NATIONAL TUBERCULOSIS CONTROL PROGRAM

ISLAMIC REPUBLIC OF PAKISTAN

STRATEGIC PLAN
(2020-2023)

NATIONAL TB CONTROL PROGRAM

The Islamic Republic of Pakistan

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National Strategic Plan for Tuberculosis Control, 2020-2023

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Acknowledgements

Ministry of National Health Services, Regulations & Coordination, acknowledges the support of international and national stakeholders in the development of NSP . We would like especially thank World Health Organization, The Global Fund, the CCM Pakistan, TB experts from National, Provincial & Regional TB Control Programs, The Indus Hospital, Mercy Corps and all implementing partners for their lead role and active participation in preparation of NSP/PSPs documents.
NTP Pakistan duly acknowledges the contribution of consultants: Dr Paul Nuun, in the development of NSP/PSP documents.

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List of abbreviations

aDSM active Drug Safety Monitoring and Management
ACD Association for community development
ASD Association for social development
AKUH Aga Khan University Hospital
ART Anti- Retroviral Therapy
BC Bacteriologically Confirmed
BHU Basic Health Units
BISP Benazir Income Support Program
BMU Basic Management Unit
CAD4TB Computed Aided Diagnostics for TB
CHS Community Health Solutions
CMU Common Management Unit
CPT Co-trimoxazole Preventive Therapy
CXR Chest X-ray
DFID Department for International Development (United Kingdom)
DHIS2 District Health Information System 2
DHQs District Headquarter Hospitals
DOT Directly Observed Therapy
DOTS Directly Observed Therapy – Short Course
DR-TB Drug Resistant TB
DST Drug Susceptibility Testing
DS-TB Drug Susceptible TB
EPI Expanded Program of Immunization
EPTB Extra Pulmonary TB
EQA Externa Quality Assurance
FAST Find TB Actively, Separate Safely, Treat Effectively
FATA Federal Administered Tribal Areas
FDCs Fixed Dose Combination Drugs
FLDs First Line Drugs
GB Gilgit Baltistan
GDP Gross Domestic Product
GDF Global Drug Facility
GLC Green Light Committee
GoP Government of Pakistan
GPs General Practitioners
GSM Greenstar Social Marketing
HIV Human Immunodeficiency Virus
ICT Islamabad Capital Territory
IHN Indus Health Network
IPT Isoniazid Preventive Therapy
JPRM Joint TB Program Review Mission
KP Khyber – Pakhtunkhwa
LHWs Lady (Community) Health Workers
LPA Line Probe Assay
LTBI Latent TB Infection
MC Mercy Corps
MDRTB Multi Drug Resistant TB
M&E Monitoring and Evaluation
MNCH Maternal, Neonatal and Child Health
MoHs Ministries of Health (Provincial)
MoNHSRC Ministry of National Health Services, Regulation and Coordination
NCDs Non -Communicable Diseases
NGO Non- Governmental Organization
N/PTPs National and Provincial TB Programs
NTRL National Tuberculosis Reference Laboratory
NTP National TB Program
OOP Out of Pocket
OPD Out Patient Department
PAS Para Amino Salicylic Acid
PATA Pakistan Anti- TB Association
PC Planning Commission
PDHS Pakistan Demographic and Health Survey
PHC Primary Health Care
PLHIV People Living with HIV
PMDT Programmatic Management of Drug Resistant TB
PPHI People Primary Health Care Initiative
PPD Purified protein derivative
PPM Public Private Mix
PPs Private Providers
PR Principal Recipient
PSM Procurement and Supply Chain Management
PTPs Provincial TB Programs
PWIDs People Who Inject Drugs
RHC Rural Health Centre
RR-TB Rifampicin Resistant TB
Rs Pakistan Rupees
SDGs Sustainable Development Goals
SLDs Second Line Drugs

SOPs	Standard Operation Procedures
STR	Short Treatment Regimen
TA	Technical Assistance
TB	Tuberculosis
THE	Total Health Expenditure
THQs	Tehsil Headquarter Hospitals
TB-NSP	TB- National Strategic Plan
UNGA-TB-HLM	United Nations General Assembly TB High Level Meeting
TST	Tuberculin Skin Test
TWG	Technical Working Group
UHC	Universal Health Coverage
USAID	United States Agency for International Development
VCT	Voluntary Counseling and Testing
WB	World Bank
WHO	World Health Organization
XDRTB	Extensively Drug Resistant TB

The Core Plan

Executive summary

Through this National Strategic Plan (NSP), Pakistan aims, in the next four years, to treat successfully 1.6 million cases of tuberculosis (of which 200,000 are children), and an additional 35,000 cases of multi-drug resistant TB, and provide 1.6 million courses of post-exposure (preventive) treatment throughout the country, at a cost of US$ 621 million.

This is a full expression of Pakistan's needs for 2020-2023 for controlling tuberculosis. It follows a consultative, "bottom-up" process involving representatives of all stakeholders in each of the provinces, regions and territories, which has been organised by the World Health Organization (WHO) and the National TB Control Programme (NTP) between September and December 2019. This NSP recognises the failure to achieve the targets set in the NSP, 2017-2020 and takes into account the reasons for this. It has drawn substantially on the analyses that came out of the patient-centred workshop on the epidemiology of TB in Pakistan in January, 2019, and the clear-sighted recommendations of the Joint Pakistan Review Mission (JPRM) for TB in February, 2019.

The Burden

Pakistan has the world's 5th highest number of people falling ill with TB each year - 562,000 in 2018. Only India, Indonesia, China and the Philippines have more cases. While the Eastern Mediterranean has only 8% of the global burden, Pakistan is responsible for 75% of it. However, only 369,000 cases were notified in 2018, meaning that 193,000 – over one third - were not notified. This was especially true of the elderly, and of men. These "missing cases" could have been diagnosed in the private sector and perhaps treated there (but not notified), or they could have gone without treatment of any kind, continuing to spread the disease to their families and loved ones.

While most large countries in Asia are seeing significant falls in incidence of TB, in Pakistan the estimated TB incidence has been static for 20 years, which means that with Pakistan's vigorous population growth, the number of cases goes up every year.

WHO estimates that 44,000 Pakistani citizens died from TB in 2018, the highest number from any infectious disease. Tuberculosis is the 7th largest cause of lost years of life in Pakistan, behind the major causes of death in infants and children, and ischaemic heart disease.

In 2018 there were an estimated 28,000 multi-drug resistant (MDR-TB) cases, but only 11% were diagnosed and put on treatment. The HIV epidemic is relatively small and concentrated in Pakistan. Nevertheless, 3,800 patients with HIV-associated TB were estimated to have occurred in the same year, yet only 636 were diagnosed, and of these only 417 received anti-retroviral treatment.

The proportion of new and relapse TB cases that are children (0-14 years) is within the expected range of 5-15% (12.3% in 2017), but GB, KP and FATA had a very high proportion of childhood notification in 2017 (41.2% and 29.7% and 28.4% respectively). In these areas, therefore, childhood TB in all probability is being over-diagnosed.

Nationally, 61% of patients seek care in the formal private sector (Punjab 76%), 24%, in the informal private sector (Balochistan 27%, KP 35% and Sindh 33%), and only 13% in the public sector. Yet only 5% of the national total of (private) general practitioners is engaged in TB control.

The Achievements

From near zero in 2000, Pakistan was notifying over 150,000 cases of TB annually by 2007. A further growth in notifications followed to a peak of over 360,000 in 2017. A detailed NSP for 2017-2020 was prepared. The NTP has treated more than 4 million people with quality assured drugs since its revival while maintaining treatment success rates of more than 90% for many years.

The new rapid molecular diagnostic tests (MTB-RIF tests on the GeneXpert platform) have been introduced and are now available throughout the country. The public sector has engaged several private sector partners, notably the principal recipients of the Global Fund, Indus Health Network (IHN) and Mercy Corps, and their sub-recipients, Greenstar Social Marketing, Community Health Solutions (CHS), The Pakistan Lions Youth Council (PLYC), Association for Community Development (ACD), the Association for Social Development (ASD), Bridge Consultants Foundation (BCF) and others, who have introduced active case finding and other innovative approaches, and helped to boost case finding, especially among the clients of private practitioners. The NTP has supported provincial TB programmes in the development and implementation of the "Mandatory TB Case Notification" bill which has been passed by three Provincial assemblies and by-laws developed.

The Challenges

The NSP 2017-2020 was never properly funded. As reported by the 2019 JPRM, the highest level policy makers were – and are - generally unaware of the health and economic burden created by TB. Domestic funding for TB has therefore never adequately materialised. The TB Free Initiative announced by the President in April 2019 appears to have fizzled out through lack of national level staff.

While over the past two decades there has been a huge increase in TB case finding, over one third of cases is still not notified in Pakistan. This is because neither the public, nor the private, sector, is fully mobilised to find all the cases presenting to them: of over 5,000 basic health units (BHUs) only about 124 are fully, officially, engaged in TB control, that is they have both the resources to diagnose and treat TB, or to refer the patient to a competent facility for diagnosis and care. With the exception of a few pilot projects like those in Sindh, lady health workers (LHWs) are also not involved in TB case finding or management, despite their major role in visiting families and communities. In the private sector, only 5% of GPs are engaged with the local TB control programme, and yet they are providing 23% of the patients notified.

A major bottleneck is the lack of a systematic mechanism to transport sputum specimens from each primary health care (PHC) facility to the nearest diagnostic facility, usually a rural health centre (RHC), where microscopy is available, or to transport the sputum to the nearest GeneXpert facility for MTB-RIF testing. The GeneXpert machines are therefore under-utilised. Results take too long to return to the clinical staff.

In practice, still today in Pakistan, diagnosis of TB largely depends on symptoms, followed by sputum microscopy. Yet, the 2011 prevalence survey showed that only 61% of the diagnosed TB cases screened positive on symptoms (cough >2wks) - other TB cases were detected by the finding of abnormalities on chest X-ray. Furthermore, about one-third of cases of TB are sputum smear negative, meaning that these patients, even if they had symptoms, would be missed by the routine case detection that relies on microscopy only. This plan therefore aims for a significant increase in the sensitivity of the diagnostic process through the inclusion of chest X-ray, where possible, as a screening test, followed by an MTB-RIF test.

The lack of domestic engagement and financial support has also translated into a failure to financially support a national level central unit. Such a unit, or Institute, is essential to provide

organisational and management support and strategic and technical policy guidance to the provinces and regions, especially around the introduction of new techniques and approaches. It also has a key role in advocating for domestic support for TB.

Historically, Pakistan has reserved preventive treatment (PT) for the under 5s, although even in that group, implementation has been at a low level. WHO's recommendations, since the UN High Level Meeting on TB in 2018, now advocate PT for infected contacts of any age, which will require a significant shift of thinking, policy and practice, that is starting in this NSP.

The Plan's goals and key strategies

The vision of this NSP is a **TB-free Pakistan with zero deaths, disease, and poverty caused by TB.** The mission is to e**ffectively end the TB epidemic in Pakistan by 2035.** The vision and mission are unchanged from the previous NSP, however, the goal is to **get back on track to end the TB epidemic by 2030,** and therefore this Plan aims to treat successfully at least 1.6 million cases of tuberculosis. Multi-sectoral accountability is key to achieving these targets and is, for example, an important element of the Islamabad Model Health City Initiative by the ICT authorities and the Ministry of National Health Services, Regulations and Coordination (MoNHSR&C). To achieve these targets the following strategies will be implemented, and assessed within the context of the multi-sectoral accountability framework:

1. All four provinces and most of the territories and regions aim to ensure engagement of almost all BHUs in the public sector in TB control. In Sindh, for example, this will be achieved mainly through the PPHI, which has already been subcontracted by the provincial government to manage BHUs, and which will train all their front-line clinicians, and provide access for all BHUs to appropriate diagnostic facilities within the PPHI network. Elsewhere, this includes provision for referral of any presumptive case to a diagnostic facility, and/or the provision of a reliable, systematic mechanism for the transport of sputum specimens (see later). Many provinces, with the exception of Balochistan (where this has already been tried and failed), intend to engage the LHWs in case finding activities, and in monitoring treatment. Further case finding strategies include intensified hospital: DOTS linkages, contact-tracing of both the under 5s and, innovatively, those over the age of 5 years, partnerships with community based organisations to find and support cases, and improved advocacy and communications to stimulate public and health worker awareness of the importance of TB.

2. The proportion of private general practitioners engaged in TB control will be increased in almost all provinces from around 5% to around 20%, primarily through ensuring increased awareness of the mandatory notification legislation and involvement of field staff who will coordinate with GPs through a call centre system, which will facilitate firstly, registration of the practitioner, then the diagnosis of presumptive cases, and the registration of a confirmed, or clinically diagnosed, case.

3. To address the 24% of people who first attend the informal sector for treatment, this plan includes a significant increase in the involvement of the informal providers (hakim, pharmacists, homeopathic clinics and others). These providers will be trained to recognise and refer presumptive cases, and linked with diagnostic facilities through informal networks that will be strengthened.

4. This plan aims to significantly increase the sensitivity of the diagnostic algorithm through far greater use of MTB-RIF testing for the diagnosis of TB (not just for diagnosing DR-TB), while ensuring that costs remain manageable through expanded use of chest X-ray as a screening tool. The plan thus envisages supply of 102 additional X-ray machines over the four-year period, with 1.6 million chest x-rays, and 2 million Xpert tests performed annually.

5. Most provinces and regions include a systematic approach to sputum transport from BHUs to diagnostic facility, and from diagnostic facilities to GeneXpert sites, through outsourcing to professional courier companies or suitable local solutions Regular timetables will be established and patient visits timed to ensure that their specimens can be transported for diagnosis with the minimum of delay.

6. This plan envisages federal level support for the establishment of a Central TB Programme to act as a national level central unit, providing organisational and management support and strategic and technical policy guidance to the provinces and regions on the introduction of new techniques and technology. It will also strengthen the monitoring and evaluation of TB control activities throughout the country, training of trainers of appropriate numbers of medical, nursing and paramedical staff, establishing research priorities and a low-cost mechanism for funding essential operational research, and to coordinate foreign and domestic investment in TB control. The plan includes continued support to the National TB Reference Laboratory at federal level to enhance its current role providing routine and advanced mycobacteriology services , capacity development, quality assurance, surveillance of drug resistance, research, and technical assistance for scaling up quality assured TB laboratory services.

7. Monitoring and evaluation will be further enhanced primarily through accurate estimates of the national burden of TB and its trend since the last survey in 2011, through a national prevalence survey, powered to provide a significant result for each of the four provinces. Further expansion of DHIS2 will facilitate gradual roll-out of case-based, web-based electronic recording and reporting to the whole country over the four-year period.

8. This plan aims to secure and sustain political commitment, through continuous advocacy directed at high level policy makers in Pakistan. It aims to increase national ownership and oversight, increase the financing for TB especially via sustainable domestic resources, and facilitate a supportive legal and regulatory environment. Pakistan will also adopt a multi-sectoral approach with an accountability framework.

1. Introduction

1.1 What this NSP is

This National Strategic Plan (NSP) for 2020-2023 is the document that lays out the full expression of Pakistan's needs in controlling tuberculosis (TB), and describes the plan to meet those needs between 2020 and 2023. The NSP will guide the interventions that Pakistan will undertake to address its epidemic of TB. It takes into account the context of the national health system - both private and public sectors – and government health policies and strategies. It is backed by an up-to-date understanding of the epidemiology of TB in Pakistan, and the recommendations of the Joint Pakistan Review Mission (JPRM) conducted in February 2019.

Crucially for Pakistan, this NSP, in line with the 18th Amendment of the Constitution, is built up from the provincial strategic planning process of the provinces, territories and regions. The authors have followed the clear instructions from Dr Rana Muhammad Safdar, National Coordinator, Central Management Unit (CMU), and the Global Fund, that the national plan should be "built from the bottom up" and fully reflect each province's, territory's and region's aspirations and intentions. Moreover, each province, territory and region has its own strategic plan to guide local actions, and local investments.

This document forms the Core and the Monitoring and Evaluation components of the National Plan, and describes the global, regional, national and provincial contexts for TB care, prevention and treatment in Pakistan. It lays out the national vision, mission and goal as well as the objectives and interventions to achieve that goal. It includes an assessment of all the main technical areas of TB control in the country, which contribute to an overall gap analysis. The Budget Plan brings together the costs for the Plan and will be summarised at the end of this document. The details of the budget plan will be found in a separate excel file. The technical assistance and operational plans follow the budget plan.

This NSP, and its provincial, regional and territorial counterparts, is therefore designed to guide the actions not only of the Ministry of National Health Services, Regulations and Coordination (MONHSRC), but also all decision-makers and implementers within the government at national, provincial and regional levels, and in the non-governmental sector, both national and international, whose work touches on TB control in the country. It should be the main guide for funding agencies considering investment for TB control in Pakistan during this period.

1.2 Results of the Pakistan Joint TB Program Review Mission (JPRM) 2019

Objectives

The JPRM's mission in February 2019, was to measure progress in the implementation of the TB National Strategic Plan 2017-2020 and assess Pakistan's readiness to meet the commitments of the United Nations General Assembly Political Declaration on TB. The mission sought to determine if Pakistan's TB Programme was supported by a broader health and development agenda including the Sustainable Development Goals, and Universal Health Coverage. The JPRM reviewed programme sustainability factors with a particular emphasis on domestic and international financing. It assessed the progress in establishing a multi sectoral approach for ending the TB epidemic and in reaching the End TB Strategy targets, with a focus on finding the missing cases of TB, and the prevention, identification, care and treatment of drug resistant tuberculosis.

Findings

The burden of TB in Pakistan was still very high: in 2017, it was estimated that over half a million people developed tuberculosis and well over 50,000 died from it. The gains that had been made to keep TB "under control" were threatened by an increasing burden of drug resistant TB. In 2017, it was estimated that Pakistan had more than 27,000 people with this form of TB.

The JPRM observed that the enormity of the TB health crisis in Pakistan was not familiar to sufficient decision-makers at national or provincial level. On the contrary, several people thought TB had been "eradicated" in Pakistan. Very limited effort had been made to establish and nurture the multi-sectoral approach to TB care and prevention. No Multi–Sectoral Accountability Framework had been set up.

Even though Pakistan had increased its effort to identify and place on treatment people who develop TB, it was estimated that up to 200,000 people with TB and 25,000 people with drug resistant TB were missed every year, either because they were not diagnosed at all, or, if diagnosed (and perhaps treated), were not reported to the public system.

While significant progress had been made to find cases of TB, including expansion of TB diagnostic services and engagement of private health care providers - and a significant increase in TB case notification of about 22% had been observed between 2013 and 2017 - the number of persons not reached with high quality TB services, including appropriate support, remained high. Opportunities had been missed to engage the wide network of Primary Health Care services in the public sector.

Similarly, the engagement of the very wide network of private health care service providers, who provide about 85% of initial care to persons when they fall ill in Pakistan, had a coverage of a meagre 5% or less.

The TB response was financially very constrained. The TB National Strategic Plan, 2017-2020 was budgeted at US$ 520 million. Of this only US$ 179 million (35%) had been made available, leaving a gap of 65%. Additionally, of the available funding, US$ 144 million (80%), was from the Global Fund. The over-dependence on external financing suggested a lack of ownership of the TB health crisis in Pakistan. Thus, the TB situation in Pakistan qualified as a "continuing health emergency", requiring emergency-type actions to be addressed.

Recommendations

The JPRM recommended that Pakistan needed to secure and sustain political commitment in the fight against TB as a demonstration of national ownership of the TB crisis. To this end, the JPRM strongly advised the Prime Minister at the national level, and the Chief Ministers at the provincial levels, to declare a Pakistan END TB Initiative, on or before World TB Day, 24th March 2019[1], and to establish National / Provincial Steering Committees chaired and under the oversight of the Prime Minister and Chief Ministers.

While recognising Pakistan's constraints, the JPRM recommended a significant increase to the Government's contribution to anti-TB efforts, as well as contributions from the private sector and development partners.

The JPRM also advised Pakistan to take immediate action to adopt a multi-sectoral approach - with an accountability framework - under the oversight of the Prime Minister and the Chief Ministers - with active involvement of all concerned ministries, local governments, private sector stakeholders,

[1] WTBD 2019 was commemorated on April 3, 2019 in the Pakistani Presidency where the President of Pakistan announced a TB Free initiative. However, this work has not moved forward owing to the expiry of the contracts of the designated staff.

civil society organizations, affected communities, non – governmental organizations, academia and others to track and reach the End TB and Sustainable Development Goals targets.

The JPRM crucially recommended expansion of quality TB service provision, both public and private, to all levels of the health care system up to the community level. Given that the private health care sector dominates the provision of health services in Pakistan, increasing the engagement of private healthcare providers for TB was of paramount importance. National and Provincial TB Programmes were advised to methodically expand TB service provision throughout all levels of the Primary Health Care system. The JPRM thought that more cases of TB could be found if communities were more engaged in TB responses, including integrating TB in the work of Lady Health Workers, and addressing TB among key populations including PLHIV, prisoners and migrant/mobile populations.

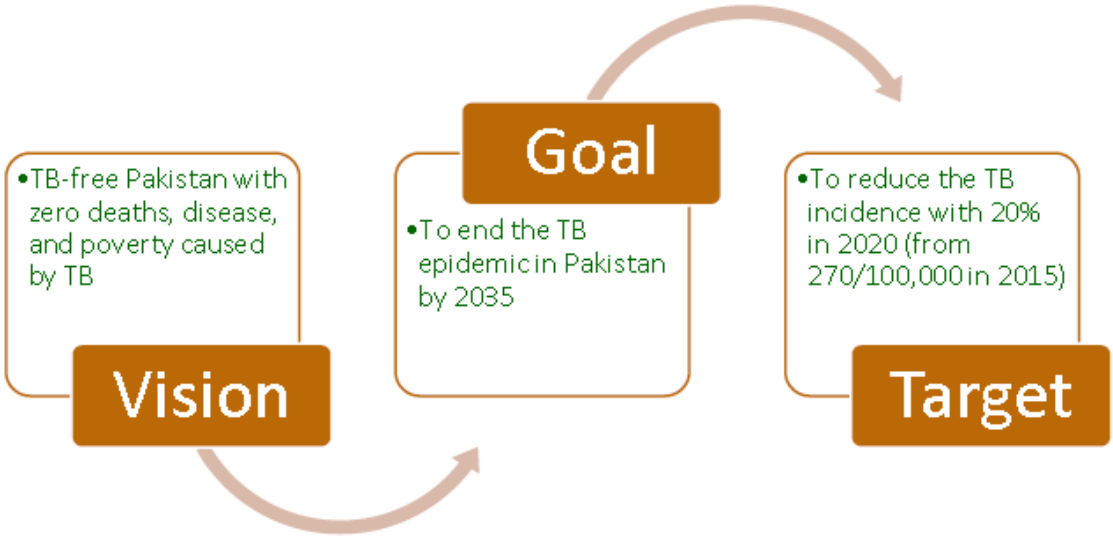
Additionally, the JPRM criticised the targeting of Xpert testing. Although mostly employed to test smear positive patients for rifampicin resistant (RR) TB, the numbers of RR-TB cases detected had not risen much in previous years – from 3,243 in 2014 to 3,824 in 2018. Furthermore, the proportion of drug sensitive cases that was clinically diagnosed had increased, rather than decreased, which suggested that Xpert machines were being insufficiently used to detect TB among the presumptive cases - thus limiting the impact on transmission, a key goal in TB prevention. Comprehensively decentralized services were recommended to prevent, detect (as early possible), and treat and care for both drug sensitive and drug resistant TB.

1.3 The NSP 2017-2020

1.3.1 Vision, goal, target and objectives

The 2017-2020 TB-NSP was ambitious, with a vision of a Pakistan without TB, and the goal of effectively ending the TB epidemic by 2035 (Figure 1). The main target of the NSP was to reduce the incidence of TB by 20%, by 2020, compared to 2015. However, this target was not measurable and could be argued was over-ambitious. Nevertheless, the NSP was used as the basis for the funding request to the Global Fund.

Figure 1. The vision, goal and target of the NSP 2017-2020.



The first four objectives (Table 1) mostly addressed the conventional TB control strategies first formulated under the WHO's DOTS strategy, and then re-worked as Pillar 1 of the End-TB strategy

(integrated patient centred TB care and prevention) endorsed by the World Health Assembly in 2014[2]. The NSP added "Innovative care" to this pillar. The four objectives aimed to increase case notifications and treatment success of both drug sensitive and drug-resistant TB. The interventions or "programmatic components" to deliver these objectives list the main activities to be implemented and the target groups. The "innovative" element refers to the target groups of the elderly, tobacco users and diabetics. Objectives 5 and 6 aim to improve the support for TB in the policy environment, and the only mention of public/private collaboration is here. Objective 7 is to establish research collaboration to optimise "implementation and impact".

Table 1. The objectives and programmatic components of the Pakistan NSP for TB, 2017-2020

PILLAR	OBJECTIVES	PROGRAMMATIC COMPONENT
PILLAR 1: INNOVATIVE CARE INTEGRATED PATIENT CENTERED TB CARE AND PREVENTION	1. To increase the number of notified TB cases (all forms) from 63% in 2015 to 90% in 2020. 2. To maintain the treatment success rate at 93% till 2020.	• Diagnosis • Management of Drug-Susceptable TB (• Contact management • TB prevention among high-risk groups including: • Children • The elderly • Tobacco users • Diabetics • People living with HIV (PLHIV)
SEARCH, TREAT AND CURE	3. To increase the notification of Multi-Drug Resistant TB (MDR-TB) from 20% in 2015 to 60% by 2020 of the estimated incident of pulmonary TB cases. 4. To increase the treatment success rate from 69% to 75% by 2020.	• Programmatic Management of Drug-Resistant TB (PMDT) • Diagnosis • Treatment (short course, new drugs) • Contact management • Social support • Palliative care
PILLAR 2: BOLD POLICIES AND SUPPORTIVE SYSTEMS SUPPORT, CARE AND ENGAGE	5. To ensure that TB remains on high political agenda. 6. To ensure that all TB policies are developed by stakeholders and implemented by the NTP by the end of 2020.	• Political commitment and resource generation • Public/Private Mix (PPM) • Regulatory framework and rational use of medicines • Vital registration • Partnerships and community development • Infection control and prevention
PILLAR 3: INTENSIFIED RESEARCH AND INNOVATION SEEK, KNOW AND APPLY	7. To establish institutional collaboration on TB regarding research priorities in the country by 2020.	• Research to optimise implementation and impact

1.3.2 Strategic directions

The NSP 2017-2020 describes strategic interventions or directions which flesh out the programmatic components. These are listed in the plan by WHO's three Pillars of the End TB Strategy.

Pillar 1. Innovative care; integrated patient centred care and prevention: search, treat and cure.

- Ensure early identification of presumptive TB cases (private, public).
- Provide universal access to quality TB diagnosis (including drug-resistant (DR) TB).
- Build capacity to HCW on existing screening methods for LTBI.
- Ensure early initiation of treatment to all patients diagnosed with TB.
- Improve TB treatment adherence.
- Prevent TB in key affected persons such as prisoners, miners, HCWs, children, injecting drug users, and PLHIV.
- Implement behavioural support interventions developed through TB and tobacco trials in routine settings.

[2] WHO. The End TB Strategy. End TB Brochure, 2016, WHO, Geneva. http://www.who.int/tb/End_TB_brochure.pdf?ua=1 Accessed 12 November, 2019.

Activities are listed in the plan, but in some areas, eg "Diagnosis", p 101, they confuse descriptions of what was happening at the time, with future plans. In "Contact management and case identification", p 102, the activities are generic, not clearly linked with each other, and non-specific. Two diagnostic algorithms are shown, an "interim" and a "preferred" version, but there is no discussion of which to use, or when, or rationale for so doing. In some areas, eg "Management of DR-TB" the activities are significantly clearer, and connected up. However, even here, there are important gaps, for example, the drugs to be used for preventive therapy of contacts of MDR-TB cases are not mentioned. The activities for "TB in the elderly", "TB in diabetics", "TB and tobacco smoking" are sketchy: those for TB/HIV sketchy and repetitive (p 108-9), although largely following the WHO guidance on collaborative TB/HIV activities.

