ADDIS ABABA UNIVERSITY

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Utilization Of External Quality Assessment In Case Of proficiency test at Government Hospitals In Addis Ababa

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List of Acronyms

ACC	Acceptable
ALP	Alkaline phosphates‟
AMREF	African medical and research foundation
BUN	Blood urea nitrogen
CLIA	Clinical laboratory improvement amendment
EPHI	Ethiopian public health institute
EQA	External quality assessment
EQAS	External quality assessment scheme
FGD	Focused group discussion
HDL	High density lipoprotein
Hgb	Hemoglobin
ISO	International organization for standardization
KII	Key-informant in-depth interview
MOH	Ministry of health
NEQAS	National external quality assessment scheme
OSHA	Occupational safety and health administration
PT	Proficiency testing
PI	Principal investigator
QMS	Quality management system
RIA	Radio immune assay
SLIPTA	Stepwise laboratory quality improvement towards accreditation
SGOT/AST	Serum glutamate oxalactate transaminase/Aspartate aminotransferase
SGPT/ALT	Serum glutamate pyruvate transaminase / Alanine Aminotransferase
THHP	Target health hazard program
TSH	Thyroid stimulating hormone
UNACC	Unacceptable
VB	Variability of bias
WHO	World health organization

Annex

Abstract

Back ground:-Participating in proficiency testing (PT) is crucial for clinical laboratories to evaluate their gaps based on the feedback from PT providers, and taking corrective action should used to improve the quality of service provisions.

Objective:- The objectives of this study was to evaluate the utilization and challenges of proficiency test panel in government hospitals at Addis Ababa.

Method:- Retrospective study was conducted among 12 government hospitals laboratories in Addis Ababa, who had been participated in proficiency tasting schemes for 20 clinical laboratory test parameters in 6 cycles from 2012 to 2013 G.C. Data on institutional performance and test results plus problems of each parameter participation were extracted from proficiency test feedback reports stored at the data base of Ethiopian Public Health Institute(EPHI). Focused group discussion (FGD) and in-depth interview were used to assess the major challenges of institution participating PT. Trend of analytical performance scores of institutions in six cycles was analyzed using SPSS version 20. Likewise, qualitative data obtained through the focus group discussion and in-depth interview were classified in major thematic areas and summarized accordingly.

Result:- A total of 12 hospital participated, of these 5(41.7%) owned by federal ministry of health and 4(33.3%) were under Addis Ababa Regional health Bureau plus 3(25.0%) were uniformed service hospitals. A total of 12 laboratories participated in all six cycles of 20 test parameters panel tests. The overall acceptable analytical performance score was 2643 of 6984 PT challenges (37.85%) and the overall participation rate throughout the 6 cycle was645 of 1440 (44.7%). *Of reviewed performance of 20 analyte in six cycle, the total failure rate participant institution was 4341 of 6984 PT challenges(62.15%) Of which , 2880 of 6984(41.23%)of the observed EQA failures occurred in 4 of the 12 laboratories.* EQA fail rates among the 12 laboratories were 63.8% for AFB,50% for ALP,48.6% for CD4, 68.1% for creatinine,75% for Direct bilirubine,88.9% for gram stain,68.1% for HBsAg,76.3% for HCV,44.5% for Hgb, 51.4% for HIV, 55.6% for morphology identification,82.7% for parsitology,38.9% for PLT, 50.0% for

RBC, 56.6% for SGOT, 44.4% for SGPT,75% for Syphilis, 75.4% for Total bilirubine, 79.2% for Urea, 39.9% for WBC was identified in this study.

Conclusion:- PT is not utilized effectively among 12 governmental hospital laboratories in Addis Ababa through 6 cycles. There are challenges for effective utilization of PT (the major identified challenges was knowledge gap, poor staff commitment ,equipment down and reagent out of stock) so stakeholders and collaborators need to resolve or minimize the challenges for effective utilization of the coming PT.

Key words:- Panel Test, EQA, Utilization, Participation rate, Trend of analytical score

1.INTRODUCTION

1.1 Background

Proficiency Test [PT] is a program in which objectively one or more samples are periodically sent to a members of a group of laboratories for analysis and each laboratories results are compared with those of other laboratories in the group or with pre-assigned value and the feedback reported to the participating laboratories (1).

The beginning of today"s PT is more than 6 decades ago, when a group of some laboratories in Philadelphia compared their result for Hgb testing. Results were by far discrepant then committee on laboratories of the Pennsylvania medical society initiated a program to compare the accuracy of number of chemistry tests throughout the state. This initiate give birth to PT program. Quality improvement, atisfying accreditation requirement, atisfying payers requirement and positioning the laboratory on the competitive market place are the main reasons to PT in laboratory setting (2).

In 1972 the United States occupational safety and health administration [OSHA] and target health hazard program [THHP] was aimed to identify possible health hazards. The identified problems encountered by state and federal laboratories performing the OSHA compliance sample analysis for THHP made a collaborative PT program a necessity. National institute for occupational safety and health was given the responsibility for developing and implementing collaborative PT program. By may 1972, National institute for occupational safety and health initiated the PT program and distributed the first PT samples to 10 government laboratories (3).

To monitor the performance of HIV screening laboratories a national external quality assessment scheme [NEQAS] within the national referral laboratories for AIDS[NRLA] of Ethiopian public health institute [EPHI has been initiated in collaboration with MOH since 1992. PT was started in 15 blood bank and regional referral laboratories at the end of 2001, 29 HIV screening laboratories was participated in NEQAS. It was the first kind of assessing and monitoring the HIV screening laboratories in the country (4).

The PI seek to get back ground information on the type and number of current PT provider and participants in Ethiopian context from different sources including website of EPHI (the main

stakeholder of clinical laboratories in Ethiopia),MOH and collaborators but no published information source is available.

1.2:- Statement of the problem

Institute of medicine in America report a data on the reason and impact of medical errors in U.S. Moreover causing serious danger to patient medical errors translate to huge cost to country economy. Estimated cost of medical errors in U.S was between $17 billion to 29 billion per year in 1999 Berwick and Leap published it (5). In 2006, the cost of medical errors was approaching to $ 282 billion . Many areas of health care services are struggling to minimize medical errors and maintain patient safety laboratory diagnosis has been precursor in pursuing of this struggle (6).

Participating in PT alone is not enough to improve the performance of the laboratory but evaluating the gap based on the feedback from PT provider and taking corrective action will improve the performance of the laboratory sustainably. Implementation of the corrective action is primarily the responsibility of the laboratory personnel and the management. Even if Making participation in PT program is the mandatory part of implementation of Stepwise laboratory quality improvement towards accreditation (SLIPTA) participant laboratories in developing countries have many challenges to utilize it (7).

Quality is a vital in the diagnostic service of clinical laboratories for multiple perspectives like health improvement, customer satisfaction, cost, time & labor effectiveness, waste minimization, so it is very crucial to assess the utilization of PT scheme in the clinical laboratories it helps to look for the trend and the gap from participating laboratories in order to develop improvement plan by the authorized bodies for effective utilization and also increase the competence of participating laboratories by aware of their competence performance.

The effective utilization of the PT scheme is the one tool to achieve accreditation by the clinical laboratories for a reason that 80% or more achievement for PT panel is a regulatory requirement of ISO 15189 clinical laboratories accreditation standard. In Ethiopia EPHI with stakeholders and collaborators working to strengthen laboratory management towards accreditation so this

study help as an input information source for the success of such national program during strengthening laboratory management towards accreditation.

1.3:- Rationale of the study

Until recently, the majority of Ethiopian public health laboratories delivered suboptimal service and were not in a position to contribute to a quality health system. Many performed poorly, hindered by dilapidated infrastructures, and poor development and implementation of quality management systems (QMS), including inadequate participation in external quality assessment (EQA) programs. Now, through strong commitment and leadership by the Federal Ministry of Health (FMOH) through the Ethiopian Health and Nutrition Research Institute (EPHI), and the concerted effort of local and international partners, this has begun to change. In recent years, public health laboratories in Ethiopia have begun to implement national and international QMS to provide quality laboratory services including participation in external quality assessment (EQA) programs. Participation in EQA program alone is not guarantee to insure the analytical quality but the laboratory management and the laboratory staffs need to work hard for improve the quality by filling the gap identified from EQA feedback but it is gap utilization of EQA in participant laboratories as indicated in the literature review part of this study.(8)

This study helps as an information source for the policy makers to take action for the effective utilization of PT in order to minimize hazards due to analytical error, and from this study participant laboratories aware their performance trend which help them to plan future utilization of PT program, also this study helps as a tool of motivation for the participant laboratories to address regulatory requirements and customer satisfaction; as well used as an information source for researchers.

This study help the stakeholders and participant laboratories to look forward for improvement of effective utilization PT to add value on minimization of laboratory medicine error by identifying the challenges and providing recommendations for analytical quality laboratory services.

