitment from top management to regular employees...In addition, since it is a new and emerging method and works with numbers, it requires self-motivation and interest at first...This is useful for obtaining positive professional support”

Theme four: - corrective actions in the future

Any activity or plan that can be a solution to overcome the challenges

A participant said” By preparing additional positions. That is, by increasing the awareness and interest of the senior managers, there will be one quality officer in each department, so that a total of five quality officers will work together. By having the senior managers participate in the training program that was provided. EPHI is an institute that already implement the method so by sending a worker to exchange knowledge and experience from them, we tried to exchange ideas”

A participant said” Someone who has knowledge should create awareness for others. Prepare trainings and demonstrate”

A participant said” To overcome these problems, we have decided to increase awareness of the Six Sigma method by sharing what we know about it. To do this, we first explain (position) our idea and share our knowledge so that they have some basic information. This will make it easier

for them to understand it when the training program is released. Finally, to create a continuous training program to create a qualified specialist”

Theme five: - budget and staff support

An employ with better motivation and good attitude toward practicing six sigma method and money issue relate to implementation of six sigma in laboratory

A participant said” We do not have a problem with staff support and financial capacity for a training program”

A participant said” I think there will be employee support, but money is an issue, so instead of waiting for funds to be released and a training program to be developed, it is better to increase awareness by sharing knowledge with those who already have it”

A participant said” Financial and professional support is a problem in our laboratory. Financial support is needed to develop a training program, so first of all, before we asked for this, we thought of getting employee support. By explaining and understanding the idea”

Recommendation

A participant suggest” If it is formulated as a policy or as a standard and implemented by all laboratories, it can be adapted or expanded. A laboratory with a low sigma score should correct it and take appropriate action. In general, although it is a new method for Ethiopian laboratories, I believe that if everyone implements this, they can improve the services they provide and be competitive with laboratories providing similar services in the world”

A participant suggest” I think that if we dare to try the Six Sigma method in addition to the current quality management, we can achieve better quality”

A participant recommend”...I have understood that it can be implemented by any laboratory at any level. It can be just for one laboratory test. It does not have to be a large laboratory. All of them can test the services they provide. Therefore, I encourage all service providers to use this method to ensure that the services they provide are accurate and genuine”

8. DISCUSSION

Six sigma method is a best methodology for quality improvement in clinical laboratory by reducing variation, less errors, less unnecessary reruns and troubleshooting (67). This study showed that sigma value for 8(40%) of 10 tests at Hospital A and none of 9 tests at Hospital B had above three sigma value. The finding is similar to the findings from the studies done in Ethiopia, Dessie Comprehensive Specialized Hospital Clinical Chemistry Laboratory, as except ALP, all routine clinical chemistry tests were below the standard ($\sigma < 3$) (14) and study done in India showed that urea, creatinine, BD, AST, ALT and Cholesterol have poor sigma values (66).

The finding of this study at Hospital A with ALT, BT and HDL achieved acceptable values was higher than that of the study done in Ghana, as unacceptable sigma levels were achieved for all parameters using both control levels (72). The finding of this study was lower than that of the study done in India, as all laboratory tests achieves good sigma values (64), our finding at Hospital A was similar to the study done in Ethiopia, EPHI, using Roche Cobas analyzer, for tests like HDL for L1 and AST and BT for L2 were reported world class sigma values, and also CR was reported poor sigma value for both controls and our finding at Hospital B was lower as GLU, ALT, ALP, BT, BD, T.CHO, and TG were reported acceptable sigma value . Most of tests had sigma value with acceptable sigma metrics (73).

The finding of this study at Hospital B using Beckman Coulter is lower than that of the study among 26 tests as it reported only 7 tests have $\sigma < 3$. The variation can be explained by that of Hospital B is working on using third party control during study period. This type of control is not prepared by Manufacturer Company but can used them when reagent stock out. Because of this variation between daily IQC data became high so as SD and CV% (62). And among 30 tests using Roche Cobas which is the same analyzer used at Hospital A all of tests have good sigma values in Turkey (68) and study done in Tokat, Turkey showed that Creatinine and Na provided < 3 but about 79% of tests achieved acceptable sigma values sigma value using similar analyzer like Hospital A (69). on the other hand in India only CR for C2 has poor sigma value others 20 tests achieve good sigma value (75). The finding of this study at Hospital B using Beckman Coulter showed different reason which was inaccuracy for poor sigma from study done in India all poor sigma values are because of Imprecision (74).

