

TUBERCULOSIS CONTROL; WHERE DO WE STAND TODAY IN PAKISTAN

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Tuberculosis (TB) is a bacterial infection caused by the organisms belonging to Mycobacterium Tuberculosis complex and is spread by droplet infection¹. It is an ancient disease well known for the last 5000 years but still is infecting one third of the world population and is a major public health problem globally.

Robert Koch's discovery of causative organism of TB on 24th March 1882 brought to the forefront, a totally new era in the struggle against TB & inspired many facets of research in prevention, control and therapeutic aspects of the disease. Unfortunately there was no breakthrough in the treatment of TB for a long time to come. The only available mode of treatment in the pre chemotherapy era was isolation, providing good food and ventilation in a sanatorium.

Bacillus Calmette Guerin (BCG) vaccination as a preventive measure, was extensively used in most of the European countries in 1920s². Mass BCG vaccination took off on a large scale in Indian sub continent in early 50s. Despite its debatable impact on prevention of TB BCG is still mandatory for every new born in this country.

The development of anti-TB drugs was chequered and sporadic over a period of two decades starting from 1940s. Streptomycin and Para-Amino Salicylic Acid (PAS) were first

introduced in 40s followed by Thioacetazone and Isonicotinic Acid Hydrazide (INH) in 50s and later followed by Ethambutal, Pyrazinamide and Rifampicin. This gave a global impetus for treatment and control of TB.

Although drugs that can cure TB have been available for over half a century; however with nearly 1.7 million deaths from TB annually, the disease ranks 2nd only to HIV as a cause of death from infectious diseases³.

The estimates of the global burden of disease caused by TB in 2009 are 9.4 million incident cases, 14 million prevalent cases, 1.3 million deaths among HIV-negative people and 0.38 million deaths among HIV-positive people. Most cases were in the South-East Asia, African and Western Pacific regions (35%, 30% and 20%, respectively). An estimated 11–13% of incident cases were HIV-positive; the African Region accounted for approximately 80% of these cases⁴.

The annual number of new cases of TB has continued to grow all over the world reaching 9.4 million in 2009. 22 high burden countries account for 80% of total global TB which includes Pakistan. Although sub-Saharan Africa has the highest incidence rate, Bangladesh, China, India, Indonesia and Pakistan together account for half of the global TB burden⁵.

The crises of TB situation, forcing World Health Organization (WHO) to declare it as a global emergency in 1993, would not have existed, but for gross neglect of this disease over 2-3 decades prior to 1993^{6,7}. Public health interventions were derailed by false perception, that TB would be eliminated from industrialized countries and steadily decline with the advent of effective chemotherapeutic agents. But this did not happen as most of the developing countries had no strategy, no plan and few resources to combat TB during that period⁸. Pakistan was one of the victims of that neglect both at national and international level.

TB control has been high on the international public health agenda since 1993. Global targets for reduction in epidemiological

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burden of TB have been set for 2015 and 2050 within the context of Millennium Development Goals (MDGS) and by the Stop TB Partnership. The principal targets are that the incidence rate should be falling by 2015 (MDG 6, target 6C), that prevalence and death rates should be halved by 2015 compared with their level in 1990, and that TB should be eliminated as public health problem by 2050. Reaching these targets is the focus of national and international efforts in TB control and WHO has established a global Task Force on TB Impact Measurement to ensure the best possible evaluation of whether or not the targets are achieved⁹.

Worldwide, several initiatives have been taken to combat TB, one of the most important being the directly observed treatment, short course (DOTS) strategy. DOTS strategy is considered to be the best prospect for control of Tuberculosis. The DOTS strategy for TB control is based on the widespread use of simple technology and good management practices integrated into an existing network of health services. Its integration into existing services allows the DOTS strategy to reach a majority of the population in any country. DOTS strategy has been determined to be the most cost-effective strategy for TB control. DOTS is a methodology for making sure that every patient starting TB treatment gets the best chance of being cured. The patients take their medicines everyday under the direct observation of a healthcare worker or some other responsible person. The treatment course lasts from 6-8 months and includes therapy with the 1st line anti TB drugs; isoniazid, rifampicin, pyrazinamide, ethambutal and streptomycin. The success of the DOTS strategy on a national level depends on the implementation of a five-point package which consists of:

- Government commitment to a National Tuberculosis Programme (NTP).
- Case detection through case finding by sputum smear microscopy examination of TB suspects in general health services, with priority given to detecting infectious cases.
- Standardized short-course chemotherapy (SCC) for at least all smear-positive TB cases under proper case management conditions – health personnel or trained volunteer “directly observed treatment” (DOT) by watching patient ingest anti-TB drugs
- A regular, uninterrupted supply of all essential anti-TB drugs
- A monitoring system for programme supervision and evaluation.