To the extent of PI knowledge there is no study that have examined the effective utilization of PT program among participant laboratories in Addis Ababa governmental hospitals. Therefore

this study aimed to evaluate the utilization of PT program among participant laboratories in Addis Ababa governmental hospitals through looking the trend of laboratories PT performance, rate of participation and identify challenges for effective utilization.

2. LITRATURE REVIEW

2.1:- Challenges of participant laboratories in PT utilization

PT is system of objectively checking laboratory results by means of external agency (9).

Proficiency testing/EQA is an important component of clinical laboratory quality assurance. It provides a mechanism to compare analytic test performance among different laboratories, which is important for determining the consistency of test results for a common analyte. Participants in formal PT programs periodically receive specimens. Participating laboratories return the results of the requisite analyses to the PT program, which then compiles the data and provides summarized results and educational insights to the participants. These programs provide an independent measure of laboratory performance in comparison with an external standard or a mean value obtained by other participating laboratories. Participation in PT allows laboratories to recognize analytic and interpretive errors that may indicate internal problems with quality control, calibration, assay design, or test interpretation (10).

The main objective of PT is to develop inter-laboratory comparability and standardization of diagnostic testing and also provide laboratories with the necessary information to maintain and improve analytical quality, detect equipment fault, reagent problems, staff training gaps, and initiate to evaluate gaps and take corrective action, compare performance of different analytical methods so ongoing monitoring of PT performance will help to reduce laboratory errors, produce accurate PT result and mainly improve patient care (11).

Starting from 1993 African medical and research foundation [AMRF] provide simple EQAS for primary health care laboratories. 81 laboratories from 5 countries in Eastern Africa region were participant in the scheme and 9 distributions were submitted science the start of the scheme. No laboratory participate in all distributions 24 [30%] of 81 laboratories participated in 4 or more distributions the Kenya and Tanzania hospital laboratories showed improved average mean score s between the first two distribution subsequently. The educational benefit for participation in the

scheme was emphasized then there was an overall 35% of participation which is low rate. Contributing factors for low participation was shortage of staff and lack of time in busy rural laboratories together with difficulties in communication and lack of appreciations of the benefit of participation was identified challenges. To increase participation in the scheme and to address the quality of laboratory services throughout the region, AMREF is currently developing a Regional EQAS in collaboration with the Ministries of Health of Kenya, Tanzania and Uganda, in affiliation with the World Health Organization (WHO) (12).

Seventy four government and non government HIV screening laboratories in Ethiopia were supervised in 2001, 58.4% and 54.7 % of them report shortage of reagent and protective materials respectively and the commonly identified gaps was maintenance problem, weak referral system, poor laboratory management, lack of follow up. (4).

2.2 The PT competence performance trend of PT participant laboratories

To be recognized by WHO afro a laboratory must scored ≥ 80% on the two most recent PT panels. A laboratory that failed to achieve ≥ 80% on the two most recent PT panels will not be awarded any star, regardless of the checklist score it received during the onsite assessment (13).

According to CLIA of 1988 PT conducted 3 times a year and each event contain 5 challenges. Attaining score of 80 % is a minimum satisfactory performance. The study of PT performance of U.S laboratories from 1994 through 2006 showed that hospitals and independent laboratories PT performance improved for some analyte where as no improvement for some analyte (14).

CLIA‟88 requirement for PT program to include all laboratories performing laboratory testing on patient sample. 10 years [1994-2004] long term failure rate was evaluated for selected chemistry, hematology and microbiology analyte. The PT failure rate for chemistry and hematology of the year 1994 to 2004 respectively shows cholesterol from 18.7% to 3.2%, sodium from 16.9% to 5.5%, HDL from 16.4 % to 3.6 % , Glucose from 15.6% to 2.4% , Protorombine time from 12.1% to 3.2 %, Potassium from 6.3% to 1.1 % , criatinine from 5.7% to 2.4 %, Hemoglobin from 4.3% to 1.2 %, where as microbiology gram stain PT failure rate in 1995 it was 18.5 %, in 1997 it was 13.7 % and in 2004 it becomes 5.4 %. The laboratories with unsatisfactory PT result in 2004 for one or more event is that bacteriology 5.1%, cholesterol

3.4%, sodium 4.9%, HDL 4.0% ,Glucose 3.5% , Protorombine time 5.2%, potassium 1.9%, criatinine 3.1%, Hemoglobine 3.3%. (15)

The study conducted on evaluation of external quality assurance performance of clinical research laboratories in sub-Saharan Africa shows, from the reviewed 40 to 60 months of EQA results for 8 analytes albumin, alanine aminotransferase, creatinine, sodium, WBC, hemoglobin, hematocrit, and the human immunodeficiency virus antibody rapid test. 1.63 % failure rate which was 76% of failure rate is accounted in 4 of 21 laboratories.(16)

In western region of Amhara national regional state of Ethiopia quality of eight public medical laboratories were assessed for liver and kidney function tests of six analyte [SGOT,SGPT,ALP, BUN, criatinine, Total cholestrol]. The study showed that non of eight laboratories could deliver all test of six analyte for the estimation of both kidney and liver function test during the study period. 213 values from expected 324 [65.7% rate of participation] values were reported and 65% of 213 values reported was failed outside of the allowable limits of errors for the chemistry test of the control specimens of Humatrol P and Humatrol N used for the study (17).

EQA of national public health laboratories were conducted in 2002 to 2009 to test the proficiency of microbiological testing national public health laboratories in Africa for epidemic prone disease which shows commulative acceptable performance was 65% for bacterial enteric disease, 52% for bacterial meningitis, 87% for Tuberclosis were acceptable result and for malaria 82% of response for species identification were acceptable where as quantification of malaria parasite was poor, with only 51% of response considered acceptable performance (7).

21th Iranian EQA of microbiology laboratories were evaluated in 2007 and in the survey Salmonnela paratyphi B and Staphylococcus aureus were distributed to PT participant laboratories of 1122 only 523[46.6%] laboratories were identify Salmonnela paratyphi B correctly, where as 767 [68.4%] identifies Staphylococcus aureus organism correctly (18)

In India external quality assessment was conducted for RIA of thyroid related hormones. Thirty-five laboratories (35 for T4, 34 for T3 and 23 for TSH) from different parts of India participated in the program. Twenty-four samples (16 pools: 5 simple and 11 manipulated pools) in 8 batches, 3 per batch per month were sent for analysis of T4, T3 and TSH. Some of the samples were repeated 3 times at different occasions to assess the imprecision of the laboratory. The

overall mean percent CV obtained for T4, T3 and TSH were 22.7, 36.32 and 52.38 respectively. The recovery for added T4 was 86.73% while that for T3 was 117.4%. A large variation was obtained for recovery of TSH. For T4 estimations, 13 laboratories had a desirable performance i. e. bias less than ±10.0% and variability of bias (VB) and imprecision (IP) less than 15.0%. None of the laboratories had a desirable performance for T3 or TSH. The number of laboratories with acceptable performance i. e. bias between ±10.0–15.0%, VB and IP between 20.0–25.0% for T4, T3 and TSH were 4, 3 and 0 respectively. The number of laboratories which required attention (bias between ±15.0–20.0%; VB and IP between 20.0–25.0%) were 5,7 and 1 respectively. The unacceptable results with larger bias, VB and IP for T4, T3 and TSH were 6, 18 and 17 respectively. (19)

In developing countries, establishment of national EQAS by preparing homemade quality control material is a useful scheme in terms of resources and time to monitor the laboratory performance. The study conducted on implementation of an EQAS to monitor the analytical performance of the district laboratories in Bhutan showed that , Lyophilized human serum including normal and abnormal levels were prepared and distributed to 19 participating laboratories. Nine routine analyte were included for the study. There was significant decrease in CV at the end of the study. The percentages of results in acceptable VIS as „A" were 63, 60, 66, 69, 73 and 74, 75, 76 and 79 % in November 2009–July 2010 respectively (20).

A regional external quality assessment scheme (REQAS) for anti-HIV serology aimed to objectively assess reliability and quality of HIV testing processes in the African region showed that, the study involved the distribution of proficiency testing (PT) panels to participating laboratories. During the survey period, this included 16 distributions of PT panels to 49 laboratories in 30 countries, and the overall average score during the nine-year survey period was 98.9%, with a frequency of accurate detection, of anti-HIV-1 and/or anti-HIV-2 antibodies in the PT panels, ranging from 93% to 100%. Problems highlighted included lack of human resources and frequent stock outs of test kits, reagents and consumables for routine HIV testing. The design of the REQAS allowed appraisal of the reliability of anti-HIV serological testing methods utilized by laboratories for clinical assessment of patients and/or surveillance programs .(21)

Challenges using a standard group C Streptococcus (S.equlisimilis) was presented in 1 of 15 challenges of the throat culture module in each year from 1996 through 2001. For each events

feedback returned to the participant laboratory including individual and group performance data and discussion of the results that that address problems in performance. In case of C Streptococcus the reason it should be differentiated from group A Streptococcus was discussed and recommendation to avoid pit falls in differentiation was addressed. But performance of EXCEL PT participants on group C streptococcus challenges from 1996 through 2001 of unacceptable performance was 19.6%,16.7%,19.5%,18.2%, 20.2%,19.0% in each year respectively. Despite continuous feedback , there was no significant changes in participant performance throughout the study period (22).

