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Ethiopian National Tuberculosis Reference Laboratory Ten Year External Quality Assurance-Panel Test Performance Review

Mengistu Tadesse K.[1, *], Getahun M.[1],Kebede A.[1], Yaregal Z.[1], Meaza A.[1], Dagne Z.[1], Moga S.[1], Addise D.[1], Tesfaye E.[1], Yenew B.[1], Mollalign H.[1], Diriba G.[1], Girmachew F.[1], Dimssea D.[1], Marondera B.[2]

[1]National Tuberculosis Reference Laboratory, Ethiopian Public Health Institute, Addis Ababa, Ethiopia

[2]FIND Diagnostics/Expand TB Project, EPHI, Addis Ababa, Ethiopia

Email address:

mengistutadesse86@gmail.com (Mengistu T. K.), mimishaget@yahoo.com (Getahun M.), abesh_k@yahoo.com (Kebede A.), zollazede@gmail.com (Yaregal Z.), abimeaza@gmail.com (Meaza A.), dagnezekarias@yahoo.com (Dagne Z.), shewki2002@gmail.com (Moga S.), desalegnaddise@gmail.com (Addise D.), ephremt13@gmail.com (Tesfaye E.), bazezewyenew@yahoo.com (Yenew B.), tersit21@gmail.com (Mollalign H.), diribagetu@yahoo.com (Diriba G.), fevtiz@yahoo.com (Girmachew F.), ddemissie7772@gmail.com (Dimssea D.), tissotent@yahoo.co.uk (Marondera B.)

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Abstract: The Objective of this review was to see the ten year EQA performance trend from 2005 till 2014 at Ethiopian national tuberculosis Reference laboratory. The finding shows that 81.3% and 11.2%of participation were ZN-AFB and of phenotypic DST respectively. The remaining participation was for LPA-PT with proportion of 4.6% and 2.3% for GeneXpert. Most of EQA-PT performance of NTRL scored above 80% and above 90% for Phenotypic DST of 1st and 2nd line Anti-TB drug. DST efficiency reveal that most tested drugs at NTRL were achieved acceptable performance and good agreement result compared to SRLN laboratory test with record data of above 90% for all 1st line and 2nd line drugs with the exception of Ethambutol. Over all TAT record were acceptable with the exception of phenotypic DST which is Critical TAT findings that ranges from 100 to 841 days from total 4 round 1ST and 2nd line DST -PT participation With the median TAT of 205 days. The most frequently committed error type were High false Negative, which accounts 3% contribution for total loss of PT score. The review finding shows there were some gaps on Critical TAT therefore a periodic review and evidence based corrective action has to be made in short time interval after feedback obtained since laboratory error will have devastating impact on clinical management of Patients and laboratory information.

Keyword: AFB-PT, NTRL, NICD, DST, EQA, TAT

1. Introduction

Standardization of existing TB laboratory service in more accessible approaches and periodic monitoring of performance using EQA tools within the hub of net worked Laboratory system is a key strategy to assure the Quality of laboratory service [1]. In addition Sustainable EQA performance is one of the criteria for accreditation [2]. More over the EQA participation and performance is a key for Evaluating, customizing and producing data from advanced new diagnostic Technologies with the vast spectrum of diagnostic values to detect Mycobacterium tuberculosis complexes with level of drug resistance pattern in a short Turnaround Time [3]. Expansion and standardization of existing routine TB laboratory service in more accessible approaches and periodic monitoring of performance through EQA by involving all EQA tools such as on site evaluation, blind rechecking and panel testing is valuable tool to create confidence and address the demand of information to users

like NTP, Researchers and primary health care service providers [1].

Another issues need to be addressed through EQA is the laboratory networking and service delivery in hierarchy of reference laboratory, regional laboratory and primary health care facilities based on the respective excellence of diagnostic test service for Culture and DST[4]. In this contextTB diagnostic and research Laboratory networking and sharing and developing Service standards, protocols and guidelines for harmonized service delivery and generation of valid data, understanding and communications with other similar laboratories within the continent as well as supra national laboratories is one key aspect of TB laboratory system. Hence EQA is a key channel to trust each other and competency tool to create well harmonized communications between laboratories and customers moreover it will validate the results produced from standardized laboratory approaches and practices.