Pillar 2. Bold policies and supportive systems: Engage, support and care

- Secure high level political commitment and mobilise domestic resources towards ending TB.
- Link TB patients and households with social support schemes to reduce catastrophic out-of-pocket expenditure to the patients.
- Increase number of private health care providers engaged with NTP and enhance scope of services provided in line with ISTC standards of quality of care.
- Target behaviour change to generate demand for health services and empower communities to play a role in accountability of health care provision.
- Prevent the loss of TB cases in the cascade of care within health system by HDL (treatment supporters and linkage to care between primary and tertiary level).
- Legislate and implement regulatory mechanisms for mandatory TB disease notification and rational use of ATT.
- Minimise the risk of disease transmission within populations through effective TB infection control.
- Advocate for establishing a vital registration system in Pakistan.
- Strengthen partnerships within the health sector to enhance case detection and address comorbidities.
- Capitalise on inter-sectoral partners' strengths for TB care and support.

As in Pillar 1, the description of activities is mixed in terms of clarity, comprehensiveness, and appropriateness, but those that are proposed for public-private mix (PPM) are mostly well-structured, appropriate and clear (pp 116-7). Multi-sectoral collaborations are proposed and a few benefits to TB control are mentioned (p 114), but no reasons are given for why the other sectors should become engaged, or how they might be convinced to do so. The same criticism applies in the "Community Engagement" section in discussion of engagement with other elements of the health sector, eg Lady Health Workers (LHWs), and the Maternal, Neonatal and Child Health Programme (MNCH).

Pillar 3. Intensified research and innovation: Seek, know, and apply

- Build supportive structures for surveillance, research and innovations at national and provincial level
- Identify and prioritise research gaps
- Strengthen research capacity at local level
- Share research evidence and emerging best practice to strengthen policy and practice
- Strengthen the stewardship role of governments at all levels for research and knowledge management systems
- Build institutional capacities to promote, undertake and utilise research for evidence based policy-making in health at all levels

Many of the activities are clear, specific and appropriate.

1.3.3 What was achieved (and not achieved)

The main NSP 2017-2020 targets are not on course to be achieved (Table 2). Tuberculosis treatment coverage (TC) for DS-TB and DR - TB should, by the end of 2019 be at 88% and 50% respectively but, while there has been a tiny improvement from 63% in TC for DS-TB in 2015, the baseline year, to 64% in 2018, TC for DRTB is unchanged since 2016. Only 25% of notified cases of TB were tested with a World Health Organization Recommended Rapid Test (WRD) in 2018 and almost all of these were tested to detect rifampicin resistance, rather than to look for TB. There are no data on coverage of treatment for latent TB infection (LTBI), and a patient cost survey has not yet been conducted, so Pakistan may not be able to report to WHO on the proportion of TB patients who experience catastrophic costs as a result of TB by 2020.

Table 2. Annual targets for the TB-NSP 2017-2020 and achievements by 2018 (all in percentages). TC = treatment coverage, TS = treatment success rate, DS = drug sensitive, DR = drug resistant.

Indicator	2015 baseline	Target by year					Achieved by 2018
		2016	2017	2018	2019	2020	
TC:DS-TB	63	72	80	85	88	90	64
TC:DR-TB	20	21	30	40	50	60	21
TS:DS-TB	93	93	93	93	93	93	93
TS:DR-TB	69	72	72	73	74	75	64
Households with catastrophic expenditure	NA	Survey to be planned and implemented					Survey not done

Funding of the NSP

There was a very large funding gap for the TB-NSP 2017-2020. Of the costed budget of US$520 million, only US$179 million was available through the Government and the Global Fund combined (US$ 34 million or 7% of the total request, and US$144 million or 28% of the total, respectively), leaving a financing gap of US$341 million or 65%. At the federal level, there were plans to increase funding for health from consistently less than 1% of government spending for over 20 years, to about 3%, but there is no evidence of progress[3]. At the provincial level, funding for TB has been small and often based on project-type funding through the Planning Commission mechanism, known as a PC1. The PC1 approach is a project-based mechanism in which funds are approved in principle, but released subject to availability, typically only partially, and after delays. Over the last three years, of the allocated funds, only 48% in 2016, 43% in 2017, and 51% in 2018 were released.

Challenges in inception

There was considerable delay in identifying and selecting a team of consultants (one international and two national consultants) to support the NTP for NSP development. There were consultative meetings with provinces and regions but there was insufficient time invested to win the trust and ownership of provinces. At province level the NSP was largely perceived, though incorrectly, as an activity of the central level. There was a lot of pressure to finalize the document in time for the Global Fund application window. These lessons have been learned for the NSP 2020-2023, and the

[3] Chapter 11, 2018-2019 Health and Nutrition Economic Survey.

result is a more bottom up approach, with greater emphasis and more time given to Provinces for the development of their provincial plans.

The plan itself may not have been as clear as it could have been, and the strategies proposed were conventional, even conservative, but the activities were rational. Other countries have made much greater strides in reducing their TB burden using similar strategies, eg Cambodia, Thailand, and Myanmar. Had the strategies been fully implemented, it is likely that they would have made a much bigger impact than they have so far.

The inevitable conclusion is that the main reason the NSP 2017-2020 has not achieved much progress beyond the 2015 baseline is because it was never adequately funded. The supply of both federal and provincial funds was meagre. Government commitment was absent, as noted by the JPRM. Lack of domestic funding and political ownership were the main limiting factors. Weakening of the central unit's role as a national-provincial interface in the post devolution scenario resulted in poor advocacy from the Federal level in support of domestic resource mobilization from the provinces. There may also have been a lack of understanding that the NSP was a full expression of demand (programmatic & financial) aimed at securing both domestic financing, as well as donor funding.

In spite of over 25 years of global advocacy, including the Moscow Ministerial Conference on TB and the UN High Level Meeting in 2018, the JPRM makes clear that provincial and federal decision-makers have failed to recognise the health burden, and the tragic social consequences, due to TB. They have therefore failed to release sufficient funds to make a difference to the TB epidemic in Pakistan. (A more detailed exploration of health expenditures follows below in Section 2.2.5 and 2.3.3).

1.4 Process of development of this NSP

The goal of the development process was to have the NSP ready by mid-December 2019, in order to formulate the funding request for the Global Fund in Quarter 1 of 2020, so that funds could be certain to flow to the country by January 2021. Important preparatory milestones were achieved, notably the epidemiological analysis, through the medium of a "patient-centred workshop" in January 2019, and the Joint Review Mission in February, 2019.

Since the 18th Amendment, health is a provincial issue, and this NSP has therefore been constructed from the four provincial strategic plans (PSP) and those from the regions and territories, with guidance at each step provided by the international consultant, Paul Nunn.

An NTP national advisory team on the NSP was constituted with staff from the NTP and from the WHO country office, Islamabad. Six national consultants were recruited, one for each province, one for the regions and territories as a whole, and one to support the budget preparation. The national NSP team organised the following steps:

1. A three day national consultation was held in September 2019 which decided on the goal of the NSP and its associated targets, broken down for each province, region and territory. The targets selected were adapted from the national End TB targets prepared by the Stop TB Partnership, Geneva, from the global targets set by the UN High Level

Meeting[4], and were intended to be measurable, and in line with international guidance[5]. The priority areas, the structure and alignment of the NSP and PSPs and the provincial and federal consultation framework were also agreed upon. The participants included people with TB, members of civil society and of the CCM, Stop TB Pakistan, MoNHSRC staff and members of the Technical Working Group on TB, NTP, PTP and RTP staff, but no staff from Ministries that might be thought to have an interest in TB work. The private sector was represented by Indus Hospital Network, Mercy Corps, Greenstar Social Marketing, and Aga Khan University. Day 3 of the meeting exclusively focused on consultations with the Provinces of KP, and Balochistan, ICT, FATA , AJK and GB.

2. Two 2-day provincial consultations were held in each of the provinces of Punjab and Sindh.
3. A similar round of meetings was then held in October, 2019 to present the early versions of the plans and ensure alignment. These meetings were also used to encourage participation of the private sector, which had been rather standing back from the process, especially in Punjab and Sindh. The type and quality of interventions was discussed further in attempts to make the plans achievable and focused and to increase the probability of achieving the targets. The set of indicators was drafted, based on the End TB targets, and including the top 10 targets of the WHO End TB Strategy[6].
4. The PSPs and RSPs were submitted during November 2019 to the international consultant for comment and for incorporation into the NSP. Budgets were prepared at the same time and synthesized for the national budget.
5. The regional and territorial budgets took longer than anticipated to assemble, but were all ready by early January. The NSP Core, Monitoring and Evaluation (M&E), and Technical Assistance (TA) Plans were finalised and submitted for approval at the Endorsement Meeting, January 20-21, 2020.

2. Background

2.1 Global TB context

2.1.1 Global epidemiology of TB

Globally, an estimated 10.0 million (95% uncertainty interval, 9.0–11.1 million) people fell ill with TB in 2018, a number that has been relatively stable in recent years[7]. The slow decline in incidence of about 1.6% per year between 2000 and 2018 is offset by the rise in population. Men account for 57% of the cases, women for 32%, and children, 11%. Two-thirds of the cases occurred in Africa and East Asia, while 8% occurred in the Eastern Mediterranean Region, in which Pakistan is the largest country. Pakistan alone accounted for 6% of the global incidence, and is ranked 5th in the world for TB incidence.

TB is a fatal disease if left untreated, and it is the top infectious killer worldwide, causing more deaths than HIV/AIDS. About 1.45 million people are estimated to have died with TB in 2018, of whom a quarter of a million were infected with HIV. Drug resistance is perceived as a major threat,

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[4] UNHLM, 2018. http://stoptb.org/assets/documents/global/advocacy/unhlm/UNHLM_Targets&Commitments.pdf Accessed November 13, 2019.

[5] Harries AD, Lin Y, Kumar AMV et al. What can National TB Control Programmes in low- and middle-income countries do to end tuberculosis by 2030? F1000Res. 2018; 7: F1000 Faculty Rev-1011. Published online 2018 Jul 5. doi: 10.12688/f1000research.14821.1

[6] WHO, 2015. Implementing the End TB Strategy: the essentials. WHO, Geneva.

[7] WHO, 2019. Global Tuberculosis Report. WHO, Geneva.

with about half a million cases of rifampicin resistance in 2018, of whom 78% would have had multi-drug resistant TB.

2.1.2 Global political response

At the 2014 World Health Assembly in Geneva, Pakistan committed to the End TB Strategy, which aims to end the global TB epidemic, with targets to reduce TB deaths by 95% and to cut new cases by 90% between 2015 and 2035, and to ensure that no family is burdened with catastrophic expenses due to TB. It sets interim milestones for 2020, 2025, and 2030 (Table 3).

Similarly, Pakistan is signed up to the United Nations' (UN) Sustainable Development Goals whose Goal 3 addresses health, and aims by 2030, to end the epidemics of AIDS, tuberculosis, malaria and neglected tropical diseases[8]. In November, 2017, Pakistan attended the Moscow Ministerial Conference organised by WHO to increase commitment globally to reduce the burden of TB. The comment of the WHO's Director-General was especially apt for Pakistan: "One of the main problems has been a lack of political will and inadequate investment in fighting TB," added Dr Tedros. "Today's declaration must go hand-in-hand with increased investment."[9]

Table 3. The WHO End TB Strategy main indicators, milestones and targets

INDICATORS	MILESTONES		TARGETS	
	2020	**2025**	**2030**	**2035**
1. Reduction in TB incidence rate compared with 2015 (%)	**20%**	50%	**80%**	90%
2. Reduction in number of TB deaths compared with 2015 (%)	**35%**	75%	**90%**	95%
3. Percentage of TB patients and their households facing catastrophic costs due to TB	**Zero**	**Zero**	**Zero**	Zero

The Ministerial Conference was followed in September, 2018 by the unprecedented UN High Level Meeting on TB (UNHLM), during the General Assembly in New York. Heads of States and Governments committed to several actions through endorsement of a political declaration which is expected to lead to ending the public health menace of TB - if fully implemented. Governments committed to increase financing for TB, establish robust multi-sectoral responses to the fight against TB, increase identification and treatment of TB to narrow and then eliminate TB case finding gaps, and to increase funding for research into discovery of new tools (diagnostics, medicines and vaccines) and new delivery systems through operational research. Pakistan was a signatory to the declarations that were made at both the Ministerial Conference and the UNHLM.

2.1.3 Global achievements against the targets

Seven million cases of TB were notified and started on treatment in 2018, which hit the target for case finding that year, and was up from 6.4 million in 2017. The bulk of this increase was almost

[8] United Nations Sustainable Development Goals. http://www.un.org/sustainabledevelopment/health/ Accessed November 13, 2019.

[9] WHO. News Release, 17 November, 2017. https://www.who.int/en/news-room/detail/17-11-2017-new-global-commitment-to-end-tuberculosis Accessed November 13, 2019.

entirely due to the increases in notification in India and Indonesia, the two highest burden countries. Notwithstanding this performance, 3.0 million cases around the world were not notified. Furthermore only one third of the half million rifampicin resistant cases were started on treatment.

Case finding may be on track, but the reduction in estimated incidence between 2015 and 2018 is only one third of the target for that period. The treatment success rate target is 90%, but was only 85% in the cohort treated in 2017, although this is an increase on the 81% in 2016.

The preventive treatment target is 30 million for the 5 years between 2018 and 2022, 6 million people living with HIV (PLHIV) and 22 million household contacts. While 1.8 million PLHIV took preventive treatment in 2018, suggesting the 5 year target is achievable for this sub-group, only 350,000 contacts of 5 years or below, were treated, and 80,000 above the age of 5 years. There is a long way to go before the targets for preventive treatment are reached.

As for funding, only US$ 6.8 billion is budgeted for 2019, which is US$ 3.3 billion less than the target required by the Stop TB Global Plan to End TB, 2018-2022, but about 50% of the target set by the UNHLM.

2.2 National context

2.2.1 Geography

The Islamic Republic of Pakistan is in South Asia and borders India to the East, Afghanistan to the West, Iran to the South West and China to the far North West. The 2,430 km long border with Afghanistan is particularly important for TB care and prevention in Pakistan because of the movement of Afghans into Pakistan to seek medical care, particularly in facilities offering specialized services. The country is administratively divided into the Islamabad Capital Territory (ICT); 4 provinces: Balochistan , Khyber–Pakhtunkhwa (KP), Punjab and Sindh; and two regions (Gilgit-Baltistan (GB) and Azad Jammu and Kashmir (AJK)) and the Federally Administered Tribal Areas (FATA), which are officially to be merged with KP: the 25th Amendment of the Constitution on 31 May 2018 signified that FATA was officially merged with Khyber Pakhtunkhwa. However, de facto, the merger will take many years to complete. Since no concrete steps have yet been taken to merge heath service delivery, for the purposes of this NSP, they will be regarded as separate.

2.2.2 Population

The population of Pakistan has been steadily increasing in recent times (Figure 2) and was officially estimated in 2018 at 212 million, based on the 2017 census, with a 2% estimated annual increase[10]. This would make the 2019 mid-year population 216 million and Pakistan the sixth largest country by population. The only recent total population figure available on the Pakistan Bureau of Statistics website is 207 million in 2017[11]. However, no further commentary or assumptions are given, although the census data by block are available. Many informants in Pakistan asserted that undercounting was known to have occurred in some blocks in the census, especially in the regions and tribal areas.

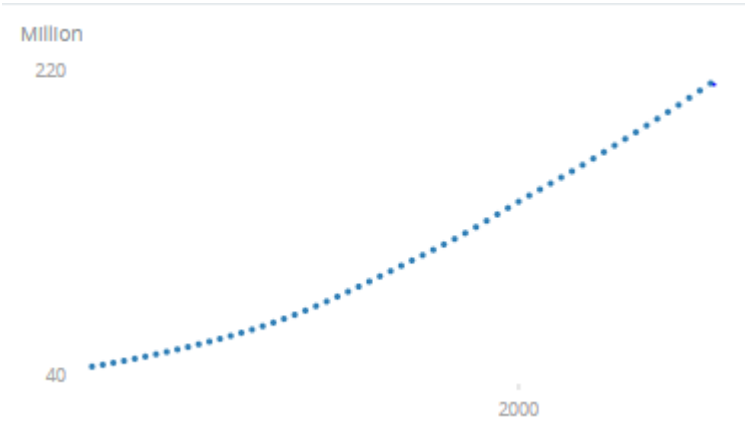
The provinces, territories and regions base their population figures on the 2017 estimates, with province, territory and region-specific annual growth rates which vary from 0.6% in Balochistan to 2.9% in KP.

[10] Wikipedia. https://en.wikipedia.org/wiki/Demographics_of_Pakistan Accessed 13 November 2019.
[11] Pakistan Bureau of Statistics. http://www.pbs.gov.pk/content/population-census Accessed 13 November 2019.

There have been drastic social changes in Pakistan which have ushered in a new era of urbanization and the creation of a couple of megacities within the country – Karachi and Lahore. The country is now one of the most urbanized cities in all of South Asia - city dwellers make up about 36% of the entire population. About 50% of Pakistani citizens live in a place where at least 5,000 other citizens reside as well[12].

The population growth rate in Pakistan is expected to halve to less than 1% by the year 2050. The population is predicted to near 210 million by 2020 and 245 million by 2030, but is not expected to stabilise until the end of this century, when it is predicted it will have reached 364 million.

Figure 2. Population of Pakistan from 1900 to 2018 (millions). Source: The World Bank[13]



Pakistan is a youthful country, with over 53% of the population below the age of 24 years, while only 10% of the population is 55 years or older (Figure 3). However, the population is ageing, and the proportion of older people is expected to double by 2050. This ageing is already putting a strain on the provision of health services[14], and over time, will put further upwards pressure on the incidence of TB. There are slightly more males than females in the country. Life expectancy at birth in 2019 is 67 years, up from less than 40 in 1950[15]. This compares with 69 for India, and nearly 77 years in Sri Lanka.

Approximately 8.8 million Pakistanis live abroad, with the vast majority, over 4.7 million, residing in the Middle East. The second largest community, at around 1.2 million, live in the United Kingdom[16]. According to the UN Department of Economic and Social Affairs, Pakistan has the 6th largest diaspora in the world. As far as we can find, no sex differences are reported among out-migrants, but the majority are assumed to be male. In 2017, overseas Pakistanis sent remittances amounting to US$15 billion.

Figure 3. The Pakistan population pyramid, 2018.

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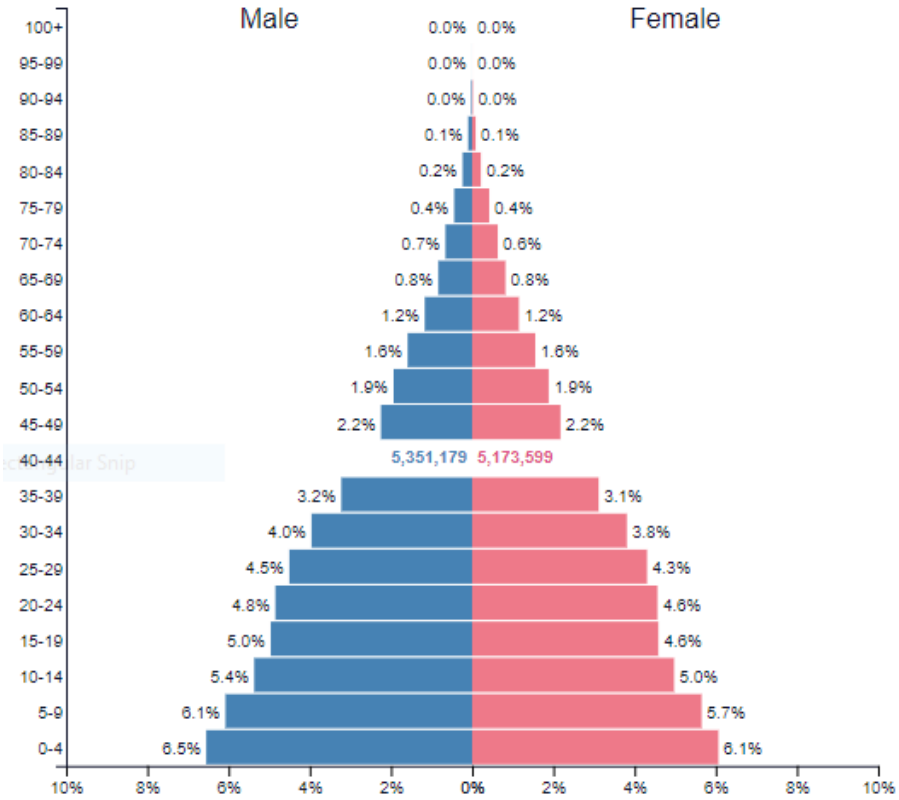
[12] World Population Review. http://worldpopulationreview.com/countries/pakistan-population/ Accessed 26 November, 2019.
[13] The World Bank. https://data.worldbank.org/country/pakistan Accessed 24 October 2019.
[14] Ashiq U, Asad AZ. 2017. The rising old-age problem in Pakistan. Journal of the Research Society of Pakistan Volume No. 54; 2: 325-333
[15] https://www.macrotrends.net/countries/PAK/pakistan/life-expectancy Accessed 26 November, 2019.
[16] Wikipedia. https://en.wikipedia.org/wiki/Overseas_Pakistani#1971_to_present Accessed 26 November, 2019.



Source : https://www.populationpyramid.net/pakistan/2018/

2.2.3 Politics

Pakistan is currently a multi-party democracy, but has passed through several phases of military government since independence from Britain in 1947. The country is a federal parliamentary republic in which, since the 18th Amendment, passed in 2010, provincial governments enjoy a high degree of autonomy. Executive power is vested with the national cabinet which is headed by the prime minister. The nominal head of state is the President who is elected by an electoral college for a five-year term, but whose major powers were stripped away by the 18th amendment. Since then, Pakistan has had a purely parliamentary government.

The current Prime Minister is Imran Khan, well-known to cricket fans, who is the head of the Pakistan Tehreek-e-Insaf (PTI) party. Following the 2018 election campaign, the PTI party won 116 of the 272 seats available, and has joined with several smaller parties to form a majority in parliament, which looks stable.

2.2.4 Socio-economic development

The economy of Pakistan, as judged by measures of gross domestic production (GDP) has been increasing in size since 1990, with several plateaus relating to political events (Figure 4). A nominal GDP per capita of US$1,357 in 2019, ranks it 154th in the world and giving it a purchasing power parity (PPP) GDP per capita of US$ 5,839 in 2019[17]. However, Pakistan's undocumented economy is estimated to be 36% of its overall economy, which is not taken into consideration when calculating per capita income. Pakistan is a developing country, but is thought by some economists to have a high potential of becoming, along with the BRICS countries, one of the world's largest

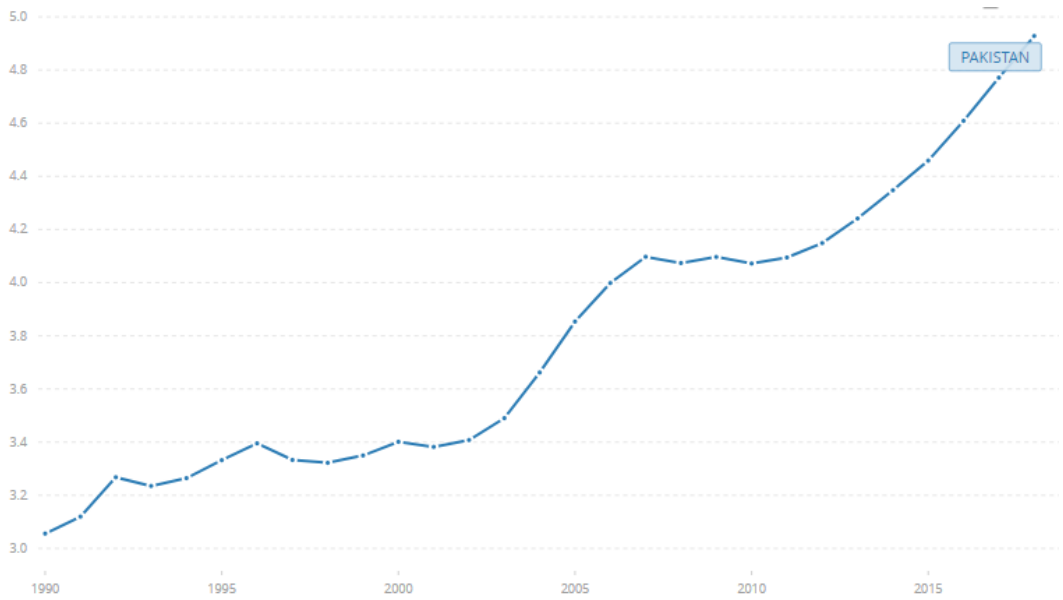
[17] Wikipedia. https://en.wikipedia.org/wiki/Economy_of_Pakistan Accessed 26 November, 2019.

economies in the 21st century. In 2019, however, the economy was semi-industrialized, with centres of growth along the Indus River. Primary export commodities include textiles, leather goods, sports goods, chemicals, carpets/rugs and medical instruments.

The diversified economies of Karachi and major urban centres in the Punjab coexist with less developed areas in other parts of the country. The economy has suffered in the past from internal political disputes, a fast-growing population, and mixed levels of foreign investment. Foreign exchange reserves are bolstered by steady worker remittances, but a growing current account deficit – driven by a widening trade gap as import growth outstrips export expansion – could draw down reserves and dampen GDP growth in the medium term. Pakistan is currently undergoing a process of economic liberalization, including privatization of all government corporations, aimed at attracting foreign investment and cutting the budget deficit.

In October 2016, the IMF chief Christine Lagarde confirmed her economic assessment that Pakistan's economy was 'out of crisis', in large part because it was benefitting from Chinese investment. In May 2019, though, the IMF predicted that future growth rates would be 2.9%, the lowest in South Asia. Nevertheless, poverty in Pakistan fell from 64.3% in 2002 to 29.5% in 2014.

Figure 4. GDP per capita by purchasing power parity (PPP) in 2011 (constant US $ in thousands). Source: The World Bank[18]



2.2.5 Health expenditure

Total health expenditure was 3.1% of GDP as of 2016, down from a peak of 3.4% in 2006 (Table 4). Of total health expenditure in Pakistan, 34% is funded by the public sector[19]. The government's contribution to total health expenditure in terms of GDP is about 1%. At US$ 11, the per capita annual government expenditure on health is one of the lowest in the world[20].

[18] The World Bank. https://data.worldbank.org/indicator/NY.GDP.PCAP.PP.CD?locations=PK Accessed 24 October 2019.
[19] Pakistan Bureau of Statistics. The National Health Accounts, 2015-2016.
[20] IHME. http://www.healthdata.org/pakistan Accessed 10th December 2019.

Out of total public sector health expenditures, 21.8% are funded by the federal government - 58% from its civilian part and 42% from its military component. Around 64.4% of total health expenditures are funded through the private sector out of which 89% is out of pocket (OOP) health expenditures by private households. OOP health expenditure in Pakistan was therefore about 57% in 2016, as a percentage of total expenditure on health, which amounts to over Rs 1,000 per household per month. The ratio of general government health expenditures to total general government final consumption expenditure was nearly 10% (9.7%) in 2016, but this denominator probably excludes military spending.

The government's federal budget of 2017-2018 (1 July to 30 June) was Rs 4.75 billion, which increased with Prime Minister Imran Khan's first budget to Rs 5.9 billion for 2018-2019. It was difficult to tease out the total government health budget from the reports available. Some health projects and programmes saw an increase in budget, eg Health Affairs and Services, which includes hospitals, but others did not, eg the Public Sector Development Programme. There was no specific mention of TB, or even infectious diseases, or public health programmes, in the budget reports[21]. The budget was clearly an attempt to stimulate the economy.

Table 4. Main health economic indicators from the National Health Accounts

Main indicators	2005-06	2007-08	2009-10	2011-12	2013-14	2015-16
Total health expenditures ratio to GDP	3.4	3.3	3.0	2.8	3.0	3.1
General government health expenditures ratio to General government final consumption expenditure	7.6	8.6	9.2	9.7	9.3	9.7
Private health expenditures ratio to household final consumption expenditure	3.4	2.9	2.5	2.1	2.5	2.5
Per Capita (In Rs)	1,822	2,106	2,611	3,099	4,067	4,688
Per Capita (In $)	30.4	33.7	31.2	34.7	39.5	45.0

Pakistan is spending the lowest on health in the Eastern Mediterranean Region[22]. At the same time, however, health departments are not able to spend the disbursements completely. A significant amount of budget stays unspent at the end of the fiscal year. "Proper financial management is a big issue", according to the inter-ministerial council. One Provincial Minister reported that budgets are not evidence based and there are a lot of procedural delays due to unnecessarily lengthy bureaucratic and legal processes.