The key elements in tuberculosis (TB) control are to cure the individual patient, interrupt transmission of TB to others and prevent the tubercle bacilli from becoming drug resistant.

Effective treatment of tuberculosis requires adherence to a minimum of 6-8 months treatment.

Incomplete treatment may result in excretion of bacteria that may also acquire drug resistance and cause increased morbidity and mortality.

Epidemiology of TB in Pakistan

Pakistan's present projected population is estimated to be over 180 million which spreads over an area of 852392 sq km. The population growth rate is around 2.5 %, life expectancy is about 63 years and the average literacy rate is 50 %. Per capita income is US \$ 492. Health expenditure (public sector) is 0.08 % while total health sector investment is 3.9 % of GDP.

Administratively Pakistan comprises of four provinces besides some Federally Administered Areas and the state of Azad Jammu and Kashmir. The country has a mixed society, which is predominantly Muslims. Urdu is the National language while multiple regional languages are spoken in the country; however, English is used for most official purposes. Each province/area is divided into districts, which are the basic administrative units.

There is little reliable epidemiological data available for Pakistan, although TB is considered to be a major cause of ill health¹⁰. According to the revised WHO estimates the incidence of TB in Pakistan is 230 per 100,000. The prevalence and mortality are 310 per 100,000 and 39 per 100,000 respectively³. Pakistan ranks 8th amongst the high burden TB countries in the world and harbor 63% of tuberculosis burden in the Eastern Mediterranean Region of WHO. Approximately 420,000 new TB cases emerge every year and among those half are sputum smear positive and 69 000 people die from TBs in Pakistan every year⁴.

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%¹¹. A prevalence study is being carried out by NTP and its partners for obtaining a more accurate and precise information of the TB burden in the country.

TB control in Pakistan was almost nonexistent due to dormant and ineffective National TB control programme (NTP) until 2001, reasons being lack of Government commitment and funding for TB control in the past

and hardly any support by the national and international partners.

Measurement of case detection & treatment outcome is central to tuberculosis control programme. Two targets focusing on TB control programme performance are: to detect at least 70% of the incident cases: and to successfully treat the 85% of the cases that are detected.

Historical Review of TB control activities in Pakistan

The first Tuberculosis survey in Pakistan was carried out in 1962. The results triggered a collaborative effort between Ministry of Health (MoH), World Health Organization (WHO) and UNICEF for a twenty year TB control programme that focused on establishing specialized TB centers and special TB wards at the DHQ Hospitals. In 1985 UNICEF withdrew its financial support. Since 1993 efforts have been made to expand partnerships and bring all stakeholders on board in order to control this disease more effectively. Government of Pakistan endorsed the DOTS strategy, following WHO's declaration of TB as a global emergency and adopted DOTS strategy in 1995. In 1994 the Ministry of Health (MoH) in collaboration with WHO revised the TB control policy. National policy and technical guidelines were drafted. In 1995 the MoH decided on the location of 5 DOTS pilot sites, but only 1 site became operational. A highly centralized 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 Medical Superintendent of the TB Centre in Rawalpindi was 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. Later it was decided that each province would be responsible to plan and manage its own NTP under Federal NTP guidelines.

Although DOTs strategy was piloted in Pakistan from 1995 but the real progress in TB control was witnessed after revival of NTP in 2001, when TB was declared as national emergency through Islamabad declaration. The NTP has been responsible for overall TB control activities in the country i.e. policy guideline, technical support, coordination, monitoring and evaluation, and research where as the Provincial TB Programmes (PTPs) are responsible for the actual care delivery process including program planning, training of care provides, case detection, case management, monitoring and supervision. The overall objective of NTP is to reduce mortality,

morbidity and disease transmission so that TB is no longer a public health problem. The National targets are in line with the millennium development goals (MDGs) i.e. to cure 85% of detected new cases of sputum smear positive pulmonary TB and to detect 70% of estimated cases once 85% cure rate is achieved. High government Commitment coupled with strong technical leadership in the program resulted in clear vision, which was translated into multi-year strategic plan (2001 – 2005) to achieve 100% DOTS coverage by year 2005. The strategic plan was revised for the period from 2005 to 2010 and then for 2010 - 2015.

