ORIGINAL ARTICLE

Critical Appraisal of Tuberculosis Dots Diagnostic Centers in Lahore District

SAIMA AYUB, ANJUM ZUBAIR BHUTTA, ZARFISHAN TAHIR

ABSTRACT

In DOTS strategy sputum smear microscopy in diagnostic centre's is the main tool for diagnosis of the tuberculosis, unfortunately it is the most neglected component of the program so appraisal of the diagnostic centers working under DOTS program in Lahore district regarding the physical infrastructure, quality and quantity of lab supplies, human resource was done to identify their gaps and weaknesses. The study was conducted in Lahore district from October 2007 to December 2007. It was cross a sectional descriptive study, for which data was collected with the help of check lists. There are 40 diagnostic centers in the Lahore district out of which 30 (75%) centers were functional. All the functional diagnostic centers did not have facilities according to WHO standards. Separate area for TB work was available in only 8 (26%) DCs. Safety standards were grossly deficient, adequate ventilation was present in 18 (60%) centers, disinfectant available in 9 (30%) centers and only 8 (26%) workers wore lab coats. Waste disposal practices were another neglected area found in the study: 28 (93%) centers were disposing the waste without prior disinfection while incineration of sputum containers was being done in only 4 (13%) DCs. It is concluded that non-functional centers should be made functional and deficiencies at the functional diagnostic centers should be rectified.

Key words: DOTS, Critical Appraisal, Diagnostic center

INTRODUCTION

WHO declared Tuberculosis a global emergency in April 1993. Tuberculosis is the leading infectious cause of death.[1] According to WHO prediction, without radical changes in our approach to Tuberculosis, 200 million people alive today will eventually develop this disease[2]. Tuberculosis is on WHO surveillance list. In spite of available modern health technology for the prevention, control and treatment of Tuberculosis, the disease remains a major public health problem. Tuberculosis is an insidious disease. By the time the classical symptoms of cough, fever, expectoration and loss of weight are evident, the person has already infected many people. It is therefore necessary to detect the cases early[3]. The essential services needed to control TB, based on diagnosis and treatment of infectious cases and incorporating the essential management tool, were developed and packaged as DOTS in early 1990s. DOTS have been promoted as a global strategy since the mid 1990s. In Peru incidence dropped by approximately 6% per year over the past decade. Mortality has also fallen in China and 30,000 deaths have been avoided each year by implementing DOTS[4,5]. Pakistan ranks 8th among the countries with highest disease burden and contribute 44% of the disease burden in EMRO region[4.] Around 250,000 new TB cases occur in Pakistan each year. Many TB patients die and also are a cause of spreading the disease, because they are not detected, detected late, inappropriately treated or fail to complete treatment. Low case detection and poor management of TB patients lead to many millions of people in Pakistan becoming infected with TB and some with MDR TB[6].

Tuberculosis was declared a national emergency in 2001 through the Islamabad declaration. Out of approximately 160 million people, 1.6 million are suffering from Tuberculosis. The delay in diagnosis and inability to cure a high proportion of smear positive cases are the main reasons of the increased risk of infection, high death rate and MDR cases in Pakistan. Current DOTS treatment success (New ss+ cases) in Pakistan is around 75%[10]. WHO target is 85% or more cure rate for effective control of Tuberculosis in Pakistan.[7] The cornerstone of the diagnosis of tuberculosis is direct microscopic examination of appropriately stained sputum specimens for Tubercle bacilli[8]. The technique is simple, inexpensive and detects those cases of tuberculosis which are infectious i.e. those responsible for maintaining the tuberculosis epidemic. Currently no other diagnostic tool is available which could be implemented affordably especially in developing low income countries. In many countries with the high prevalence of tuberculosis, direct sputum smear microscopy

