

# Tuberculosis Control in Pakistan: Critical Analysis of its Implementation

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## Introduction

Tuberculosis (TB) constitutes a major public health challenge. Due to the emergence of HIV, increased migration and the deterioration of the health services in many countries, the incidence has risen so drastically in recent years, that TB was declared a global emergency by WHO in 1993<sup>1</sup>. Without increased investment in intervention strategies, the global tuberculosis situation is expected to worsen in the near future<sup>2</sup>.

## Epidemiology of TB in Pakistan

There is little reliable epidemiological data available for Pakistan, although TB is considered to be a major cause of ill health<sup>3</sup>. The annual incidence rate of infectious TB cases is estimated to be between 85-100/100,000 persons. Annually around 120,000 new TB cases are being added to the existing number of infectious individuals. Some areas in the country have much higher figures, such as Northern Pakistan where a prevalence figure of 554/100,000 cases was observed<sup>4</sup>.

As in other developing countries, young age groups are affected the most. Male patients outnumber females in most age groups, except in the adolescents. Based on Burden of Disease estimates, TB represents 5% of the total DALYs (disability adjusted life years): which indicates that the burden of tuberculosis in Pakistan is substantially higher than the world average of 3%<sup>5</sup>.

## Historical Review of TB control activities in Pakistan

The first survey was carried out in 1962. The results triggered a collaborative effort between MoH, WHO and UNICEF for a twenty year TB control programme, that focussed on establishing specialised TB centres and special TB wards at the DHQ Hospitals. In 1985 UNICEF withdrew its financial support. WHO declared TB a global emergency in 1993 and the GoP endorsed the DOTS strategy. In 1994 the MoH, in collaboration with WHO, revised the TB control policy. National policy and technical guidelines were drafted: however, to date there is no draft yet for operational guidelines. In 1995 the MoH decided on the location of 5 DOTS pilot sites, but only 1 site became operational. A highly centralised and vertical five-year development plan was prepared by the Federal NTP. Since the Provinces expressed certain reservations with regard to the plan, it was not approved. In 1996 the Directorate for TB Control of Pakistan was abolished and the MS of the TB Centre in Rawalpindi made responsible for National TB Control programme, but without any additional support. In 1998 Pakistan was declared I of the 16 countries without an appropriate NTP. Recently it was decided that each province would be responsible to plan and manage its own NTP under Federal NTP guidelines. Funding for the plans will be provided through SAPP II.

## Critical Analysis of the NTP

Given the magnitude of the TB problem in Pakistan as well as the size of the country, a vertical TB control programme is financially prohibitive and difficult to sustain. Integration of the TB control programme in PHC has recently been opted for, as a solution to its technical and managerial deficiencies. Hereto, a network of laboratories needs to be created as well as a system for ensuring quality of sputum smear microscopy put in place.

## The Objectives of the NTP

## **Policy**

### **The two major objectives are:**

- a) To increase the cure rate of positive cases to at least 85%; sputum smear
- b) To increase the detection of new cases to 70%, once the first objective is reached.

### **Federal role in the NTP**

Provision of a policy framework, technical assistance, supervision, surveillance, co-ordination. research and development and advocacy.

### **Provincial role in the NTP**

Planning, accessing funds, management of programme, implementation of E)OTS through integration with the P1-IC.

### **Practice**

The NTP has been unable to come close to, let alone achieve, its ambitious objectives. TB control activities in Pakistan have suffered during the last five years because of the dilemma of either managing the programme from the federal level or handing it over to the provinces. A decision in favour of the latter option was taken as late as mid-1998. Under this arrangement the roles of the provinces and the federal government have been well defined. The provinces have been given the responsibility of independently developing and implementing their own TB control programmes. TB control activities suffered in the past as there were no funds earmarked for TB control in the provinces. District managers were expected to support TB control activities from their already insufficient regular budgets. For the fiscal year 1999-2000 the federal government has indicated support and earmarked funds for all the provinces as well as for the federal component. Health sector reform is a major driving force for improving the health systems throughout the world<sup>6</sup>. Proponents of this reform believe services to be more cost-effective and sustainable if they are integrated into and delivered through a comprehensive district health care system.