NTP organization structure

The National Tuberculosis Control Program (NTP) is a national body, under Ministry of Health, responsible for overall coordination of TB Control Program in the country. The NTP is not directly involved in the TB care delivery, which is responsibility of the provincial/ /district health services. The main responsibilities of NTP includes policy formulation and strategic planning, liaison with partners and donors, monitoring and evaluation and research and development. NTP mainly formulate evidence-based national policies for effective tuberculosis control in the country. This means continuous ongoing efforts for gathering, from within and outside Pakistan, and reviewing the current scientific evidence to keep the national policies and strategies updated and responsive to the latest developments. NTP also coordinate the national level exercise, with active involvement of provinces and districts, leading to the development of national strategic plan and PC-1. In addition, NTP facilitates the provincial level strategic and program planning (PC-1) exercises, with an active involvement of districts.

The Provincial Tuberculosis Control Programmes (PTP), under the provincial department of health, are responsible for coordinating the planning, implementing, managing and financing of the tuberculosis control activities in their respective provinces. A Provincial Manager heads the PTP. A team of technical and administrative staff assists him in the province-wide coordination of TB control activities. The PTPs are involved in providing technical and administrative support to the district health services, and other partners, for effective implementation of TB control activities in the districts as well as teaching and specialized hospitals.

The delivery and management of TB care has been integrated within district healthcare services so that continuing care can be provided close to the patient's home. The TB care has

become an integral part of healthcare at all levels of healthcare starting from district hospitals to primary healthcare facilities to community health workers. This integration has made possible to plan and carry out TB control in a district without an addition any TB-specific care delivery health person. In the devolution context, the district authorities are primarily responsible for advocating, planning, financing, implementing, and monitoring TB care services in their respective districts.

It is pertinent to mention that the implementation of TB Control Program is mainly at the provincial and districts levels. NTP is not directly implanting program activities. Most of the activities are implemented through the provincial and district TB program. In case of Global Fund grants, NTP is Principal Recipient and implementation is again through the Province Program and Partners (Sub-recipients).

Strategic decisions and infrastructure improvements

Following Islamabad declaration, a 5 years plan was devised leading to universal DOTS coverage in the public sector by year 2005. Expansion of DOTS coverage all over meant availability of free diagnosis and treatment to all patients. Difficulties faced during the initial period of DOTS implementation were because of problems with human resources, poor quality of services and lack of commitment at public health facilities at peripheral levels towards DOTS.

Subsequently a 5 years federal work plan was approved from year 2006, for which Rs. 1.81 billion were allocated for TB related activities including staff training, expansion of laboratory network, availability of quality drugs, surveillance, monitoring and evaluation, research and development, public-private mix (PPM) and behavior change communication.

An important step taken by Federal Ministry of Health & NTP towards TB control in the country was that of effective & meaningful partnership building. An Interagency Coordinating Committee guide & facilitate donor support and technical assistance for the programme & Country coordination mechanism facilitate partner's coordination. The NTP and PTPs organize annual joint programme reviews on TB care in collaboration with all partners.

Since 2003, WHO programme officers, based at national, provincial and district levels have been helping in monitoring TB control activities and providing technical capacity building support. Monitoring the overall performance of programme is the responsibility of NTP.

One of the major components of DOTS strategy is the uninterrupted drug supply. The NTP and provincial governments have ensured the availability and accessibility of locally manufactured first-line ATT at all levels, purchased through the federal and provincial budgets or through interim grants from the Global Drug Facility.

Treatment is delegated from the diagnostic centre (rural health centres or hospitals) to the basic health unit (BHU) level. Lady health workers serve as the main treatment supporters. A 6 month regimen for new cases consisting of 2 months of intensive phase with Rifampicin, Isoniazid, Ethambutol & Pyrazinamide followed by 4 months of Rifampicin & Isoniazid according to WHO recommendations¹² & Pakistan Chest Society guidelines is being implemented¹³. An 8-month treatment regimen for new cases, with 6 months' Isoniazid & Ethambutol (HE) in the continuation phase, still in place at programme level is being phased out.