Quality management system also one of the key strategic area which potentially expressed in EQA performance through monitoring and evaluation of key quality indicators such as EQA participation and turnaround time [TAT][5]. Even though Periodic monitoring of EQA participatory feedback data's and associated corrective action still a gap in most laboratory practice; Periodic EQA performance evaluation and corrective action, based on identified EQA gaps is important to improve laboratory service. Therefore the purpose of this review was to seethe ten year EQA performance trend; average score of EQA from inter laboratory comparison data, TAT trend for each EAQ participation and to see possible gaps for some of EQA failure at Ethiopian national tuberculosis Reference laboratory [NTRL].

2. Objectives

The aim of the review was intended to see ten-year EQA performance trend, average score of EQA, TAT trend and possible gaps for some of EQA failure at Ethiopian national tuberculosis Reference laboratory [NTRL].

3. Methods

Method of the review was done by reviewing retrospectively all archived EQA PT participation and scored feedback with comparatively with other similar participating laboratories data Reviewing and summarizing in to table and graph of all EQA-PT data for AFB, Culture and DST of 1st and second line. at EPHI-NTRL archived over ten year period since 2005-2014.

4. Data Source

Ten Year EQA Participation and feedback data was used as data source for this review which was archived at EPHI-NTRL over a period of 2005-2014. EQA feedback hard copy data base was accessed after obtaining appropriate permission from the institute.

5. Review Finding

From total EQA participation starting from 2005 till 2014, Ten Year EQA data shows that 81.3% [35/43] of participation were basic Microscopy examination specifically ZN-AFB and The second frequent participation were phenotypic DST with proportion of 11.2% (5/43) among this DST participation 1st line DST were 9.3% [4/43] that involves five 1St line anti-TB drug and 2.3% [1/43] were for 2nd line phenotypic DST that involves the second line drug of choose such as Amikacin, Kanamycinloxacin, and capromiycin [6, 7, 8]. The remaining participation were for Molecular DST Such as LPA-PT with proportion of 4.6% [2/43] and 2.3% [1/43] for GeneXpert verification.

Overall AFB-PT performance data shows that 59.2% (16/27) Participation scored 100% randomly and the remaining score were with the range of 80%-95% of good performance [Fig 1]. Compared to Digital PT and SRL-Uganda AFB-PT participation. NTRLable to achieve 74.08% of PT participation from NICD AFB- PT above 80% which is acceptable performance and Pass mark for most PT participation [1, 10]. There maining 25.92% (7/27) fail performance below 80% over the ten year participation period. From the remaining two PT providers NTRL able to achieve Above 80% from two round participation from SRL-Uganda and scored100% in three round from six Digital PT participation in five years period. From total participation of AFB-PT the most frequently committed error type were High false Negative, which accounts 3% contribution for total loss of score.1ST line DST efficiency data reveal that most tested drugs at NTRL were achieved acceptable performance and good agreement result (p value <0.05) compared to SRLN laboratory test with record data of above 90% for all listed 1st line and 2nd line drugs with the exception of Ethambutol [EMB] as it was also observed in a review from EU regions [9, 11]. Line probe Assay [LPA] and GeneXpert Verification data only convoy Qualitative data of Correct Result Feedback from Global Laboratory Initiatives [GLI].

Inter laboratory comparison data from ten year NICD- PT participation from shows that 77.7% (21/27) NTRL able to achieved good comparison result and only fail below the average performance with 22.2% (6/27) of AFB PT survey. From this 22.2% fail records 18.5% (5/27) were due to lack of giving test feedback within provided TAT or fail to participate [Fig 1]. Overall, average score were above 80% [Fig. 2] which is acceptable from the rest two PT providers Digital-PT and SRL-Uganda respectively [1].