Department of Bacteriology, Institute of Public Health, Lahore
Correspondence to: Saima Ayub, Senior Demonstrator,

remains the most effective tool.[9] The World Health Organization (WHO) strategy for tuberculosis control (DOTS) relies on a network of laboratories that provide acid fast bacilli (AFB) sputum smear microscopy. If the laboratory diagnosis is unreliable, all other activities will be affected. Microscopic errors are likely to result in failure to detect persons with infectious Tuberculosis who will then continue to spread infection in the community, or unnecessary treatment for "Non cases". Sputum smear-positive cases are the focus of DOTS program because they are the principal sources of infection to others. Patients with smear-positive disease typically suffer higher rates of morbidity and mortality than smear-negative patients. The key observation in relation to the WHO target is that the DOTS case detection increased from 27% in 2003 to 50% in 2008 – an additional 350,000 new smear-positive cases – the largest annual increase so far reported[5].

The diagnostic center is the rural health centre or a hospital where the diagnosis of TB is made. It is also the health facility where periodic sputum examination and clinical reviews take place[6]. According to NTP protocol, all the RHCs, and selected BHUs have been declared as diagnostic centers for DOTS. In many countries with the high prevalence of tuberculosis, direct sputum smear microscopy remains the most effective tool[9]. The World Health Organization (WHO) strategy for tuberculosis control (DOTS) relies on a network of laboratories that provide acid fast bacilli (AFB) sputum smear microscopy. The establishment of a broad network of well functioning peripheral laboratories within the context of the health system and readily accessible to the population is a high priority for any tuberculosis control program[10,11]. If the laboratory diagnosis is unreliable, all other activities will be affected. It is generally recommended that one microscopy centre should be developed for each unit of population having 50,000–150,000 inhabitants, according to the incidence of tuberculosis and the geographic distribution of the population. It should include the following distinct sections – a bench space or a table for incoming specimen, one well-lit working bench for smear preparation, a staining sink with running water for washing hands, a bench area for microscopy reading directly below a window, a bench area or a table for the laboratory register books and slide storage space[12,20].

It is necessary to have well equipped laboratory with services that reach the entire population. Such laboratory services should be provided within the context of the already existing health service structure, and the duties of sputum smear technicians already present within the health services[8,10]. There is no need for specialized personnel for performance of sputum smear microscopy. Every general laboratory technician within the health services should have the skills to perform the diagnostic procedure for Tuberculosis. So the critical appraisal of diagnostic center would help in finding out the problems faced in microscopy at the grass root level. This analysis would also be helpful for policy makers in strengthening the diagnostic centers and making them more reliable and efficient. This will ultimately assist in achieving WHO target of case detection rate (CDR) i.e. 70% which is currently only 50%[13].

OBJECTIVES

1. To asses the physical infrastructure of the diagnostic centers.
2. To asses the quality and quantity of supplies (chemicals, stains and microscopes).
3. To identify gaps and weaknesses of diagnostic centers

MATERIAL AND METHODS

It was a Cross sectional descriptive study. Lahore is the provincial capital of Punjab and has both urban and rural areas with a total of 40 Diagnostic centers. All the 40 diagnostic centers (100%) of TB DOTS of Lahore district were included in the study for finding out the study variables namely physical infrastructure and quality and quantity of supplies. For data collection checklists of "on site evaluation" were used which included work place and supplies. During the on site evaluation, physical infrastructure, quality and quantity of supplies and actual working conditions of the diagnostic centers was assessed. During these visits, it was also checked if the diagnostic centers were following the standards set by NTP. The evaluation was broad in scope covering administrative and technical components. 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

There are 40 diagnostic centers in Lahore district out of which 30 (75%) were functional (figure 1).In 10 non-functional diagnostic centers, doctors were not present in 2 (20%), lab workers were not present in 6(60%) and DOTS was not implemented in 2 (20%) diagnostic centers (Table 1). Amongst 30 functional DCs, 8(26%) had separate area for TB work, in 20 (66%) labs were clean and tidy,29(96%) had water supply, all(100%) had electric supply while in