In order to achieve the 70% case detection target set by WHO, DOTS implementation at public health facilities only is by no means enough to achieve the MDGs. Despite the claim by NTP of 100 % DOTS in the public sector, it is widely believed that it is actually not the case, especially in the difficult terrain of Northern mountainous areas, war torn Tribal Territories, Internally displaced people and in the remote areas of Baluchistan & interior Sind. Whereas NTP needs to strengthen the DOTS at the difficult areas in the public sector, it is of paramount importance to engage private sector in to the TB control since this sector is used as the first point of entry to the health care by most users. High priority has been given by the NTP to developing partnerships with the private sector¹⁴. It is also important in view of the fact that majority of the private practitioners in Pakistan do not follow NTP guidelines and have fairly poor knowledge of TB control¹⁵⁻¹⁷.

To introduce TB control according to NTP guidelines into the lagging private sector, the NTP has engaged a network of private & non-profit organizations for the implementation of PPM DOTS. WHO-assisted mission in 2008 found that in the year 2007, PPM contributed to nearly 20% of total case detection, a remarkable achievement.

Another PPM strategy is "hospital DOTS linkage" which is implemented in public and private tertiary care hospitals by enhancing laboratory services for Sputum microscopy, introducing standardized treatment and developing referral systems between the hospitals and peripheral treatment centres through DOTS centres.

Data from districts where DOTS linkages have been introduced showed an increase of up to 50% in case notifications during 2009. It is pertinent to mention here that majority of the private sector is still not in line with NTP & the DOTS strategy and a lot more effort is required in order to sustain & further intensify the DOTS expansion in this very large private sector.

Progress of National TB Control Program

A steady progress has been made from 2001 onwards to improve the case detection and treatment success rate by emphasizing on quality assurance of smear microscopy, drug management, community mobilization, involving tertiary care hospitals, NGOs, and inter-sectoral organizations and above all involving private sector for service delivery. Following are the main achievements;

One of the key milestones achieved in Pakistan's fight against TB dates back to 2005, when the National TB Control Programme (NTP), in partnership with its provincial counterparts, achieved 100% DOTS coverage in health facilities within the public sector health delivery system. This achievement demonstrated the country's seriousness to reach the targets enshrined in the global Stop TB Strategy, which envisages detection of 70% of new sputum smear-positive TB cases and a treatment success rate of at least 85%.

- Number of TB cases diagnosed was increased from 20,707 in 2001 to 268,780 in 2010. Since the revival of the program in 2001, NTP has successfully treated more than 1.5 million TB cases free of cost. Current case detection rate of new smear positive TB cases is 63 % and treatment success rate is around 90%³.
- 5,800 diagnostic and treatment centers have been established in the public sector provide which are providing free TB testing and treatment services.
- National TB guidelines have been developed for TB Control, childhood TB, difficult to diagnose TB, TB/ HIV co-infection and MDR-TB. NTP has trained doctors, paramedics, laboratory technicians and LHWs all over the country.
- Resources have been secured for 50% requirement of TB drugs for next 5 years. Through Global Fund Round 8, NTP is establishing drug management system and refurbishing warehouses all over the country.
- 1170 peripheral microscopy centers have been established all over the country and approximately 600,000 TB suspects are tested each year free of cost. In addition NTP has established and functionalized BSL-3 reference laboratory at National level. Five more BSL-3

labs will be established during this year in the provinces.

- Joint Coordinating Board and National Technical Working Groups have been constituted for TB/HIV & MDR- TB under Federal Ministry of Health for policy guidelines to address these challenges.
- TB/HIV guidelines and manuals have been developed for the screening and management of TB/HIV co-infected patients in consultation with Technical Working Group. Sixteen sentinel sites are selected and strengthened, through collaborative efforts of TB & AIDS control programs and non-government partners for screening, care and support of TB/HIV co-infected patients.
- MDR-TB management has been started at 3 pilot sites. Resources have been secured for comprehensive management of 15000 MDR-TB patients (diagnosis, treatment and social support).
- Childhood and difficult to diagnose TB case management started through piloting in 30 DHQ hospitals and 27 tertiary care hospitals. Program is providing free pediatric drugs and Purified Protein Derivative (PPD).
- National TB Control Program is spearheading on Public Private Partnership for sustainable solution to quality TB services in the country. A network of private and non-profit organization is involved in TB care. During 2009, 16% TB cases in national data were contributed through the PPM.
- NTP has a functional research unit which has linkages with national and international organizations. There have been a number of publications and some are in the pipeline.