The study conducted at department of Hematology, all Indian institute of medical sciences, New Delhi, which has been conducted in external proficiency testing program since 1992, showed that an improvement in overall percentage of laboratories with acceptable result. It increased from 38%, 40%, 40 % in 1992 to 85%,90%, 94% in 2006 for Hgb, total leucocytes count, reticulocytes count, however for peripheral smear assessment is improved marginally (23).

3.1General objective

To evaluate the utilization and challenges of proficiency test panel in government hospitals at Addis Ababa.

3.2 Specific objective

- To assess analytical performance score of laboratories participated in proficiency testing program using 20 analyte in 6 cycles from 2012 - 2013 G.C.
- To determine PT failure rate of study laboratories in each cycle
- To assess participation rate of participant laboratories in proficiency testing program in each cycles from 2012 - 2013 G.C
- To identify challenges in participation of proficiency testing.

4.Materials and Methods

4.1. Study setting

The study was conducted in Addis Ababa which is the capital city of Ethiopia, covers a landmass of 540 sq. km. and a total population of 2.98 million millions according to 2008 central statistical agency report. There are 45 hospitals 31 health centers and 551 clinics. The study area was chosen because it is most accessible area for good utilization of PTP (24).

Of 14 governmental hospitals found in Addis Ababa 1 hospital was excluded using exclusion criteria and 1 hospital was piloted and the study was conducted in 12 governmental hospitals. Of which 5 hospitals were from Addis Ababa city administration, 3 hospitals were from uniformed hospitals services, and 4 were from federal hospitals. All 12 hospitals were provided PT from digital PT through EPHI by postal services and the PT analytical result and PT feedback were exchanged using both the postal and online services.

4.2. Study design and period

Cross-sectional study design was applied from September 2013 to June 2014.

4.3 Data collection instrument

4.3.1 Quantitative Data collection instrument

For the quantitative study retrospective data was collected using three tables. 2 of the tables were suitable for trend analysis of qualitative and quantitative laboratory test parameters and the remaining 1table was suitable for data collection used to assess participation rate. From PT feedback the collected data was Participation rate, Problems identified and analytical Performance score.

4.3.2 Qualitative Data collection instrument

In this study qualitative data collection were conducted through FGD and KII using semi structured open ended questioner. This tool is important to collect in-depth information from different key laboratory professionals engaged at different positions.

4.4. Source population

The source population was all government health facilities having clinical laboratory services in Addis Ababa.

4.5. Study population

12 government hospitals in Addis Ababa having clinical laboratory services and participating in EQA Scheme/ PT for 6 cycles (2012 and 2013 G.C) were included as study population.

4.6. Sample size

12 government hospitals found in Addis Ababa was addresses through this study for quantitative data. 17 laboratory professionals among 10 hospitals of the 12 hospitals were participated on 2 FGD 8 laboratory heads and 9 laboratory quality officers was participated on the two FGD and 2 KII was also conducted.

4.7. Sampling technique

Purposive sampling was used to include 12/14 government health facilities who were enrolled in EQA for 6 cycles (2012 and 2013 G.C). Data on results of EQA samples for 20 commonly performed tests were collected retrospectively from laboratory PT feedback. Parameters such as(SGOT,SGPT,ALP,BUN,Criatinine,TBI,DBI**,**WBC,RBC,Hgb,PLT,Morphologytest:Parasitological-examination, Syphilis,HBsAg,HCV,HIV,CD4 count **,**AFB, Gram stain) were included in the study.

Qualitative data was collected using non-random sampling a total of 17 laboratory professionals (8 laboratory heads and 9 laboratory quality officers) were purposively participated on the FGD because of they have relatively more exposure in managing the utilization of PT in their facilities. And 2 key informant having good experience in mentoring hospitals under their offices for quality management system was addressed.

Dependent variable

- Performance of laboratories in proficiency testing program

- Rate of participation in proficiency testing program
- Challenges in participating proficiency testing program

4.8 Operational definition

Analytical performance score: A value given by the PT provider to the participant laboratory for their PT performance in each cycle for each test parameter on the PT feedback.

Failure rate:- The frequency of obey less than 80% analytical performance score in each test parameter.(80% performance score is a regulatory requirement of WHO-Afro). (25).

Acceptable performance of participating laboratory :- Defined a minimum achievement of 80% or more for each test run in proficiency testing program (2,13)

External Quality Assessment (EQA)- A system for objectively checking the laboratory‟s

performance using an external agency or facility.

PT Challenges:- Are the number of tests distributed in the panel of one test parameter in a single PT cycle. (e.g.:_ AFB panel contain 5 slides(challenges) in a single cycle for a single participant.

Utilization of PT:- continuous improvement in analytical performance score and participation rate through the gap identification, root cause analysis and improvement plan to meet the regulatory requirement, payers requirement and to put the laboratory in the competitive market place.

4.9. Inclusion criteria and Exclusion criteria

Inclusion criteria

Those governmental hospital laboratories participated in EQA scheme/PT in 6 cycles of 2012 and 2013G.C and only volunteer hospitals and laboratory managers as well quality officers for this study were included.

Exclusion criteria

Hospital used for pilot study was excluded.

4.10. Data collection procedure.

4.10.1. Quantitative data collection procedure

One day training was given for 3 data collectors and one supervisor, and Retrospective data of 6 PT cycles(2012 and 2013 G.C) was collected for 20 test parameters by using piloted data collection table.. Data was collected from 12 government hospital laboratories as well the missed data were also obtained from EPHI archived PT feedback by decoding the name of health facility to secure the performance of individual hospital laboratory.

4.10.2.Qualitaive data collection procedure

Both the quantitative and qualitative data were collected from March to May 2014 G.C.

One day training was given for one reporter one mediator and 1one supervisor and the ethical clearance and supportive latter submitted to all participant health facilities and the FGD was conducted at Addis Ababa City Administration Regional health research laboratory meeting hall by reminding each study subject the place and time of the discussion through the phone. There was two FGD conducted on the same day at different time 8 laboratory heads and 9 laboratory quality officers were addressed. The focus group discussion was conducted by introducing the objective of the study prior to the discussion and the discussion was proceed after the consent was signed verbally. Using open ended questioner the discussion was conducted and the participant opinion for each question was captured through the minuets and voice recorder and at the end the discussion was closed by acknowledging the participant for their participation.

4.11. Quality Assurance

One day training was conducted for 5 data collectors (3 for quantitative data collectors, 2 for FGD and KII) and for 2 supervisor. All data collection instruments were pre tested at one of government hospital laboratory and appropriate modification has been made. . During data entry the quality of data entry was crosschecked by supervisors against the collected data.

participant on FGD and KII were laboratory professionals and the data were collected after consent form was signed verbally by all participants the signed consent was captured using minuets and voice recorder.

The quality of data entry was crosschecked by supervisors against the collected data and the quality of collected data was cross checked against the original data from EPHI, the quality of information jotted by the reporter during the KII and FGD was cross checked against the voice record.

The duration of data collection was from March to May 2014 G.C.

4.12. Data processing and analysis

Quantitative data analysis

Responses and scores were entered and analyzed on a Microsoft Excel spreadsheet. For quantitative analyte graded as ACC (Acceptable) *when the analyzed analytical value reported by the participated laboratory meet the established target value of the PT provider* or UNACC (unacceptable) *when the analyzed analytical value reported by the participated laboratory doesn't meet the established target value of the PT provider* this is true for both quantitative and qualitative test parameters.

For all cycles (i.e. one cycle or an entire six cycles), the proportion of acceptable responses were calculated. Assessment of overall or cumulative performance in a component was performed by grouping all grading area responses together and calculating the proportion with acceptable scores was done using SPSS version 20 descriptive statistical frequency chart and those meet 80% and above are interpreted as acceptable analytical performance score or satisfy the regulatory requirement.

Failure rate=

$$\left(\frac{Total\ \#of\ challanges\ graded\ as\ UNACC\ \ for\ a\ single\ test\ parameter\ in\ one\ PT\ cycle}{Total\ \#of\ challanges\ distributed\ to\ the\ laboratory for\ a\ single\ test\ parameter\ in\ one\ PT\ cycle}\right) \text{X}100\%$$

Commulative analytical performance rate

$$= \left(\frac{Total\ \#\ of\ PT\ analytical\ performance\ score\ owe\ 80\%\ and\ above}{Total\ \#\ of\ PT\ samples\ distributed\ through\ out\ the\ cycle(one\ cycle\ or\ the\ entire 6\ cycle)}\right) X100\%$$

$$Participation\ rate: -$$

$$= \left(\frac{The\ total\ \#\ of\ PT\ samples\ performed\ by\ the\ laboratory\ in\ each\ cycle}{Total\ \#\ PT\ samples\ distributed\ in\ each\ cycle}\right) \text{X}100\%$$

Qualitative data analysis

Qualitative data obtained through the FGDs and KII were classified in major thematic areas and summarized accordingly.