2.2.4 National health structure

Pakistan has a mixed health system, which includes government (public) infrastructure, para-statal health institutions, the private sector, civil society and philanthropic contributors. A major strength of the public health care system in Pakistan is considered to be its outreach primary health care, delivered at the community level by 100,000 Lady Health Workers (LHWs), and an increasing number of community midwives (CMWs), and other community based workers. Complementary, alternative and traditional systems of healing are also popular in Pakistan. Not all practitioners in these areas are qualified.

Public health care is delivered in the provinces mainly through a chain of primary, secondary and tertiary level health facilities. The primary health care facilities include civil dispensaries, basic health units (BHU), rural health centres (RHC), MCH Centres, urban health units and urban health centres

[21] The News, Pakistan. https://www.thenews.com.pk/latest/310231-here-is-all-you-want-to-know-about-budget-2018-19 Accessed 3 December 2019.
[22] Inter-ministerial health and population council meeting, June 2019.

(Table 5). The secondary level health care facilities comprise taluka (tehsil) hospitals and district hospitals. Tertiary level health care is provided through teaching and specialized hospitals.

However, multiple public sector agencies also have large hospitals – the para-statal health institutions - such as the military hospitals, which also provide services to the dependents of service personnel, and the Pakistan Railways. Employee social security systems, such as the Sindh Employees Social Services Institution (SESSI), also provide services to labourers working in factories and their families through networks of health facilities, including hospitals, in many major cities. Furthermore, health services are also provided by various other agencies to their own employees like Pakistan International Airlines (PIA), the Water and Power Development Authority (WAPDA), utilities such as K-Electric, based in Karachi, the Pakistan Steel Mills, Karachi Port Trust, Sui Southern Gas Company, Pakistan Petroleum Limited, Oil and Gas Development Corporation etc.. Only a minority of these public and private facilities has a TB Basic Management Unit, or is engaged in anyway with public sector TB control activities.

A series of programmes and projects are on track in Pakistan to improve the health status of the people and to reduce the burden of communicable and non-communicable diseases while vertical programs have been devolved to the provinces. There have been significant increases in the number of facilities within the public health service, and the official numbers for 2018 are in Table 5. These facilities together with over 220,000 registered doctors, more than 22,000 registered dentists and 108,000 registered nurses bring the current ratio of one doctor to every 963 people. By the end of 2018 there was one hospital bed for every 1,608 people.

Table 5. Estimated Number and type of the major public health facilities in Pakistan, 2018. *Source: NTP.*

Facility Type	Catchment population	Number
Dispensaries	25,000-50,000	5,671
Basic Health Units	25,000- 50,000	5,202
Rural Health Centres	100,000- 250,000	686
Tehsil headquarters hospitals (THQ)	0.5-1.0 million	450
District headquarters hospitals	1-3 million	
Public tertiary and specialised hospitals	National access	

In Pakistan, the private health sector is a hugely significant component of the health sector: an estimated 84% of initial healthcare seeking takes place in the private sector, 24% with informal providers and 61% with formal providers, especially GPs[23]. Private healthcare providers include at least 100,000 GPs, over 67,000 pharmacies, thousands of laboratories, and around 5,000 hospitals.

[23] Patient Pathway Analysis; Report of National Workshop on Data and Evidence for Policy Actions Towards Ending TB in Pakistan; Jan 2019

While they are concentrated in urban areas, GPs and informal providers also serve small towns in rural areas.

Public-private mix approaches for TB have been explored in recent years and will be addressed below (Section 2.4.4).

2.2.5 Health performance

Pakistan is facing a double burden of disease (BoD) and the burden is higher in the poor. Communicable diseases, maternal health issues and under-nutrition dominate and constitute about half of the burden of disease, with non-communicable diseases the remainder. With Afghanistan and Nigeria, Pakistan is one of only three remaining countries where polio is still endemic. Population growth is recognised as a challenge, and access to contraception is failing to meet women's needs.

Non-communicable diseases (NCDs) along with injuries and mental health, now constitute over half of the burden of disease, causing disabilities and premature deaths among the economically productive adult age groups, as well as among the retired. The government recognises that the common underlying factors for NCDs, which include lifestyle, nutrition and smoking have not been addressed adequately. Injuries account for more than 11% of the total disease burden, and are likely to rise. With respect to risk factors for TB, Pakistan is ranked 7th highest in the world for diabetes prevalence, and smoking levels are high - 38% among men and 7% among women.

The Government of Pakistan (GoP) recognises that vertical service delivery structures and low accountability for performance within the public sector reduce efficiency and quality of provision. The public sector is inadequately staffed and job satisfaction and work environment need improvement. Largely unregulated for quality and appropriateness of care and pricing, there is also duplication of services by the private sector (see below). Unsurprisingly, the private sector contributes least towards preventive and promotive health services. The health sector, overall, also faces an imbalance in the number, skill mix and deployment of the health workforce, and inadequate resource allocation across different levels of health care i.e. primary, secondary and tertiary.

Overall health performance can be looked at in different ways, but health access and quality (HAQ) is key. The HAQ indicator provides a summary measure of healthcare access and quality and is based on an assessment of risk of mortality from causes that, in the presence of quality healthcare, should not result in death. Pakistan's HAQ indicator improved from 26.8 in 1990 to 37.6 in 2016[24] –Pakistan ranks 154th in the world[25] for its HAQ status – in exactly the same position as its ranking on GDP per capita.

In some aspects, however, Pakistan ranks rather below its overall position, particularly in relation to child health, especially immunisation rates and under 5 mortality (Table 6). Interestingly, it also ranks 10th in the world for mobile phone subscriptions.

National indicators in Pakistan, however, conceal significant variation between provinces, and even more between provinces and territories – Punjab and ICT generally having better health indices than AJK, GB and FATA, with the other provinces in between.

[24] IHME. http://www.healthdata.org/pakistan Accessed 14th December, 2019

[25] GBD 2016 Healthcare Access and Quality Collaborators. Measuring performance on the Healthcare Access and Quality Index for 195 countries and territories and selected subnational locations. Lancet, 2018: 391; 2236-71

Table 6. Recent general health indicators. *Sources: see Table*

Indicator	Date	Value	International Ranking
Maternal mortality rate	2017	140 (per 100,000 live births)[26]	130th[27]
Under 5 mortality rate	2018	69.3 (per 1,000 live births)	169th[28]
Measles immunization	2018	76%	176th[29]
Neonatal tetanus cases	2015	667	-
HIV prevalence	2018	0.1%	-
Fertility rate	2017	3.6 (births per woman)	-
Mobile phone subscriptions	2018	72.6%	10th[30]

2.2.6 Health priorities, policies, strategies and regulatory frameworks

National Health Vision

There is a national vision for health[31], developed in 2016, which promises "universal access to affordable quality essential health services, delivered through resilient and responsive health system,… and to attain the Sustainable Development Goals". It states that the national vision is within the framework of post 18th Amendment Constitutional roles/responsibilities, but government: province coordination mechanisms are not clearly laid out.

The vision aims to build convergence with important national programs and policy settings such as the Pakistan Vision 2025, the Poverty Reduction Strategy, and pro-poor social protection initiatives.

While, "government is cognizant that adequate, responsive and efficient health financing is the cornerstone of a country's well-functioning health systems", the vision's promise that "Federal and Provincial governments will increase allocation to health … to 3% of GDP" had not yet materialised by 2018, thus placing in doubt that the vision can be financed.

The National Health Vision has five objectives, most of which focus on aspects of central government: provincial coordination. Of note for TB control, is that the GoP "will be encouraging and supporting the integration of vertical programmes at the provincial level for optimal and efficient utilization of resources and better performance". What this may mean in practice is not spelt out. However, "governments will be enforcing the public health laws promulgated, related to smoking, drug safety, … etc.", although there is no reference to mandatory notification of infectious diseases. Collaboration with the private sector is seen as essential: "Efforts would be geared toward building synergies with the private sector in essential health services delivery (preventive and curative)".

[26] https://knoema.com/atlas/Pakistan/Maternal-mortality-ratio Accessed 14th December, 2019
[27] https://en.wikipedia.org/wiki/List_of_countries_by_maternal_mortality_ratio Accessed 14th December, 2019
[28] https://www.indexmundi.com/facts/indicators/SH.DYN.MORT/rankings Accessed 14th December, 2019
[29] https://www.indexmundi.com/facts/indicators/SH.IMM.MEAS/rankings Accessed 14th December, 2019
[30] https://www.theglobaleconomy.com/rankings/Mobile_phone_subscribers/ Accessed 14th December, 2019
[31] MoNHSRC. National Health Vision, 2016-2025.

Disease control

In November, 2019, Pakistan became the first country[32] to adopt the 3rd edition of Disease Control Priorities, DCP - 3[33], which is a global package of Essential Health Services brought together by more than 500 scholars, policy makers and technical experts. It consists of a concrete set of priorities for universal health coverage (UHC), "grounded in economic reality and intended to prove appropriate to the health needs and constraints of low- and middle-income countries (LMICs), by (1) developing a model benefits package referred to as essential UHC (EUHC); (2) identifying a subset of interventions termed the highest-priority package (HPP); and (3) presenting a case all countries—including low-income countries—could strive to fully implement the HPP interventions by the end of the Sustainable Development Goals." Pakistan is in the process of developing the Essential Universal Health Coverage (EUHC) Package in line with the DCP3. This will reorganize the health services across the country and will eventually be linked with health insurance.

Multi-sectoral involvement in health

The End TB Strategy is facing problems in country-level implementation of its second pillar[34] – bold policies and supportive systems - which promotes "strategic actions within and beyond the health sector" to contribute to the implementation of policies that will address TB, as well as other benefits and health advantages, eg Ministries of Food or Agriculture placing restrictions on sugar content of fizzy drinks to limit the rise of diabetes, a major risk factor for TB.

In response, WHO's Global TB Programme is pursuing multi-sectoral involvement in health[35] through its *Multi-sectoral Accountability Framework* (MSAF). The aims are to accelerate the multi-sectoral response to the tuberculosis epidemic at global, regional and country levels, in recognition of the fact that investments and actions were falling short of those needed to reach the targets and milestones of the WHO End TB Strategy and the target of ending the epidemic by 2030 that is part of the United Nations Sustainable Development Goals.

In Pakistan, the Inter-Ministerial Health & Population Council of Pakistan has met once on 20th June 2019, chaired by the Special Assistant to Prime Minister/ Minister of State, Dr. Zafar Mirza with the Health and Population Ministers from the Provinces and Federal Areas. They addressed TB, noting that a huge funding gap exists in the TB Programme. All provincial ministers were urged to enhance domestic funding and address case detection and better management of drug resistant TB. It was suggested that a National Awareness Campaign of 2-4 weeks may be launched engaging community as well as health care providers.

This Inter-Ministerial Group, however, brings together the national Special Adviser/Minister and his provincial/regional/territorial counterparts. That is, all the participants come from within the health sector, and not from outside, thus limiting the group's impact on multi-sectoral advances. In any case, further work on the MSAF seems unlikely in the immediate future due to abolition of the partnership development post in the NTP that was intended to address this issue.

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[32] https://en.dailypakistan.com.pk/25-Nov-2019/pakistan-becomes-first-in-world-to-adopt-disease-control-priorities-3 Accessed 14th December

[33] Disease Control Priorities. DCP3. http://dcp-3.org/ Accessed 14th December

[34] Nunn PP. A review of national strategic plans for tuberculosis in the countries of the WHO South East Asia Region, as of December 2017. Prepared for WHO, SEARO.

[35] WHO, 2018. The multi-sectoral accountability framework: to accelerate progress to end TB by 2030. WHO, Geneva.

2.2.7 Social protection for health

The Sehat Sahulat Progrmme (SSP)

The MoNHSRC, in collaboration with provincial governments, has started a social protection initiative for health care, the *Sehat Sahulat Programme*, previously known as the Prime Minister's National Health Programme. The objective is to lead a path towards Universal Health Coverage (UHC) in Pakistan, with special focus towards those living below the poverty line in the country. The program is being implemented in a phased manner.

By February 2019, this programme was covering 38 districts and had contracted 154 public and private hospitals. When fully rolled out the SSP should cover over 50% of the Pakistani population. For now, the program does not cover primary care. The identification of beneficiaries is based on household poverty surveys where every household is scored between 0-100 with 0 being the poorest and 100 the richest. A score of 16 is equivalent to a daily income of one US$. A new poverty survey is currently ongoing.

Access to SSP benefits depends upon receiving an Insaf card, which can be obtained through sending the citizen's National Identity Card Number via SMS with to the SSP number, and if eligible, the card is received from the district SSP distribution centre. Once admitted, the patient's costs are charged to the Sehat Insaf card, and the hospital is reimbursed.

In Phase I of the SSP each enrolled family is insured for up to Rs. 50,000 per year for secondary care treatment and up to Rs. 250,000 per year for 7 priority care treatments – which do not include TB, as TB treatment is already supplied free of charge. Patients who have consumed their limits will be provided with additional limits by Pakistan Bait-ul-Mal.

In Phase II of the SSP, the benefit package of each enrolled family will be raised to Rs. 120,000 per year for secondary, inpatient (indoor), care and treatment and up to Rs. 600,000 per year for treatment related to 8 priority diseases or illnesses – still not including TB.

SSP is a cashless scheme in which no cash assistance or cash transfers will be provided to the beneficiary except in-patient health care services and a traveling allowance of Rs. 350 per discharge, for a total of 3 discharges per year, from residence to hospital and back. In Phase-II of SSP, this will be increased to Rs. 1,000.

As of 9th February 2019, a total of 3,237,660 families had been enrolled in the SSP and more than 117,726 families have been treated for various illnesses from 157 empanelled hospitals across Pakistan. There is also an option of inter district portability in the program which enables the enrolled beneficiaries and families to access quality in-patient hospital services from any empanelled hospital, both in the public and private sectors.

The SSP is being implemented through the State Life Insurance Corporation of Pakistan, hired through an open and transparent bidding process. Services are delivered to the beneficiaries by empanelling secondary and tertiary level health care facilities, both in the public and private sectors, in all involved districts and metropolitan cities. The hospital empanelling is based on pre-established criteria.

Bait-ul-Mal

Pakistan's Bait-ul-Mal or (PBM) is a charity and social welfare organisation to help the poor and needy in Pakistan. It is a semi-autonomous body set up through a 1992 Act of the Government of Pakistan and provides financial help to "deserving poor people" earning less than Rs 10,000 per month. Established in 1992 through an act of parliament and funded largely by the Government, it has an annual budget of about of Rs 5-6 billion. It is present in every district in which a team checks eligibility of would be beneficiaries using a standard check list. Beneficiaries receive support that does not exceed Rs 600,000 per patient. Interestingly for TB, PBM also has residential

accommodation in shelter homes for the deserving homeless and abandoned elderly people, and has set up free hospitals and rehabilitation centres for the poor to provide free medical treatment. There are no current links between PBM and any of the provincial or regional TB services.

Benazir Income Support Program (BISP)

Initiated in 2008, the BISP is a cash transfer program that reaches about 5.2 million women across Pakistan. Each woman receives about USD 40 every quarter. Through this program, nearly 60 million people (the women and their families) are reached. The beneficiaries are identified through poverty surveys as in the PBM program and the program has a dynamic registry. The Government of Pakistan spends about USD1.2 billion on this program with 86% of the funding coming from domestic sources. The other donors include World Bank/Asian Development Bank (ADB) and the United Kingdom's Department for International Development (DFID). A major focus of this program is addressing malnutrition. The cash transfers are currently non-conditional but there are plans to explore conditionalities through complementary opportunities which may include cash transfers for educational programs in which the beneficiary is given an incentive to take her child to school.

Social protection for people or families with TB

Existing social protection mechanisms, the SSP and Biat-ul-Mal, do not specifically provide cover for TB services. In any case, TB is mostly diagnosed and treated in the Out Patient Department (OPD), while the Sehat Insaf card only covers indoor (inpatient) expenses. The Global Fund has been providing significant financial support for patients (and families) with MDR-TB (Rs1000 for patients and Rs600 for travel for the patient ,and Rs600 for a supporter, per month).

2.3 National tuberculosis situation

2.3.1 Organisation and management of TB services

Major implementing agencies – Federal level

The National TB Control Programme (NTP) was established in July 2000 for country wide implementation of the DOTS strategy. The GoP had adopted the DOTS strategy in 1995, and in 2001 declared TB as a National Emergency - the "Islamabad Declaration", giving the NTP the mandate to design and regulate TB control activities in the country utilizing both domestic and donor resources. The programme has been decentralized to provincial and district level and integrated with Primary Health Care services. It is also moving towards integration in secondary and tertiary care services. Since the 18th Constitutional Amendment in 2011, the provincial governments are mainly responsible for dealing with health related matters in their jurisdiction, and their Provincial TB Control Programs are now responsible for the organisation and management of provincial TB services.

The National TB Control Programme was reinforced through a GoP, Ministry of Inter-Provincial Coordination notification, dated 14th October 2011. From that date until 30th June 2016, the NTP functioned as a National Programme. Then, a joint PC-1 was approved for the period 1st July 2016 to 30th June 2019, extended until June 2020, to create the Common Management Unit (CMU) to manage Global Fund grants for AIDS, TB and malaria. However, formally, the CMU was not established under one roof until 1st January 2018 with the start of the 2nd tranche of the new funding model (NFM-2) grant. Nominally, the NTP is a technical unit of the CMU, as are the National AIDS Control Programme (NACP) and the Department of Malaria Control (DoMC). Global Fund-related support functions like finance, PSM, audit, monitoring and evaluation, surveillance and research were integrated for the three diseases. The NTP also functions as a subordinate department of the MoNHSRC.

From the central level, the NTP collaborates with several technical and implementing partners, notably the WHO, the US Agency for International Development (USAID), the International

Organisation for Migration (IOM), the National Rural Support Programme (NRSP), the Pakistan Chest Society, the Pakistan Paediatric Association, Mercy Corps (and their partners, see below), Indus Hospital Network (IHN – and their partners, see below)), the Aga Khan University (AKU), Green Star Social Marketing, the Pakistan Anti TB Association (PATA) and other national NGOs.

Of particular relevance to this NSP, the NTP has taken some key steps for TB control:

- **TB management information system:** Integrated District Health Information System (DHIS-2) for HIV, TB and Malaria has been developed and is expanding through the districts; the majority of GeneXpert machines are connected by the automated GxAlert system; the NTP carried out the first prevalence survey for TB conducted to current international standards (2010-11), and the first drug resistance survey (DRS) in Pakistan:
- **TB care provision:** Provision of free anti-TB medicines at 5,000+ public sector health facilities; provision of free diagnostics through 1,400 public sector facilities; 22 biosafety laboratories for culture and DST (BSL2 & BSL3); established WHO recommended rapid testing (Xpert testing) at 450 centres; 34 special centers for DR TB patient management; provision of social support to all DR TB patients; guidelines and training material for patient management; operational guidelines and training material to engage 5,000 private heath care providers for TB management; TB awareness campaign through print and electronic media:
- **TB Legislation**: the NTP has assisted PTPs with developing and implementing "Mandatory TB Case Notification" Bills, which have been passed by three Provincial Assemblies and bylaws have been developed; pilot intervention for legislation for mandatory TB case notification; however, the Bill in Balochistan and, notably, at Federal level is still in process;
- **Research in TB**: Capacity building in research workshops organized by the NTP has trained researchers from all across the country and around 50 TB papers in national and international journals have been published.

At federal level, the core responsibilities retained with the NTP, include strategic planning, formulation of policy guidelines, technical support to the provincial/ regional programmes and other implementing entities, disease surveillance and dissemination of data to national and international stakeholders, monitoring and supervision of programme activities, coordination and communication with national and international partners (bilateral and multi-lateral agencies and donors), and research and development. The critical mass of TB experts is needed at the central level to carry out these fuctions.

Current staffing levels at the federal level of the NTP includes: 1 Deputy National Coordinator (DNC) or NTP manager; 1TB advisor, 1 laboratory advisor,1 PPM focal person; 2 MDRTB specialists; . Only six central unit professional staff for a population in excess of 200 million, with major coordination challenges between provinces, regions and territories is short-sighted. While only the NTP Manager is paid by the federal level, reluctance of external agencies to support more staff is understandable, but this small number goes a long way to explain the poor level of grant disbursement (see 2.3.3).

Further challenges faced by the Central Unit in disease management and grant implementation include:

- Adhoc management arrangements at federal level and HR limitations
- coordination with the provinces for a coherent national response to disease control
- disease surveillance and international reporting
- Policy formulation for TB management
- Technical support to prepare TB management guidelines & training material for the country uniform
- Development of the M&E framework and guidelines for the country
- Data analysis, evidence generation

- Research capacity building
- Gaps in multi-sectoral collaboration at all levels
- Absence of integrated disease surveillance system to timely pick unusual occurrence of cases and respond efficiently
- Compromised M&E
- Limited domestic financing - government contribution is approximately 7% as health financing is a provincial subject now
- Tax exemptions required for CESS, GST and Provincial Tax (Punjab)
- Collaboration with other health programs especially at implementation level
- Implementation of mandatory case notification law

Finally, confusions around the roles and responsibilities of the NTP and its staff after devolution, and after the formation of the CMU, have not been entirely avoided.

Province and district level

There are regular coordination meetings at district and provincial levels where TB data is examined, challenges identified, and corrective action proposed. These meetings (intra-district, and inter-district at the provincial level) occur every quarter. However, regular inter-provincial level meetings at the national level were no longer supported which was a cause for concern for the JPRM in relation to national coordination of the TB response.

The PTP is part and parcel of the Department of Health structure at the provincial level and is led by a senior member of the Provincial Health Team. However, while technical experts are available, there has been a rapid turnover of program leadership in some provinces, affecting programme performance, accountability and sustainability.

In the post-devolution scenario at provincial level, the Provincial TB Programmes had already become sub-recipients (SRs) to the principal recipient (PR), the NTP, in a single stream funding (SSF) grant which started on 1st January 2014. Until that point, the PTPs had worked as implementing partners of the NTP-PR, just as AJK, GB and FATA implement grants nowadays.

At the district level, though, a multipurpose staff is normally the district focal person for TB, and does not usually work full-time on TB, but can be pulled away for more priority issues, or those that are attracting politicians' attention. The post is not usually a regular position of the Ministry of Health (Province) at that level.

In contrast, attempts have successfully been made to ensure that TB Basic Management Unit (BMU)/ RHC have staff responsible for TB activities. Thus, at the BMU/RHC a TB focal point who is a medical officer, a Direct Observed Therapy Short course (DOTS) facilitator and laboratory technician have been put in place in most provinces.

In general, the health sub- system below the level of the RHC is not currently involved in TB services representing a lost opportunity to bring TB services closer to the community and people affected by tuberculosis.

As for the private partners (see below - , by Round-6, in November 2007, Mercy Corps became the private sector PR, along with NTP, as the public sector PR. IHN became an SR to NTP-PR in 2009 in Round-9 of the Global Fund grant, and in May 2016, it was granted the status of second private sector PR by the Global Fund, which continues to-date.

Organisation of TB Care services - Periphery

The 155 districts in Pakistan are the implementation units of the NTP/PTPs, and are responsible for the care delivery processes including program planning, training of care providers, case detection,

case management, monitoring and supervision. The PTPs provides the districts with overall technical and material support including drugs, lab supplies, hardware etc.. National numbers of diagnostic and treatment services are shown in Table 7.

Table 7. Numbers of public and private diagnostic and treatment services, 2019

	Public	Private	TOTAL
Diagnostic Services			
Microscopy Laboratories	1,360	454	**1,814**
GeneXpert machines	334	34	**368**
Culture laboratories	18	04	**22**
Genotypic drug susceptibility testing (DST) facilities – line probe assay (LPA)	05	02	**07**
Phenotypic DST	03	02	**05**
Digital X-Ray CAD4TB machines	09	52	**61**
Treatment Services			
Basic Management units (BMU)*, including (PPM 2,3,4 – see 2.4.4 for explanation)	1,360		**1,360**
General Practitioners (PPM-1)		6,421	**6,421**
Programmatic management of drug resistant TB treatment sites	28	05	**33**
HIV surveillance sites	40		**40**

*In addition to these, 15 Military hospitals are BMU as well.

The most peripheral elements of the NTP in the public sector are the BMUs, which cluster together some 4-6 BHUs. However, in practice, the number of BHUs actively and formally engaged with the PTPs is very small (Table 8). There is therefore concern that the engagement of the PTPs/RTPs and NTP with the BHUs is insufficient, which was borne out by visits to BHUs by the JPRM members, and the JPRM had made this point forcibly.

Table 8. Numbers of BHUs formally engaged with the RTP or PTP/NTP. ***Source: NTP***

Province	No. of BHUs Engaged	Total No. of BHUs
Punjab	6	2500
Sindh	48	810
Balochistan	39	688
Khyber-Pakhtunkhwa	7	769
Azad Kashmir	12	227
Islamabad	3	16
Gilgit Baltistan	6	23
Khyber-Pakhtunkhwa (Tribal Districts)	3	169
Total	**124**	**5202**

Private sector PRs - Mercy Corps (MC)

Mercy Corps has been engaged in TB control interventions in Pakistan since 2002, and as the private sector PR of the Global Fund to support TB control activities since 2007, initially implementing Advocacy, Communication and Social Mobilization (ACSM) interventions in 57 districts of Pakistan. In 2010, MC started implementing Public-Private Mix (PPM) interventions to increase TB case detection and to ensure that a standardized diagnosis and treatment process was provided to TB patients.

MC is currently implementing the current Global Fund grant in 67 districts across the country with the support of six implementing partners, and is directly implementing itself in a few of the districts (Table 9). MC is currently using three different approaches to reach the missing TB cases and enhance TB case notification. These approaches include; a) GP Model, b) active case finding and c) enhanced case finding. Through all these interventions, MC was able to register over 55,000 TB cases, all forms, since January 2018, with a treatment success rate of 94% (Table 10). A total of 289 rifampicin resistant (RR) cases were also notified. Overall, the PPM contribution in the districts in which MC in working increased from 8% in 2015 to 24% in 2018.

The interventions are as follows:

Engagement of private healthcare providers and labs (the GP model)

1. Mapping and selection
2. Training
3. Provision of anti-TB drugs, lab reagents and other consumables
4. Data recording and reporting, supervision and monitoring

Active case finding

1. Community gatherings
2. Engagement of Lady Health Workers
3. Conventional chest camps
4. Mobile screening camps with digital x-rays and Gene Xpert

Enhanced case finding

1. TB screeners in large private hospitals
2. GeneXpert testing

Table 9. Sub-recipients and their geographical coverage. *Source: Mercy Corps*

	Sub Recipients	Province	No. of Districts
1	Association for Community Development (ACD)	Khyber Pakhtunkhwa	12
2	Association for Social Development (ASD)	Punjab	13
3	Bridge Consultants Foundation (BCF)	Sindh	11
4	Pakistan Lions Youth Council (PLYC)	Punjab + Sindh	4 + 4
5	Strengthening Participatory Organization (SPO)	Balochistan	6
6	Marie Adelaide Leprosy Centre (MALC)	Azad Jammu & Kashmir; Gilgit-Baltistan,	7
7	Mercy Corps Project Implementation Unit (PIU)	Punjab	7
8	Mercy Corps – Quetta	Balochistan	3
	Total		**67**

Table 10. Intervention wise progress. *Source: Mercy Corps*

Sr. #	Indictors	Jan 18 to Sep 19		
		Target	Result	%
1.	All Forms Cases notified	69,509	66,247	95%
2.	Cases from private healthcare providers	59,481	58,653	99%
3.	Treatment Success Rate	62,784	58,969	94%
4.	Cases form chest camps	6,188	4,445	71%
5.	Cases from LHWs	1,545	974	63%
6.	Rifampicin Resistant Cases notified	352	335	95%
7.	Labs performing adequately under EQA	87%	90.7%	104%

Targets of cases from chest camps and LHWs component were not met because of delayed initiation of the interventions as well as temporary halts due to reasons beyond MC's control.