NICID -TAT data from receiving and giving feedback shows that 96.3% were returned back within acceptable TAT and with the median date of 20 day, 55.5% (15/27) were returned with the date below median days. in this data only one data were outlier with 45 days [Fig. 3]. Digital PT participation lacks feedback data for most of the participation and only two were documented below 5 days. SRL-Uganda TAT data ranges from 2 to 25 days. Another critical TAT

findings in this review were DST PT participation from SRLN Antwerp. the overall TAT ranges from 100 to 841 days from total 4 round 1st and 2nd line DST -PT participation With the median TAT of 205 days.

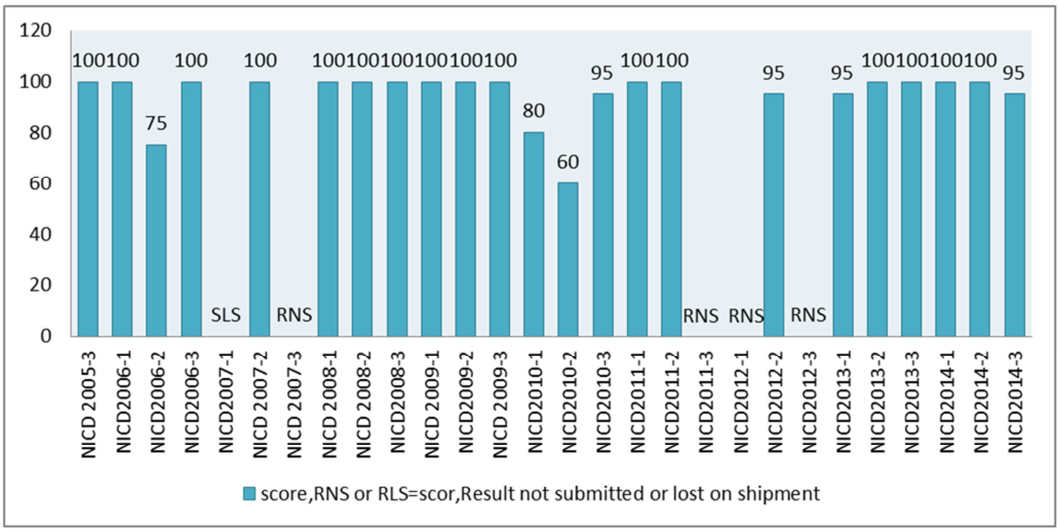

Fig. 1. *Ten Year trend of AFB PT-EQA performance at Ethiopia NTRL since 2005-2014.*

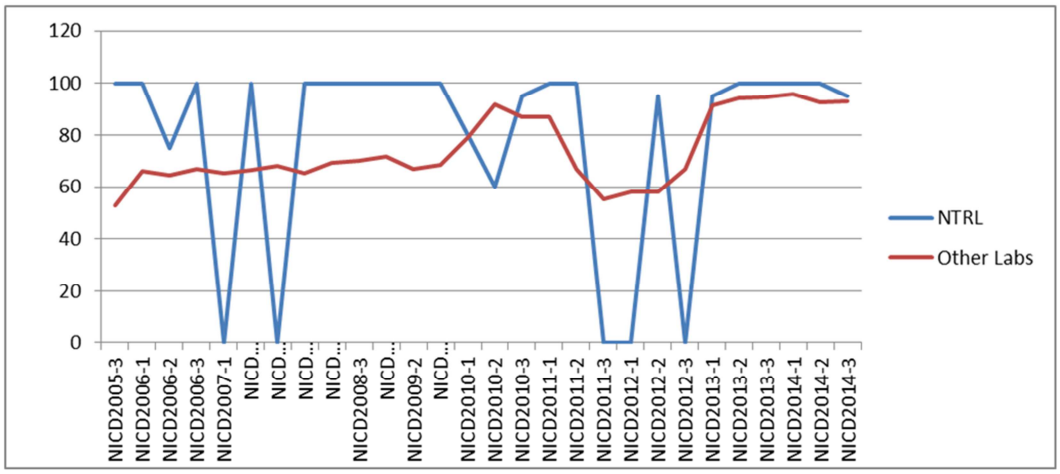

Fig. 2. *Ten -year Average Score of AFB PT-EQA performance of Ethiopia NTRL compared to NICD PT scheme participatory Laboratory in Africa since 2005-2014.*