4.13. Ethical consideration

Ethical approval was given from Departmental Research and Ethics Review committee (DRERC) of School of clinical laboratory sciences, Addis Ababa University Collage of health science In addition ethical approval also given from Addis Ababa city regional Health office. Official permission to access the external quality assessment scheme feedback of last two year was obtained from EPHI. Official permission was obtained from each study hospital for the questionnaire of gap identification. All results and information obtained from the study was kept confidential at all times in the lockable cabinet.

5. Result

5.1. Characteristics of participated institutions/facilities

A total of 12 hospital participated proficiency testing program, of these 4(33.3%) owned by federal ministry of health and 5(41.7%) were under Addis Ababa Regional health Bureau plus 3(25.0%) were uniformed service hospitals. A total of 12 laboratories participated in all six cycles from 2012 and 2013 G.C .All data of year 2012 and 2013 (6 cycles) PT feedback were collected. 17 individual study subject were participated on in two FGDs and 5 of them were female and 2 of the 3 eligible for in-depth interview were participated (Table 1).

Table 1:- Characteristics of quantitative and qualitative study subjects and laboratories participated in six cycle proficiency testing schemes from 2012 -2013., Addis Ababa , Ethiopia

Type of institute	Number of institute	Quantitative study participant institutions	Male FGD participant	female FGD participant
Federal Hospitals	4	4	2	2
Uniformed Services hospitals	5	5	5	1
Addis Ababa regional hospitals	3	3	5	2
Total	12	12	12	5

The table two below shows the cumulative analytical performance for each(20 test parameters) of 12 hospital laboratories in each cycle of 2012 and 2013 G.C. There was 5 PT challenges for each test parameter except CD4 (2 challenges) evaluated in this study for each. 12 hospital laboratories were participated in which the total distributed PT challenges were 60 in each cycle for single test parameters. Among 6 cycle only cycle 1/2013 shows relative better performance.

EQA fail rates among the 12 laboratories of 20 test parameter were **Bacterilogy**[63.8% for AFB, 88.9% for gram stain,] **Clinical chemistry** [50% for ALP, 56.6% for SGOT, 44.4% for SGPT, 75% for Direct bilirubine, 75.4% for Total bilirubine, 79.2% for Urea, 68.1% for creatinine,] **Immunohematology [**48.6% for CD4,] **Hematology** [39.9% for WBC, 50.0% for

RBC, 44.5% for Hgb, 38.9% for PLT, 55.6% for morphology identification,] **Serology** [68.1% for HBsAg, 76.3% for HCV, 51.4% for HIV, 75% for Syphilis,] **Parasitology** [82.7% for parsite identification,] was identified in this study.(Table 2)

Table2:- Distribution of laboratory performances for 20 analyte in six cycles of proficiency testing program carried out during the years 2012–2013.

Cumulative Analytical performance score per cycle for each test parameter														TOTAL cumulative In the 6 cycle	
Analyte	Grade offered for each PT challenge	Cycle 1/2012		Cycle 2/2012		Cycle 3/2012		Cycle 1/2013		Cycle 2/2013		Cycle 3/2013			
		#	%	#	%	#	%	#	%	#	%	#	%	#	%
AFB	ACC	10	16.7	24	40.0	25	41.7	40	66.7	15	25.0	20	33.3	134	37.2
	UNACC	50	83.3	36	60.0	35	58.3	20	33.3	45	75.0	40	66.7	226	63.8
Gramstain	ACC	0	0	5	8.3	5	8.3	5	8.3	5	8.3	20	33.3	40	11.1
	UNACC	60	100	55	91.7	55	91.7	55	91.7	55	91.7	40	66.7	320	88.9
ALP	ACC	50	83.3	20	33.3	15	25.0	45	75.0	25	41.7	25	41.7	180	50.0
	UNACC	10	16.7	40	66.7	45	75.0	15	25.0	35	58.3	35	58.3	180	50.0
SGOT	ACC	40	66.7	15	25.0	20	33.3	45	75.0	15	25.0	25	41.7	160	44.4
	UNACC	20	33.3	45	75.0	40	66.7	15	25.0	45	75.0	35	58.3	200	55.6
SGPT	ACC	45	75.0	10	16.7	15	25.0	50	83.3	55	91.7	25	41.7	200	55.6
	UNACC	15	25.0	50	83.3	45	75.0	10	16.7	5	8.3	35	58.3	160	44.4
DBI	ACC	10	16.7	10	16.7	15	25.0	25	41.7	10	16.7	10	16.7	90	25.0
	UNACC	50	83.3	50	83.3	35	75.0	35	58.3	50	83.3	50	83.3	270	75.0
TBI	ACC	20	33.3	10	16.7	15	25.0	15	25.0	10	16.7	15	25.0	85	23.6
	UNACC	40	66.7	50	83.3	45	75.0	45	75.0	50	83.3	45	75.0	275	76.4
Urea	ACC	25	41.7	10	16.7	5	8.3	10	16.7	20	33.3	5	8.3	75	20.8
	UNACC	35	58.3	50	83.3	55	91.7	50	83.3	40	66.7	55	91.7	285	79.2
Creatinine	ACC	20	33.3	5	8.3	15	25.0	35	58.3	25	41.7	15	25.0	115	31.9
	UNACC	40	66.7	55	91.7	45	75.0	25	41.7	35	58.3	45	75.0	245	68.1
CD4	ACC	22	91.7	8	33.3	2	8.3	20	83.3	12	50	10	41.7	74	51.4
	UNACC	2	8.3	16	66.7	22	91.7	4	16.7	12	50	14	58.3	70	48.6
WBC	ACC	50	83.3	25	41.7	25	41.7	50	16.7	35	58.3	35	58.3	220	61.1
	UNACC	10	16.7	35	58.3	35	58.3	10	83.3	25	41.7	25	41.7	140	39.9
RBC	ACC	40	66.7	20	33.3	20	33.3	40	66.7	30	50.0	30	50.0	180	50.0
	UNACC	20	33.3	40	66.7	40	66.7	20	33.3	30	50.0	30	50.0	180	50.0
Hgb	ACC	50	83.3	25	41.7	20	33.3	40	66.7	30	50.0	35	58.3	200	55.5
	UNACC	10	16.7	35	58.3	40	66.7	20	33.3	30	50.0	25	41.7	160	44.5
PLT	ACC	55	91.7	25	41.7	25	58.3	55	91.7	30	50.0	40	66.7	220	61.1
	UNACC	5	8.3	35	58.3	35	41.7	5	8.3	30	50.0	20	33.3	140	38.9
Morphology	ACC	15	25.0	20	33.3	15	25.0	50	83.3	30	50.0	30	50.0	160	44.4
	UNACC	45	75.0	40	66.7	45	75.0	10	16.7	30	50.0	30	50.0	200	55.6
HBsAg	ACC	0	0	30	50.0	25	41.7	10	16.7	25	41.7	25	41.7	115	31.9
	UNACC	60	100	30	50.0	35	58.3	50	83.3	35	58.3	35	58.3	245	68.1
HCV	ACC	0	0	25	41.7	30	50	5	8.3	5	8.3	20	33.3	85	23.7
	UNACC	60	100	35	58.3	30	50	55	91.7	55	91.7	40	66.7	275	76.3
HIV	ACC	0	0	25	41.7	35	58.3	45	75.0	35	58.3	35	58.3	175	48.6
	UNACC	60	100	35	58.3	25	41.7	15	25.0	25	41.7	25	41.7	185	51.4
Syphilis	ACC	0	0	25	41.7	20	33.3	5	8.3	20	33.3	20	33.3	90	25.0
	UNACC	60	100	35	58.3	40	66.7	55	91.7	40	66.7	40	66.7	270	75.0
Parasitology	ACC	0	0	10	16.7	5	8.3	10	16.7	15	25.0	5	8.3	45	17.3

	UNACC	60	100	50	83.3	50	91.7	50	83.3	45	75.0	55	91.7	215	82.7
Total cumulative of 20 test parameters in 6 cycle												ACC		2569	36.8%
												UNACC		4415	63.2%

Trend of 6 cycles PT performance score

A line graph below shows the trend of cumulative analytical performance for 20 test parameters among 12 hospital laboratories in each cycle of 2012 and 2013 G.C. As illustrated in the line graph below no improvement was observed throughout the 6 cycles even high failure rate was observed in the 2012 than 2013.Whereas the in cycle 1/2013 shows relatively good performance.