Indus Health Network (IHN) as PR

Under their Zero TB – Search, Treat, Prevent - model, IHN conducts three main activities:

Active case-finding in adults

Facility - Based Screening model: Active Case Finding (ACF) among adults is conducted through digital chest x-rays using computer-aided detection- CAD4TB technology for identification of presumptive TB and access to GeneXpert Testing (at baseline) of all presumptive TB. This intervention engages with health facilities across the intervention city, screening all individuals coming in to hospital OPDs as well as in-patient departments (where the program is operational). Screening camps are also conducted in the catchment populations of these hospitals

Community Screening model: A significant proportion are missed in the community. The program conducts community based screening (along with private partners) in high-burden areas identified as hot-spots for disease and amongst high-risk groups/populations in districts where the program is operational.

Contact management and prevention treatment

Facility-Based contact screening: The program reaches out to the families of TB patients and invites them in health facilities for TB disease evaluation. All contacts are thoroughly screened for TB by a doctor. All those diagnosed with TB are started on TB disease treatment. All household contacts who are free of TB disease are eligible for TB prevention treatment. The intervention offers preventive treatment to all the household contacts ensuring completion rate of at least 65%.

Targeted community based contact screening to improve access and coverage of services: Household contacts of TB patients are mostly healthy individuals having no symptoms. It is difficult to convince them to visit health facilities for screening as that is time consuming and most of the families are from working class earning their wages on a daily basis. Visiting facility means compromising their

daily wage. This allows for provision of services near their doorstep maximizing numbers of contacts screened.

Active case finding in children

Screening of children visiting pediatric OPDs (at the health facilities where the program is active) is conducted using a dedicated nurse trained on a verbal symptom screen tool for TB and with assessment of risk factors such as presence of TB contact and/or TB history. Those identified as TB presumptives are referred to a trained medical officer who further evaluates the children for TB and confirms TB diagnosis. Patients identified with TB are started on treatment and followed through their course of treatment to ensure adherence and favorable treatment outcomes.

Table 11. Results summary by partner for 2018 to end of quarter 3, 2019. *Source: IHN*

Activities	Program/SRs	Jan – Jun 2018	Jul – Dec 2018	Jan – Jun 2019	Jul-Sep 2019	Total
DSTB Cases Notified (New and Relapse)	GSM GPs (SR)	14,364	14,448	13,493	7,300	49,605
	CHS Centers (SR)	5,280	6,587	7,612	4,664	24,143
	Indus Hospital site (PR)	1105	838	877	385	3,205
	Zero TB Intervention Private sites (PR)	519	820	1,041	510	2,890
	Zero TB Intervention Public sites (PR)	4,970	5,813	6,267	2,924	19,974
	Total TIH	**26,238**	**28,506**	**29,290**	**15,783**	**99,817**
DSTB Cases Treatment Outcomes	GSM (SR)	88%	92%	89%	86%	
	CHS (SR)	80%	72%	79%	80%	
	Indus (PR)	88%	82%	91%	91%	
	Total TIH	**86%**	**87%**	**87%**	**86%**	**87%**
Conventional Chest Camps	GSM (SR)	621	521	662	338	2,142
X Ray Van Camps (Community Based)	CHS (SR)	1130	1344	1,062	713	4,249
X Ray Vans Camps (Community and Health Facilities Based)	Indus (PR)	984	1866	2,603	1246	6,699

	Total TIH	**2,735**	**3,731**	**4,327**	**2,297**	**13,090**
DS TB cases (N+R) notified among prisoners (Jail Screening Output)	CHS (SR)	31	60	23	0	114
	Indus (PR)	11	4	3	0	18
	Total TIH	**42**	**64**	**26**	**0**	**132**
DR TB Cases Notified (Detected and Enrolled)	GSM GPs (SR)	35	40	35	23	133
	CHS Centers (SR)	98	97	91	52	338
	Indus Hospital site (PR)	36	25	38	14	113
	Zero TB Intervention sites (PR)	57	51	55	39	202
	Total TIH	**226**	**213**	**219**	**128**	**786**
TB cases with RR TB and/or MDR - TB that began on Second line treatment (Enrolled)	PMDT (PR)	650	615	570	251	2,086
	Total TIH	**650**	**615**	**570**	**251**	**2,086**

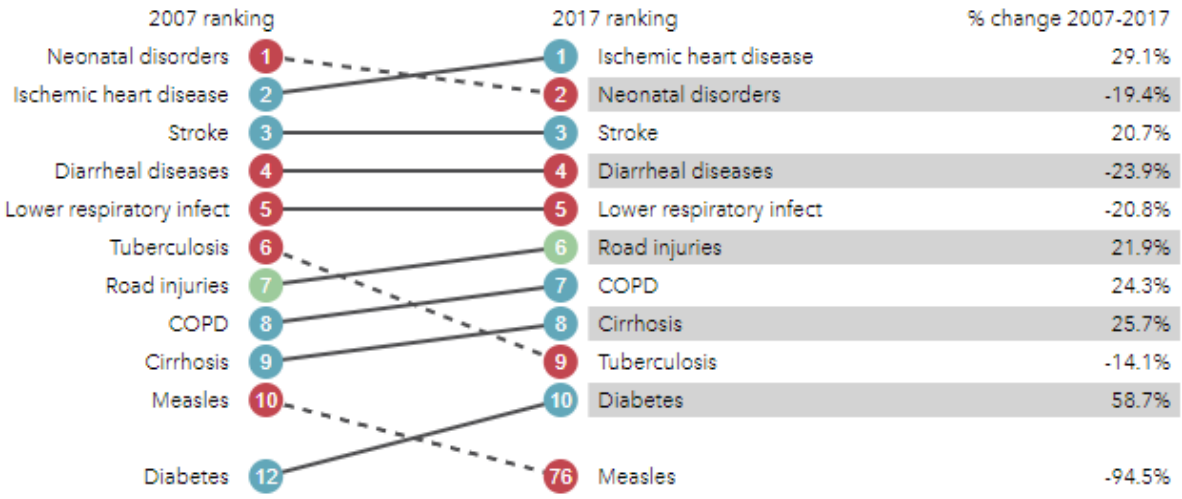
IHN, CHS, GSM and MC all invest considerable resources in a variety of mass screening camps, often with digital x-ray and Xpert, at hospitals, outside GP clinics, or in communities and worksites. In 2018, the three main NGOs operated 27 x-ray vans (some of which also have Xpert), conducted 4,667 screening camps of various kinds, and found 5,838 cases (an average of 1.25 per camp) through this approach. Even assuming an average of just 15 cases per GP per year (the average is 23 under PPM1), this same number of cases could be generated by engaging an additional 397 GPs; assuming the current staffing pattern of 1 field officer per 15 GPs, this could be achieved with 26 field officers which is a third of the staff required for the 27 vans alone, and many more are needed for the conventional camps.

The NTP has recently begun to strengthen partnerships, through provision of training, drugs, diagnostics, recording and reporting tools supervision to the Agha Khan Development Network, which operates over 450 clinics, 5 secondary hospitals, and the flagship Agha Khan University Hospital (AKUH) in Karachi, and 15 major Military Hospitals. Both partnerships seem to have the potential to contribute substantially to TB case notification from 2019, if properly managed.

2.3.2 Current epidemiological status[36]

Tuberculosis may have dropped down the ranking of those diseases and conditions that cause most deaths, but in 2017, TB remained the 9th most important cause of death in Pakistan, and the most lethal infectious disease (Figure 5).

Figure 5. The top ten causes of death in Pakistan, 2007 and 2017. *Source: IHME, Seattle, USA.*

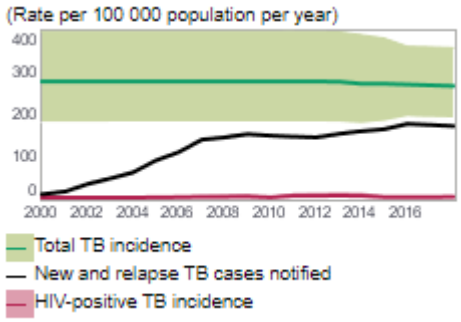


In 2018, WHO estimated that 562,000 people developed TB, at a rate of 265/100,000 population per year, and 43,000, or one in twelve, died from it. In addition, 28,000 cases of rifampicin resistant (RR) or MDR-TB developed that year. The WHO estimates that the incidence of TB is falling gently (Figure 6), but the rate of fall is exceeded by population growth, and therefore there are more cases occurring each year.

Notifications rose 22% between 2012 and 2017 as coverage of national TB efforts increased, but fell slightly thereafter. In 2018, 369,548 cases were notified, about 650 more than in 2017, but (because of population growth) this represents an important fall in case detection rate from 68% to 64%.

Alarmingly, the first two quarters of 2019 have seen a significant (9.5%) fall from the same quarters in 2018 – 189,849 compared to 171,307 in 2019. The reduction was greatest in the Punjab, but was also seen in AJK, FATA, GB, KP and Sindh. Case detection is therefore falling, both in absolute numbers, and also in incidence rate, suggesting that there are significant problems with the anti-TB efforts in Pakistan.

Figure 6. Tuberculosis epidemic profile, 2000-2018. *Source: WHO, Global Control Report*



[36] Data from the WHO 2019 Global TB Control Report, unless otherwise stated.

Nationally in 2018, 80% of all notified cases were pulmonary, and 20% were extra-pulmonary TB (EPTB). Of the pulmonary cases, 48% were bacteriologically confirmed, as a result of the steady increase in this category over the years, probably due to the availability of GeneXpert testing. Extra-pulmonary cases appeared extraordinarily high in ICT, KP and FATA at 51%, 38% and 34%, respectively, in 2017, which is probably due to the high prevalence of tertiary hospitals in ICT, which have facilities to diagnose EPTB, as well as the fact that the more rural and pastoral areas globally tend to produce more EPTB.

Since 2015, there has been a significant increase in the proportion of cases found through collaboration with the private sector (Figure 7), especially those cases found by private general practitioners (GPs) who contributed about 17% of the total cases in 2018, while the PPM private sector as a whole contributed 32% of total cases. This is discussed in more detail in section 2.4.4 and Table 17, but also of note is that the proportion of bacteriologically confirmed cases is significantly higher in the public sector than in the private sector (Table 12). This is probably due to greater use of radiology in the private sector, and especially the use of computer-aided diagnosis (CAD4-TB), and the readiness on the part of private physicians to make a diagnosis on the basis of radiological findings alone. Simply changing the sensitivity in the CAD4-TB system can alter the rate of clinical diagnoses which may assist in achieving the targets in the private sector, but it may encourage the diagnosis of TB in patients without the disease.

Figure 7. Case notifications from non-NTP/PTP sources (PPM models – see 2.4.4) 2015-2018.
Source: NTP data

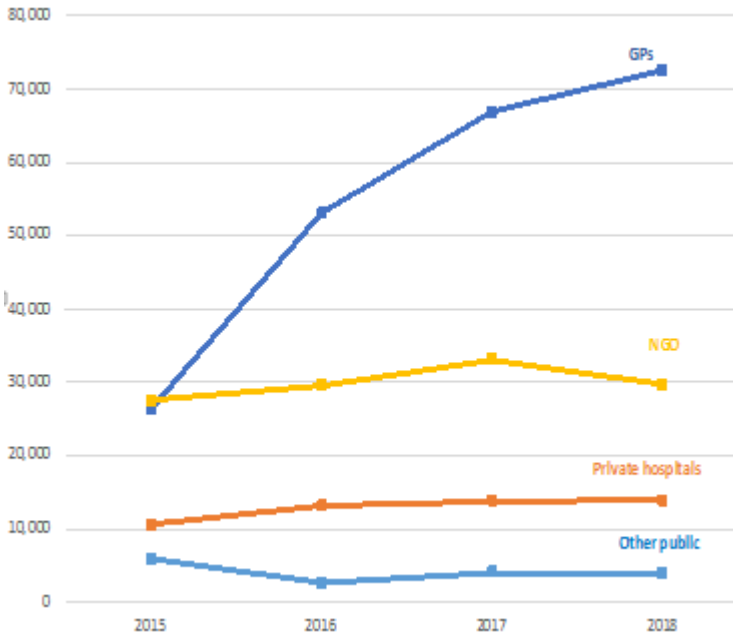


Table 12. Proportions of different TB case types deriving from public and private sector case-finding. *Source: NTP*.

	Public	Private	Total
B+ve	41.9%	31.5%	38.5%
B-ve	38.0%	49.9%	41.8%
Total Pulmonary	79.8%	81.4%	80.3%
Children	14.1%	11.6%	13.3%
EP	20.1%	18.6%	19.7%
EP Children	4.2%	3.1%	3.9%

The RR/MDR-TB cases arise in 4.2% of the new cases, and 16% of the retreated cases[37]. In 2018, however, only 3,824 cases were diagnosed and 3,106, or 11% of the total estimated incidence, were started on treatment. At first sight these figures suggest a massive gap between the numbers of cases estimated (43,000), and those treated but, effectively, this is not quite as serious as it seems: RR/MDR-TB cannot be diagnosed unless it is bacteriologically confirmed. Therefore, if we apply the same proportion of 38% of all cases of all types being bacteriologically confirmed to the estimated number of RR/MDR-TB cases, this is about 16,500. RR/MDR-TB case finding is therefore 23% of the bacteriologically confirmed. Ninety-five cases of XDR-TB were also diagnosed and 71 of these started treatment.

Treatment success rates fell with increasing levels of resistance (Table 13) but there were no data on the outcomes of patients with HIV-associated TB.

Table 13. Treatment success rates reported to WHO for the 2019. *Source: WHO 2019 Global TB Control Report*

Treatment success rate and cohort size	Success	Cohort
New and relapse cases registered in 2017	93%	358 730
Previously treated cases, excluding relapse, registered in 2017	79%	9 673
HIV-positive TB cases registered in 2017		
MDR/RR-TB cases started on second-line treatment in 2016	64%	2 804
XDR-TB cases started on second-line treatment in 2016	35%	77

In 2017, 7,300 cases of TB were estimated to have occurred in Pakistan, but HIV testing was only done in xx% and 121 cases were diagnosed. By 2018, HIV testing had increased significantly and 636 cases of TB with HIV infection were diagnosed, of whom 66% were started on anti-retroviral treatment.

Children (less than 15 years of age) constitute about 11% of all incident cases, and 13% of all notified cases. However, the proportions of all TB that are in children are much higher in FATA, GB and KP (28.4%, 41.2% and 29.7%, respectively) than elsewhere in Pakistan. In many cases, these appear to be over-diagnosis of abdominal TB on the part of a limited number of practitioners[38]. Of the household contacts less than 5 years of age, only 5.7% were started on preventive therapy in 2018.

[37] NTP. Drug resistance survey, 2011.
[38] Dr Sabira's data

Drivers of the TB epidemic

Age, male sex, undernutrition, smoking, diabetes mellitus and HIV are the main specific drivers of TB in Pakistan, leaving aside poverty in general.

TB notifications generally increase with age in high prevalence areas. In the oldest ages a drop-off of notification is sometimes observed, but this is most likely due to reduced access to care among the most elderly.

The sex ratio among notified cases in Pakistan in 2018 was 1.3 males to each female, which is rather less than the 1.78 adult men to 1 woman reported globally for 2018[36] (with 1.1 million children, sex undefined).

Four in ten under five children are stunted[39]. A 2019 national survey showed a 4 per cent decrease since the last survey conducted in 2011, and that nearly two out of every ten children under five also suffered from wasting. Boys suffer disproportionately: one in every eight adolescent girls and one in every five adolescent boys suffers from being underweight. Over half of the adolescent girls in Pakistan are anaemic. The highest rates of malnutrition are seen in Balochistan .

Smoking is known to at least double the risk of TB. "Based on the World Health Organization's 2013 standardized estimate of smoking prevalence, 31.8 % of men, 5.8 % of women, and 19.1% of Pakistan's adult population currently use tobacco in one form or another. Of these, 17.9 % of men, 1 % of women and 9.6 % of the adult population overall are daily cigarette smokers, while 4.4 % men, 1 % women and 2.7 % of the adult population are daily water pipe smokers. Moreover, 10.5 % men, 3.5 % women and 7.1 % of adults use smokeless tobacco daily. Among the youth, 13.3 % of boys, 6.6 % of girls and 10.7 % of all youth currently use tobacco or a tobacco product."[40]

Diabetes mellitus increases the risk of TB between 2- and 3-fold[41]. Of nearly 20,000 participants above the age of 20 years in a recent study using HbA1c levels[42], the prevalence of prediabetes was a frightening 11%, and of type 2 diabetes was 17%, with both associated with female sex, older age, a family history, rising body mass index, and central obesity, and inversely associated with level of education. A 2016 meta-analysis of 22 studies[43] gave a slightly lower figure of 11.77%. The prevalence was higher in males than females and more common in urban areas compared to the rural areas.

Pakistan is, in general, a low-incidence HIV country, but it has a significant, and rising, concentrated epidemic of HIV. While general population rates are below 0.1%, this still represents about 165,000 people with HIV/AIDS (PLHIV) with an estimated 20,000 new infections annually, of which only 6,000 are diagnosed. Antiretroviral treatment, however, is only being provided to 18,000 cases. Physicians are reluctant to start treatment early in spite of clear international evidence.

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[39] MOHNSRC. National Nutrition Survey (NNS), 2019.

[40] Tobacco Free Initiative. Tobacco control in Pakistan. https://www.who.int/tobacco/about/partners/bloomberg/pak/en/ Accessed 11 December, 2019.

[41] WHO, 2011. Collaborative framework for care and control of tuberculosis and diabetes. WHO, Geneva.

[42] Aamir AH, Ul-Haq Z, Mahar SA, et al. Diabetes Prevalence Survey of Pakistan (DPS-PAK): prevalence of type 2 diabetes mellitus and prediabetes using HbA1c: a population-based survey from Pakistan. BMJ Open 2019;9:e025300. doi:10.1136/ bmjopen-2018-025300

[43] Sultan Ayoub Meo et al. Systematic Review: Type 2 diabetes mellitus in Pakistan: Current prevalence and future forecast. J Pakistan Med Assoc, December 2016, Volume 66, Issue 12.

Among people who inject drugs (PWID) HIV prevalence is 38%, transgender 7%, female sex workers (FSW), 2.2% and men who have sex with men (MSM) 5.4%[44]. Levels are rising at the fastest rates among the MSM and FSW. These results were from a survey carried out only in the large provinces.

Among TB patients in a large cross-sectional study performed in 2013-2015, 145 (0.66%) patients were found HIV reactive[45]. The prevalence of HIV was higher (1.02%) in extra-pulmonary and male TB patients (1.23 %) as compared to pulmonary (0.55%) and female patients (0.09%). Massive outbreaks of HIV due to poor injection practices have recently been reported in Pakistan. Among 1,150 cases, mainly children, detected in Larkana, in 2019, 13 were diagnosed with TB[46]. Of the 12,000 PLHIV in Sindh, 92 are known to have contracted TB. The prevalence of TB in HIV-infected injectable drug users is estimated to be fifteen times higher compared to the general population[47].

TB screening is carried out at baseline and most subsequent visits of PLHIV to the HIV Clinics, using a four-symptom screen. IPT is not often given and about 50% of known PLHIV are thought to have been treated. Physicians are reluctant to prescribe it for fear of anti TB drug resistance. Although PLHIV are eligible for MTB/RIF-Xpert testing, this is not regularly performed.

There are no records of HIV-associated MDR-TB outbreaks and HIV rates in MDR-TB patients have been very low to date, but HIV-associated MDR-TB outbreaks are probably a disaster waiting to happen.

2.3.3 TB Programme Funding

Government

Government funding for the TB NSP 2017-2020 was about US$ 34 million or 7% of the total request (see Section 1.3.3). Government funds come through the Annual Development Program (ADP), managed by the Provincial Planning Commissions (PC), and this is the main mode of mobilizing resources from the Government for TB activities in the provinces – the so-called PC-1 funding mechanism. It is a project-based mechanism in which funds are approved in principle but released subject to availability, typically only partially and after delays. Over the last three years, only 48%, 43% and 51% of allocated funds for TB have been released (Figure 8).

The ADP funds do not include staff salaries and infrastructure costs which are covered in the provincial and regional regular budgets. The Sindh Provincial Government has agreed in principle to move TB funding to the regular (SNE) budget from FY 2019-20, which should significantly increase both the amount of funding for TB and the reliability with which it is released to the Program.

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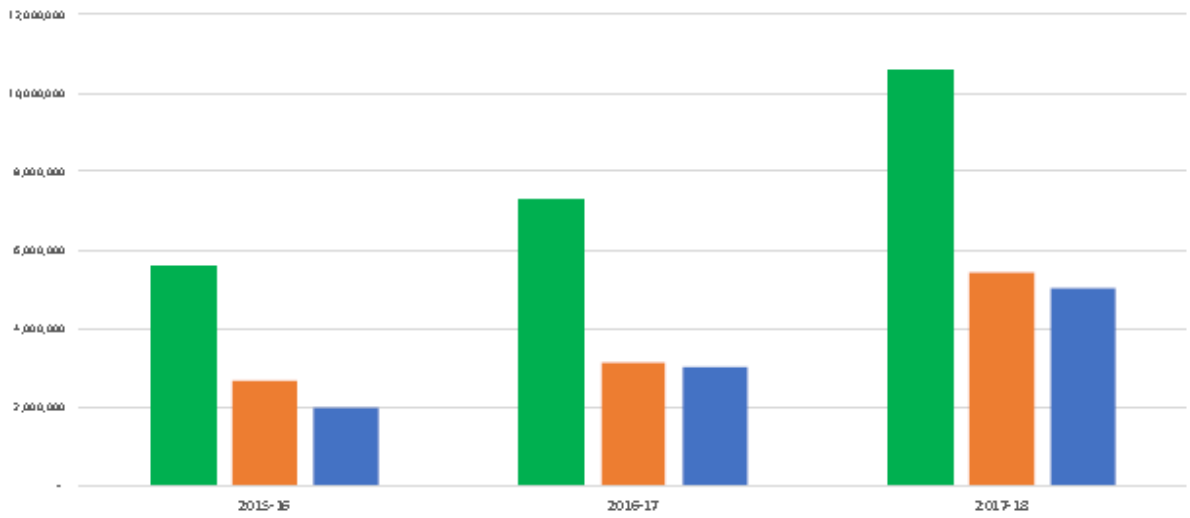
[44] National AIDS Control Program, Pakistan. Integrated behavioural and biological survey, 2016-2017. https://www.nacp.gov.pk/repository/whatwedo/surveillance/Final%20IBBS%20Report%20Round%205.pdf Accessed 11 December 2019.

[45] Muhammad Aamir Safdar, Razia Fatima,Nasir Mahmood Khan et al. Prevalence of Human Immune Deficiency among Registered Tuberculosis Patients across Pakistan during 2013-2015 —Prevalence of TB-HIV Co-Infection in Pakistan. Journal of Tuberculosis Research, 2018, 6, 96-103 http://www.scirp.org/journal/jtr ISSN Online: 2329-8448 ISSN Print: 2329-843X DOI: 10.4236/jtr.2018.61009 Mar. 27, 2018.

[46] NACP. Personal communication, October, 2019.

[47] Tahseen S, Shahnawaz H, Riaz U, Khanzada FM, Hussain A, Aslam W, von Euler-Chelpin M. Systematic case finding for tuberculosis in HIV-infected people who inject drugs: experience from Pakistan. Int J Tuberc Lung Dis. 2018 Feb 1;22(2):187-193. doi: 10.5588/ijtld.17.0390. PubMed PMID: 29506615

Figure 8. PC-1 funding, in US$, for the financial years, 2015-16, 2016-17 and 2017-18. Budgeted in green bars, released in brown, and disbursed in blue. Source: JPRM 2019.



Global Fund

In the current grant cycle (2018-2020), the Global Fund originally promised US$ 144 million distributed among three Principal Recipients (PRs) to cover the Global Fund's modules: TB care and prevention, MDRTB, TB/HIV, Building Resilient and Sustainable Systems for Health (RSSH) and program management. Of the 144 million US$, the GoP through the Central Management Unit and the National TB Programme, as the Government PR, was allocated US$ 89 million (61% of the available GF financial resources for TB in Pakistan), Indus Hospital Health Network (IHN) US$ 40 million (27%) and Mercy Corps US$ 15million (10%).

In a special agreement with the Global Fund, additional resources were provided for the procurement of GeneXpert machines and cartridges in 2016-2017, which brought the total contribution up to US$ 148 million (Tables 14 and 15).

For the 2016-17 period, there was a significant underspend of 11%, or US$ 9.86 million, that was returned to the donor. A similar underspend looks likely for 2018-19, with only one eighth of the grant period still unreported. The under-spend is across all categories of spending, except for procurement costs. The disbursements for drugs and other commodities will be reduced by the failure to reach case-finding targets. Of note is the dismal 17% for the living support costs for MDR-TB patients and families. It is a relatively small amount of total funding, but is desperately needed by the affected families. In a country desperate for resources and with minimal federal level support, this funding absorption failure suggests major problems of management and organisation. The TB Global Fund grant in Pakistan is achieving the intended results, just, with a rating of B1.

Table 14. Budget v actual expenditure, July 2016- December 2017

	Budget	Actual	Variance	Burn Rate
1. Human Resources (HR)	15,795,644.24	11,187,173.73	4,608,470.51	71%
2. Travel related costs (TRC)	7,113,455.57	4,121,641.28	2,991,814.28	58%
3. External Professional services (EPS)	381,432.23	137,529.84	243,902.39	36%

4. Health Products - Pharmaceutical Products (HPPP)	19,718,733.48	22,708,539.16	(2,989,805.68)	115%
5. Health Products - Non-Pharmaceuticals (HPNP)	13,231,636.50	4,073,551.96	9,158,084.54	31%
6. Health Products - Equipment (HPE)	6,379,905.58	19,187,388.43	(12,807,482.85)	301%
7. Procurement and Supply-Chain Management costs (PSM)	6,388,113.11	4,657,306.89	1,730,806.22	73%
8. Infrastructure (INF)	1,891,785.69	957,364.36	934,421.33	51%
9. Non-health equipment (NHP)	1,891,508.86	639,584.56	1,251,924.30	34%
10. Communication Material and Publications (CMP)	1,296,193.97	530,198.48	765,995.50	41%
11. Programme Administration costs (PA)	1,968,448.13	1,152,624.26	815,823.87	59%
12. Living support to client/ target population (LSCTP)	5,589,248.31	3,276,764.23	2,312,484.08	59%
TOTAL	**81,646,105.68**	**72,629,667.19**	**9,016,438.49**	89%

Table 15. Budget for January 2018 to December 2019, Actual expenditure to end Q3 2019.

	Budget	Actual	Variance	
1. Human Resources (HR)	12,001,662.14	7,592,958.44	4,408,703.70	63%
2. Travel related costs (TRC)	4,303,280.18	2,103,339.97	2,199,940.21	49%
3. External Professional services (EPS)	155,444.16	102,209.18	53,234.98	66%
4. Health Products - Pharmaceutical Products (HPPP)	34,390,071.18	23,375,474.44	11,014,596.74	68%
5. Health Products - Non-Pharmaceuticals (HPNP)	1,913,153.33	942,974.22	970,179.11	49%
6. Health Products - Equipment (HPE)	4,823,360.50	3,224,425.06	1,598,935.44	67%
7. Procurement and Supply-Chain Management costs (PSM)	5,770,205.61	5,867,582.52	(97,376.91)	102%
8. Infrastructure (INF)	70,861.06	50,573.31	20,287.75	71%
9. Non-health equipment (NHP)	134,064.40	69,615.48	64,448.92	52%
10. Communication Material and Publications (CMP)	107,359.74	83,998.16	23,361.58	78%
11. Programme Administration costs (PA)	798,484.17	464,863.18	333,620.99	58%
12. Living support to client/ target population (LSCTP)	1,922,219.52	326,748.54	1,595,470.98	17%
TOTAL	**66,390,166.00**	**44,204,762.51**	**22,185,403.50**	67%

2.4 TB service components

2.4.1 Case identification and diagnosis - drug susceptible TB

The problem

In a nutshell, case finding is falling, when it should be rising (Section 2.3.2). While there have been notable successes in recent years in finding children with TB, and in getting GPs to diagnose and notify cases of TB, the overall efforts, particularly in the Punjab, have not been enough to find more than 74% of estimated incidence.