A similar study in USA showed that laboratory performance using different analyzer for common chemistry tests the result showed Roche 57% and Beckman 52% to achieve world class. The comparison between the analyzer is not that much of differ but COBAS is better for achieving world class sigma metrics whereas the percentage have big differ between the analyzer but the finding of this study is similar like COBAS was excellent for good sigma value than Beckman coulter (61). Another similar study done in Turkey reported among 18 tests for L1 CR, UREA, and Na for L2 CHOL, CR, UREA, Na have <3 sigma value using Beckman coulter analyzer and for L1 only NA and for L2 Na, UREA have <3 sigma value using COBAS analyzer. Fewer laboratory tests have poor sigma value using COBAS analyzer (76)

The finding of this study show staff having good attitude toward knowing and learning about the method may become more motivated and committed to implement six sigma method. Similar result was observed in study done in India that showed only 38% of the respondents have the basic knowledge but lower result showed 30% of the respondents didn't agree on applying six sigma method (60). The result of this study was similar that of fewer professionals 10% of health-care personnel from government hospital have good knowledge and 18% of them had positive attitude (47). According to this study lack of top manager commitment, lack of knowledge and lack of formal training related to the method are major challenges for not implementing six sigma method in the two hospitals. None of participants get training related to six sigma method but some of them are participated in quality management training program. Similar result was observed in study of literature review done in 2021 and 2020 (50, 55).

A similar result was observed in hospitals found Pune city, Indian showed that 12 % health-care personnel on a position of top management from government hospital have good knowledge score and only 4 % have good attitude score. Our finding describe better basic knowledge among top manager and quality officers at both hospitals. However, among four managers expected to participate in the study two of them got a chance to participate in training related to six sigma method. So they have a better understanding of how to implement the method. Three of participants give adequate answer to the questions. This implies that they have good knowledge and positive attitude (59). According to response of two participants in the qualitative study resource like staff with good knowledge and attitude (human resource), difficulty on getting budget

for training program (financial resource), lack of individual with advance statistical skill, time consuming method to calculate the final result, believing that six sigma is not suitable for our laboratory because of its need time and personnel with advance skill, professionals exaggerate the complexity of six sigma method (40).

9. STRANGTH AND LIMITATION OF THE STUDY

The findings of this study contribute valuable insights for the two hospitals because they are planning to implement the six sigma method in the future. Thus, it can serve as a baseline for laboratory managers and quality officers. And for other hospitals who want to implement the method. However, it is crucial to acknowledge certain limitations that may impact the generalizability and depth of the findings.

- All tests performed in the laboratory were not included because of incomplete internal and external quality control data
- Evaluation of six sigma metrics was only calculated at selected hospitals not included other hospitals
- Three personnel were used for qualitative data there is no additional key personnel who participated in training related to six sigma method which may have given deeper insight of professionals on the issue.
- Only 37 staff at selected hospitals were included in this study.

10. CONCLUSION.

Finally, the finding of this study show that there is gap for achieving minimum acceptable sigma value and basic knowledge related to six sigma method among medical laboratory professionals. Critical laboratory tests that we need to give attention to improve quality of our service. The study identify imprecision of IQC data is the primary reason behind poor sigma value mainly at Hospital B. Type of quality control used is the primary justification for the variation. Inaccuracy is also reason for Hospital A poor sigma value so improvement in EQA is needed.

11. RECOMMENDATION

Based on the finding of this research we recommend that:-

- Medical laboratories should regularly evaluate their sigma value.
- Training program should be available for staff members
- Academic sector should work together with healthcare sector to increase basic knowledge about the method.
- Future researchers should conduct this study on a larger scale, ideally every laboratory and other department

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Annex i: Informed consent form and questionnaire

1. Subject information sheet

Hello, my name is Selam Eshetu, I am currently a master's student in the department of clinical laboratory Management in Addis Ababa University, planning to conduct research on evaluation and professional perspective related to of six sigma method among medical laboratory professionals at selected hospitals, Addis Ababa.

Objective of the study: The main objective of this study is to assess knowledge and attitude of six sigma among medical laboratory professionals at selected hospitals, Addis Ababa.