Programmatic reforms in the health sector of Pakistan have over the years improved public health services through better targeting of populations, funds and services. The TB Control Programme is one example. Recently there has been an effort on the part of the provincial health departments to introduce structural and management reforms in the health sector in order to improve the efficiency of service delivery and resources development.

Interest in the control of tuberculosis has been further renewed through a recent policy initiative to strengthen PHC services through an integrated approach. The Social Action Programme, with multi-donors' support, has also pushed TB high on the agenda, and the programme priorities of Provincial Health Departments have been redefined.

## **Screening and Diagnosis**

### **Policy**

According to the NTP guidelines, detection of pulmonary TB should be based on sputum examination<sup>7</sup>. From TB suspects at least 3 specimens should be collected and examined.

Criteria for "AFB caseness" consist of 2 positive smears OR one AFB+ sputum as well as radiographic abnormalities consistent with active pulmonary tuberculosis. OR if determined by a competent medical officer.

The diagnosis of a "Smear-Negative" TB case is made if the following 3 criteria are met: At least 3 specimen AFB- sputum by microscopy

- Radiographic abnormalities consistent with active tuberculosis
- Clinical evidence substantiated by a competent medical officer.

### **Practice**

In Pakistan TB detection and diagnosis is generally based on X-ray, clinical impression and blood examination rather than on sputum examination. Some clinicians rely on Mantoux results, although tuberculin is rarely available.

The network of laboratories able to correctly carry out sputum examinations, is inadequately developed with virtually non-existent supervision. Consequently many laboratory results are not reliable. These unreliable test outcomes weaken the trust of the clinicians in the laboratory results and strengthen their belief in clinical impression. ESR and/or X-ray as diagnostic tools.

Many centres start TB treatment even when no sputum is available: in the Rawalpindi study<sup>8</sup> no sputum was available for 6.2% of the patients. In Delhi, India<sup>9</sup> it was found that for only 12% of the TB suspects, a sputum examination was advised.

In practice the number of diagnostic AFB exams is limited to two. A recent study has shown the sensitivity of 2 AFB exams to be 93% of that of 3 AFB exams<sup>10</sup>. PCR (Polymerase chain reaction), although more sensitive and specific than smear microscopy, is prohibitively expensive<sup>11</sup>, and is not routinely used in Pakistan. As a routine exam, the ELISA test for detecting tubercular antigen in sputum has not yet been implemented in the country.

### **Contact Tracing Policy**

Bacteriological examination of all the contacts with a smear positive index case. Especially children and young adults should undergo 3 sputum examinations.

### **Practice**

In Pakistan only some specialised centres routinely perform contact tracing, although not appropriately. Since the NTP guidelines do not detail the mechanisms of contact tracing; this is an area that needs attention, especially for operational guideline preparation.

### **Treatment Regimens**

#### **Policy**

The NTP proposes short course chemotherapy for all sputum positive cases for 8 months duration. The guidelines distinguish 3 main categories of patients:

- Category I patients are new AFB smear positive cases;

Category II refers to smear positive re-treatment and failures after a full short chemotherapy course;

Category III refers to sputum smear-negative and extra-pulmonary cases and to children who are unable to produce sputum.

The recommended treatment strategies for these three categories are described in

**Table. National TB treatment strategy.**

Category of patients	Treatment	
	Intensive phase	Continuation phase
I	2HRZE (or 2HRZS)	6HT (or 6HE)
II	2HRZES	1HRZE+5HRT
III	2HRZ	6HT (or 6HE)

H: Isoniazid; R: Rifampicin; E: Ethambutol; S: Streptomycin; Z: Pyrazinamide; T: Thiacetasonc

NB: The figure in front of the treatment schedule refers to the number of months the drug is given.