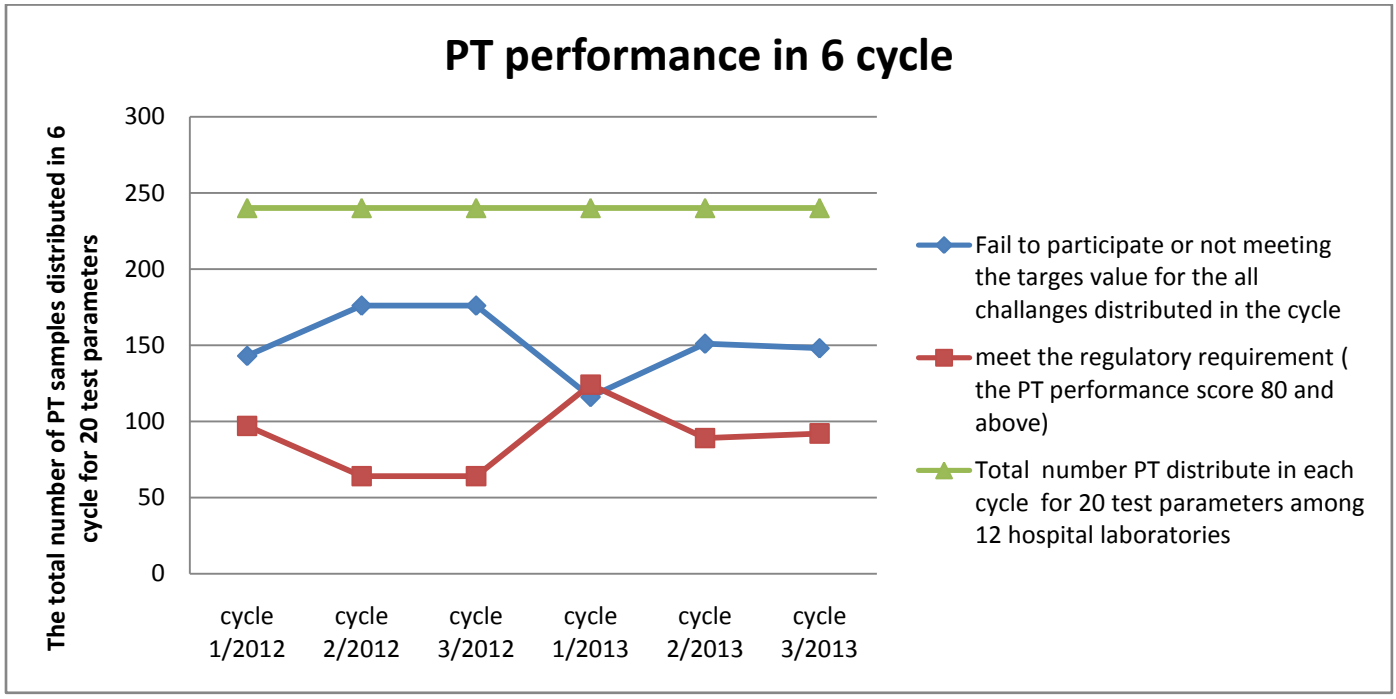

Figure 1 :- The trend of cumulative proficiency test performance for 20 test parameters among 12 hospital laboratories in each cycle of 2012 and 2013 G.C

Trend of PT performance score by health facilities

Among 12 hospital laboratories PT for 20 test parameters was distributed by the PT provider (Digital PT) in 2012 and 2013 (6 cycles). The finding indicated that A total of 120 PT samples were distributed in the 6 cycles for each study hospitals. Those hospital laboratories coded as 105, 107,108,109 (4 laboratories) accounted 41.23% failure rate among 12 hospital laboratories. As illustrated in the figure out of the 120 PT samples distributed throughout the 6 cycles for 20 test parameters for each hospital laboratory only two hospital laboratories (code 102, and, 110) analytical performance score were 78 and 72 respectively, even though which did not meet the regulatory requirement, these results were relatively better as compared with the rest hospital laboratories. (Figure 2).

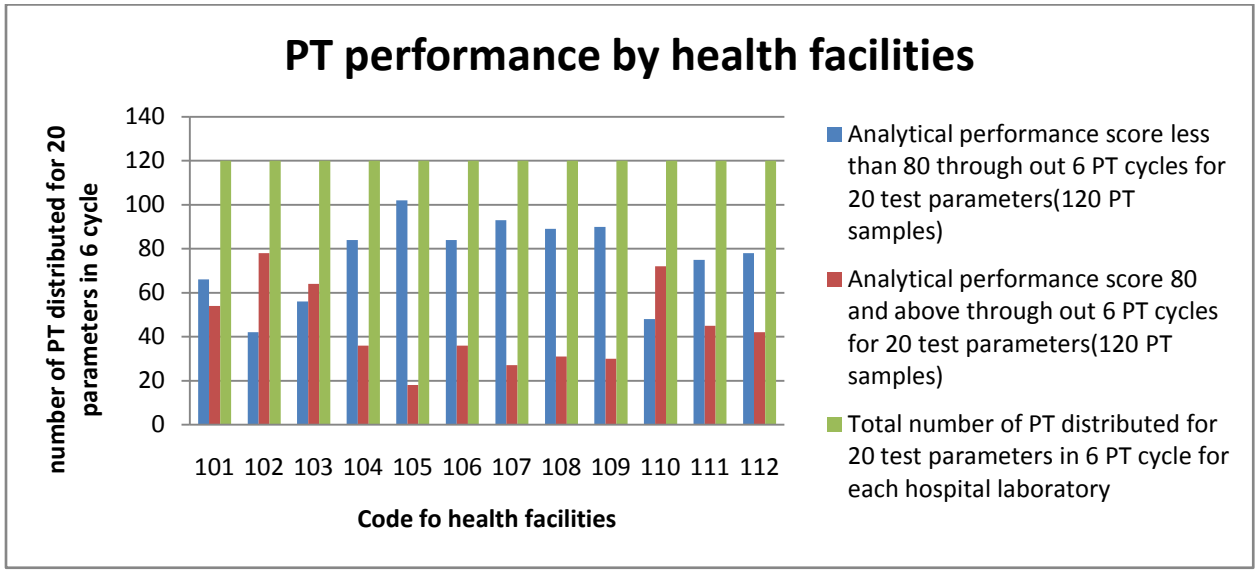

Figure:-2 Analytical performance score of 12 hospital laboratories through 6 PT cycles for 20 test parameters, (120 PT samples), in public hospitals, Addis Ababa, 2014.

Trend of PT performance score by 20 test parameters

In each cycle 12 PT samples were distributed for each test parameter. Which makes, a total of 72 PT samples were distributed for each individual test parameters throughout the 6 cycles. Even though all test parameters have 80 and above performance score, the frequency has variation for different test parameters. Among the study hospital laboratories, the least performance, was observed on Gram stain PT test parameter, which was only 8 of the 72

distributed samples. While Platelet test parameter PT performance was relatively higher, (which was 46 out of 72 distributed samples), as compared to other test parameters. (Figure 3)