Participation: You are kindly asked to voluntarily participate in this study. Your completion of the self-administered questionnaire will help me to assess knowledge, attitude and practice of six sigma among medical laboratory professionals at selected hospitals, Addis Ababa.

Risks and Benefits: Participating in the study will not cause any harm, except for taking a few minutes of your valuable time to answer the questions in the questionnaire. There will be no compensation for your participation in the study. However, the information you provide will be incredibly valuable in identifying and addressing gaps in knowledge, attitude and practice of six sigma at your workplace.

Confidentiality: All the data obtained will be kept strictly confidential, and personal identifiers will not be recorded; instead, labeling will be done using codes. The records of this study will be securely stored and kept confidential. Your participation is voluntary, and you are not obliged to answer any questions that you do not wish to answer. Please be aware that all information you provide is valuable and important.

For any information, you can contact:

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2. Informed consent form

Informed Consent form for participants in the study of Evaluation and Professional Perspectives toward Implementation of Six Sigma Metrics in Clinical Chemistry Tests at selected hospitals, Addis Ababa, Ethiopia

I have read the information sheet on the topic stated above and had a verbal discussion with the investigator. I clearly understand the purpose as well as the anticipated benefits of the research. I hereby assure, with my signature below, that I have voluntarily decided to take part in the study without any pressure or forceful act by the research coordinators. I understand that my participation is important for the successful completion of the research on knowledge, attitude and practice about six sigma among medical laboratory professionals at selected hospitals, Addis Ababa

Unique code no. _____ Signature _____ Date _____

Thank you for your cooperation

3. Questioner

A self-administered questionnaire for Assessment of knowledge and attitude about six sigma among medical laboratory professionals at selected hospitals, Addis Ababa

Participant Code: _____

Part I-Socio-demographic characteristics		
Instruction: please encircle the number of your choice		
1.	Gender	1. Male 2. Female
2.	Age	_____years
3.	Educational level	1. Diploma 2. First degree (BSc) 3. Second degree (MSc) 4. Third degree (Ph.D.)
4.	Work experience in years	_____years
5.	Position in laboratory	1. Laboratory head 2. Quality officer 3. Laboratory member
6.	Have you ever been participated in any training of laboratory quality management?	1. Yes 2. No
7.	If “yes” how long did you take the training?	1. <1 year 2. 1year 3. 2 years 4. >2 years
8.	Have you ever been participated in training related to six sigma method	5. Yes 6. No

Part II-Knowledge related to six sigma method questionnaire

Instruction: please encircle the letter of your choice if your answer is not among those listed please use the space provided to give your answer

1.	What does six sigma means?	
2.	What is the foundation tool for six sigma?	<p>A. DMAIC</p> <p>B. PDSA</p> <p>C. 5s</p> <p>D. Kizen</p>
3.	What is the main theory of six sigma?	<p>A. Development of new strategy</p> <p>B. More on less</p> <p>C. Reduction of variation</p> <p>D. Reduction of non-added value</p>
4.	Who involve mainly in practicing six sigma?	<p>A. Everyone</p> <p>B. Top managers</p> <p>C. Staff outside laboratory profession</p>
5.	Coefficient of variation related to...	<p>A. Impression</p> <p>B. Inaccuracy</p> <p>C. Systematic error</p> <p>D. External quality control</p>
6.	Bias related to...	<p>A. Impression</p> <p>B. Inaccuracy</p> <p>C. Random error</p> <p>D. Internal quality control</p>
7.	For single laboratory test using different total allowable error get different sigma values.	<p>A. True</p> <p>B. False</p>
8.	In a normal distribution 68% of data occur within?	<p>A. + or – 3SD</p> <p>B. + or – 2SD</p> <p>C. + or – 1SD</p>

9.	What does it means DPMO?	
10	A process operating at 6 sigma means?	<p>A. Expecting 3.4 defect per million opportunities</p> <p>B. Expecting 5 defect per million opportunities</p> <p>C. Expecting 4.3 defect per million opportunities</p>
11	Which one of the following companies was the first to establish and use six sigma?	<p>A. General electric</p> <p>B. Health care center</p> <p>C. Motorola</p>
12	In DMAIC methodology in which phase root cause analysis perform?	<p>A. Define</p> <p>B. Measure</p> <p>C. Analyze</p> <p>D. Improve</p> <p>E. Control</p>

Part III: Attitude toward six sigma questionnaire

Instruction: This section of the questionnaire asks for your opinion about whether you agree or disagree at this ideas. For each of the following statements, please indicate whether you strongly agree = 5, agree = 4, Neutral = 3, disagree = 2, strongly disagree = 1.