The JPRM was very clear that the peripheral parts of the health system were unengaged in TB case detection: "Most of them, except for a very few dispensaries and BHUs in Punjab and Sindh Provinces, have not yet been involved in the process of TB case-finding among patients who seek care. The health staff of these PHC facilities have not been trained and involved in the identification and registration of presumed TB patients or in collecting samples from them for laboratory testing. Most of the presumed TB patients who seek care in the BMUs, visited during the review, do not do so following health provider-initiated screening and referral from a PHC level; they are usually self-referred (patient-initiated pathway). This suggests that the process of TB case-finding is not taking place in the existing PHC network in Pakistan. In addition, the staff of the dispensaries and BHUs have no information on, nor are they engaged in, the management of the TB patient living in their catchment areas who are treated and followed by the BMUs."

In Sindh Province, however, it was observed that BHUs, whose staff were trained on the identification of presumed TB and linked to the relevant BMUs, were able to identify patients with TB signs and symptoms, use the register of presumed TB cases and refer them to the closest BMUs. This experience strongly suggests that the involvement of PHC facilities is feasible. The great number of such health facilities (> 11,000) which have not yet been involved in TB services provision constitutes a major asset for TB case-finding in Pakistan. Similar observations were made of staff in the OPDs of large hospitals.

The JPRM also observed that the majority of physicians had not been trained in TB case identification, follow up, management, or the guidelines of the NTP. Lack of funds had prevented any significant amounts of training of physicians and other staff after 2016. Very few facilities had NTP guidelines, algorithms, desk aids or wall charts, available to the clinicians.

Contact screening and examination is a significant, if relatively small, source of cases in most programmes, but in Pakistan, NTP data collected routinely in 2015 to 2017 show that:

- approximately 10% of the identified contacts are screened for TB,
- 2 to 4% of the screened contacts had active TB, and
- contact investigation contributed to hardly 1% of TB notifications.

The immediate causes for this neglect of a basic public health duty appear to be guidelines that do not reflect recent (or even old) WHO recommendations, a failure to use the guidelines, an absence of guidelines and training materials in health facilities, and a lack of training of frontline doctors and nurses on this topic. What is more, the emphasis placed by the UNHLM on increasing preventive treatment has significantly increased the targets for preventive therapy for all countries, and, for the first time, strongly emphasised the need to treat contacts <u>over</u> the age of 5 years.

Various approaches were included in the NSP, 2017 including the involvement of lady health workers (LHWs), but this was mainly for the organisation of screening camps and treatment support, rather than finding cases in the community through their normal daily rounds. Since then, LHW engagement in 3 remote districts of Sindh suggests there is untapped potential to use LHWs to find

additional TB cases[48]. However, the June 2019 inter-ministerial meeting raised the issue of "financing the vertical programs especially the Lady Health Worker (LHW) Program. The program has been regularized, salaries are being paid but lacks the funds for operational (sic). … Minister Health Punjab mentioned that LHW are too occupied with various other tasks that they fail to do their original designated tasks. Minister Health Sindh endorsed this point. It was suggested that LHWs are very important workforce and need to ensure national coordination. The Federal Government should take the ownership and provide the financial support to the province. "

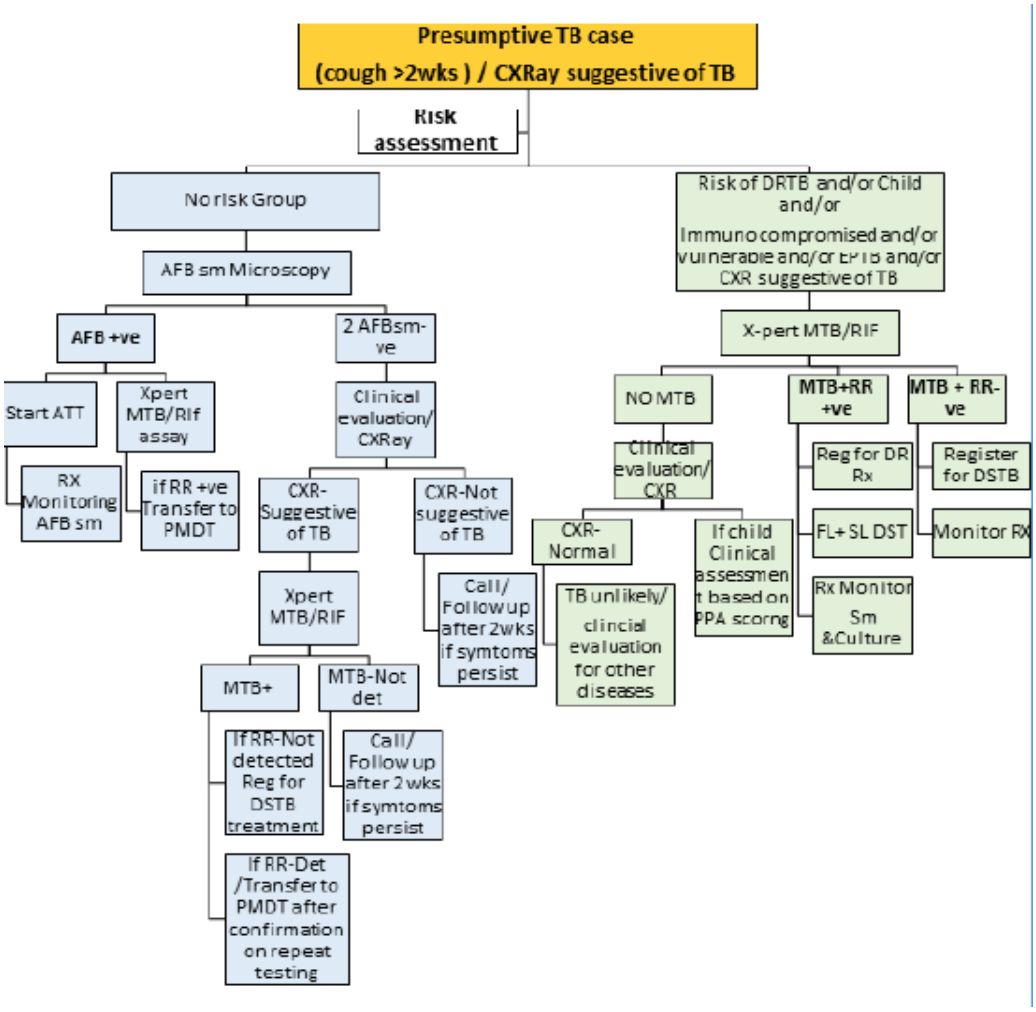
The conclusion is that any approach to the LHWs has to be a) done in full coordination with the managers of the LHW programme, province by province, and b) fully funded, if there is to be a chance of success.

Data from the private sector show that this sector has significantly contributed to case finding in recent years, and also that there is large, untapped potential to increase this contribution, especially through the GPs. This will be addressed in detail in section 2.4.4.

Furthermore, the currently used diagnostic algorithm, especially in the public sector, still largely relies on symptom screening and sputum smear microscopy (Figure 9). It is therefore too insensitive, yet technologies exist that have been proven to be more sensitive. The most important of these is the GeneXpert MTB-RIF test. However, its use has been largely confined to universal testing of sputum smear positive cases for drug susceptibility testing, rather than using the technology for case finding. Exceptions were those at high risk of MDR-TB, PLHIV, and children.

[48] Mercy Corps report. 806 LHWs screened ***544,717 individuals*** for symptoms of TB during a one year project implementation and identified ***7,698 individuals*** with symptoms, ***83%*** of whom reached a healthcare facility for testing. Of the individuals tested, ***18%*** were diagnosed with TB and registered for treatment – 463 bacteriologically confirmed and 702 (60%) clinically diagnosed. This constitutes 0.2% of the entire population. Compared over time, there was a ***5% increase in case notification*** in the intervention districts, while the control districts experienced a 13% decrease. The intervention included verbal screening during household visits by LHWs, outreach chest camps and contact screening during household visits by LHWs. Each LHW was give around US $10 for a registered case. The treatment delay was shown to be significantly reduced compared to case finding by private practitioners.

Figure 9. Diagnostic algorithm of NTP, Pakistan. *Source: NTP National TB Guidelines, 2019*



2.4.2 Programmatic Management of Drug Resistant TB (PMDT)

The number of RR cases enrolled onto treatment has stagnated since 2016, despite a rapid increase in Xpert testing, (see next section 2.4.3). There are 33 PMDT sites for 155 districts and the number of PMDT treatment sites has not increased in recent years. The treatment success rate among RR-TB patients has declined gradually from over 70% in the early years of the program to 62% in the 2016 cohort, mainly because of increasing deaths and patients lost to follow-up. The deaths are probably mainly caused by patients being diagnosed with TB very late, having spent many months in the health services before being diagnosed with TB, and less in delay in diagnosis and treatment of DR-TB.

Most PMDT sites are separate units inside public tertiary hospitals, administered by partners and funded by the Global Fund. This raises sustainability concerns and has not contributed to a sense of ownership by the PTPs. Long distances and high travel cost for patients to come for monthly evaluations and medicine supplies have contributed to high levels of patients lost to follow-up which is compounded by the weak link between PMDT sites, district TB programs and BMUs. Treatment supporters are mainly family members.

The rate of resistance to the most important second-line drug (SLD) family, the fluoroquinolones (FQs), is around 40% in RR -TB patients in Pakistan - very high compared to other countries. And resistance to one of the new drugs, bedaquiline, is increasing around the world, including in

Pakistan: among 98 RR patients started on BDQ-containing regimens, 9 have failed, and 7 developed BDQ resistance[49].

The 2019 ATS/CDC/IDSA guidelines now recommend the use of bedaquiline in routine MDR-TB treatment and enable the choice of an all-oral regimen for the treatment of MDR-TB. Rapid advice from WHO in December 2019 has mostly followed suit and now recommends that a "shorter, all-oral, bedaquiline-containing regimen may be used instead of the standardized shorter regimen with an injectable.[50]" In addition, a green light has been given to the 3 drug 6-9 month course of bedaquiline, pretomanid and linezolid under "operational research conditions". Further developments can be expected to occur rapidly in the coming months and years. The NTP/PTP will need to be on top of them.

2.4.3 Laboratory network

Background

The TB laboratory network Pakistan is arranged in four tiers: national, provincial, district and peripheral. Across the country there are more than 1,313 health facilities and 420 private laboratories providing microscopy facilities. GeneXpert rollout started immediately after the endorsement of WHO in 2010 and by December 2018, 303 facilities were equipped with GeneXpert and all districts now have access.

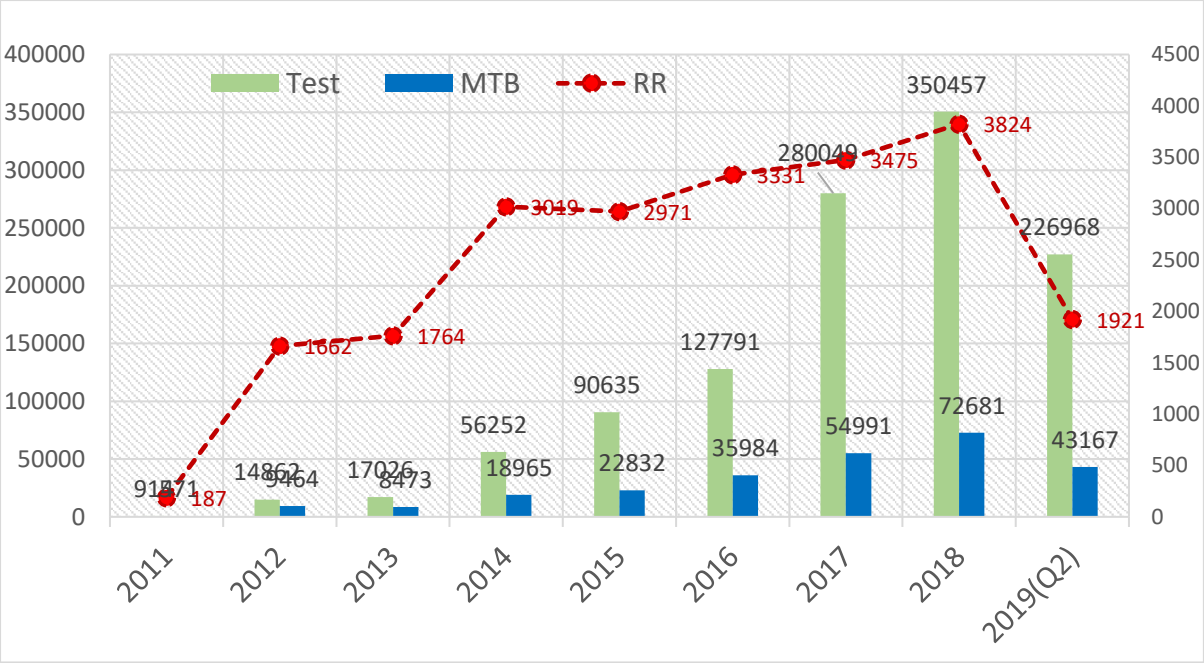
Provincial reference laboratories are functioning in each of the four provinces, with two in Punjab, providing DST services for patients enrolled in the PMDT program. These laboratories have facilities for automated liquid culture and rapid molecular DST for first and second line DST (line probe assay (LPA)). Beside these reference laboratories, 15 culture laboratories are established at sub-provincial level to provide services for monitoring the response to treatment of DR-TB patients. There are two TB laboratories having DST capacity in the private sector both located in Karachi – the Indus and AKU hospitals.

AFB microscopy still remains the first line diagnostic test for most presumptive cases seeking care due to low coverage of Xpert, and weak or negligible specimen transport systems. This is in spite of the three- fold increase in Xpert machines from 100 in 2017, to 303 by the end of 2018 (Figure 10). The diagnostic guidelines have now been updated and upfront testing is recommended for all presumptive TB cases having an abnormal CXR, a high risk of MDR, children, the immunocompromised, and EPTB cases where a suitable specimen can be obtained. However, these new guidelines are not yet fully implemented.

[49] Ghodousi A, Rizvi AH, Baloch AQ, Ghafoor A, Khanzada FM, Qadir M, Borroni E, Trovato A, Tahseen S, Cirillo DM. Acquisition of cross-resistance to Bedaquiline and Clofazimine following treatment for Tuberculosis in Pakistan. Antimicrob Agents Chemother. 2019 Jul 1;. doi: 10.1128/AAC.00915-19. [Epub ahead of print] PubMed PMID: 31262765.

[50] WHO, 2019. Rapid Communication: Key changes to the treatment of drug-resistant tuberculosis.

Figure 10. Numbers of MTB-RIF (GeneXpert) tests carried out 2011-2019 (quarter 2), with numbers of cases of TB and rifampicin resistance (RR) detected. *Source: NTRL*



All patients detected as RR are referred to PMDT sites. A reasonably effective transport mechanism exists between current PMDT sites and Culture/DST laboratories, where rapid DST is performed for first and second line drugs (rifampicin, isoniazid, fluoroquinolones and injectables) and culture is processed. Phenotypic DST is performed for FLD and SLD.

Problems

- There is a very limited access to MTB-RIF testing for people seeking health care from facilities not equipped with Genexpert – which is about 70% of all facilities and 40% of patients. An effective and robust specimen transport system for transport of specimens from most peripheral health facilities (or communities) to the nearest health facility with Xpert testing facilities is therefore essential.
- In some places scale up of Xpert to the sub-district level, provided the infrastructure is good enough to support its functioning, will be appropriate.
- Conventional CXR is available at most of the health facilities but machines are often old and produce suboptimal quality Xrays. They are not usually available free of cost to the patient. This is not a viable option for screening of all presumptive cases.
- Digital CXR facilities are limited, and usually employed to offer free services only in chest camps or other active case finding activities. Therefore, provision of digital Xray machines to health facilities with high OPD patient volumes is required.
- Due to current limited DST capacity, services are not offered systematically to all previously treated rifampicin sensitive TB patients for susceptibility testing to other first line drugs. With planned scale up of PMDT care, well-trained human resources, uninterrupted supplies, well-maintained (additional) equipment and laboratories, QA, and a transport system linking to all the district DRTB sites will be required for culture and DST laboratories.
- Additional culture laboratories with capacity to perform LPA will be required for provinces where disease burden is high and coverage is low.

- **National TB Reference Laboratory :** To continue its current role with regard to provision of mycobacteriology services, capacity development, quality assurance, research and technical assistance for scale of QA laboratory services at country level;
- **Surveillance of drug resistance:** There is high fluoroquinolone resistance in Pakistan[51]and new and repurposed drugs (Bedaquiline, delamanid, clofazimine, and maybe, in the future, pretomanid) will now be used for treatment of DR-TB. Ongoing surveillance for emerging drug resistance to new drugs needs to be strengthened, with capacity for whole genome sequencing in collaboration with established collaborating partners at national (AKU) and international level(SRL-Milan and Antwerp).

2.4.4 Engaging all care providers - Public-Private Mix (PPM)

The problem

In Pakistan, an estimated 84% of initial healthcare seeking is estimated to take place in the private sector: 24% with informal providers and 61% with formal providers, especially GPs[52]. Private healthcare providers include at least 100,000 GPs, over 67,000 pharmacies, thousands of laboratories, and around 5,000 hospitals (Table 16). While they are concentrated in urban areas, GPs and informal providers also serve small towns in rural areas.

Table 16. Proportion of estimated private healthcare providers actively engaged in PPM, 2018

Type	Estimated total number	Actively engaged	% Actively engaged
Pharmacies	67,000	1,000	1%
GPs	100,000	4,207	4%
Labs	n/a	431	n/a
Subtotal primary	**167,000**	**5,638**	3%
Hospitals	5,000	167	3%

Using pharmaceutical market research data, the volume of anti-TB drugs sold in the private market in Pakistan was estimated to be equivalent to 265,850 patients in 2008 and 272,135 in 2015[53]. The market leader is *Myrin-P*[54], sold in FDC formats, with a full 6-month treatment course costing a total of around Rs 6,000 (US$ 39) for the average adult.

There are four main models of Public-Private Mix for TB PM in Pakistan: PPM1 for GPs, PPM2 for NGOs, PPM3 for private hospitals, and PPM4 for parastatal or other public hospitals. The total number of TB case notifications from PPM increased from 58,288 (20% of the total) in 2013 to 119,814 (32% of the total) in 2018 (Table 17). The biggest increases have come from the GPs since 2016. Still, less than 5% of private primary care providers are actively engaged with the NTP, and some large public and private hospitals are not screening for TB in OPD and nor are they effectively linked with NTPs or PTPs.

[51] Zignol M, Dean AS, Alikhanova N, et al. Population-based resistance of Mycobacterium tuberculosis isolates to pyrazinamide and fluoroquinolones: results from a multicountry surveillance project. Lancet Infect Dis. 2016 Oct;16(10):1185-1192.

[52] Patient Pathway Analysis; Report of National Workshop on Data and Evidence for Policy Actions Towards Ending TB in Pakistan; Jan 2019

[53] Wells (2011), Malhotra (2018) cited in WHO (2018) Engaging private healthcare providers in TB care and prevention: a landscape analysis

[54] Wyeth/Global Pharmaceuticals Ltd

Table 17. Case finding by different types of private provision, 2015-2018. *Source: Guy Stallworthy*

Description	2015	2016	2017	2018
Notifications				
PPM1 = GP	26,292	53,040	66,826	72,511
PPM3 = Pte Hosp	10,525	13,063	13,729	13,891
subtotal private for-profit	**36,817**	**66,103**	**79,332**	**86,402**
PPM2 = NGO	27,461	29,533	33,090	29,608
PPM4 = other public	5,846	2,533	4,017	3,804
Subtotal PPM	**70,124**	**98,169**	**114,974**	**119,814**
Percent of total notifications				
PPM1 = GP	8%	15%	18%	20%
PPM3 = Pte Hosp	3%	4%	4%	4%
subtotal private for-profit	**11%**	**19%**	**22%**	**23%**
PPM2 = NGO	8%	8%	9%	8%
PPM4 = other public	2%	1%	1%	1%
Subtotal PPM	**22%**	**28%**	**32%**	**32%**
Number of participating facilities				
GPs (PPM1)	1,991	3,316	2,891	
Labs (PPM1)		425	431	
Private hospitals (PPM3)	27	35	45	84
NGO (PPM2)	105	122	158	158
Other public (PPM4)	57	33	30	41

The proportion of pulmonary TB cases that is bacteriologically confirmed is particularly low in PPM: 42% overall, and just 37% for GPs, in 2017. The NTP is not able to disaggregate treatment success rates for PPM.

Greenstar Social Marketing (GSM) and Mercy Corps (MC) --with its 6 NGO sub-recipients-- implement very similar models of GP engagement (PPM1) in 20 and 65 districts, respectively. They deploy one field worker to support an average of 15 GPs. The approach consists of: mapping and selection of providers; short training for GPs and their paramedical staff; engagement and equipment for private labs; provision of free NTP drugs for notified TB patients; payment of small incentives for GPs and lab staff; deployment of NGO field staff who carry much of the reporting and recording burden; and quarterly review and data validation meetings with the District or Provincial Programme. A published study demonstrated a 71% increase in case notifications by GPs after the introduction of cash incentives in 2015.[55] GSM and MC report treatment success rates among patients treated by private providers in excess of 90%, whereas a published study reported 81% treatment success amongst 883 TB patients treated by private providers in Lahore in 2015.[56]

Since 2015, Community Health Solutions (CHS) has developed a network of 61 *Sehatmand Zindagi* TB diagnostic and treatment centres, supported by 20 vans equipped with digital x-ray for mass screening. In 2018, the centres that had been in operation for the full year detected an average of 22 cases per centre per month. Each centre drew presumptive cases from an average of 58 GPs and

[55] Ashraf R et al (2018) Does cash incentive effect TB case notification by Public Private Mix General Practitioners Model in Pakistan? *Journal of Tuberculosis Research* 6, 166-174

[56] Khan BJ et al (2017) Alarming rates of attrition among tuberculosis patients in public-private facilities in Lahore, Pakistan, *Public Health Action* 7(2): 127-133. The study also reported 64% initial loss to follow-up, but acknowledged that it was not able to account for patients treated at public facilities or at private facilities not included in the study, so the degree of overestimation is unknown

diagnosed cases from an average of 24 GPs. In 2018, 54% of cases were referred from private providers, 25% came from screening camps, and 21% were walk-ins.

The leading NGO provider of TB services is the Pakistan Anti-TB Association (PATA), which has been active since 1955, operates 42 centres, and contributed 18,000 cases in 2017.

Private hospitals have made steady contributions of around 15,000 cases per year in recent years, while the contribution of parastatal facilities has been small. The leading contributors are the Gulab Devi Hospital in Lahore and Indus Hospital Network (IHN), based in Karachi. IHN is funded by the Global Fund to use the FAST approach[57] to actively detect TB cases in 22 public and private hospitals and to conduct contact tracing and operations research. IHN has also led the development of MDR treatment, currently managing 10 of 33 PMDT sites in Pakistan. The NTP has recently begun to strengthen partnerships with the Agha Khan Development Network (which operates over 450 clinics, 5 secondary hospitals, and the flagship AKUH in Karachi[58]) and 15 major Military Hospitals. Both partnerships seem to have the potential to contribute substantially to TB case notification if properly managed.

IHN, CHS, GSM and MC invest considerable resources in a variety of mass screening camps, sometimes with digital x-ray and Xpert, at hospitals, outside GP clinics, or in communities and worksites. In 2018, they conducted 4,667 screening camps of various kinds, and found 5,838 cases. Analysis for the JPRM in 2019 suggested that these resources could be more effectively deployed to expand passive case finding in private facilities.

Some provinces have contracted out the management of many of their public healthcare facilities to NGOs. In Sindh, the People's Primary Healthcare Initiative (PPHI) manages 971 public primary care facilities (58% of the total) while Integrated Health Services (IHS) manages 96 Rural Health Centres (73% of the total).

Most provinces have passed Mandatory Notification Acts, providing for jail terms up to two years for healthcare providers who fail to notify TB cases. Implementing regulations have not been issued, but pilot projects have been initiated in 5 districts, 3 in Sindh and 2 in KP. An electronic case notification system via a call centre has been started and a help line has been introduced.

Strengths, challenges and opportunities

There are several strengths in PPM in Pakistan and opportunities for improving it. The NTP has very strong NGO partners with many years of experience engaging private providers. There are precedents for government contracting of NGOs in health, and since 2015 there has been provision for TB strategic purchasing from private providers. There is considerable innovation within the PPM field in Pakistan. Mandatory Notification Acts have strengthened the legal foundations of PPM and the NTP is motivated to explore ways of effectively implementing them. Pakistan has made progress in the development of a national social health insurance program, targeting low-income families and contracting private as well as public hospitals. The benefit package does not yet include TB, and primary care facilities/services are not yet covered, but such schemes have the potential to play a key role in both the financing of TB care and the engagement of private healthcare providers as they develop over the medium- and long-term.

To realize the potential for PPM in Pakistan, it will be necessary to overcome several challenges and constraints. PPM initiatives have not reached a scale that is commensurate with the magnitude of the

[57] Find cases Actively, Separate safely and Treat Effectively

[58] https://www.akdn.org/where-we-work/south-asia/pakistan/health-pakistan

TB epidemic or the role of the private sector, especially at the primary care level. Given its importance for TB prevention and care in Pakistan, PPM has been relatively neglected in previous National Strategic Plans and in budget allocations. Funding for PPM remains insufficient and has been almost entirely dependent on external donors, mainly the Global Fund. PPM partners have been trying to use the same paper registers and forms as are used in the public sector, rather than benefitting from modern digital, case-based systems. In some cases, relationships between NGO partners and the NTP/PTPs have suffered from rivalry, competition and mistrust.

The 2019 JPRM concluded that Pakistan will not achieve the End TB goals and targets unless it prioritizes a major expansion of PPM, based on a spirit of genuine partnership. It recommended that the proportion of private primary care providers actively engaged in the TB program should be increased from <5% to >20%, and that the number of privately-managed TB patients receiving the full package of publicly-funded TB services should double within three years. Specific recommendations included increasing private patients' access to Xpert, making full use of modern digital technologies, and increasing engagement of private labs, pharmacies and informal providers. It will not be possible to meet any of Pakistan's TB goals without systematic and full-scale engagement of Pakistan's dominant private sector. Strong foundations for private provider engagement have been built over the last 15 years, and Pakistan has several NGOs that are world leaders in this area.

Unqualified providers – drug sellers, hakims, "quacks" - also provide services to people with TB in Pakistan, but little is known about them. The attitude towards them among the public services is that they should simply refer any suspected cases to a qualified practitioner. Unless this is linked to some kind of monetary incentive it is unlikely to succeed. A more useful strategy would be to combine that with using them as treatment supporter, especially if that role comes with an honorarium of some sort. Bangladesh's Damien Foundation has successfully employed them in this way for several years. In northern India, informal providers are very often linked to qualified providers in nearby towns (for referral, learning).

2.4.5 TB in children

The problem

Pakistan reported 47,804 children (0-15 years) with TB in 2018 - a 7.7% increase from 2017, and very close to the UNHLM TB target for children of 48,600 for 2018[59]. Sindh contributed 45% of this increase and reported 13,352 children with TB in 2018 (up 13% from 2017). Punjab with 60% of Pakistan's population is expected to contribute the bulk of TB notification, however it contributed to 7% of child TB in 2018.

The drivers of TB in children in Pakistan include the high levels of chronic and acute malnutrition that still exist, with over 10 million stunted children[60]. Malnourished children with TB are at risk of high mortality rates. HIV is a further driver, and TB is the biggest killer of children living with HIV (CLHIV), in TB endemic settings[61]. An HIV outbreak occurred in the district of Larkana in Sindh in April 2019, as a result of unsafe injection practices. More than 600 children with HIV have been identified, more

[59] UNHLM TB country commitments 2018. Available from: http://www.stoptb.org/assets/documents/global/advocacy/unhlm/1.%20UNHLM%20on%20TB%20-%20TB%20Country%20Targets.pdf

[60] UNICEF. Nutrition in Pakistan. 2018.

[61] WHO. Global tuberculosis report 2018. Geneva, Switzerland: World Health Organization; 2018. WHO/CDS/TB/2018.20. Available from: http://apps. who. int/iris/bitstream …; 2018.

than half of whom are <5 years age. The biggest challenge in tackling the outbreak and the increasing numbers of children found with HIV has been lack of safe and effective systems, diagnostic capacity and ART for children in Sindh.

The recent achievements in childhood TB have brought Pakistan closer to the target expected by the global community than in any other indicator. However, evidence of clear over-diagnosis of extra-pulmonary TB, particularly abdominal TB from some sites in the regions, and marked under-detection in Punjab (a detection gap of >50%) and significant underreporting from the private sector (78% not reported)[62] need urgent attention. A recent inventory study in childhood TB has emphasized the amounts of TB diagnosis in the private sector, largely based on X-ray, and the massive under-reporting[63].