21(71%) there were separate tables for receiving samples, smear making and microscopy (Table 2). Regarding the presence of standard operating procedures in Diagnostic Centers (table 3), lab manual was present in 21 (70%) DCs and staining charts were displayed in 11 (37%) DCs. In 14 (47%) DCs reagent bottles were labeled and record of positive and negative control slides was not available in any (0%) DCs. Regarding lab safety, out of 30 lab coat was worn by lab staff in 8 (26%) DCs, there was proper ventilation in 18 (60%), disinfectant was available in 9 (30%) while hand washing facility and sand alcohol jar was present in 9 (30%) and 5 (16%) of DCs respectively (Table 4). Table 5 which is about Waste disposal shows that waste containers with lid were present only in 5 (16%) DCs, while staff of 4 (13%) DCs was throwing the infectious TB waste along with general waste of the center, only 2 (7%)were boiling the sputum containers before disposal, 8 (26%) were burning them directly without decontaminating them, 19 (63%) were burying them, only 4 (13%) were sending their waste for incineration. Regarding availability of lab items, functional microscopes were present in 26(87%) DCs, consumable items were available in 20 (66%) while non consumable items were present in 18 (60%) of the DCs. Stains were present in all DCs (Table 6).

Table 1: Factors Responsible for non-functional diagnostic centre (*n=10)*

Description	No.	%
Doctor was not present	2	20.0
Lab worker was not present	6	60.0
DOTS program not implemented	2	20.0

Table 2: Distribution of diagnostic centers based upon Infrastructure Facilities (n=30)

Description	Yes	%	No	%
Separate area for TB work	8	26.0	22	74.0
Cleanliness/tidiness	20	66.0	10	34.0
Water supply	29	96.0	1	4.0
Gas supply	19	63.0	11	37.0
Power supply	30	100.0	-	-
Separate tables for specimen reception, smear making, and microscopy	21	70.0	9	30.0

Table 3: Distribution of Diagnostic Centers having proper Standard Operating Procedure (n= 30)

Description	Yes	%	No	%
Lab manual present	21	70.0	9	30.0
Charts displayed	11	37.0	19	63.0
All reagent bottles labeled	14	47.0	16	53.0
Record of positive and negative control slides available	-	-	30	100.0

Table 4: Lab Safety measures in Diagnostic Centre (n =30

Description	Yes	%	No	%
Lab coat worn	8	26.0	22	74.0
Ventilation of lab	18	60.0	12	40.0
Availability of disinfectant	9	30.0	21	70.0
Facility for hand washing	21	70.0	9	30.0
Sand alcohol jar present	5	16.0	25	84.0

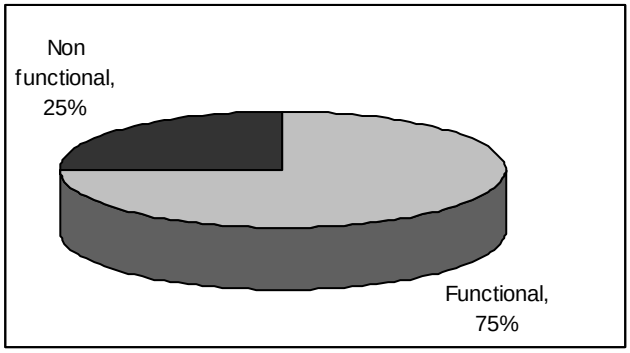
Table 5: Distribution of diagnostic centers regarding waste disposal (n =30)

Description	Yes	%	No	%
Waste container with lid	5	16.0	25	84.0
Disposal with general waste	4	13.0	26	87.0
Boiling of sputum container before disposal	2	7.0	28	93.0
Direct burning of sputum container	8	26.0	22	74.0
Direct burial of sputum container	19	63.0	11	37.0
Incineration of sputum container	4	13.0	26	87.0

Table 6: Availability of lab items (n =30)

Laboratory item	Yes	%	No	%
Functional Microscope	26	87.0	4	13.0
Consumables items	20	66.0	10	34.0
Non consumables items	18	60.0	12	40.0

Fig.1: Distribution of diagnostic centers according to status of working.