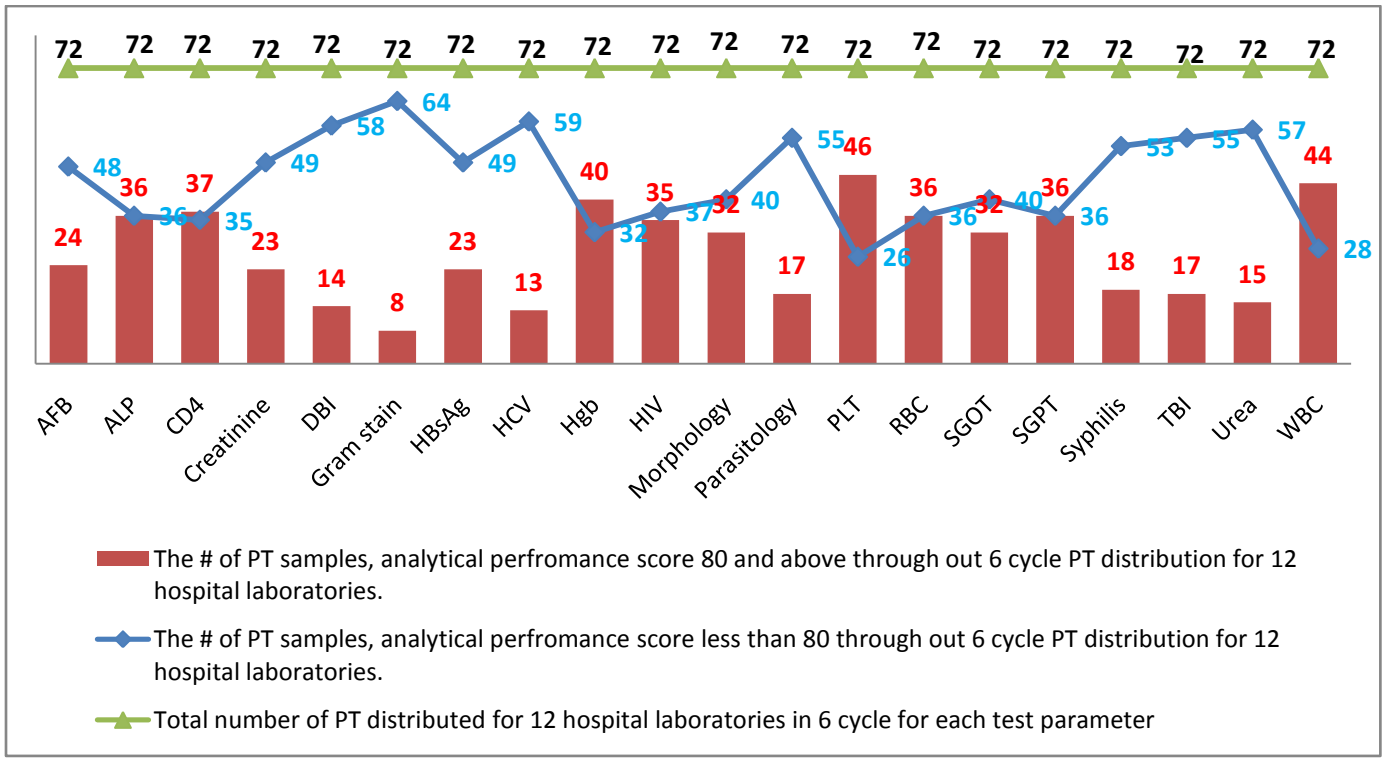

Fig 3 :- Cumulative analytical performance score for each individual test parameters throughout 72 PT samples distributed within 6 cycles among 12 Public hospital laboratories , Addis Ababa, 2014.

5.3 :- Identified Problems from PT feedback.

In this study, there were 5 challenge for each test parameter except CD4 (2 challenges) , for each cycle was distributed for 12 hospital laboratories and a total of 6984 challenges were distributed. Different problems which can affect the performance score were identified based on PT feedback for the 6 cycles in 20 test parameters. The PT feedback result indicated that, the major problems were failure to participate, test suspended during the test event, equipment failure and below linear limit of the analyte were 54.4%, 2.5%, 1.03% and 0.04 % respectively.(Figure 4)

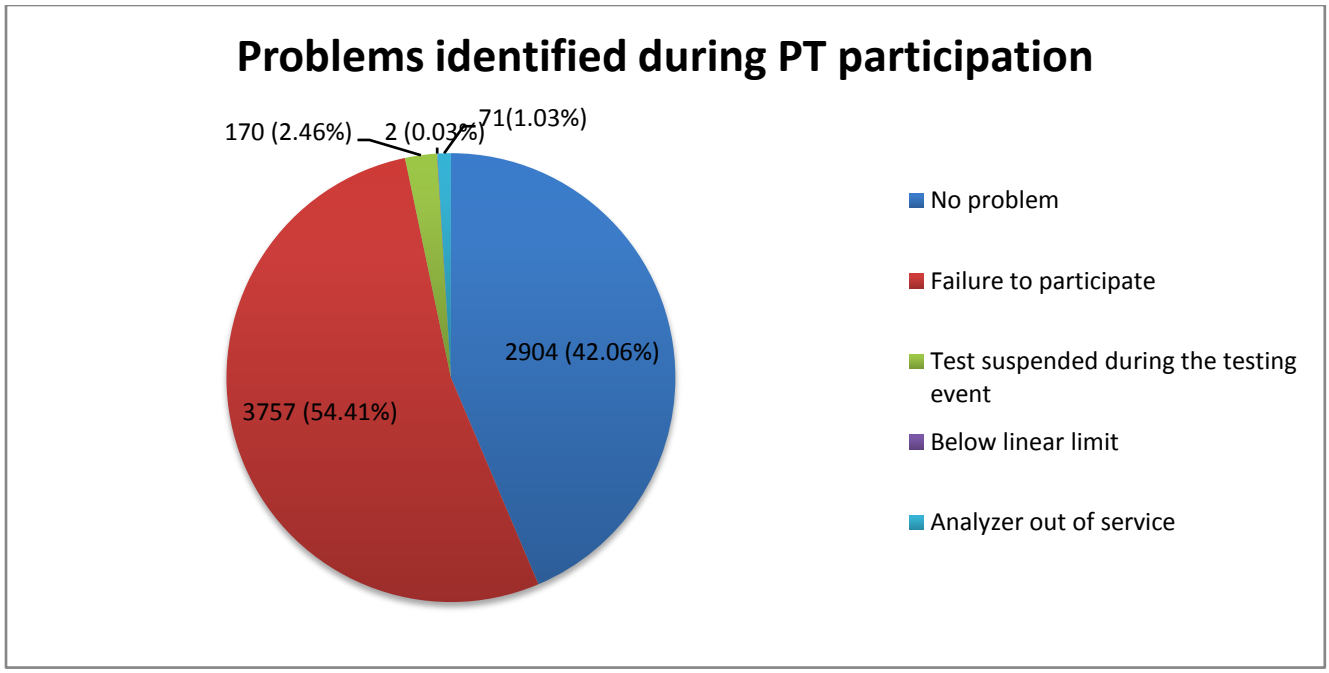

Figure 4 :- Problems reported during PT performance in 6 cycles (2012 and 2013G.C) from 12Public hospital laboratories Addis Ababa, 2014.

5.4 :- Failure rate of PT analytical performance from 6 cycles of 20 test parameters.

In this study, a total of 6984 PT challenges were distributed for 6 cycles in the study hospital laboratories. The result was categorize the performance as acceptable or unacceptable for each PT challenges based on the data obtained the failure rate from the total of 6, 984 challenges, were 4,341 (62.2 %) (Table 3 & Figure 5).

Table3:- Distribution of PT sample grade in six cycles of proficiency testing program carried out during the years 2012–2013 from a total 20 test parameters.

	# samples graded UNACC	# samples graded ACC
Due to reagent stock out	-	170
Due to analyzer out of service	-	71
Due to below lower limit of the analyte	-	2
Without any problem	1437	2400
Due to failure to participation	2904	-
TOTAL	**4341**	**2643**

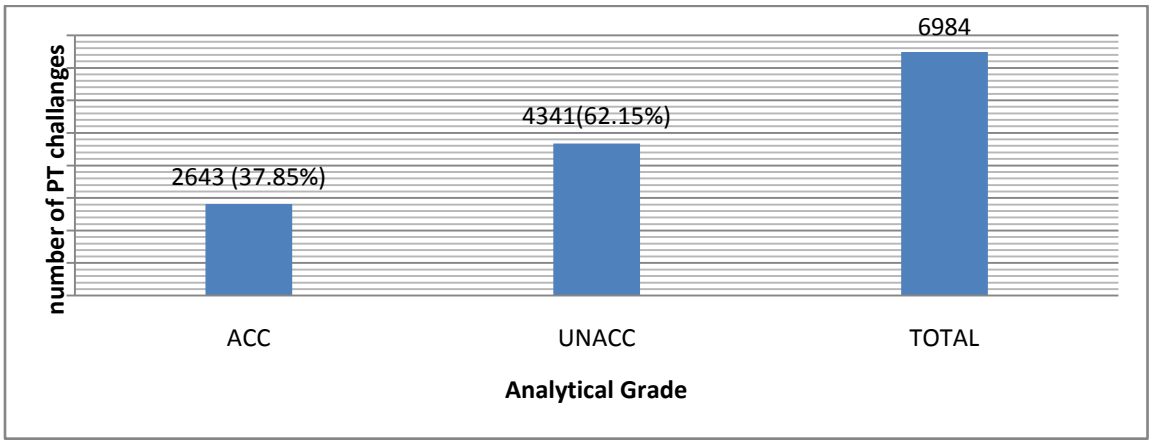

Figure 5 :- Acceptability of analytical performance in 12 hospitals in 6 cycles (2012 and 2013G.C) from 12Public hospital laboratories Addis Ababa, 2014.

5.5 :- Participation rate from 6 cycles PT of 12 hospital laboratories for 20 test parameters.

In this study, the participation rate of the selected facilities indicated that, among 12 hospital laboratories no laboratory was participate for all 20 test parameters in each cycle of PT. Partial participation or no participation is observed from each laboratories (Table 4).