In order to further scale-up the progress, NTP has planned the following interventions¹⁸;

- ❖ An uninterrupted supply and funding for first-line ATT drugs has been assured until 2012 through funding from the Government and partners. However, long-term strategies for financing an uninterrupted supply of quality-assured first- and second-line ATT drugs, including paediatric formulations, are needed.
- ❖ Improvement in the drug management system. As banning across-the-counter sales of ATT drugs is currently not a viable strategy in Pakistan, the NTP has opted to develop a "seal of quality" for locally produced ATT drugs that meets international quality standards, while WHO is engaged in providing technical assistance to local drug manufacturers aiming to attain a prequalification status.
- ❖ Improvements in the laboratory network for culture and DST for the diagnosis of drug-

resistant TB. Efforts are being made to upgrade the existing labs & establish new ones with the support of partners. Rapid testing for MDR-TB through GenExpert is planned to be introduced in the 15 tertiary care hospitals.

- ❖ Expansion of DOTS in the remaining districts of private sector & parastatal organizations, an intervention vital for increasing detection of cases. Funding for these activities has been secured through partners support
- ❖ Addressing MDR-TB care is an urgent task. WHO estimates an annual incidence of over 13 000 MDR, SS+ cases in Pakistan based on estimates of 3.5% MDR in new cases and 35% in re-treatment cases¹⁹. A study conducted by Pakistan chest society²⁰ reports 1.8% primary resistance in a specified annual cohort of notified SS+ new cases. DOTS plus has been piloted in 2 public sector & one private sector institution in the country & further expansion of DOTS plus is in progress.

Pakistan has shown drastic expansion of TB care during the past 10 years, as is evident from the drastic increase in case notification & treatment of around 1.5 million TB patients since 2001, with a treatment success rate reaching up to 90%. In 2002 the case detection rate for all cases according to previous estimates was only 19%, way below the target of 70%. With expansion of DOTS strategy all over the country, this rate has increased to 63% in 2009. Similarly the detection rate of smear positive cases increased from 13% to 74%²¹. The treatment success rate of 90% of new SS+ cases notified during 2010 exceeded the WHO target of 85%, due to a reduction of the default rate to under 4%, and low death, failure and transfer out rates (2%, 1% and 2%, respectively). Data from DOTS strategy in teaching hospitals of one province also showed similar trend²².

This remarkable progress of the NTP in expanding DOTS to the public sector of every district, initiating Public Private Mix (PPM) strategy^{23,24}, and steadily increasing case notification and treatment success rates^{25,26} have been possible due to sustained Government commitment and funding for TB control, and technical and financial support from national and international partners.

Whereas a lot of progress has been made as is evident from the above, there are still some issues and gaps in the implementation of TB control programme like insufficient allocation of funds at provincial level and diversion of public sector funds due to recent floods, sustainability of the donor funded projects, on counter sale of 1st

and 2nd line anti TB drugs in the market & Pre-qualification of local pharmaceutical companies under WHO scheme for bio- availability and bio-equivalence.

Some of the challenges for further scaling-up of TB care in the country are upgrading TB control in the new province of Gilgit-Baltistan, intensifying TB control in underserved areas & tribal areas hit hard by war on terror; innovative approaches for enhancing case detection in marginalized groups with limited access to health services, such as workers in the informal sector and periurban slum populations, Integration of TB control strategies in Medical colleges curricula and introduction of an electronic nominal recording and reporting system for monitoring and evaluation.

Although NTP needs to be congratulated for sustaining progress for over a decade, it nevertheless needs to pursue its activities with greater vigour and expanded framework in order to achieve regional and global targets, including Millennium Development Goals. Continuous government commitment and donor support will be instrumental for ensuring sustainability and further success.

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**GRANT SUPPORT, FINANCIAL
DISCLOSURE AND CONFLICT
OF INTEREST**

None Declared