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TB DIAGNOSTIC CENTERS;
A STUDY OF QUALITY ASSURANCE OF TB DIAGNOSTIC CENTERS THROUGH PROFICIENCY TESTING IN LAHORE

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ABSTRACT… Introduction: Tuberculosis is the leading infectious cause of death and was declared as global emergency in 1993. Sputum smear microscopy is the gold standard for diagnosis of the pulmonary tuberculosis. Blinded rechecking of the slides and panel testing are WHO recommended methods for assuring the quality of the TB diagnostic centers. **Period:** Oct, 2014 to Dec, 2014. **Objectives:** To assess the quality of sputum microscopy at diagnostic centers through proficiency testing.To compare the performance of trained and untrained laboratory staff in terms of sputum microscopy. **Study Design:** Cross-sectional descriptive. **Setting:** Lahore District. **Methodology:** Blinded rechecking and panel testing was performed and data was collected with the help of checklists in all the 30 (75%) functional diagnostic centers of Lahore district. **Results:** Errors in reporting were found in 13 (43%) out of 30 diagnostic centers during the blinded rechecking. There was no error in the blinded rechecking in microscopy of 17 (68%) AFB microscopy trained lab workers, while all the 5 (100%) untrained lab workers committed error. Only 17 (56%) lab workers reported 80-100% slides correctly during the panel testing; a minimum acceptable level of skill, while 13 (44%) reported 40-60% slides correctly. One of the most striking findings of the study was the relation of training with the performance of lab workers. **Conclusion:** Untrained lab staff should immediately undergo standardized training for sputum smear microscopy and refresher training should be given to the trained lab workers to enhance their knowledge and skills.

Key words: DOTS, Critical Appraisal, Diagnostic Center, Proficiency, Blinded Rechecking, Panel Slides.

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INTRODUCTION

Tuberculosis is the leading infectious cause of death and was declared a global emergency in April 1993.[1] According to WHO prediction, without radical changes in our approach to Tuberculosis, 200 million people alive today will eventually develop this disease.[2]

Directly Observed Treatment Short course (DOTS) was recommended by WHO as a strategy for the diagnosis and treatment of TB in mid 1990s.[3] It has five components and sputum microscopy as the mainstay of diagnosis.

Pakistan ranks 5th among the countries with highest disease burden and around 250,000 new TB cases occur in Pakistan each year.[4]

The World Health Organization (WHO) strategy for tuberculosis control (DOTS) relies on a network of quality assured laboratories that provide acid fast bacilli (AFB) sputum smear microscopy. If the laboratory is not quality assured then diagnosis is unreliable and all other activities will be affected.

For an effective tuberculosis program a broad network of well-functioning laboratories in a health system should be readily accessible to the population.[5,6] It is essential that every laboratory technician should be trained in sputum smear AFB microscopy.

Quality of sputum microscopy is assured through proficiency testing which has two components; blinded rechecking and panel testing. In blinded re-checking, randomly selected slides from

the diagnostic centers are re-examined & are considered best method for evaluating routine performance of the lab workers. In panel testing a set of unstained and stained slides are provided to the microscopists and they are asked to stain the unstained slides, and report the stained slides. It provides a rapid picture of the relative proficiency of microscopists. A good quality sputum microscopy is envisaged to assist in achieving WHO target of case detection rate (CDR) of 70%.[7]

OPERATIONAL DEFINITIONS

High false positive (HFP)

It is the error when lab worker is reporting 1+ to 3+ (1+ means more than 10 AFB per 100 high power fields and 3+ means more than 10 AFB per high power field) when it is negative.

High False negative (HFN)

It is the type of error when lab worker is reporting negative when it is 1+ to 3+.[8]

OBJECTIVES

1. To assess the quality of sputum microscopy at diagnostic centers through proficiency testing.
2. To compare the performance of trained and untrained laboratory staff in terms of sputum microscopy.

MATERIAL AND METHODS

It was a Cross-sectional descriptive study in which data was collected from 30 functional diagnostic centers of Lahore district. Lahore is the provincial capital of Punjab and has both urban and rural areas. There were 40 Diagnostic centers in but at the time of study only 30 were functional.

DATA COLLECTION PROCEDURE

A checklist for proficiency testing was used. Data was entered on a standard recording form which was subsequently processed to produce the information. Data was analyzed by Computer Software Program, EPI – INFO, presented as percentage in tabulated form and with the help of figures.

Security and confidentiality of the data was ensured.

RESULTS

All the information regarding Diagnostic Centers (DCs) was out of 30 functional DCs.

Blinded Rechecking was done in all the DCs and errors in reporting was present in 13 (43%) DCs (Figure-1).

There were 20 major errors in which 15 were High False Positive (HFP) and 5 were High False Negative (HFN) type (Figure-2).