Table 4 :- The Participation rate of 12 laboratories for 20 PT parameters of 2012 and 2013 in 6 Cycles

PT participation of 6 cycles by study hospitals among 20 test parameters												
	Hospital code											
PT cycles	101	102	103	104	105	106	107	108	109	110	111	112
Cycle 1/2012	7	13	12	11	11	5	7	12	8	6	11	6
Cycle 2/2012	17	17	18	12	1	9	0	0	2	14	0	0
Cycle 3/2012	2	14	18	3	3	9	2	16	0	7	0	10
Cycle 1/2013	11	11	11	16	13	7	11	16	13	15	13	14
Cycle 2/2013	13	17	16	0	0	12	2	0	0	15	16	14
Cycle 3/2013	16	19	12	0	0	3	12	0	9	13	10	14

Key:- The number in the table indicate the number of PT performed in each cycle by respective laboratories from expected 20 test parameters to be performed in each cycle by each laboratory. *Example:- the number 0 indicate no participation among the expected 20 test parameter. And the number 7 indicate the laboratory participate only in 7 parameters from the expected 20 test parameters.*

5.6 :- Participation rate of PT among 12 hospital laboratories for 20 test parameters by cycles

It is indicated that a total of 240 PT samples were distributed with 12 hospital laboratories for 20 test parameters, in each cycle. The total PT samples were 1, 440 for the 6 cycles. Based on this data, the participation rate out of expected 1440 throughout the 6 cycles was 645 (44.79%) (sum of participated cumulative test parameter over 6 cycle / total expected participation for 20 test parameters in 6 cycle among 12 hospital laboratories X 100%) rate of participation is observed. (Fig;6)

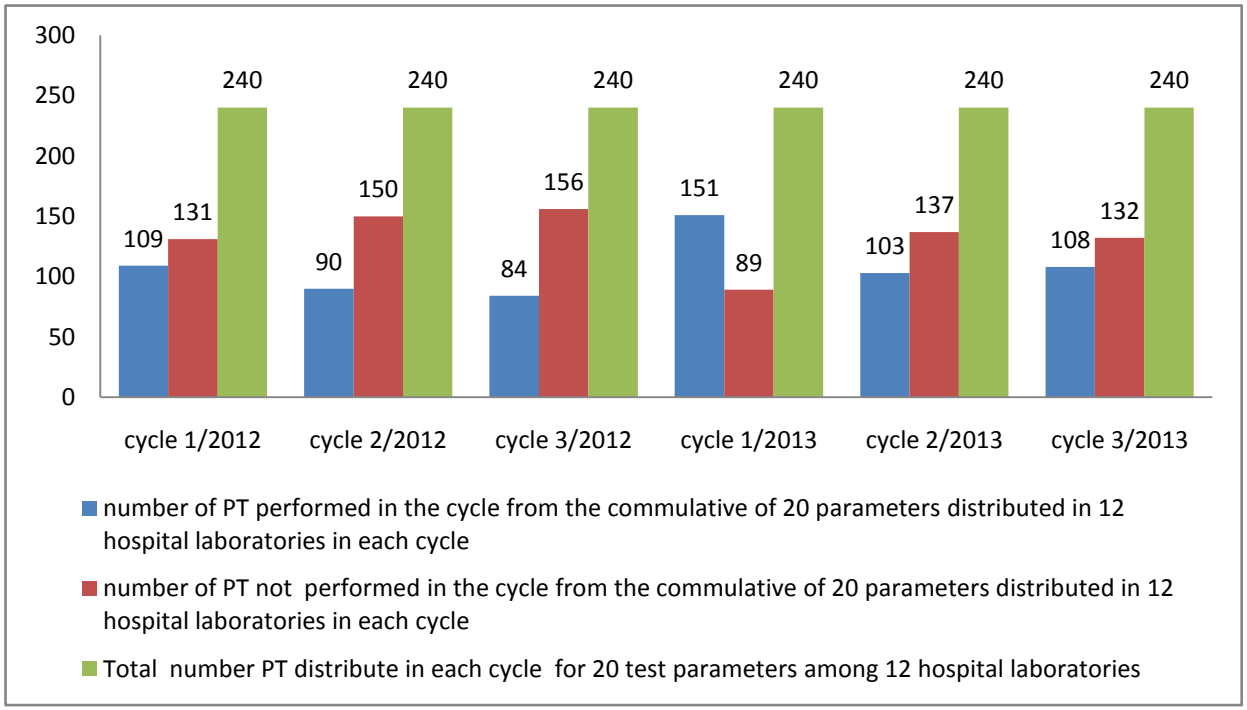

Fig:- 6 The cumulative participation rate of PT among 12 laboratories participated in 20 test parameters in 6 cycles (2012 and 2013G.C) from 12Public hospital laboratories Addis Ababa, 2014.

5.7:- Finding of Qualitative study .

5.6.1:- Finding of Focus Group Discussion and Key informant in-depth interview

Majority of the information collected in the Key informants were also stated with the FGD participants, therefore both the KII and FGD collected information was summarized in one accordingly .

In this study qualitative study was also applied to supplement the quantitative finding. In general two focus group discussions were conducted with laboratory managers and quality officers. A total of 17 participants were included during the discussion. Of which 5 of them ware female. Also 2 key persons were interviewed to collect detailed information about utilization of PT, Both key informants were male and represented from Addis Ababa regional laboratory and university partner with back ground of laboratory profession.

According to the study participants, there were different points raised regarding the objective of PT . . Almost all participants argue that PT is important ***"To identify the analytical problem and provide quality improvement for the identified gap to the maintain quality laboratory result for patient care." in addition the participants also*** said that ***"PT is a tool for the identification of the competency of the laboratory personnel" "participating on PTP and meeting 80% or more on two consecutive PT is a regulatory requirement for accreditation by ISO 15189 by ENAO."*** Based on the above PT objectives majority of FGD participant were agree as PTP is not meeting the objective in the situation of 12 hospital laboratories included in this study, whereas few participants are stated as they have good utilizations with some limitations.

The participants also asked challenges which can affect the utilization of PTP in their situation. In this regard, the participants list different challenges as follows: ***" Even there is poor documentation, almost all laboratories did not identify their gap based on the PT feedback, they are not well understood the objective of the PTP clearly."*** There are also problem on the laboratory personnel ***" staff resistance for participating on PT is one of the challenge which is because of basic knowledge gap due to poor quality of education and lack of experience on miss understandings the objectives of PT and not knowing how to interpreted the feedback, how to summarize the challenges of the PT participation of their laboratory and also I belief***

that most of us have gap to develop the quality improvement plan so more is expected from the higher education's teaching the laboratory profession on capacitate their students on the utilization of PTP and also the association must support and design different approaches and propose policy issues to the stakeholders for PTP utilization ."

The other identified challenge was ***" The reason for failure to participation of PT is due to equipment down time and reagent stock out."*** Even if the above mentioned are the challenges on effective utilization of PTP all study subjects agree that the national central laboratory (EPHI) is not couching them sufficiently on effective utilization of the PTP ***"our performance is not monitored by regulatory body in my opinion in addition to the participant laboratory the EPHI and regional laboratories are expected to identify our gap for effective utilization of PTP and early coaching."***

When the study participants were asked about their communication about PT feed back with internal and external clients, most of the study subjects were respond as they were not know their PTP participation rate. Because of the above mentioned challenges of participating PTP in their setup most laboratories are not communicate their performance of PTP for their internal, external customers and their hospital administration ***" because of the management of the hospital is not aware of PTP they are not follow and support the laboratory for effective utilization of the PTP."***

In this study , study participants were also asked about the participation in PTP should be voluntarily based or obligatory based, for this question, most of FGD participant agree that ***" participating in the PTP should voluntarily based but indirect force is mandatory for effective approach,… The type of indirect force should be creating competition among participant laboratories by awarding the best one, providing training for the staff, by increasing awareness of the administration…and the like."***

One of the KII participant put the reason for PT failure as follows "**even if the major accountability for failure of PT utilization are the laboratory personnel's working in each facility still EPHI is not invest more on mentoring, providing training, reviewing the performance status periodically rather than panels distribution"**

Almost all participant agree that as ***"PT performance is not monitored by regulatory body of internal facility of external authorized body .***"

As that of the FGD participant both KII participant agree that ***" participating in the PTP should voluntarily based but to improve the utilization more activities are expected from stakeholders and collaborators strong supportive supervision by reviewing the PT feedback periodically is never missed."***

6. Discussion

6.1:- Analytical performance score over 6 cycle

In this study each (20) test parameters EQA fail rates among the 12 laboratories were 63.8%. And for AFB,50% for ALP,48.6% for CD4, 68.1% for creatinine,75% for Direct bilirubine,88.9% for gram stain,68.1% for HBsAg,76.3% for HCV,44.5% for Hgb, 51.4% for HIV, 55.6% for morphology identification,82.7% for parsitology,38.9% for PLT, 50.0% for RBC, 56.6% for SGOT, 44.4% for SGPT,75% for Syphilis, 75.4% for Total bilirubine, 79.2% for Urea, 39.9% for WBC was identified in this study were showed there is no improvement over the 6 cycle in each (12) hospital laboratories. Whereas the cumulative trend of 20 test parameters for 12 hospital laboratories in over 6 cycle showed that those meet the analytical performance score of 80 and above (those meet the regulatory requirement) is 40.42%, 26.67%, 26.67%, 51.67%, 37.09%, 38.37% respectively in 6 cycles. This indicated that there is no continuous improvement rather than participation on PT just the trend analysis showed random and which is higher failure rate than EXCEL. This study is comparable with similar study conducted by Novak RW, which was indicated that PT reviewed feedback of group C streptococcus challenges from 1996 through 2001 the unacceptable performance was 19.6%,16.7%,19.5%,18.2%,20.2%,19.0% in each year respectively , and there was also no continuous improvement was observed in the year 1996 through 2001 (22). .