DISCUSSION

Sputum smear microscopy is the gold standard for TB diagnosis according to the DOTS strategy and is the mainstay for diagnosis, monitoring the progress and outcome of the treatment. Diagnostic Centre is a health facility where sputum smear microscopy and other laboratory tests are performed and forms the basic unit of the laboratory network National TB Control Program. This study was conducted for the purpose of situation analysis of the diagnostic centers (DCs) .Sputum microscopy and reporting are two important components of DOTS program and without their effective implementation on ground, it will be rather impossible for National TB Control Program to

achieve 70% case detection rate and 85 % cure rate, the targets set by Government of Pakistan and WHO.[9,14] There are 40 diagnostic centers in Lahore district which fulfill the criteria of WHO protocol i.e. one diagnostic centre for a population of 50,000–150,000. During the study it was found that 10 (25%) out of 40 diagnostic centers were non-functional, 2 out of these 10 DCs were in teaching hospitals and were not following DOTS strategy ,in 2 DCs no doctor was posted implying no OPD activities while in remaining 6 DCs the posts of lab workers were lying vacant.

Appropriately equipped and safe laboratories, trained staff, standardized operating procedures and assuring the observation of these standards are pre-requisites for any tuberculosis laboratory services.[15] As detailed arrangements of the microscopy laboratory vary greatly depending on local conditions, it is difficult to generalize about the design of such laboratories. Similarly TB diagnostic services have been integrated into existing general laboratory diagnostic services in many countries. WHO has set a standard for an ideal laboratory. In our study only 26% diagnostic centers fulfill the required criteria. Regarding the standard operating procedures (SOPs), it was found that lab manuals were present in majority of DCs. This was because of good commitment National Program in printing of SOPs. Reagent labeling is essential to avoid mix up of reagents and to keep a check on expiry. In our study in 47% DCs the reagent bottles were labeled and labs were clean and tidy in 66% DCs, while in a report of WHO Monitoring Mission to Korea, reagent bottles were labeled, SOPs were present and all the labs visited were neat and clean.[16] This difference is because the staff in our lab are not exclusive for TB work rather they are very busy doing all type of lab tests so they do not give due importance to SOPs and do not have time to keep the lab neat and tidy. According to WHO/NTP the stains must be stored in properly labeled amber bottles away from sunlight. As continuous exposure to sunlight decreases the staining efficacy and expired stains are major cause of false negative results.

Regarding the safety practices, use of lab coats, availability of disinfectant and sand alcohol jar are the minimum essentials and so the observed practices were unacceptable. Advantage of biosafety in the lab is for control of infection. Good ventilation is necessary for the protection of lab staff from airborne infectious droplet nuclei. The best way to ensure ventilation is by use of windows and doors ensuring that expelled air flows to the outside environment. Staff should wear personal protective clothing such as lab coats for their own safety. They must wash their hands, a key factor for infection control. Sand alcohol jar must be used during smearing for the sterilization of wire loop other wise there will be formation of infected aerosol if wire loop is otherwise sterilize on flame. [11] In our study adequate safety procedures were adopted only in 3/4th DCs. In Uganda, it was observed in a study, that lab coats were not worn in 48% of labs. Disinfectant was not available in 31% of labs, and there were no sand alcohol jar in 96% of labs. The technician does not wash hands in 17% of lab[17]. In both the situations, country economic situation was similar while a training intervention was done in Uganda for improvement of labs functioning[18].