Table. NTP guidelines recommend daily dosages according to weight.

### **Practice**

General practitioners and specialists have a poor awareness of the WHO guidelines<sup>12,13</sup> and do not adhere fully to the national treatment guidelines. Almost all treatment centres are using strengths and combinations of drugs that differ from the accepted guidelines.

This situation is not unique to Pakistan. Unsatisfactory practices of private care providers have also been observed in India<sup>14</sup>. In Delhi 102 different regimens were being reported, 51% of the patients were over-treated and only 20% of the care providers did emphasise the importance of regular treatment.

### **Follow up of Patients**

#### **Policy**

Patients should be monitored at regular intervals through:

#### **Sputum smear examination**

Regularity of drug intake, to be monitored by DOT

#### **Prompt recovery of defaulters**

Sputum has to be examined at 2,5 and 8 months after the start of treatment. For monitoring purposes, a single sputum specimen smear examination is sufficient. If the sputum results of a sputum smear positive patient are negative at months 5 and 8, he/she should be discharged from treatment after completion of the treatment course. If the sputum result is positive at 5th or 8th month. then the treatment must be changed to sputum smear positive retreatment regimen.

No post-treatment follow-up is necessary for patients who have successfully completed their treatment. Given that Rifampicin is part of the intensive phase treatment scheme, careful supervision is necessary and no Rifampicin containing regimens should be given to patients who are taking the drugs at home without supervision. When outpatients fail to attend more than two consecutive follow-up appointments during the intensive phase, they should be traced within a week of missing their second appointment. This means that a visit should be paid to the home of a TB patient who did not attend the scheduled appointment for drug supply.

### **Practice**

In Pakistan low treatment adherence prevails. In the sixties Sloan and Sloan observed dropout rates of 66% in Sindh<sup>15</sup>, similar rates were found in the recent Rawalpindi cohort study<sup>8</sup>. A characteristic of case holding in Pakistan, is the important very early defaulting. Several studies have shown behavioural factors<sup>16</sup>, including social stigma<sup>17</sup>, to contribute to non-adherence to treatment. Research has shown irregularity of attendance during the initial phase to be a major determinant for treatment adherence not only in the initial phase, but also in the continuation phase<sup>8</sup>. Incorporating DOT in the initial phase can thus have an important impact on early, as well as late defaulting. So far Pakistan has only launched a few pilot DOTS projects in selected districts<sup>18</sup>, but the DOT strategy needs far greater support than it has received thus far. Some centres hospitalise patients during the initial 2 months of treatment, to guarantee very close DOT supervision.

No firm data is available on defaulter tracing mechanism in Pakistan, but it is strongly suspected to be rather deficient. The objective is to bring the patient back to regular treatment in order to cure the disease, avoid development of resistance, and avoid spreading the disease in the community.

### **Drug Resistance and Re-Treatment**

#### **Policy**

Drug resistance is one of the consequences of low adherence to treatment. Sputum positive patients who have previously taken anti-tuberculosis drugs for 1 month or more must be suspected of discharging tubercle bacilli resistant to INH and/or other drugs. Such patients must be started on re-treatment regimen (2 SHRZFJ I HRZE/5 HRE).

### **Practice**

In Karachi resistance rates to the four first line anti-TB drugs were found to be 27% to INH, 15% to Ethambutol, 11% to Rifampicin and 13% to Streptomycin; MDR (multi drug resistance) was 8%<sup>19</sup>. The guidelines for re-treatment of resistant TB cases are based on WHO recommendations rather than on local studies.

### **Involvement of Private Practitioners**

#### **Policy**

There is no explicit policy for involvement of private practitioners in the treatment and follow-up of TB patients.