The solutions

Still needed in Pakistan are approaches that build on the WHO Roadmap towards ending TB in children and adolescents and with the aim of reaching the UNHLM TB targets and that include the following approaches:

1. **Strengthened advocacy at all levels**- needs to locate child TB firmly in national and provincial health agendas and the Prime Minister's malnutrition reduction drive in order to garner the urgent investments required to meet the UNHLM targets. Accountability mechanisms should be included.
2. **Partnerships between public and private sectors** to work on a united front to end TB.
    1. Dedicated funding for child TB training and implementation within the hybrid NGO-private, NGO-public TB care models that have shown success for adult TB;
    2. Implementation of routine reporting of children with TB to the NTP;
    3. Engagement and support of the private sector, as well as the community and PHC models to provide TB preventive therapy (TPT);
    4. Continued engagement of the Pakistan Paediatrics Association and private provider training in child and adolescent TB, TBHIV, DRTB.
3. **Scale-up of TB case finding** including the adaptation of the child TB models that have worked in the Karachi zero TB initiative to other parts of Pakistan, namely screening at hospitals and clinics, training of frontline providers, and easy access to current quality diagnostics and child friendly FDCs and TPT ,as well as screening camps/vans that include children.
4. **Integrated services for TB/HIV/malnutrition** with testing, treatment and follow-up in specific sentinel facilities. As HIV services are implemented and expanded to meet the crisis, TB symptom screening will be carried out at each CLHIV visit (to promptly diagnose and treat active TB, or LTBI).
5. Implementation of mechanisms to enhance diagnostic accuracy in the potentially over-diagnosing districts (through clinical audits, training, clinical oversight)

[62] Fatima R, Haq MU, Yaqoob A, Mahmood N, Ahmad KL, Osberg M, et al. Delivering patient-centered care in a fragile state: using patient-pathway analysis to understand tuberculosis-related care seeking in Pakistan. The Journal of infectious diseases. 2017;216(suppl_7):S733-S9.

[63] Fatima R, Yaqoob A, Qadeer E, Hinderaker SG, Ikram A, Sismanidis C (2019) Measuring and addressing the childhood tuberculosis reporting gaps in Pakistan: The first ever national inventory study among children. PLoS ONE 14(12): e0227186. https://doi.org/10.1371/journal.pone.0227186

2.4.6 TB/HIV and other comorbidities

The problems

Around 165,000 people are estimated to be carrying HIV in Pakistan, of whom only 26,000 are registered and 18,600 are on ART. The HIV epidemic is therefore concentrated at less than 0.1% of the population, and is localised, but it is rising steadily. Of the at-risk populations IDUs make up 38% of the infected, transgender 7.2%, MSM 5.6%, and FSW 2.2%. Among the people using drugs (PUDs), the highest concentrations in 2017 were found in Kasur (51%), Karachi (49%), and Bahawalpur (26%), while they are below 10% in Quetta, Bannu and Peshawar. Each year there are thought to be over 20,000 new infections, predominantly among clients of FSW, and men who have sex with men (MSM)[64]. These are the fastest growing groups of those with HIV.

Meanwhile, outdated and hazardous injection practices have been shown to fuel outbreaks of HIV such as the one in Larkana district, Sindh, where 1,150 people were found to be infected with HIV, of whom 890 were children. Among these, 13 cases of TB were identified at the same time as the discovery of HIV.

The central TB/HIV Coordinating Committee meets only annually. There are serious gaps in the coordination of TB and HIV activities in Punjab, while it is considered better in Sindh and KP. The NACP collects case-based HIV data, while the NTP does not. HIV testing of patients with TB is well below WHO recommendations, at x% nationally in 2018. Only 636 HIV infections, out of the 7,000 estimated HIV-infected TB patients were identified in TB patients in 2018, at a rate of <1%. Conservative attitudes of clinicians restrict the number of those to whom ART or preventive therapy or treatment of LTBI/PET is offered. Other, shorter, preventive regimens are not prescribed. TB screening of PLHIV by the four-symptom screen should happen at all visits to OPD, but the level of adherence to this policy is uncertain.
There are no records as yet of MDR-TB outbreaks among PLHIV, indeed, MDR-TB has yet to be detected in PLHIV in Pakistan.

There is an urgent need to enhance the implementation of TB/HIV collaborative activities in Pakistan.

Diabetes mellitus

With the large burden of diabetes in Pakistan (11.7 - 17% prevalence in adults, see 2.3.2), it is highly likely that a significant proportion of the TB disease burden is driven by this condition. Diabetes has risen to 10th in the list of diseases causing most deaths in Pakistan in 2017. However, the proportion of cases of diabetes that currently has TB in Pakistan, or will develop it over the course of a year is unknown.

While a significant number of TB patients will also have diabetes, and WHO recommends that all patients be so tested, random blood glucose estimations are not always performed, and there are no summary data on this within the NTP.

Emphasis therefore needs to be increased, first, on the detection of diabetes among TB patients, since ensuring proper control of blood glucose during the course of TB treatment has been shown to significantly improve TB outcomes. Secondly, operational research should be carried out to ascertain the prevalence of TB among diabetics that are reachable, in reasonable numbers, within the health system, public or private. Studies in other countries give very variable figures for TB among diabetic cases, and it is not worth routinely testing until such research has indicated the scale of the problem.

[64] Asian Epidemic Model.

2.4.7 Research/Innovation

Research is a key strategic area and core component identified in Pakistan's National Strategic Plan and operational (PC1) plans, as well as in Pillar III of the new WHO END TB strategy. In 2009, a research unit at the NTP was set up with the aim of designing and conducting locally relevant operational research.

The research unit has been conducting international Structured Operational Research and Training Initiative (SORT IT) courses in Pakistan under the joint collaboration of WHO TDR and the Global Fund since 2016. Through this initiative, 45 research papers have been published in international peer reviewed journals, and the unit has been recognised as an exemplar in national operational research[65]. Participants on the training courses have come from national and provincial TB, malaria and HIV/AIDs programmes, the National Institute of Health, Pakistan Health Research Council, Médecins Sans Frontières (MSF), the Health Services Academy, and research institutions. TB topics studied range from TB diagnostics, active case finding, TB in prisons, public private mix, to MDR and comorbidities associated with TB. Studies on HIV, malaria, maternal and child health, hepatitis, and measles have also been undertaken.

The research unit has designed and implemented several research projects and national level surveys on priority programme needs. These include the National TB Prevalence Survey, 2010-11[66] and two national inventory studies to measure the under-reporting of TB cases among adults[67] and children. Studies on intensified case finding using chest camps to find cases in slums[68], engaging private providers, and examining the effectiveness of widening the circle of contact screening using GIS[69] have been performed. A trial to assess the effectiveness and feasibility of 2 months hospitalization vs 1 week hospitalization for MDR-TB in Pakistan has been completed. Recently, the unit has conducted a multi-country, double-blind placebo controlled trial on tobacco cessation. Subsequently, incorporation of smoking cessation questions in the recording and reporting tools have been piloted in KP with the aim of scaling up across the country.

The Union's TB and Diabetes Guidelines[70] were piloted in Pakistan in collaboration with the UNION. The CMU Institutional Review Board was established in 2018 to provide reviews of research proposals to local researchers, free of cost.

The unit aims to play a leading role in the upcoming patient cost survey, and the repeat TB prevalence survey with sub-national level estimates, for which it will require significant resources. With the UK

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[65] Fatima R, Yaqoob A, Qadeer E, Hinderaker SG, Heldal E, Zachariah R, Harries AD, Kumar AM. Building sustainable operational research capacity in Pakistan: starting with tuberculosis and expanding to other public health problems. Global health action. 2019 Jan 1;12(1):1555215.

[66] Qadeer E, Fatima R, Yaqoob A, Tahseen S, Haq MU, Ghafoor A, Asif M, Straetemans M, Tiemersma EW. Population based national tuberculosis prevalence survey among adults (> 15 years) in Pakistan, 2010–2011. PloS one. 2016 Feb 10;11(2):e0148293.

[67] Fatima R, Harris RJ, Enarson DA, Hinderaker SG, Qadeer E, Ali K, Bassilli A. Estimating tuberculosis burden and case detection in Pakistan. The International Journal of Tuberculosis and Lung Disease. 2014 Jan 1;18(1):55-60.

[68] Fatima R, Qadeer E, Enarson DA, Creswell J, Stevens R, etal. Success of active tuberculosis case detection among high-risk groups in urban slums in Pakistan. The International Journal of Tuberculosis and Lung Disease. 2014 Sep 1;18(9):1099-104.

[69] Fatima R, Qadeer E, Yaqoob A, ul Haq M, Majumdar SS, Shewade HD, Stevens R, Creswell J, Mahmood N, Kumar AM. Extending 'Contact Tracing'into the Community within a 50-Metre Radius of an Index Tuberculosis Patient Using Xpert MTB/RIF in Urban, Pakistan: Did It Increase Case Detection?. PloS one. 2016 Nov 29;11(11):e0165813. Accessed 15th December 2019.

[70] The Union. Management of diabetes mellitus-tuberculosis: a guide to the essential practice https://www.theunion.org/what-we-do/publications/technical/management-of-diabetes-mellitus-tuberculosis-a-guide-to-the-essential-practice

Department for International Development (DFID) withdrawing from the SORT-IT consortium, the sustainability of SORT-IT courses beyond 2020 is a challenge.

3. Gap analysis

The main gaps in TB control in Pakistan are in political commitment, case finding in both adults and children, the transport of sputum to enable a bacteriological diagnosis, the prevention and management of drug resistance, monitoring and evaluation, and last, but not least, organisation and management.

The JPRM put its finger on a massive gap in **Pakistan's political commitment to TB control** in the 2019 review. Policy makers at the highest level were unaware of the burden of TB in the country.

This lack of awareness is translated into a lack of financial support for TB control. Federal level funding for TB control is virtually zero, and provincial support is mostly limited to infrastructure and staff costs within the regular budget, while only some US$ 11 million annually are made available to TB control activities. This latter amounts to about US 5 cents per person per year for a disease killing 43,000 citizens each year.

Lack of awareness of TB also prejudices the political and administrative connections required to build up the coalition of forces within the health system, both public and private sectors, as well as outside the health system, that is required for a multi-sectoral approach to TB control. The MOHNSRC, and provincial health ministries are almost entirely on their own, when addressing the issue of TB in prisons, or the military, or other parastatal health organisations – or they avoid doing so. TB is found most often among the poor, and is itself a potent cause of poverty, yet it is not addressed by Pakistan's social protection mechanisms, SSP, PBM and BISP. The President's TB Free Initiative has fizzled out before it really began. Multi-sectorality in TB does not therefore yet exist.

After some impressive increases in case notifications up until 2017, **case finding has flat-lined** in 2018 and begun to fall in the first quarters of 2019. The JPRM was instrumental in bringing this to attention, and analysing the causes – the majority of facilities within the public health delivery system is not engaged in TB control activities. Nor is most of the private health sector – only 4% of GPs are collaborating with PTPs, even though the private PRs, Mercy Corps and the Indus Health Network, have shown how to involve different facilities within the private sector, especially the GPs.

Therefore, in neither sector are patients with the disease referred in a timely fashion for further investigation. In Sindh in 2018, PPHI had identified 250,000 suspect cases, but could only investigate 38,000. The BHUs of the remaining patients had no mechanisms for referring patients for further investigation. This was compounded by frontline physicians being untrained, and the chief point of access to health care in the community, the LHWs, being uninvolved in TB case finding or case holding. Although most patient go first to the private sector to seek health care, especially to the pharmacies, there are no means at that level to suspect or detect TB.

The contacts of cases, especially (but not only) those of bacteriologically positive cases, are not routinely being identified for the reasons given in 2.4.1, and the results of the UNHLM mean that now, for the first time, there needs to be an effort to provide preventive therapy to contacts <u>over</u> the age of 5 years. This plan will address this age group for the first time in Pakistan's history.

In addition, the currently used diagnostic algorithm, especially in the public sector, still largely relies on symptom screening and sputum smear microscopy and is therefore too insensitive. New molecular technologies, such as GeneXpert, are significantly more sensitive, and exist in significant numbers in Pakistan, but are not sufficiently used for detecting cases of TB (as opposed to identifying cases of drug resistance).

However, to use the GeneXpert machines efficiently there needs to be a systematic, regular, reliable, and **effective transport system to take sputum** from the BMUs to the nearest GeneXpert facility. This is a major issue that has not yet been solved by any province or region. Simply relying on health workers who may be travelling in that direction is not effective. Nor is relying on local "riders". This Plan will address a systematic, coordinated approach to specimen transportation that recognises that what is required is a major, province-wide, logistics operation that needs to be carried out by a transport company or courier with a network of vehicles, motorbikes and drivers, and extensive experience of this kind of work. Even more important, given the intention to engage BHUs much more, is the issue of specimen transport from the BHUs to the nearest BMU.

Finding the TB that we know is in children is another gap. While Sindh has shown the way forward and reported 13,352 children with TB in 2018 (up 13% from 2017), no other province or region has shown the same determination. The Punjab has 60% of Pakistan's population but contributed <30% of child TB in 2018.

The chief issue in **drug resistance** presently is the flat case detection. Also, the limited number of PMDT treatment sites, located miles from patients' communities, is putting patients off from coming. Treatment success is also still too low, and the new, more effective, all oral regimens recommended by WHO that include the new drugs, bedaquiline and pretomanid, are yet to be introduced widely.

Viewed together, these missed opportunities for case finding constitute a crisis that this plan will address head on.

Better **monitoring and evaluation** guidance from the NTP's central M&E unit is urgently needed, in the form of simply written standard operating procedures, to guide all frontline staff in the use of all the TB forms and registers. Crucial information especially on TB/HIV, contact screening and preventive therapy provision is not currently collected. Many M&E functions would be made much more efficient by a case-based data system for TB notification, provider engagement and patient tracking, with 100% coverage of all TB notifications, which is currently lacking. Punjab is developing its own approach, but there is a risk that Pakistan will not have a standardised approach to national monitoring unless leadership is displayed at the national level.

Leadership from the central level in Pakistan is hindered not only by a lack of Federal resources, but also by an **organisational structure and management** that seriously inhibits it. Employed as they are by the Global Fund, the staff of the CMU are bound to prioritise the work of the Global Fund rather than respond to national priorities. For example, resources will tend to flow towards monitoring of Global Fund indicators and funding flows rather than the development of clear guidelines and SOPs for monitoring the epidemic in-country, or ensuring that all components of the case-finding pathway are functioning well, eg the presumptive registers. There are gaps in policy development, guideline dissemination and SOPs, not only in M&E, but also in TB/HIV, PMDT (including the new drugs), and in challenging (relatively) new issues, such as management of latent infection, how to address the diabetes epidemic, etc.. The (highly competent) current staff are insufficient in number to address these needs.

Collaboration with other health programmes also needs much more work, quite apart from Ministries, NGOs, community based organisations, and corporations outside the health sector. It should perhaps be added that the failure of the public sector and private sector to even communicate on such a vital health issue as TB in the preparation of this NSP is a very great pity. The people of Pakistan will suffer as a result.

4. Vision, mission and goals

Vision of the NSP 2020-2023

TB-free Pakistan with zero deaths, disease, and poverty caused by TB

Mission

To effectively end the TB epidemic in Pakistan by 2035

Goal, impact and targets

To get on track to end the TB epidemic by 2030

If achieved, this goal will establish Pakistan on the road towards achieving universal access to TB diagnosis and treatment by 2030**.**

Targets for the goal: **1.9 million people successfully treated** and **1.6 million started on preventive treatment** in the 4 years, 2020 – 2023.

Table 18. Treatment targets for drug sensitive (DS) patients, children, drug resistant (DR) cases, and preventive treatment, and total costs of the PSPs, 2020-2023.

Province/region/ territory	DS adults treated	DS children treated	DR patients treated	Preventive treatments	Total cost US$ million
AJK	31,463	3,526	753	55,605	15.383
BAL	53,963	7,709	1,242	56,726	28.553
FATA	26,390	2,456	485	34,137	14.325
GB	11,991	1,091	202	14,409	9.605
ICT	14,239	1,708	299	16,550	5.754
KP	238,793	29,849	4,518	162,206	48.945
PJB	951,521	85,446	18,826	931,638	387.899
SND	385,456	77,091	7,306	562,462	100.588
Federal Unit	-	-	-	-	14.767
Total	**1,713,816**	**208,876**	**33,631**	**1,729,582**	**625.819**
	DS adults and children combined	**1,922,692**			

Summary plans of Provinces, Regions and Territories

Khyber Pakhtunkhwa – Total plan cost US$48.945 million				
Objectives	**Strategic Areas**	**Main components (not comprehensive)**	**Cost (US$ million)**	**Targets**
1. Increase case detection from 52% to 68% and maintain treatment success rate at >90%			**21.352**	Adults: 238,793
	TB Free Cities	ACF (including mobile Xray vans)	5.9	Children: 29,849
		Childhood TB Diagnosis and Rx	1.7	
		Preventive therapy	0.8	Preventive therapy: 2,868
	Strengthening case detection	Hospital DOTS linkage		
		Digital XRay machines		
	TB/DM			
	TB in prisons	Screening		
	Expansion of PPM-1		2.2	
	Contact management		0.8	
	Primary health care	LHWs	0.1	
		BHUs	0	
		Sputum transport mechanism	0.1	
	Drugs		6.0	
	Laboratory strengthening		1.6	
2. Increase case detection of drug resistant TB from 354 to 4,518 (cumulative) with a treatment success rate of 65-75%			**15.6**	4,518
	Satellite sites (13)		9.9	
	58 Xpert sites		5.3	
3. Strengthen Monitoring and Evaluation			**1.5**	
4. Research Partnerships			**0.44**	

Balochistan – total cost US$28.553 million				
Objectives	**Strategic Areas**	**Main interventions (not comprehensive)**	**Cost (US$ million)**	**Targets**
1. To increase notified DS TB cases 31% in 2018 to 50% by 2023 with increasing and maintaining TSR from 88% to above 90%			**16.992**	
	Increase sensitivity of diagnosis	Procure Xpert machines	6.96	Treatment DS-TB: 53,963 adults, 7,709 children
		Expand LED microscope	1.1	
		Install dXRs at THQ level	4.9	
	Expand case finding by strengthening services	BHU strengthening	0.06	
		PPM	0.09	
		Household contacts	0.1	
		HDL extension	0.4	
		ACF (prisons, IDPs, refugees, madrassas)	1.5	
	Childhood TB		0.05	
	Drugs		1.6	
2.Increase enrolment of DR-TB (30%-90%) and increase treatment success rate	Shorter regimens Increase PMDT sites Increase support (pharmacological, psych., social)		**3.334**	1,242
3.Increase Preventive therapy	Increase screening of HHC and others		**0.211**	Preventive Rx: 56,726
4.Strengthen programme management capacity of PTP	Restructure surveillance Increase M&E support		**3.725**	
5.Operational research	Research cell establishment Research activities		**0.16**	

Sindh total cost US$100.588 million				
Objectives	**Strategic Areas**	**Main interventions (not comprehensive)**	**Cost by objective (US$ million)**	**Targets**
1. Enhance treatment coverage in Sindh province from 59% in 2018 to more than 80% by the end of 2023.	Enhance case detection in the public sector Scaling up of PPM-1 Engage pharmacies in 03 districts Enhance case finding in diabetics and HIV risk groups TB/HIV collaborative activities Increase ACF Enhance contact management Increase B +ve proportion ACSM Scale up mandatory notification	-Establish 150 additional BMUs -Strengthening Hospital DOTS Linkages (HDL) -Enhance role of LHWs -Capacity building of health staff -Inclusion of CAD4 X-Ray machines in diagnostic algorithm -Childhood TB -Engage GPs	See budget files	DS adults treated: 385,456 Children: 77,091 562,462 preventive treatments
2. Multi-sectoral involvement	Provincial Steering Committee chaired by Chief Minister Sindh District level task forces Increase patient support			
3.Enhance M&E, surveillance and supervision	Case-based DHIS2 electronic registers Quarterly surveillance meetings Increase district level M&E and supervision			
4.Increase detection of RR TB in Sindh from 75% among notified TB cases in 2018 to 90% by 2023	Scale up culture capacity To decentralize DR TB care to district level Scale up LPA (from 3 to 8) Active screening DR contacts			7,306
5. To reduce primary default from 15% to 0%	Retrieve lost to follow up Ensure all start on treatment			

6. Decentralize DR TB care to district level	Improve access to DRTB care services through establishing five more PMDT sites Capacity building of docs and others on DR-TB Redistribution of PMDT sites			

Punjab Total plan cost US$ 387.899 million				
Objectives	**Strategic Areas**	**Main interventions (not comprehensive)**	**Cost by objective (US$ million)**	**Targets**
1. a. Increase Case Detection Rate of DS-TB from 75% in 2018 to 80% by 2023 b. Increase Case Detection Rate of Childhood TB from 7% in 2018 to 13% by 2023	1. Engagement of BHUs 2. Increase in Presumptive identification and testing 3. Contact screening 4. Enhance role of private sector 5. Active Case Finding 6. Intrasectoral coordination 7. TB awareness and education 8. Monitoring and supervision	Sputum transport (community riders managed by PPM partners, plus hiring Tehsil level assistants) Engage LHWs Loosen diagnostic criteria CAD4TB digital XR machine procurement Hospital/ DOTS Linkage Inclusion of GeneXpert in diagnosis of TB Childhood TB training for BMU staff Contact screening by PPM field force and Tehsil TBAs Mandatory notification Act dissemination PPM-1 remodelling Ban OTC sale of anti TB Drugs Engage pharmacies Inclusion unqualified practitioners Camps – conventional and plus X-rays Prison screening, elderly, mental patients, rehabilitation centres, PWUD, orphanages, transgender, hospital staff Stigma reduction, SMS, community information Designated DTOs Case based electronic recording & reporting + android application		DS adults treated: 951,521 Children : 85,446

	9. Laboratory enhancement 10. Multisector task forces 11. Hospital DOTS links 12. Prevalence Survey 13. SORT-IT courses	Additional Xpert machines, LPAs, expansion culture + DST		
2. Increase CDR DR-TB from 30% in 2018 to 80% by 2023 among notified BC Pulmonary TB Cases.	1.Enhanced Testing for DR-TB	Increase Xpert testing of presumptives GxAlert; sputum transport; web portal to link PMDT sites; increase social support		18,826
3. Maintain treatment success rate of DS- TB above 90%	1.Ensure completion 2.Un-interrupted supply of QA drugs	Counselling Defaulter tracing Patient support for DS patients Reminder SMSs generated as in 1.8		
4.Maintain Treatment Success Rate of DR-TB above 90% by 2023 from 65% in 2018	1.Ensure all registered DR-TB patients to complete their treatment 2. Ensure un-interrupted supply of QA SLDs	Counselling Default tracing Increased social support Decentralisation of PMDT sites aDSM and pharmacovigilance		
5. LTBI treatment in at least 40% contacts of BC TB cases by 2023	1.Enhanced Contact Screening 2.Implementation of LTBI Management	As in 1.3 New guidelines; training of trainers, PPD procurement		931,638

AJK - Total plan cost US$15.383 million				
Objectives	**Strategic Areas**	**Main interventions (not comprehensive)**	**Cost by objective (US$ million) 8.894**	**Targets**
1.To Increase number of TB cases notified annually, from 5,146 in 2018 to 9,210 by 2023 while maintaining TSR above 90%	-Increase the number of BMUs, 12 to 227 -Increase childhood TB notification from 386 (7.5%) in 2018 to 1197 (13%) in 2023 -Referral linkages between public sector BHUs and BMUs -Specimen transportation system from BMUs to nearest Xpert site -Expand Xpert testing sites from 11 to 17 -Expansion of PPM-1 involving 80 GPs and 16 pvt labs -ACF by camps with 3 CAD4TB vans -Increase community awareness -Mandatory TB notification -Managing TB patients with other comorbidities	Training and procurement		DS adults to be treated: 31,463 Children: 3,526
2. increase enrollment of DR TB from 25 in 2018 to 265 in 2023	-Universal Xpert testing for sputum smear positive TB patients -Decentralized DR TB services 8 districts -Increase PMDT sites from 1 to 2			Treatments: 753
3.Preventive TB services all districts of AJK	-100% Household contact screening of BC TB patients			55,605
4.Establish and implement Infection Prevention & Control (IPC) in all BMUs	1.Prevention of infection in HCP 2.Infra-structure modification			
5. Establishment of Regional TB Control Program and improve M&E methodologies	1. Strengthening HR of RTP 2. Office equipment & Furniture 3.Improved M&E methodologies and surveillance			

FATA – totalcost US$ 14.325 million				
Objectives	**Strategic Areas**	**Main interventions (not comprehensive)**	**Cost by objective (US$ million)**	**Targets**
1.Increase the number of notified DS TB cases from 4,539 cases in 2018 to 7,829 cases by 2023 while maintaining the treatment success rate above 90%	Expand the TB care services from 27 to 60 PHC & 19 secondary level hospitals by 2023 Improve presumptive referral from the community by involving 1000 LHWs, 02 NGOs/ district and 50 community volunteers/ district Active case finding through mobile outreach, chest camps (80 activities/year) 320 activities till 2023. HH Contact Screening of 100% of B+ registered TB patients Ensure un-interrupted supplies of FLDs for DS TB patients by strengthening drug management All B+ registered patient's household contact tracing will be done by 2023 Expand childhood TB case management from current 07 Agency Head Quarter hospitals to all 27public sector BMU Improve coverage of new diagnostic services by scaling up of Xpert from 06 to 14 and Installation of 55 Digital X-Rays at BMUs level.			Adult treatments: 26,399 Children treated: 2,456
2.To establish PPM-1 in 10 districts through 50 GPs, PPM-4 in 8 Private Hospitals to register 500 cases per year	Scaling up of PPM-1 model to 10 districts by addition of 08 private labs & 50 GPs Expansion of PPM-4 model by involving 08 private hospitals Monitoring & Supervision of PPM Intervention			

3.Increase DR TB notification from 43% (37 cases) in 2018 to 80% (165 cases) by 2023 while increasing treatment success rate from 57% in 2018 to 90% by 2023.	Establishment of 02 PMDT sites Establishment of 02 BSL-II labs Establish sample transport mechanism from non x-pert BMUs to X-pert/ PMDT sites			485
4.Managing high risk groups and co-morbidities	Screening of all diagnosed TB cases for HIV by the end of 2023 Addressing issue of tobacco smoking Cross border TB case management			
5.To provide TB preventive therapy from 106 contacts in 2018 to 34,137 eligible contacts by 2023 6.To increase the programmatic capabilities and Monitoring & Supervision to all BMUs to strengthen the quality of Laboratory Network and Data Validation	Support in surveillance meetings and mobility Increasing the contribution of public sector TB control program funding at least 3 times by 2023 onwards in comparison to 2018. Hiring of M&E staff for enhanced M&E			34,137

GB – total cost US$ 9.605 million				
Objectives	**Strategic Areas**	**Main interventions (not comprehensive)**	**Cost by objective (US$ million)**	**Targets**
1.To increase the number of notified TB cases (all forms) from 2,823 in 2018 to 3,207 by 2023	-Mandatory TB Case notification by the provincial govt by 2020 -Expansion of TB diagnostic facilities by addition of 17 BMUs by 2023 -HDL CMH Gilgit and Skardu - Develop sputum transport mechanism from peripheral HF to Xpert sites - Involvement of LHWs and CMWs -Community empowerment by community mobilization activities - Strengthening of DHIS-2 for quality data collection	Presentation of the bill to provincial assembly		DS adults treated: 11,991 Children: 1,091 Preventive treatments: 14,409
2. Improve bacteriologically confirmation among notified cases from 344 (16%) to 2405 (75%) by 2023	- Enhancing the skills of Lab Technicians -Training of paediatricians, general physicians and paramedics on childhood TB guidelines - Capacity building for health staff on new diagnostic algorithms			
3. To increase DR-TB Cases from 3 in 2018 to 83 cases by 2023	-Scaling up of DR TB diagnosis by involving 08 new BMUs, two CMHs and City Hospital Gilgit - Establishment of sputum sample transport mechanism from PMDT site to culture lab - Decentralized DR TB services in 9 districts and enhanced HH contact screening of DR TB pts			DR cases to be treated: 171

	- Improved infection control at 44 BMUs			
4. To increase PPM contribution from 803 cases in 2018 to 962 cases by 2023 in all type of TB case notification.	Engaging private sector in TB case management including new four districts			
5. To enhance technical & M&E capacity of the Provincial Program	-Enhancing HR for PTP -Improved M&E			

ICT – total cost US$5.754				
Objectives	**Strategic Areas**	**Main interventions (not comprehensive)**	**Cost by objective (US$ million)**	**Targets**
1.To increase the number of notified TB cases from 34% (1,820) in 2018 to 80% (4,569) by 2023 while increasing the treatment success rate from 66 to 90%	Scale up of public sector BMUs by engaging 34 new BHUs, CDA medical centers, MCH center, federal government dispensaries andparastatal hospitals to provide TB care services Hospital DOTS linkages in all of the 6 tertiary care hospitals Mandatory TB Case notification by 2020 Effective sputum transportation mechanism to Xpert site through courier service Scale up childhood TB Contact tracing of DS TB cases Infection control in all 50 health facilities Managing TB with other Co morbidities			DS adult cases treated: 14,239 Child cases treated: 1,708

2. To enhance DR-TB enrolment from 37 cases in 2018 to 114 case by 2023	Referral linkages from Xpert site to PMDT site Contact tracing of DR TB cases			299
3.To enhance PPM contribution from 16% (291) in 2018 to 32% (1462) by 2023	Engagement of 100 additional GPs under PPM 1 model Enhanced case finding by engaging 10 large private hospitals			
4.To provide TB preventive treatment to 16,550 eligible persons from 2020-2023	Enhance screening of close contacts through dedicated field staff/ LHWs			16,550
5.To ensure and implement a robust and effective monitoring and evaluation system including use of digital technology	Develop a mobile application linked with IDMs where real time data entry can be ensured of validated data Supportive supervision visits by NTP, NPO, and Regional Program			

5. Summary of provincial, regional and territorial objectives

5.1 Political commitment

The NSP aims to achieve the ambitious END TB and UNGA Targets. The NTP and PTPs have committed themselves, through declaring clearly in this NSP what the country needs to do, to try and achieve these aims. The Plan will be used to secure and sustain political commitment and to lead to national ownership of the huge TB problem. It aims to increase financing for TB, especially sustainable domestic resources, and provide a supportive legal and regulatory environment. Moreover, the Plan provides a mechanism for oversight for all the anti-TB activities in the Plan, and will be essential in holding people and institutions to account for performance.