Although waste disposal is a crucial component for any laboratory but its importance is enhanced in a lab performing AFB microscopy due to the infectivity and resistance of the organism. Recommended practices include waste bins with lids and safe disposal of sputum containers after decontamination and not with routine waste.[19] According to NTP guidelines no infected material should leave the lab before it is properly disinfected. In a peripheral lab the container, lids and applicator are either placed in a waste receptacle with 5% phenol or 0.5% sodium hypochlorite solution, boiled in a waste drum with lid or Autoclaved. They can then be disposed off by burning or burying in an open pit[11]. In a study in Uganda, covered waste bins were not present in 48% of DCs and there was no decontamination of sputum containers in 60% of DCs[18] in comparison with observations in our study in which 26 (87%) diagnostic centers did not have waste bin with lid and most of the DCs were not disinfecting the sputum containers before disposal[17]. It is very important to disinfectant the container as due to direct burning there is aerosol formation and this will infect the whole area where the burning is done which is dangerous for the community. Main lab supplies of a DC consist of microscope, consumable and non-consumable items. According to WHO/NTP protocol each DC should have at least 1 binocular functional microscope along with other supplies for AFB microscopy[20].Shortage of supplies was mainly responsible for non functioning of DCs.

CONCLUSIONS

On site evaluation of the lab, supplies and equipment comprises the most important part of the critical appraisal of DCs .The purpose is to provide all supplies and functional microscope to improve the overall quality of smear microscopy. Poor performance should always be investigated to identify the problems and rectify them. Non-functional centers should either be made functional or merger with nearby functional centers considered. Deficiencies at

functional DCs should be rectified with suitable improvements in infrastructure. Regular onsite visits to problematic centers by reference lab staff should be scheduled according to NTP protocol

REFERENCES

1. Kochi A. TB Control. Is DOTS the Health Break Therapy of the 1990s. world Health Forum 1997; 18: 225-47
2. World Health Organization. The World Health Report 1998. Geneva; 1998.
3. Maxcy – Rosenau - Last Public Health and Preventive Medicine. 14th ed. Prentice Hall Internation Inc. USA; 1998: 159-62.
4. Dollen Raviglion P.J, Kochi A Global TB incidence and mortality during 1992-2000. Bull World Health Organ 2001; 77: 213-220
5. World Health Organization/ progress report on the global plan to stop Tuberculosis: stop TB partnership. Geneva; 2004.
6. World Health Organization. The World Health Report 2001: Global Tuberculosis Control. Geneva; 2001.
7. World Health Organization. Guidelines for national programmes. 3rd ed. Geneva; 2003.
8. World Health Organization. Laboratory Services in Tuberculosis Control Part II. Microscopy. Geneva, Switzerland; 1998: 5-8
9. WHO report 2002. Global Tuberculosis Control: Surveillance, Planning, Financing. Geneva; 2002.
10. World Health Organization. Laboratory Services in Tuberculosis Control Part I: Organization and management. Geneva, Switzerland; 1998.
11. World Health Organization. Laboratory biosafety manual. 3rd ed. Geneva; 2004
12. Cheesbrough M, ed. Medical laboratory manual for tropical countries, Part2. Cambridge: Cambridge University Press; 2000: 73.
13. WHO report 2006, global Tuberculosis control: Surveillance, Planning, Financing. Geneva, 2006: 96.
14. What is DOTS? A Guide to Understanding the WHO-Recommended TB Control Strategy known as DOTS. WHO Report 1999. Geneva. Report No. WHO/CDS/CPC/TB/99.270.
15. Association of Public Health Laboratories. External quality assessment for AFB smears microscopy. Washington DC; 2003.
16. DOTS implementation in DPR Korea. Report of Monitoring Mission. Delhi: WHO; 2005. Report No. : SEA-TB-281.
17. World Health Organization. Laboratory Services in Tuberculosis Control Part III. Culture. Geneva, Switzerland; 1998: 9-11
18. Buzingo T. Systeatic re-staining of sputum smears for quality control is useful in Burundi. Int J Tuberc Lung Dis 2003; 7: 439-44.
19. International Union against Tuberculosis and Lung Disease. Management of Tuberculosis. A guide for low income countries. 5th ed. Paris; 2000: 31-5.
20. Kim SJ, Laszlo A, Aziz M. Tuberculosis laboratory assessment tool. WHO 2003.