#### **Practice**

tightly percent of the TB patients consult a private practitioner first<sup>20</sup>; these findings have been confirmed in the PMRC health seeking behaviour study. I Hassan has found an even higher figure of 96%. Marsh has demonstrated poor performance of some private practitioners in screening, diagnosing, treating and monitoring their TB patients<sup>20</sup>. Ekbal<sup>21</sup> has discussed the main errors in drug prescribing practices as:

Starting with a single drug, adding a single drug to a failing regimen, inappropriate prescription, ignoring DOTS, extensive prescription of combined anti-TB drugs and insufficient instructions to illiterate patients.

The fact that most TB patients first contact a private practitioner has been revealed by several surveys. In spite of this, official policies are directed towards detection, treatment and follow-up of TB patients at public sector health facilities only. Public sector managers should be more innovative and develop public - private collaboration. One way could be to train GPs in opportune diagnosis, treatment and follow-up of TB patients and encourage them to refer these patients to the laboratories of THQ hospitals for sputum examination and registration.

### **Integration of TB control into PHC services**

#### **Policy**

The official policy is to integrate TB control services into the PHC services. A network of laboratories will be established, i in each REIC and THQ hospital. Sputum collection and smear fixation will be done at BHU level, once personnel have been adequately trained. Human and material resources will be integrated into the PHC. NTP plans to ensure a continuous drug supply by establishing a system for national procurement, storage, and delivery and monitoring of anti-TB drugs. Continuous supervision will enable prompt detection of deficiencies in implementation, motivation and skills of staff.

#### **Practice**

Pakistan has a relatively well-developed health care infrastructure. The centres have, in theory, sufficient manpower: a recent World Bank report<sup>6</sup> even speaks of overstaffing, mainly of general practitioners. But many rural areas lack female doctors, which limits the access of female patients to care. Contrary to NTP mandate, to date only sporadic training sessions for staff of public services have been held. There is limited involvement of the THQH in TB control activities and no involvement of the BHUs in case detection or follow-up.

Generally the laboratories at the RHC and THQH do not function due to either failure of necessary reagents, or insufficient training of laboratory technicians. Most of the time, however, the reason for the poor functioning of the laboratory is the lack of requests for sputum examination by the medical practitioners.

Many RHC and THQH have no regular TB drug supply, or the stock consists of a few selected drugs only. The danger is that the patients do not buy the other drugs and consequently resistance develops. Visits to several first and second line centres in Pakistan have shown that the drug supply is very irregular, partial and insufficient.

Regular supervision of the TB program activities is one of the weakest elements of the system. The concept of supervision as continuous education has not been introduced yet. There is normally no back

referral of diagnosed TB cases by the specialised centres.

### **Reporting System**

The IUATLD (International Union Against Tuberculosis and Lung Disease) recognises a reliable information system to be the key element for the success of national TB control programmes<sup>22</sup>. Experience from several countries shows the data generated by the NTP to be more reliable and complete than that generated by HMIS (Health Management Information System) and more suitable for programme management. Following IUATLD both information systems should complement each other; therefore NTP should collect the relevant TB data and communicate it to the HMIS managers at all levels of the health system.

### **Policy**

The NTP has planned to introduce a standard system of registration and reporting, to monitor the results of treatment and to assess progress of the programme by means of ongoing quarterly analysis.

#### **A series of standardised records have been created:**

TB treatment card; TB appointment card; District TB register; TB laboratory register; TB smear examination request/report form; TB culture/sensitivity Test Request/Report form; TB referral/Transfer form; Quarterly order form for TB treatment supplies; Quarterly order form for TB laboratory supplies. The case finding, smear conversions at follow-up, and final results of treatment have to be reported to the NTP on a quarterly basis. A cohort analysis has to be carried out. A feedback mechanism will also be established.