Sindh has committed to move towards a multi-sectoral approach with an accountability framework. All provinces and regions have shown determination to expand TB service provision (diagnosis and treatment) into the public primary health care system, as well as enhance and expand private provider engagement, particularly among GPs, and urgently improve the case finding and treatment of MDR-TB cases.

5.2 Increasing case finding (DS-TB)

The strong emphasis in all the provincial/regional plans on increasing case finding involves several different approaches. All provinces and regions aim to significantly increase expenditure on engaging the GPs as part of the PPM-1 process, including the hiring of PPM coordinators (as in KP) and field supervisors, including training of all the staff involved. The PHC network (dispensaries, BHUs, MNCH centres) and, in some provinces, eg Punjab, Sindh, KP, and FATA, the LHWs as well, will be engaged much more than at present in case-finding and in the process of identification, screening and assessment of household contacts as well as in the provision of IPT to eligible contacts. In line with the End TB strategy, and following the successes in this area by Mercy Corps and IHN, all provinces aim to increase their efforts on active case finding, including new sets of institutions for investigation eg, madrassas. This work will provide useful information on the TB prevalence in such places, and whether it is cost-effective to continue such work.

Sputum transportation mechanisms are included in most plans, both for drug sensitive and drug resistant TB patients, as in Punjab. For the moment they tend to rely on local “riders” and health staff, rather than the systematic, professional approaches that will be needed if this is to succeed.

Most provinces and regions support expanding the availability of diagnostic services and increasing the sensitivity of the current diagnostic algorithm through purchase of digital CXR machines for health facilities with high OPD patient volumes, as well as for ACF. This will require revision of the current national diagnostic algorithm.

If we say that we anticipate the diagnosis of 1.723 million adult cases of TB, 80% or 1.378 million of these will be pulmonary. If we assume that 50% of these come from areas where access to X-Rays is feasible and relatively easy (all urban populations, plus a further 10% of the total), and that each pulmonary case requires 10 symptomatics in order to detect a case (data from Dr Hadi), then 6.51 million X-rays will be required over a 4 year period, or 1.63 million annually on average. A digital X-ray machine can perform 150 chest examinations per day, but 70 is more likely, given other demands on the machine and its operators. At 250 working days per year, one machine can therefore handle 17,500 examinations annually. This makes a requirement of 93 machines. Allowing a conservative 10% for imperfect utilisation and distribution, this comes to 102 machines.

Alternatively, for at least part of the need for X-rays, vouchers could be provided for patients to obtain an X-ray from a private facility. This will have a different set of budget requirements.

5.3 Management of drug resistant TB (PMDT)

All provinces and regions will expand availability of PMDT and find more cases. They will further decentralize management of DRTB from PMDT sites to the district level, under close supervision. As part of overall efforts to overhaul the sputum transport system, the provinces and regions will strengthen regular sample transportation from microscopy centers to Xpert sites to ensure full coverage of drug susceptibility testing/universal testing of rifampicin susceptibility in previously treated TB cases (currently at 78% of previously treated bacteriologically confirmed (BC) cases, and 44% of new BC cases) , and a rapidly increasing proportion of new TB cases, in line with the NTP algorithm.

Some provinces will explore expansion of the transmission system of Xpert results (Gx-Alert currently connects 311 of the 345 Xpert sites – see M&E Plan) to ensure regular flow of Xpert results from Xpert laboratories to PMDT sites so that all RR patients are started on treatment promptly. Sindh, for example, will improve access to PMDT services through establishment of PMDT sites managed by the public sector – with the support of partners. Current PMDT sites managed by partners will continue as an alternate model.

The Plan aims to increase the number of PMDT sites, as well as organise their decentralisation so as to make the services they offer more palatable and convenient to patients – and hence more likely to be used by them. The effectiveness of treatment will be improved by all oral regimens that include the new, more effective, drugs such as pretomanid, as well as bedaquiline.

5.4 Childhood TB

This NSP plan has borrowed heavily from the WHO Roadmap towards ending TB in children and adolescents and with the aim of reaching the UNHLM TB targets, and includes the following approaches:

Strengthened advocacy at all levels- child TB will be firmly located in national and provincial health agendas and the Prime Minister's malnutrition reduction drive in order to garner the urgent investments required to meet the UNHLM targets. Accountability mechanisms will be included.

In this NSP **partnerships between public and private sectors** will work on a united front that will include:

1. Dedicated funding for child TB training and implementation within the hybrid NGO-private, NGO-public TB care models that have shown success for adult TB (Sindh);
2. Implementation of routine reporting of children with TB to the NTP (all provinces, regions and territories);
3. Continued engagement of the Pakistan Paediatrics Association and private provider training in child and adolescent TB, TBHIV, DRTB.

Scale-up of TB case finding including the adaptation of the child TB models that have worked in the Karachi Zero TB initiative to other parts of Pakistan (such as KP), namely screening at hospitals and clinics, training of frontline providers, and easy access to current quality diagnostics and child friendly FDCs and TPT, as well as screening camps and vans that include children.

Integrated services for TB/HIV/malnutrition with testing, treatment and follow-up in specific sentinel facilities. As HIV services are implemented and expanded to meet the crisis TB symptom screening will be carried out at each CLHIV visit (to promptly diagnose and treat active TB, or LTBI).

Implementation of mechanisms to enhance diagnostic accuracy in the potentially over-diagnosing districts (through clinical audits, training, clinical oversight)

5.5 Support to the laboratory network

This plan will ensure an effective and robust specimen transport system for transport of specimens from most peripheral health facilities (or communities) to the nearest health facility with Xpert testing facilities. To further accelerate case finding, this plan will carefully and selectively scale up Xpert to the sub-district level in a few well-chosen sites, and even to sub-tehsil levels, especially in the Punjab. Additional culture laboratories with capacity to perform rapid DST using LPA will be set up for provinces where disease burden is high and coverage is low. With the planned scale up of PMDT care, staff will be trained, and a transport system linking all the district DRTB sites to their local culture and DST laboratories will be established.

The National TB Reference Laboratory will continue its current role with regard to provision of routine and advanced mycobacteriology services , capacity development, quality assurance, surveillance of drug resistance to first and second line drugs, new and repurposed drugs, research including pilot testing of new technologies , and technical assistance for scaling up QA laboratory services at country level. For proper management of the most complex cases and transmission studies the NTRL will increase its collaboration with Antwerp and Brussels SNRLs.

To mitigate the risks of exacerbating drug resistance in Pakistan, this plan will engage in ongoing surveillance for emerging drug resistance to new and repurposed drugs, and collaborate with established partners at national (AKU) and international level (SRL-Milan and Antwerp) to establish capacity or ensure access to whole genome sequencing .

5.6 Accelerated implementation of TB/HIV collaborative activities and other comorbidities

To conform to current international standards of TB care, the N/PTPs, in collaboration with the National HIV/AIDS Control Program and partners, have planned strategies and interventions that will increase services to patients diagnosed with TB. These strategies and interventions for a national scale up of HIV testing in TB patients will be informed by the Punjab province experience where HIV testing rates in the 2018 TB cohort reached 30%. Anti-retroviral treatment (ART) and co-trimoxazole preventive therapy (CPT) will be initiated among all TB patients with HIV infection, regardless of CD4 counts. The TB recording and reporting tools will be updated to include essential data on TB/HIV collaborative activities.

This plan will ensure testing for diabetes of almost all TB patients, through routine random blood glucose estimations of all TB patients over 20 years. Secondly, operational research will be carried out to ascertain the prevalence of TB among diabetics that are reachable, in reasonable numbers, within the health system, public or private, on the basis of which national guidance will be published on bi-directional screening, recording and reporting for diabetes and TB and increase linkages between TB services and services for NCDs.

5.7 Operational research and innovation

The M&E Unit, research unit and provinces will collaborate for the **4th National TB Prevalence survey,** which aims to measure the national TB prevalence and also, by enlarging the study size, have sufficient power to provide prevalence estimates for the provinces. A national consultation workshop is planned to finalize the methodology for this TB prevalence survey with sub-national estimates with NTP, WHO and provincial representatives, and the support of WHO TME in early 2020.

The patient cost survey is required by WHO to assess progress against the important indicator of the number of families experiencing catastrophic expenditures as a result of TB. It will provide evidence

for changes to policy and practice, and priority actions to mitigate/eliminate TB patient costs through enhancing social protection and improving TB service delivery and financing.

The estimates of childhood tuberculosis cases remain weak in Pakistan – the previous prevalence surveys have not included children. It is suspected that children living in orphanages, public and private primary schools and Islamic Madaris are more prone to develop TB because of congested/crowded homes, and low nutritional status. **A pilot study to screen for TB among children** living in such institutions in Rawalpindi is therefore planned.

The research unit has been conducting **National Structured Operational Research and Training IniTiative (SORT-IT) course**s with financial support of The Global Fund, including work on HIV/AIDS, and malaria as well as TB.

5.8 Quitting smoking

Tobacco use is a cause of death of around 160,100 Pakistanis every year. Around 24 million adults currently use tobacco in any form in Pakistan, and there is evidence that a brief behaviour support is effective in achieving tobacco quit rates of over 40%[71] in Pakistan. Further work in field conditions in KP in Pakistan and Bangladesh in TB patients showed quit rates of over 25% after 12 months. Some provinces, including KP will therefore continue their efforts to provide appropriate care to TB patients who smoke to help them quit smoking.

6. Central functions

There are several essential functions that need to be carried out at central level in Pakistan to ensure optimal coordination between the provinces, regions and territories. These functions are not covered in the provincial or regional budgets and therefore this Plan includes a separate federal level budget of US$14.7 million over the four years. The elements covered include:

- Policy and strategy development and guidelines productions and dissemination
- Coordination Capacity development , Quality assurance , surveillance , specialised mycobacteriology services and coordination of the national laboratory network
- Monitoring and evaluation
- Supervision of provincial/regional programme activities
- Centralised procurement
- Research
- Coordination with external agencies

Policy guidance - The new NTP guidelines will be made widely available in all the health facilities irrespective of the health sector. Furthermore, the NTP will make available, for all health workers, clear standard operating procedures (SOPs), algorithms, desk aids and wall charts to help clinicians at these facilities to quickly arrive at key decisions in the TB diagnostic and management pathway.

LTBI treatment/PET – since the provinces are planning to treat household contacts of 5 years of age or more, the NTP will clarify their policy on household contacts with no active TB and no HIV infection receiving LTBI treatment. (It is a conditional WHO recommendation for high TB incidence countries).

The **policy space of new drug regimens for MDR/RR-TB** will be an area for rapid change during 2020-2023, the NTP will therefore take responsibility for updating national guidelines DR-TB

[71] Siddiqi K et al. Action to stop smoking (ASSIST) in Pakistan: a cluster randomised, controlled trial. Ann Intern Med 2013:158; 667-75.

treatment regimens, as new WHO recommendations become available. The emphasis will be on provision of shorter, all oral regimens of higher efficacy.

Coordination of the national laboratory network, and liaison with the SNRL requires budget not covered by the provinces, especially as drug resistance testing moves into the genomic era and whole genome sequencing is now a realistic proposition for TB isolates. In the first instance the demand may be achievable through collaboration with Milan and Antwerp, but demand may increase and need to be covered in this budget.

M&E systems – the goal is a digital, case-based data system for TB notification, provider engagement and patient tracking, with 100% coverage of all TB notifications by 2023. Punjab is developing its own system. Other regions would need to decide whether to follow Punjab, or whether they want to benefit from a coordinated national approach.

The biggest challenge for the M&E unit in 2020-2023, in coordination with the Research Unit, will be the conduct of the **4th National Prevalence Survey**, which is intended to provide sufficient sample size as to make reliable estimates of the burden in each Province. The very provisional budget estimate was around US$ 7 million.

The case for appropriate operational or implementation research is laid out in 2.4.7 and 5.7..

A more effective central unit requires additional human resources, support staff and vehicles, if they are to function properly. To address the needs of keeping the Programme Manual up to date, revising the diagnostic algorithms, expanding the role of chest X-ray in diagnosis, preparing policies, guidelines and SOPs for LTBI/PET management (especially ensuring that over age 5 children and adults are now addressed), PPM expansion, involvement of LHWs, the 4th Prevalence Survey, the new drugs for treatment of MDR/RR-TB, quitting smoking, engagement with NGOs and community-based organisations, procurement of new equipment, such as X-ray machines, and new diagnostic machines that will likely come before 2023, cost-effective analyses on active case finding, etc. some 10 or so professional staff will be needed.

The following key actions need to be taken at Federal level:

6.1 Establishing a TB Program Central Unit

As highlighted in the recommandations of the last JPRM, a Central Tehnical Unit for TB Progam should be established to ensure enssential programmatic management activities, including coordination with provincial TB programs. Its mission will be clearly defined and the staff positions and profiles will be specified accordingly. This Central Technical Unit will be responsible for: i) the formulations of policy, strategy and regulation, ii) the development of guidelines and standards of practices, iii) the harmonization of the implementation of TB activities across the NTP network, iv) the coordination with the provinces' TB Programs, v) the provision of technical support to the provinces, vi) the resources' mobilization, vii) the coordination with national and international partners, viii) the establishment of relevant national working groups to update or rearrange the existing guidelines or define new approaches, ix) ensuring the availability of a national monitoring and evaluation framework, x) building capacities for a sound monitoring and evaluation system across the NTP network, xi) the development of appropriate and standardized data analysis practices, xii) ensuring TB surveillance and international reporting and building and xiii) sustaining a momentum for operational research on TB prevention, care and control in Pakistan.

6.2 Creating, at national level, a momentum for the development of a multi-sectoral approach to end TB in Pakistan

TB Program has included the multi-sectoral approach in its policy; however, many stakeholders from key sectors are not at all aware of the issues of TB in Pakistan and no linkahges have been establishing with the existing social protection systems at the federal level like *Baitulmal, Insaf Sehat* Program or *Ehsah* program. Very few actions have taken so far to initiate the process multi-sectoral approach at national level and in Sindh; but these actions have not sustained. To this end, the following actions will be taken at federal level:

6.2.1 Developing a national strategy to implement a multi-sectoral approach with the technical support of a national or international consultant. A national workshop will be organized to define the strategic orientations and a common understanding needed for a sound multi-sectoral approach adapted to Pakistan context. Relevant representatives of provinces, regions and key sectors will participate in this workshop. Based on the discussions held in the workshop, a document on the national strategy will be prepatred and finalized by the consultant. This document will give a strong visibility to TB issues as prority in the strategic agenda of the other sectors and will be printed and accessible online in the web site of the MoNHSRC.

6.2.2 Establishing a national steering committee for the development of a multi-sectoral approach to end TB in Pakistan. This committee will include the representatives of the relevant key sectors that will play a role in ending TB in the country. It will be chaired by a highly politically influencial person or a publically well known and highly respected person. This mission will have a clearly defined mission and well specified work agenda and will meet at least twice a year.

6.3 Maintaining the current functions of the National TB Reference Laboratory through the following activities:

6.3.1 Provision of **routine mycobacteriology/ DST services** for patients from ICT,AJK and GB and for other province/s (Punjab) lacking full DST capacity,

6.3.2 **Quality assurance of DST services** by organizing annual scheme for EQA of DST services for Laboratories performing phenotypic and genotypic DST in the country,

6.3.3 **Capacity development** for culture and DST laboratories through formal training program and onsite training. Training of MDR clinicians on proper interpretation of Xpert and LPA for clinical management of cases,

6.3.4 **Technical assistance** for improving coverage and QA laboratory services including Xpert, LPA, culture and DST services and effective specimen transport system,

6.3.5 **Surveillance of drug resistance:** The ongoing surveillance of drug resistance will be continued and further strengthened; to this end, this following actions will be taken:

6.3.5.1 **Surveillance of rifampicin resistance:** Currently 260/350 Genexpert machine in public sector are connected through GXAlert to central server. Provincial staff capacity will be established for monitoring of Xpert laboratory network, identification of gaps and real-time surveillance of Rifampicin resistance by districts.

6.3.5.2 Surveillance of prevailing **Fluoroquinolone resistance**[i] and analysis of genotypic determinants.

6.3.5.3 **Emerging resistance to new and repurpose drugs** National drug-resistant TB guidelines are revised in line with WHO recommendation. Drugs including fluoroquinolone, bedaquiline LNZ and CFZ are now part of treatment regimen of all drug-resistant TB patients. The NRL has started the surveillance for bedaquiline susceptibility and first six cases of BDQ resistance are

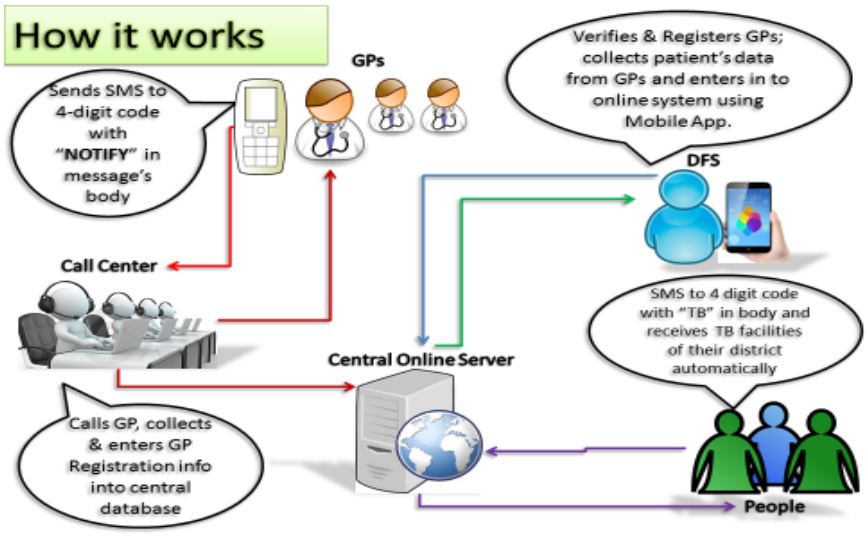
already reported in Pakistan[ii]. Currently DST capacity for new and repurposed drugs is limited to NRL. For surveillance of emerging resistance to new and repurposed drugs, all culture isolates from DRTB patient who fail to convert at three months are/will be tested in NRL. For surveillance of emerging resistance.

6.3.5.4 **The** NRL will acquire capacity for **Next Generation Sequencing** to strengthen drug resistance surveillance and transmission analysis, training of some staff has already been performed but has been placed on "hold" for the lack of funding. The acquisition of this technology will represent an incredibly important resource for proper managing of the most complex cases and resolve discordance between Phenotypic and genotypic DST.

6.3.5.5 **The** NRL will collaborate with the supra-national reference laboratory (SRL-Milan, Italy) on surveillance projects and establish capacity to perform regular molecular and phenotypic surveillance of emerging resistance and transmission studies research.

6.4 Supporting, from the federal level, the implementation of the mandatory notification of TB cases in Pakistan

The federal level is responsible for harmonizing and uniforming the implementation of Acts of Manadatory TB Notification which are approved by the respective provincial assemblies. The MoNHSRC is also regulating the sale of anti-TB medicines at retail pharmacies to be dispensed at only in authorized pharmacies declared as (Category "A") across the country. It is also responsible for the implementation of Mandatory TB Notification in the Regions of AJK & GB and ICT. The elctronic mechanism of TB case notification (see fig. hereafter) will be managed by a central level call center which will also act as toll free help line (already established with the call number: 0800-88000)



6.5 Enhancing the ongoing momentum for operational research to improve TB prevention, care and control in Pakistan

The WHO End TB Strategy recognizes research as an important third pillar in achieving the desired targets and plays a key role in the design of new strategies to ensure optimal utilization of resources

and maximize the programme outcomes. The proposed activities of research unit for new funding request 2021-23 are as follows:

6.5.1 **Pakistan SORT – IT Course (Structured Operational Research and Training Initiative):**

The journey of national Structured Operational Research and Training IniTiative (SORT IT) course started in 2016 with support from the Global Fund and led by the international TB UNION and WHO-TDR. Research unit is following national TB research strategy addressing programmatic challenges through this initiative by conducting operational researches on international standards. The courses have proven to be an effective way of building OR capacity and linking together more than 25 institutions at national & international level i.e. multiple health programs at the national and provincial level, research organizations & academia in Pakistan and across the globe. This initiative has resulted in form of approx. 50 published papers, providing local evidence for decision making on TB and other disease control programmes in open access international peer reviewed journals. This structured capacity building programme led to changes in policy and/or practice in routine implementation of a local or national programme, local or national data monitoring, introduction of new monitoring tool and providing evidence for important programme issues which incorporated in national strategic policy by i.e. Hospital DOTS linkage, evaluation of multiple intensified active finding strategies, assessment impact of screeners on TB case detection, an update on child TB under-reporting, evaluation of Infection control in PMDT sites, assessment of HIV among TB Patients and prevalence of TB and HV in prisons. The candidates are followed up on 18th month by The Union as per course guidelines to assess the policy change. The success of Pakistan SORT-IT course in improving health programme performance is well recognized[72] and acknowledge by WHO-TDR in TDR Global profile for research capacity strengthening through SORT-IT as unique example in the world. This initiative deserves to be sustained to address Pakistan health systems bottlenecks and programme implementations, thus contribute towards achieving universal health coverage. The course runs over 10–12 months with 3 modules i.e. Module 1 (Six-day module on Research Questions and Protocol Development); Module 2 (Six-day module on Data Management and Data Analysis); Module 3 (Seven-day module on Scientific paper writing) with clear milestones and measurable targets. Failure to fulfil the expected outputs linked to each module implies the candidate does not return for the next module. Outcomes can be easily measured by assessing the resulting papers published in open access journals. Training in manuscript writing (Module-III) is a vital component of SORT-IT course[73] and publications in peer- reviewed, open access journals are essential to disseminate the locally generated evidence to national/ international stakeholders and researchers. Keeping in view the importance of Module III and publication, these costs requested to be added in next grant 2021-23.

6.5.2 **Patient Cost Survey**

TB is associated with significant economic impact and may hamper national development. TB patients often incur large costs related to illness, as well as for seeking and receiving health care. Such costs are important access barriers to TB care which can affect health outcomes and increase risk of transmission

[72] Fatima R, Yaqoob A, Qadeer E, Hinderaker SG, Heldal E, Zachariah R, Harries AD, Kumar AM. Building sustainable operational research capacity in Pakistan: starting with tuberculosis and expanding to other public health problems. Global health action. 2019 Jan 1;12(1):1555215

[73] Fatima R, Yaqoob A. Strengthening and implementing operational research in National TB Programmes: the Global Fund's vital role. The international journal of tuberculosis and lung disease: the official journal of the International Union against Tuberculosis and Lung Disease. 2020 Feb 1;24(2):259.

of disease. One of the three high-level targets of the End TB Strategy is that no TB patients or their households should face costs due to TB that are catastrophic. The patient cost survey is one of the priorities identified from the latest Epi review and important indicator for The Global END TB targets. This will provide an evidence to identify policy and practice implications, and priority actions to mitigate/eliminate TB patient costs through enhancing social protection and improving TB service delivery and financing. This study will examine the level and composition of costs incurred by TB-affected households during care seeking and treatment; assesses the affordability of TB care using catastrophic and impoverishment measures; and describes coping strategies used by TB-affected households to pay for TB care.

6.5.3 **Pilot study for TB screening among the underserved and high risk children in Pakistan:**

Every day, up to 200 children lose their lives to TB, which is a preventable and curable disease. The estimates of childhood tuberculosis cases remained weak because limited surveillance data from children in many countries. Globally childhood TB cases are under-reported much due to the difficulty of confirming the diagnosis. This has made it difficult to assess the actual magnitude of the childhood TB epidemic, which may be higher than currently estimated. The children living in orphanages, public & private primary schools and Islamic Madaris are more prone to develop TB because of congested/crowded homes, low nutritional status. A pilot project is proposed to screen children living in orphanages, public & private primary schools and Islamic Madaris in Islamabad district to improve TB access and case detection in underserved and high risk children in Pakistan and to generate evidence for the future scale up. We are expecting to screen approx. 20000 children in Islamabad and this intervention will detect above 100 child TB cases.

6.5.4 **Consultative Workshop to set national Research Agenda for TB:**

Despite being recommended in END TB Strategy on setting health research priorities, there is little coordination in health research. Diverse actors including the MoH, TB Control Program at National & provincial level, Principal Recipients (PRs), Sub- Principal Recipients (SRs), research & academic institutions and other researchers conduct research according to their own interest. Since there is no research agenda to help focus on national priorities, any synergies in the research produced are only incidental. A consultative workshop is planned for setting TB research agenda by consulting all stakeholders related to TB i.e. national & provincial TB control program, PRs & SRs, MoH and other stakeholder attached with NTP. This consultative workshop is essential not only to analyze the evidence that exists, but also to clearly define research questions and collect additional evidence to ensure that NTP national and provincial programs are effective, efficient, equity promoting, and evidence based. The intent of this activity will be to establish a national (and provincial) research agenda that will inform about national health priorities and guide programs to meet these priorities.

6.6 Undertaking the fourth national TB prevalence survey

The last national TB prevalence survey was carried out in 2010/2011. Therefore, after nearly ten years, it is time to undertake the fourth one to reassess the real TB burden in Pakistan. Given the high burden of TB in the provinces and the need to adapt TB prevention, care and control interventions to each of them, the sample size of this fourth TB prevalence survey should have enough statistical power to make fair estimates not only at the national level but also at least in each of the four provinces.

An international technical assistance will be needed. The development of survey protocole will be undertaken at federal level in collaboration with provinces and partners. The coordination and the

overall monitoring of survey implementation process will be ensured from the federal level in collaboration with the provinces, regions and partners.

7. Prioritisation approaches

In all likelihood, the funds to support all the work planned in this document will not be completely forthcoming. Approaches to prioritisation are thus needed.