But this study is incomparable with similar study conducted, at department of Hematology, All Indian institute of medical sciences, New Delhi, which has been conducted in external proficiency testing program since 1992, which has showed that an improvement in overall percentage of laboratories with acceptable result and it increased from 38%, 40%, 40 % in 1992 to 85%,90%, 94% in 2006 for Hgb, total leucocytes count, reticulocytes count,, this difference could be due to due to low PT participation rate among distributed PT samples among the study hospitals (23).

From the total of 6984 PT samples distributed for 20 test parameters among 12 hospital laboratories within 6 cycles only 37.85% analytical value reported were acceptable (meet target value) ,which indicate there was 62.15% failure rate. Of which 41.23% failure rate is accounted by 4 of the 12 laboratories. This finding is comparable with similar study conducted in Western region of Amhara National Regional State of Ethiopia, which has showed that quality of eight public medical laboratories were assessed for liver and kidney function tests of six analyte [SGOT,SGPT,ALP, BUN, criatinine, and total cholestrol] 65% of 213 values reported was failed outside of the allowable limits of errors for the chemistry test of the control specimens.(17)

Too much high failure rate is identified in this study of that of the study conducted is Sub-sharan Africa with 1.63% failure rate , which was 76% of failure rate was accounted in 4 of 21 laboratories this high difference in failure rate may due to the participation rate difference and difference in strong mentorship of regulatory bodies and the staff difference in the magnitude of challenges in utilization of PT. (16)

6.2:- The participation rate of PT for 20 test parameters among 12 hospital laboratories over 6 cycle.

In this study, among 12 hospital laboratories participated in PT for 20 test parameters in 6 cycles, there is no laboratory participate in all 20 test parameters. In all 6 cycles, partial participation or no participation was identified from the PT feedback. And the overall participation rate among 12 hospital laboratories for 20 test parameters throughout the 6 cycle was 44.79% . This finding is less than the study conducted in Amhara national regional state, Ethiopia, in which the quality of eight public medical laboratories were assessed for liver and kidney function tests of six analyte the participation rate was 65.7%, these difference could be due to difference in the number of study test parameters and study inistitution.(17).

The FGD and KII participant of this study agreed that the challenges for effective utilization of PTP are basic knowledge gap on PT feedback interpretation due to poor quality of education, development of improvement plan, gap identification and root cause analysis as well as poor staff commitment on other hand maintenance problem for equipment down and reagent out of

stock are among identified challenges. This study is comparable with the study conducted by Carter JY, et.al. which was indicated that challenges identified for low rate of EQA participation in Contributing factors for low participation was shortage of staff and lack of time in busy rural laboratories together with difficulties in communication and lack of appreciations of the benefit of participation was identified challenges.(12).

Rather than participation no continuous improvement is observed in both the participation rate and the trend of analytical performance score, due to this as stated by the FGD and KII participant PT was not utilized in 2012 and 2013 throughout the 12 hospital laboratory. Another study shows Participating in PT allows laboratories to recognize analytical and interpretive error that may indicate internal problems with quality control, calibration, assay design, or test interpretation.(10) Furthermore according to Sciacovelli L, et.al. ongoing monitoring of PT performance will help to reduce laboratory errors, produce accurate PT result mainly improve patient care.(11) As described on Bulletin of the World Health Organization, participating in PT alone is not enough to improve the performance of the laboratory but evaluating the gap based on the feedback from PT provider and taking corrective action will improve the performance of the laboratory sustainably.(7)

7. Strength and limitation of the study

Strength of the study

- -This study use both qualitative and quantitative data to address the study objectives. I tried to incorporate 20 test parameters

Limitation of the study

- Shortage adequate literature to make adequate comparison
- The test parameter was too much and difficulty to illustrate the trend using line graph for each test parameter.

8. Conclusion and recommendation

8.1. Conclusion

Based on the finding, among 12 hospital laboratories rather than PT participation no improvement is observed. There are many factors which contribute for PT failure, these factors were related with personnel, equipment, and supplies. As indicated in the result, the major challenge for PT failure is due to failure to participate. In general PT was not effectively utilized in the study period among the 12 hospital laboratories.

9. Recommendations'

Based on the finding of quantitative and qualitative study the following points are recommended by the PI for effective utilization of PT.

- -The EPHI and regional laboratories together with partners should work hard on training for the laboratory personnel‟s on service and pre service on utilization of PTP as well as assess the educational quality of laboratory schools for improvement of the quality of graduates.
- - The higher education laboratory schools should provide in-depth practically supported knowledge on PTP for their student .
- -The laboratory manager together with the hospital administrative should minimize service interruption due to equipment down and reagent stock out
- -Laboratory associations should support by designing different approaches for effective utilization of PTP
- -EPHI should promote those laboratories having best performance Periodically to increase the effective utilization of PTP.

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Annex I

Key-informant indepth interview and FGD Guide

Introduction and consent

Greetings: My name is---------- and I am from Addis Ababa university school of medical laboratory science professional on the behalf of PI. We are conducting a study on utilization of PTP in governmental hospital laboratories in Addis Ababa. That aims to assess the trend of performance of each laboratories in PTP, the rate of participation on PTP and to identify gaps on effective utilization of PTP.

This assessment is about utilization of PTP in governmental hospital laboratories in Addis Ababa, I am interested in finding out your knowledge and opinion regarding gaps or challenges on effective utilization of PTP focused on personnel, logistics or legislative [system] issues.

Your participation on this study is voluntary; you can refuse to participate now or at any time of the interview. You are free to refuse to answer any question . All your answer will be kept strictly confidential. There are no direct benefits to you if you choose to participate in this study; however you will be Ethiopian clinical laboratories to develop better plan to improve analytical quality of clinical laboratories.

At this point do you want to ask any thing about the study? Yes/ No

I would like to give the opportunity to my collogues [the reporter and his assistance] to introduce themselves.

May I begun the discussion now ? Yes/ No. If yes continue.

Questions.

1. In your opinion do you think the PTP in Ethiopia is address all test parameters available in each laboratory ?
2. What are the objective of PTP?
3. Do you think the PT panels distributed to your/ each hospital laboratory utilized effectively according to its objective ? justify your fact ?
4. Do you communicate the EQA feed back to the laboratory staffs, to the top management of the hospital, to your internal and external customers, if you communicate explain the way you communicate ? If not communicate what are the challenges ?
5. Do you develop the improvement plan for the PT felt ? If no what are the challenges ?
6. Please tell me the PT participation rate of your laboratory ?
7. Do your laboratory participate PTP in all test parameters of the last two years ?If no please what was the gaps ?
8. In your opinion do the participation in PTP should be obligatory or voluntary based please justify your answer [advantage and disadvantage]
9. What should be done to effectively utilize PTP
    A. By EHNRI
    B. By associations
    C. By Universities
    D. By the hospital Administrative
    E. By the laboratory director
    F. By the laboratory staff

Any other comments

Thank you.

Annex-II

Data collection table for PT performance feedback data collection

Cycle	Sample Code	Problem code	Grade	Analyte score
Type of Test----------				
	A			
	B			
	C			
	D			
	E			
	A			
	B			
	C			
	D			
	E			
	A			
	B			
	C			
	D			
	E			
	A			
	B			
	C			
	D			
	E			
	A			
	B			
	C			

	D			
	E			
	A			
	B			
	C			
	D			
	E			

Annex III

Chart used to assess the participation rate

Hospital code……

S.N	Test Menu	Participation in each PT panel distributions							
		Round…..	Round…..	Round…..	Round…..	Round…..	Round…..	Round…..	Round…..

Annex IV. Declaration

I the undersigned, declare that this is my original work and has not been presented for a degree in this or any other university and all sources of materials used for this thesis have been acknowledged.

Name: Ashebir Gurmessa (BSc, MSc candidate)

Signature: _____

Place:, Federal Prison Administration General Hospital

Date of submission: June 23, 2014

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

Name :-

1. Fatuma Hassen (BA, BSc, MPH)

Signature: _____

2. Beniyam Taye (Bsc,MPH,PhD Cand.)

Signature: _____

Place: Department of Medical laboratory Science, College of Health Science, Addis Ababa University

Date of submission: June 23, 2014