The results of training on panel test and blinded rechecking reveals that 17 trained lab staff made no error while all 5 untrained lab staff had error on blinded rechecking. (Table-I)

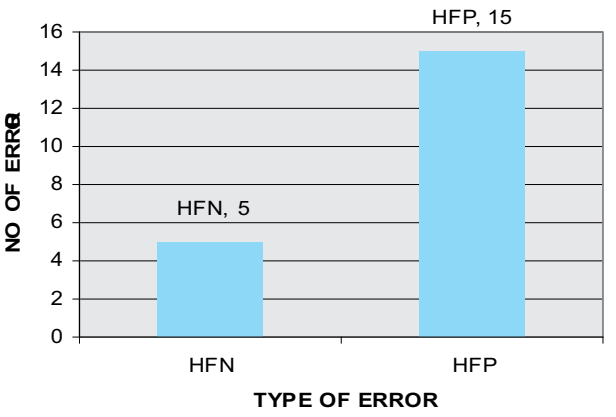

Figure-2. Types of error in blinded rechecking

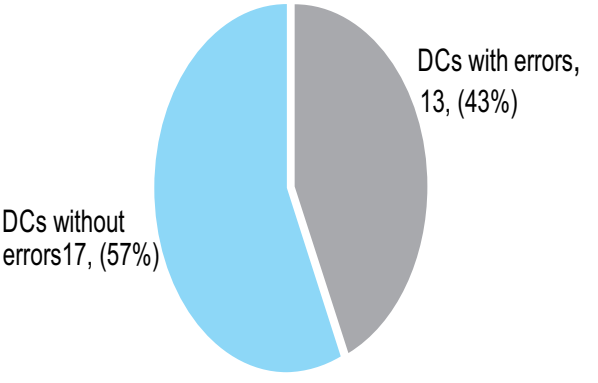

Figure-1. Distribution of diagnostic centers (DCs) regarding results of blinded rechecking

Status of Training	Panel results and blinded rechecking		Total
	80% -100% panel results No error in blinded rechecking	40% - 60% panel results Error in blinded rechecking	
Trained n= 25	17	8	25
Untrained n=5	0	5	5
Total	17	13	30

Table-I. Result of training of AFB microscopy on panel results and blinded rechecking

DISCUSSION

TB is highly prevalent in Pakistan but is considered one of the neglected areas in our health sector. 2001 National health policy of Government of Pakistan endorses the WHO recommended DOTS strategy for TB control.[9]

The targets set by Government of Pakistan and WHO for National TB Control Program is to achieve 70% case detection rate and 85% cure rate which will be impossible without effective implementation of sputum smear microscopy.[10,11]

This study was conducted to assess the proficiency of lab workers at TB Diagnostic centers of Lahore district. In blinded rechecking, major errors were found in 13 (43%) diagnostic centers comprising 15 (70%) errors of High false positive-HFP in 10 diagnostic centers and 5 (25%) errors of High False Negative-HFN in 3 diagnostic centers. Identification of major errors in 13 (43%) DCs mean very limited technical capacity of lab staff. In a similar study, blinded Rechecking of 36 labs in Mongolia revealed 6 labs (16.7%) with poor performance namely reporting of HFN and HFP results etc.[12] Similarly major errors of reporting were seen in Mexico in 9 (65%) and 29 (89%) diagnostic centers in the two states respectively.[13] These studies highlight the need of quality assurance of peripheral labs as AFB microscopy reporting requires the higher level of personal skills in this era of high technology. Reporting even one major error is not acceptable. Reporting one false positive (FP) means that one person being labeled as a TB case and waste of resources. False negative (FN) result is considered more dangerous and it means one sputum smear positive (ss+) patient being ignored which pose a public health threat to the community; a rich source of TB transmission as One SS+ case can infect 10–15 new people in one year if left unattended.[14]

Also in this study correlation was observed between training and errors in blinded rechecking. Out of 25 trained lab staff, 17 (68%) were having no error in blinded rechecking. In comparison all (100%) untrained workers had error in blinded rechecking; showing a highly significant difference between the performance of trained and the untrained workers. With regards to panel testing, in our study it was seen that out of 30 lab workers, only 4 (13%) reported all (100%) the slides correctly, 13 (43%) reported 80% slides correctly. Similarly 5 (17%) lab worker reported 60% slides correctly while 8 (27%) lab workers had only 40% correct results. Indicating proficiency gap, this needs to be addressed. Performance of lab workers in the study area is poor as compared with the proficiency testing in other studies. In a similar study in Mexico, 587 labs were inspected where 604 microscopists were given 10 slides test. Results of the lab workers were as under; 54% scored more than 80%, 33% scored 60-80%, and 13% scored less than 60%. Subsequently training was given to 216 lab workers scoring less than 80%, and their average score improved significantly (from 65% -90%; p value < .0001).[13] Similarly in another study in Mexico it was concluded that regular quality assessment and training improve the diagnostic performance.[15] This study confirms the finding of other studies that training has direct impact on the performance and competencies of lab workers.

Quality Assurance shows contribution in improving the accuracy of the results. FP declined from 3.6% to 1.8% while FN declined from 3.5% to 1.3% respectively in a study in Nepal.[16] This study through blinded rechecking and studying

the effect of training of staff aims to bridge the gap between the standard recommendations and ground practices of TB diagnostic centers.

CONCLUSIONS

- Untrained Lab staff should be immediately undergoing standardized training for sputum smear microscopy.
- Trained staff with compromised competencies should receive refresher training to enhance their proficiency skills.
- Regular on site visit to problematic centers by senior lab supervisor and reference lab staff should be scheduled i.e., operationalizing the NTP recommended procedure.
- Feedback of blinded rechecking should be given to the peripheral workers as well as to other stake holders. Regularity and effectiveness of intra-district meetings should be ensured.

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AUTHORSHIP AND CONTRIBUTION DECLARATION

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3	Saim Maqsood	Helping in research	
4	Maryam Ayub	Paper writing	
5	Ayub Ali	Editing	