		1	2	3	4	5
1.	I believe laboratory manager committed to support and implementation of Six Sigma.					
2.	I believe laboratory manager established communication process.					
3.	I believe there is no fear of my supervisor for telling him/her about error in the laboratory.					
4.	I believe the laboratory work hard toward achieving world class.					
5.	Six Sigma is an effective method for reducing errors in clinical chemistry.					
6.	I believe the laboratory manager encourage participation in practicing six sigma.					
7.	I believe Six Sigma can improve the quality of our laboratory services.					
8.	I believe the laboratory have formal training program related to six sigma.					
9.	I feel that Six Sigma is too complex for our laboratory setting.					
10.	I believe doing IQC is important for patients.					
11.	I believe performing IQC is necessary.					
12.	Do you document IQC results for all tests that you assigned daily?					
13.	Do the laboratory participate in EQC program?					
14.	Do the laboratory calibrate its equipment for better measurement?					

15.	I believe laboratory have adequate staff with good knowledge and attitude to implement six sigma method.					
16.	Implementing Six Sigma would require too much time and effort.					
17.	I would be willing to receive further training on Six Sigma.					
18.	I am motivated to apply Six Sigma principles in my daily work.					

Part IV: practices and Challenges for practicing six sigma questionnaire

Instruction: This section of the questionnaire asks for your opinion about whether you agree or disagree at factors led to poor practice for six sigma method. For each of the following statements, please indicate whether you strongly agree = 5, agree = 4, Neutral = 3, disagree = 2, strongly disagree = 1.

Practice of Six Sigma		Yes			No	
1.	Our laboratory’s quality control processes are aligned with Six Sigma principles (tools like DMAIC, control)					
2.	We analyze and calculate Sigma metrics for critical tests in the laboratory					
3.	We review Sigma metrics regularly to improve lab performance					
4.	Error rates in our laboratory have decreased due to application of Six Sigma					
	Challenges for practicing six sigma questionnaire	1	2	3	4	5
5.	Ineffective time					
6.	Poor production planning strategy					
7.	Poor organizational working culture					
8.	Deficiency in clear vision and future plan					
9.	Deficiency in organizational top management involvement and support					
10.	Lack of structured scheduling					
11.	Poor six sigma experts’ selection strategy					
12.	Use of inappropriate performance measurement system					
13.	Lack and poor utilization of resources (finance, human, technical, etc.)					
14.	Deficiency in proper statistical and visual control technique					
15.	Deficiency in consideration of human factors					
16.	Lack of social, environmental and economic thinking					

Thank You for your participation

Interview questions

- 1) What do you think about six sigma metrics?
- 2) What do you think about purpose of six sigma?
- 3) What do you think about challenge for not implementing six sigma in your laboratory?
- 4) How do you plan addressing this challenges in the future?
- 5) Does your laboratory have adequate budget and staff support for implementation of six sigma?

Thank you

Annex ii: Dummy table

Variables		Frequency	Percentage
Gender	Male		
	Female		
Age	<25 years		
	25-35 years		
	36-45 years		
	>45 years		
Educational level	Diploma		
	First degree (BSc)		
	Second degree (MSc)		
	Third degree (Ph.D.)		
Work experience in years	<1 year		
	1-3 years		
	4-6 years		
	>7 years		
Position in laboratory	Laboratory head		
	Quality officer		
	Laboratory member		
Participation in any quality management training program	Yes		
	No		

Participation in six sigma training program	Yes		
	No		
Correct answer for knowledge related questions	Less than mean		
	More than mean		

13. DECLARATION

I declare that this thesis Paper entitled “Evaluation and Professional Perspectives toward Implementation of Six Sigma Metrics in Clinical Chemistry Tests at selected hospitals, Addis Ababa, Ethiopia” is my original work in partial fulfillment for a Master of Science degree in Clinical Laboratory Management and Quality Assurance.

Name	Signature	Date
Selam Eshetu	_____	_____

“This paperwork has been submitted for examination with our approval as advisors.”

Advisors	Signature	Date
Dr. Abay Sisay	_____	_____
Dr. Fatuma Hassen	_____	_____

Place of submission

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

Date of Submission