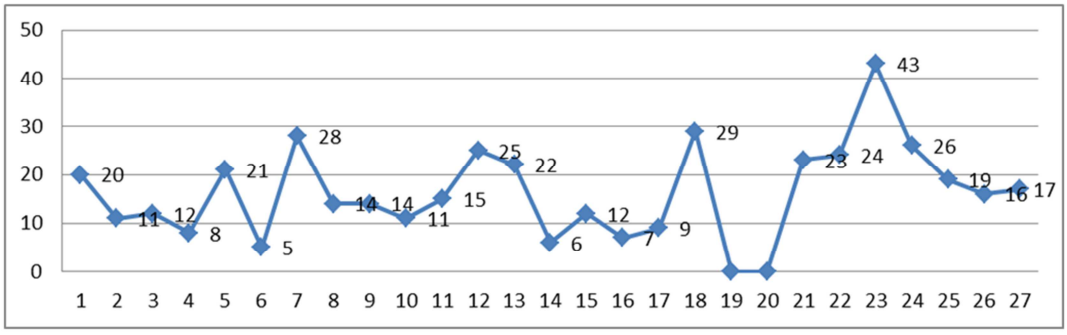

Fig. 3. *Turnaround time trend for the last Ten year AFB-PT participation at NTRL since 2005-2014.*

Two-year GLI Xpert MTB/RIF verification data at NTRL in 2013 and GLI- LPA -PT EQA participation of NTRL for the year 2013-2014 lacks TAT data. incurrent review In addition to test Performance and TAT data availability of a feed back with certification were also assessed. According to the data PTparticipation from SRLN-Antwerp have a system of certification with feedback, hence the NRL awarded with documented achievement of Phenotypic 1st and 2nd line DST with acceptable performance above 95% and Very recently in 2013 NICD–AFB-PT provider start certification from full participation of the PT rounds. Hence NTRL 2013th performances were scored 98%. From total participation

32.5% (14/43) result that needs corrective action documentonly 50% (7/14) were recorded with corrective action documentationfor farther improvement and 30.2% (13/43) of Participation doesn't have back log record documented for farther verification.

As the review summary we concluded that most of EQA-PT performance of NTRL is scored above 80% For most AFB-PT and above 90% for Phenotypic DST of 1st and 2nd line Anti-TB drug. This score for both method were excellent performance according to recommendation by WHO/IUATLD and reviewer finding some were else [1, 11] and the achievement eventually validates all the associated service and research output from NTRL including the first Ethiopian population based TB prevalence survey and MDR-surveillance researches. more over 2nd line DST EQA score validate and capacitate NTRL to doing XDR-TB diagnostic service and research among few laboratories in Africa. LPA and GeneXpert verification data were also correct and acceptable as per the GLI report. One of the Advantages of oversea EQA participation is inter laboratory comparison, accordingly NTRL were above the average score in most EQA–PT participation but some of data were recorded with down shift outlier due to technical difficulties and lack of timely feedback.

Over all TAT record were acceptable with the exception of phenotypic DST. as evidenced from the review most error type were high false negativea type of error were examiner unable to detects smear with scanty and one pulse. which is very critical in the area of high TB prevalence and low case detection rate. There is record of backlog and examiner, but no record of EQA based corrective action to improve technical competency of examiner when ever fail to achieve EQA. Number of DST EQA participation was very minimal compared to AFB-PT over ten year Participation. From all PT-provider SRLN-Antwerp and NICD only has a system of full survey commentary and Certification which is crucial record for accredited laboratory and subsequent application of Assessment.

As a reviewer, we strongly recommend more attention has to be given to improve DST participation since TB reference laboratories expected to deliver more DST service than TB Microscopy service. LPA and PT participation needs to be supplemented with on site evaluation and blind rechecking from SRL. Aperiodic review and evidence based corrective action has to be made in short time interval after feedback obtained since laboratory error will have devastating impact on clinical management of Patients and laboratory information. A due attention and system must be implemented to harmonized and sustain EQA success story particularly good score and TAT. EQA evidence based personal competency improvement package need to be implemented and addressed to fill the gap of technical difficulties observed during the review.

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