### **Practice**

At present there is no uniform system of recording and reporting in the public sector. The HMIS has a different format from that suggested by NTP. In some areas where DOTS is implemented a dual system exists. The method of recording and collecting information differs from one centre to another and is generally not in accordance with WHO guidelines. Case definitions for pulmonary and extra pulmonary cases may differ and cohort analyses are computed differently as well. Data is as yet not being used for the planning and management of TB services. No reliable national data is available concerning TB case detection and TB case holding. The quality of the HMIS data is inferior to the recommended NTP recording, it is not standardised and generally not in accordance with WHO recommendations.

### **NGO's**

#### **Policy**

The NTP proposes to strengthen co-operation and co-ordination with NGO's<sup>23</sup>. The latter are expected to play a crucial role in enhancing patient education and community assistance.

#### **Practice**

The majority of NGOs are working in isolation, involved mainly in the treatment and drug provision. Some NGO's have not yet adopted the NTP Guidelines. Little effort has been undertaken to streamline the NGO's' efforts.

### **Role of Communities**

#### **Policy**

#### **Four main roles for the communities are envisioned:**

To encourage the TB suspects to promptly visit a health facility for assessment.

To support the diagnosed cases to complete treatment.

To improve general understanding of the disease and its prevention.

#### **Practice**

#### **To supervise treatment.**

The national policy makers perceive the community as a natural partner for public sector development. However, hardly any sustainable model has been designed and practised in the health sector and almost none for either reduction or control of TB. In pilot projects going on in Balochistan and NWFP provinces. LHWs are being used to implement the DOTS, with encouraging outcomes. However, to

fully realise the additional benefits obtained from community participation, the NTP may have to design some culturally appropriate, socially acceptable and sustainable partnerships between the people and the public health sector of this country.

### **Political Commitment**

A strong political commitment is essential for the success and sustainability of any TB control programme.

### **Practice**

The political commitment at the federal and provincial levels is rather weak, although interesting pilot projects are at present being undertaken in the provinces of Balochistan and NWFP.

### **Future Strategies and Recommendations**

The weaknesses and shortcomings at each level of the NTP need prompt political, technical and/or managerial solutions.

At the political level: TB should be given much greater importance, and commitment, as well as support and resources. The Federal NTP unit should be made fully operational.

At the technical level: All care providers working in both the public and private sectors should be updated on the NTP guidelines. District and Tehsil headquarter hospitals should be equipped to carry out reliable sputum exams. Laboratories should adhere to quality control principles. DOTS will have to be applied throughout the country, and lessons learned from patient counselling experiences should be incorporated in patient management. The communities should be involved in the DOTS scheme.

At the managerial level: The NTP has to be strengthened, and specific tasks for all levels (federal, provincial, district and community) have to be planned. The activities have to be implemented, monitored and assessed with clearly defined indicators. Following the lessons learned from neighbouring countries, private practitioners should be involved. The co-operation with NGO's has to be strengthened. The public should be much better informed, and the message that the disease is curable should be spread through all means of communication. There is a need for continuous laboratory supplies, as well as for a continuous drug supply system. There is a need for a drug resistance surveillance system. The personnel in charge of Tehsils and districts should be trained in data management and analysis, so that programme management will become more evidence based.

At the community level: Strategies to overcome the stigma attached to TB have to be developed.

At the individual care level: The continuity of the care has to be addressed in the context of the socio-economic constraints of the households and communities. Specific treatment should be given free of charge, and efficiency improved by reducing the number of visits to the least required, and by following up the patients as close to their homes as possible.

At the research level: Operational research is needed to find solutions for the constraints and to continuously optimise the programme output.

Behavioural research is needed to create awareness of the TB problem<sup>24</sup> and to contribute to its destigmatisation; as well as to develop a socially acceptable DOTS programme. Socio-economic research is needed to quantify the burden of disease, the cost of defaulting and the benefits of DOTS. Epidemiological research is needed to determine the magnitude and spread of the disease, and the drug resistance in order to analyse the risk-factors for the incidence of infection and disease, and to determine the nosocomial risk.

Therapeutical research is needed to find more cost-effective ways of treatment.

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