First to be excluded should be those activities that are likely not to be cost-effective. When pressured to find more cases, the mind often moves towards **active case finding (ACF).** ACF has a simple logical appeal, but unfortunately, in practice, often fails to deliver the goods. WHO has already carried out cost-effectiveness simulations (based on real world experience) and provided recommendations that warn against screening activities in populations with a prevalence of TB of less than 1%. Evidence to date suggests that much mass screening in Pakistan falls short of this baseline, and this includes most "conventional camps", or even "X-ray camps", as well as more sophisticated approaches. At the very least, this type of activity needs close monitoring (ideally by a disinterested central unit) to measure the yield and cost-effectiveness in order to define rapidly its utility, and contribution to TB case-finding in Pakistan. If it fails to meet its targets within 6 months of operation, at most, the activity will be terminated and the resources re-allocated to other more productive activities.

In Pakistan the yield from GPs is so high, and the proportion of GPs engaged in programme activities so low, that **PPM-1 approaches** must be of high priority. It has already been pointed out that PPM-1 approaches are significantly more efficient and cost-effective at finding cases than community, or even targeted, screening.

The JPRM added "if the settings with more than 1% prevalence are confirmed in this evaluation as hot spots for TB burden, N/PTPs should develop and adapt specific approaches to improve and strengthen {routine, "passive" case finding,} TB prevention, care and control in these areas." This is because case-finding through the conventional approach of enabling the patient to enter a facility of his/her own accord is usually much more efficient, and lower cost, than more active forms of case finding.

Case-finding activities of any sort should be **focused, when resources are limited, on districts that are deteriorating,** or at risk of doing so – defined by low, and falling, presumptive testing rates, and low or falling case notification rates. Too much attention should not be paid to case rate comparisons against the national average. There is too much variation in a country as varied as Pakistan for that to be valid.

Health facilities with low performance (usually in case-finding, see paragraph above) should be prioritized for support supervision by the districts' TB units in order to assess the quality of the procedures that are used to establish the diagnosis of TB.

Preventive therapy approaches generally turn out to be less cost-effective than case-finding and treatment. Provincial programmes are beginning to consider a somewhat complicated programmatic approach to preventive therapy, with registers, adherence monitoring and smart-phone apps. It should be remembered that stopping or interrupting a course of preventive therapy does not have the potentially dire consequences of interrupting treatment of active TB, and in high incidence countries like Pakistan, case-finding and treatment should remain the focus.

Many provinces and regions plan to procure more GeneXpert machines in order to make them accessible to patients. We already know that most people diagnosed by Xpert, are diagnosed in

their own facility. Thus GeneXpert machines seem accessible only to those nearby. However, an efficient sputum transport mechanism, proposed by several provinces and regions, would obviate the need for many more Xpert machines. Any proposed procurement should be looked at critically.

Human resources are expensive. Some provinces have plans to hire a lot of staff, which should be examined carefully when resources are restricted.

8. Modelling results of achievements with proposed inputs

8.1 Overview of the TIME model

TIME Impact is an epidemiological transmission model available within the open-source Spectrum suite of policy models. TIME is used by TB policymakers and national TB programs (NTPs) to develop strategic responses and strategies for TB and to produce projections that inform funding applications. The model has been used in many TB settings, including in countries where TB is driven by HIV, by weak health systems, countries with high MDR burden, and countries where TB programs depend on a high level of private sector involvement. The Estimates component of TIME was used by the Global TB Programme (GTB) to produce estimates for HIV-TB burden towards the Global TB Report.

The TIME model reflects key aspects of the natural history of TB including primary and latent infection, reinfection, and reactivation of latent TB. Smear positivity, negativity, and smear conversion are explicitly handled in the model. Like all models implemented in Spectrum, TIME is demographically explicit and operates on the latest demographic estimates published by the UN Population Division (UNPD) as the World Population Prospects, currently in its 2017 revision. TIME has additional structure for HIV/ART that mimics the structure of the Spectrum AIDS Impact Model (AIM) and directly uses its HIV programmatic data. The model also accounts for the characteristics of paediatric TB, treatment history, and drug resistance. TIME includes two generic strains by MDR status: susceptible and resistant to treatment. Resistance can be acquired during treatment or by direct transmission, at rates that distinguish it from the susceptible TB type.

TB control interventions can be represented in TIME by changing model parameter values directly over time, or by making use of the explicit intervention structure available for some general TB interventions. For example, users can opt to represent changes in the diagnostic algorithm by manually changing net diagnostic sensitivity and specificity over time, or by making use of a Diagnostic Algorithm Tool (DAT) which allows users specify the mixture of diagnostic pathways over time. Other explicit interventions include household contact investigation and preventive therapy for children <5 and for adults 15+ by HIV/ART strata (HIV-, HIV+ not on ART, and HIV+ on ART).

8.2 Model calibration

Like all models, TIME must be calibrated to historical epidemiology such as estimates of incidence and prevalence, and programmatic outcomes such as notifications, and numbers of TB suspects tested by various methods, and numbers successfully treated. Calibration involves collaboration with NTP experts in order to gather data, understand the history of the epidemic and the programme response, and assess the reliability of various estimates and reported data. A good calibration will reproduce various aspects of the epidemiology and programme data independently.

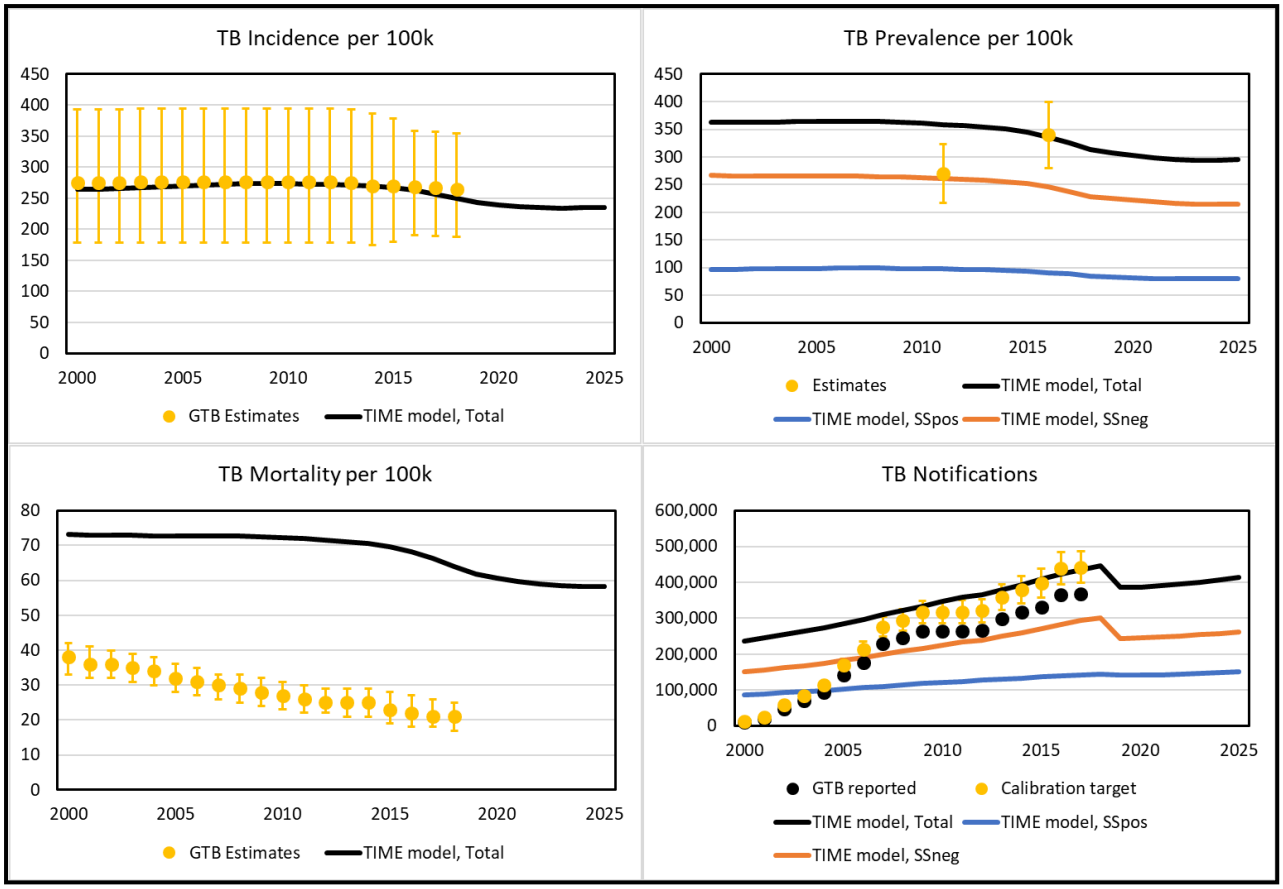


Figure 11. Key calibration results. Calibration targets are shown in gold. Top left shows a good fit to WHO Global TB Programme (GTB) estimates for incidence per 100,000 population. Top right shows total prevalence in the model (black line) is highly relative to the most recent prevalence survey estimate from 2011-12; however, total prevalence agrees with a more recent estimate. Bottom left shows that the model significantly exceeds GTB estimates of per capita mortality. Bottom right shows good agreement with total notifications, accounting for an estimated 20% ratio of underreporting.

8.3 Model scenarios

We present results for three scenarios:

- S0: Scenario 0 is simply the calibrated file with all parameters fixed after 2019. taken as a counterfactual for comparison.
- S1: Scenario 1 involves scale up of preventive therapy, increased GeneXpert coverage in the public sector, increased treatment coverage and treatment success, and an increase in the overall rate of screening.
- S2: Scenario 2 retains the coverage increases for S1, while expanding the scope of current ACF programs based on CXR and Xpert.

In all cases, parameter values were linearly increased over the period 2019-2023 (first increase in 2020) in order to achieve stated targets for total number of TB cases successfully treated and total numbers on preventive therapy over the period for S1 and S2. Specific values are given in Table 19 below.

Table 19. Scenario definitions.

	2019	2023 (S1)	2023 (S2)
Screening rate, SS+	155	180	215
Screening rate, SS-			
HIV-	109	180	215
HIV+	124	180	215
Preventive therapy coverage			
Child contacts	5.7%	95%	95%
HIV+ adults	0%	95%	95%
HIV- adults	0%	1.8%	1.8%
DS-TB			
Linkage to care	90%	95%	95%
Treatment success	94%	95%	95%
DR-TB			
Linkage to care	85%	95%	95%
Treatment success	64%	70%	70%
Coverage of GeneXpert	40%	67%	67%
Coverage of ACF pathway	12%	12%	24%

Scenario results are shown in Table 2 below. Parameter values for S1 and S2 were chosen in order to achieve the cumulative targets of 1.6m (S1) and 1.75m (S2) TB cases successfully treated, and 1.9m total on preventive therapy (both S1 and S2).

Table 20. Key results from model scenarios

	S0	S1	S2
TB cases successfully treated	1,471,678	1,602,592	1,754,389
Total number on preventive therapy	75,015	1,891,644	1,974,733
Child contacts	75,015	890,077	974,580
HIV+ adults	0	595,901	595,902
HIV- adults	0	405,666	404,251
Incident TB cases	2,024,105	1,740,490	1,580,677
Notified TB cases	1,571,414	1,799,931	1,967,784
TB Deaths, adjusted to 2018 estimate	167,403	138,057	121,860
Incidence per 100,000 in 2023	235	171	138
% reduction, relative to 2015	12%	36%	48%
Prevalence per 100,000 in 2023	295	174	118
% reduction, relative to 2015	15%	49%	66%

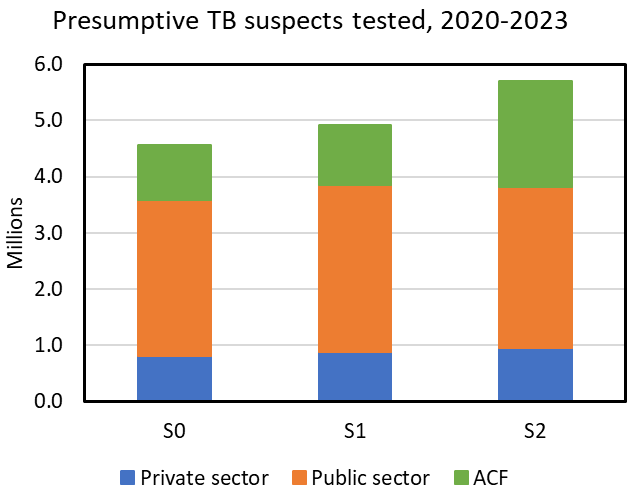


Figure 12. Total number of presumptive TB suspects tested, by sector, over the period 2020-2023. Increased screening rates lead to more presumptive TB suspects tested in S1 (7.9m) and S2 (8.6m) relative to S0 (7.3m) over the period. The expansion in ACF coverage is also evident in S2.

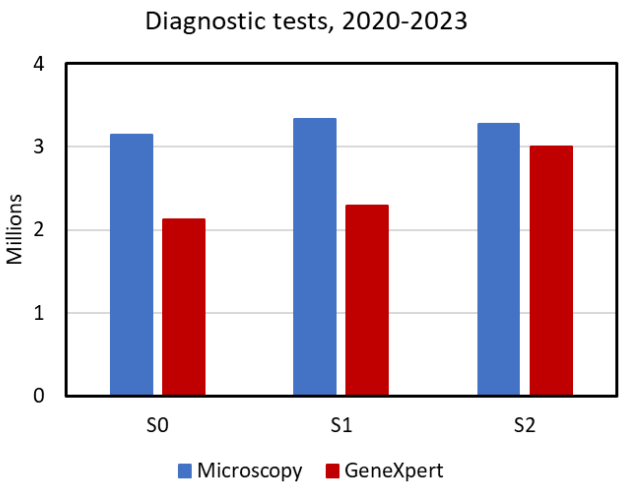


Figure 13. Total number of smear microscopy and GeneXpert tests, by scenario, over the period 2020-2023. Increases from S0 to S1 are primarily driven by increased screening rate, leading to more presumptive TB suspects tested. The increase in GeneXpert tests from S1 to S2 is due to the expansion of ACF pathways based on chest x-ray followed by GeneXpert, with increase in tests overall driven by the further increase in number of presumptive TB suspects tested.

9. The Monitoring and Evaluation Plan

1 Introduction

This monitoring and evaluation plan is the framework that defines the indicators aimed at assessing the achievement level made to reach the goal(s), objectives and targets specified in the NSP. It also will:

- monitor the progress made in the implementation of planned activities and in delivery of services,usually on a continuous basis;
- evaluate the progress made towards the intended goal(s), objectives and targets,
- evaluate and make recommendations specifically on the M&E system itself.

It is intended to be fully consistent with the other components of the P/RSPs.

As of January 10 2020, all provinces and regions, apart from KP and Sindh, have simply listed the original indicators to be used, but have not yet populated the tables with baseline data or targets. KP has listed just the top ten WHO End TB indicators, together with the baseline figures, but without the annual targets. Sindh has focused on the treatment targets for all types of TB, with baseline and annual targets. The list below in this national plan, developed by the NTP staff, M&E Unit, and WHO, is intended to be the template for the provincial and regional plans. Therefore all provinces and regions need to deelop further their M&E Plans. This NSP should help guide them in so doing.

2 Description (summary) of the information system for TB

2.1 The Health Information context

The Health Information Management System in Pakistan is still fragmented. There are numerous health information and disease surveillance systems that are currently not communicating with each other, although efforts are underway to integrate these systems. Operational systems in place currently include District Health Information System 2 (DHIS2) and information systems that serve vertical programs such as maternal, neonatal and child health (MNCH), HIV/AIDS, TB, the Expanded Program of Immunization (EPI), malaria, dengue, service statistics, and the Human Resource Management Information System, among others. Most of these data systems do not capture information from the private sector. To address the multiplicity of data systems and the vertical nature of these systems, the MoNHSRC recently established a technical unit, the Health Planning, Systems Strengthening and Information Unit to revitalize the National Health Information and Resource Centre. One major task of this unit will be to work towards integrating the various information systems and to produce annual health reports in addition to reporting internationally on the progress Pakistan is making on Sustainable Development Goals (SDG).

2.2 Monitoring and Evaluation for TB

The NTP has developed an adequate information system to monitor TB notifications and the implementation of TB prevention, care and treatment activities and to evaluate their outcomes. This system includes:

i) Presumed TB Patients' register,
ii) Request form for sputum examination,
iii) TB microscopy and Xpert register,
iv) laboratory culture and DST request form,
v) TB culture and DST register
vi) TB treatment register,
vii) facility-based patient treatment card,
viii) patient identity card,
ix) sputum conversion reporting form,
x) referral form,

xi) quarterly TB registration reporting form,
xii) quarterly treatment outcome reporting form, and
xiii) quarterly TB drugs' inventory reporting form.

Data on TB notification and treatment outcomes are collected in the BMUs and reviewed and compiled at district level, then at the province and NTP Central Unit levels. For the information on TB contact investigation activities, the facility-based patient treatment card includes a small section where this information can be collected. To monitor and evaluate PMDT activities, a specific registration system, including a case-based computer database, has been developed and implemented in the PMDT sites.

The District Health Information System 2 (DHIS2) is being implemented in Pakistan, but the NTP information system has not yet been linked to this system. The NTP information system needs to be linked to this DHIS2.

2.3 Strengths (derived from the JPRM)

- The required definitions of TB cases and treatment outcomes are in general well understood and used by the health staff in charge. The registers are generally adequately filled, and include, most of the time, the required information. The quarterly reports on TB notification and treatment outcomes are filled in almost all BMUs and include detailed information.
- In many districts, but not all, the data included in the quarterly reports are reviewed and discussed in the district quarterly meetings with the staff of the relevant BMUs.
- Data on TB activities undertaken in the private sector are collected through the NGOs and included subsequently in the NTP information system.
- The NTP's information system has succeeded in collecting a significant amount of data that are used for advocacy purposes, epidemiologic surveillance and programmatic management, including supervision activities. The results of data analysis contribute to identifying hypotheses for operational research.
- The NTP prepares and issues every year an Annual Report that gives TB notifications, TB service outcomes, and interventions that have been developed and implemented. This report is widely distributed and forwarded to those who need to be kept informed.

2.4 Weaknesses

- Even though the NTP has issued a register to specifically identify presumed TB patients, it is not always available in BMUs, and even when it is, information on patients identified as presumed TB cases is not always collected. In addition, the NTP has not issued clear guidance on how to use this register, especially how it should be linked to the TB laboratory register and OPD register.
- The request form for bacteriological examination is not standardised. In some health facilities, the request forms for sputum examination do not include the items to collect information related to a request for Xpert testing. Different TB laboratory registers are used, some are old, while others are more recent and include the Xpert component as recommended by WHO.
- Given the low proportion of previously treated patients among all registered TB cases in some districts and provinces (Balochistan , Khyber Pakhtunkhwa and Punjab), a misclassification of retreatment patients as new TB cases is probable in these settings. The high proportion of "other previously treated TB patients" among all retreated TB cases in some provinces (Gilgit Baltistan, Sindh and FATA) suggest that the definitions of the different categories of retreatment TB cases are probably not fully understood and, therefore, not appropriately used by the health staff of BMUs.

- Different TB treatment registers are used in the BMUs. The most recent of them includes unnecessary columns for CXR, especially at the 2nd and 5th months of treatment. Regardless of the age of the TB treatment registers, no columns are included on HIV screening, ARV treatment or co-trimoxazole provision. In some BMUs, there is a separate register on HIV screening and treatment, with ARVs and co-trimoxazole.
- As highlighted above:
    - the component on contact investigation included in the facility-based patient treatment card does not allow the collection of all the relevant data on TB contact investigation activities and preventive treatment,
    - the N/PTP has not yet established a registration system for preventive treatment and
    - no indicators have been defined to monitor the implementation of TB contact investigation activities, or TB preventive treatment, nor to evaluate their outcomes.

Although significant efforts have been made through the SORT-IT Initiative, capacities to undertake in-depth data analysis are still sub-optimal, especially at provincial level. This is reflected by the lack of consistency in some of the reported data.

2.5 JPRM Recommendations relevant to this NSP

- In the training on basic TB, a focus should be made, on the definitions of TB cases and treatment outcomes, including on the previously TB treated patients and their various categories.
- In supervision, more data quality checks are needed from the various registers and compiled reports. The quality and the consistence of the data that are compiled at province and national levels should be checked and assessed by the relevant staff at PCP and NTP Central Unit levels.
- The NTP should clearly define indicators to monitor the implementation of TB contact investigation and to evaluate its outcomes. The following indicators were proposed:

Monitoring indicators focusing on contact management bearing in mind the need to address contacts of all ages

- The ratio of the number of index cases whose contacts were investigated divided by the number of TB cases registered in the TB treatment register who meet the criteria of a TB index TB case. In the ideal situation, this ratio will be slightly less than 1.
- Proportion of identified contacts who were screened and assessed for TB.
- Proportion of contacts aged less than 5 years with no active TB who were prescribed IPT. If the NTP policy considers that IPT should be prescribed to contacts aged more than 5 years with LTBI, then the proportion of this category of contacts who were prescribed IPT will need to be included in the monitoring indicators.

Evaluation indicators

- Prevalence of active TB among the contacts who were screened and assessed. The prevalence should be calculated, if possible, for each form of TB (BCPTB, CDPTB, EPTB).
- Proportion of TB cases identified through contact investigation among TB patients registered in the TB treatment register. This proportion should be also calculated, if possible, for each form of TB.
- Proportion of contacts aged less than 5 years with no active TB who completed IPT. If the NTP policy considers that IPT should be prescribed to contacts aged more than 5 years with LTBI, then the proportion of this category of contacts who completed IPT will need to be included in the evaluation indicators.

- The NTP should also define clear indicators to monitor the implementation of LTBI management and to evaluate its outcomes.

2.6 Moving ahead

This NSP should move towards establishing a fully digital, case-based, web-based data system for TB notification, provider engagement and patient tracking, with 100% coverage of all TB notifications by 2023. This is essentially a function that needs to be centrally led by the NTP M&E Unit.

To take full advantage of such a digital system, the relevant provincial staff should be further trained on the methodology of data analysis, using, for example, the Data for Action Course that has been developed by the IUATLD.

3. Targets and indicators for the NSP

	INDICATOR	**Baseline - 2018**	**Baseline -2019**	**2020**	**2021**	**2022**	**2023**
1	**DSTB treatment coverage**	63%	50%	66%	71%	73%	75%
N	Number of new and relapse cases that were notified and treated, divided by	358592	281620	384511	420556	443918	464840
D	the estimated number of incident TB cases in the same year, expressed as a percentage.	567392	567450	580987	592405	604058	615945
2	**DSTB treatment coverage-TB cases notified private provider**	33%	36%	38%	39%	40%	41%
N	Number of new and relapse cases that were notified and treated by private providers , divided by	118261	101179	146989	165279	177615	190609
D	Number of total new and relapse cases that were notified and treated.	360018	283392	386176	422463	445859	467036
3	**DSTB treatment coverage- Pulmonary TB (PTB)**	80%	80%	81%	81%	81%	81%
N	Number of new and relapse PTB cases that were notified and treated, divided by	289254	227206	312679	344197	360473	377890

D	Number of all (PTB+EPTB) new and relapse cases that were notified and treated.	360018	283392	386176	422463	445859	467036
4	**DSTB treatment coverage- Child hood PTB**	12%	14%	13%	13%	14%	15%
N	Number of new and relapse CHPTB cases that were notified and treated, divided by	36188	33300	43212	49631	54738	61295
D	Number of All new and relapse PTB cases that were notified and treated.	306592	244810	336061	370210	388796	408920
5	**DSTB treatment coverage- Bacteriological confirmed PTB**	48%	50%	50%	57%	61%	65%
N	Number of new and relapse bacteriologically PTB cases that were notified and treated, divided by	139326	114519	159181	197109	223521	246962
D	Number of new and relapse PTB cases that were notified and treated.	292542	230423	315638	347458	364235	382003
6	**DSTB treatment success rate**	98%	124%	92%	92%	92%	92%
N	Number of notified TB patients who were successfully treated.	349218	350773	347784	383252	401126	421249
D	Number of new and relapse cases that were notified and treated	355953	282296	376903	414376	437508	458415
7	**DSTB services coverage in BHUs**	9%	10%	47%	59%	61%	62%
N	Number of Primary health facilities (BHU) offering TB diagnostic and/or treatment services.	589	609	2860	3573	3678	3763
D	Total number of Primary health facilities (BHU)	6372	6372	6056	6056	6056	6056

8	**DSTB services coverage in Private sector**	255%	255%	368%	111%	164%	165%
N	Number of Private GP engaged in TB control	3071	3071	4962	10075	14858	14924
D	Total number of Private GP registered.*(Incompletel data)*	1202	1202	1350	9050	9050	9050
9	**DRTB treatment coverage**	44%	44%	65%	74%	79%	81%
N	Number of RR/MDR TB cases that were notified and treated, divided by	3195	2688	5928	7745	9376	10582
D	Estimated number of incident DRTB cases among bacteriologically confirmed PTB cases notified in the same year, expressed as a percentage.	7300	6158	9055	10455	11832	13090
10	**DRTB treatment success rate**	65%	65%	69%	71%	78%	86%
N	Number of notified RR/MDR TB patients who were successfully treated.	1918	1767	4069	5509	7328	9058
D	Number of RR/MDR TB cases that were notified and treated	2952	2739	5873	7745	9376	10582
11	**DRTB patients- social support coverage**	37%	36%	63%	83%	83%	83%
N	Number of notified RR/MDR TB patients who received social support during treatment	1033	828	3706	6406	7757	8771
D	Number of RR/MDR TB cases on treatment	2767	2330	5928	7745	9376	10582
12	**DRTB services coverage**	32%	31%	37%	76%	76%	76%
N	Number of Districts(population ≥1M) having minimum of one functional DRTB treatment site	29	29	35	74	74	74

D	Total number of district (Population ≥ 1M)	90	93	95	97	97	97
13	**Percentage of TB-affected households that experience catastrophic costs due to TB**	0%	0%	0%	0%	0%	0%
N	Number of people treated for TB (and their households) who incur catastrophic costs (direct and indirect combined), divided by	0	0	0	0	0	0
D	the total number of people treated for TB.	363940	285656	391075	427590	446158	467530
14	**Percentage of new and relapse TB patients tested using a WHO-recommended rapid diagnostic (WRD) at the time of diagnosis**	28%	42%	71%	74%	76%	80%
N	Number of new and relapse TB patients tested using a WRD at the time of diagnosis, divided by .	99901	118027	275687	315195	341691	373694
D	total number of new and relapse TB patients, expressed as a percentage.	360692	279282	389153	424667	447542	468178
15	**Latent TB infection (LTBI) treatment coverage**						
15 a	**Latent TB infection (LTBI) treatment coverage in <5yrs HH contact of B+PTB**	69%	49%	24%	49%	64%	66%
N	Number of children aged <5 years contacts of people with bacteriologically confirmed TB enrolled on LTBI treatment divided by the	5949	4172	46042	149607	213519	231867
D	number children <5yrs HH of B+ PTB	8586	8590	194968	304986	331721	349551

	eligible for treatment,						
15 b	**Latent TB infection (LTBI) treatment coverage in people >5ys HH contact of B+PTB**	3%	16%	24%	33%	49%	52%
N	Number of people aged >5 yrs who are household contact of people with bacteriologically confirmed PTB, enrolled on LTBI treatment divided by	387	2021	110057	207836	336722	370545
D	Number of people aged > 5yrs who are household contact of people with bacteriologically confirmed PTB	11483	12500	458074	635686	682247	713835
15 c	**Latent TB infection (LTBI) treatment coverage in people living with HIV**	85%	115%	77%	85%	87%	87%
N	Number of people newly enrolled in HIV care enrolled on LTBI treatment divided by	662	874	703	1159	1380	1393
D	Number of eligible people newly enrolled in HIV care *(incomplete data)*	777	758	909	1361	1579	1596
16	**Contact investigation coverage** *(Incomplete data in denomoniatorhence,resulting in massive proportion in 2018-19)*	182%	201%	95%	96%	97%	97%
N	Number of contacts of people with bacteriologically confirmed TB who were evaluated for TB, divided by .	137900	152237	602226	679561	712741	744116
D	the Total number eligible contact of Bacteriologically conformed TB expressed as a percentage.	75824	75806	636691	709934	737086	768994

17	**Drug-susceptibility testing (DST) coverage for TB patients**						
17 a	**Drug-susceptibility testing (DST) coverage for New TB patients**	45%	68%	70%	70%	57%	73%
N	Number of bacteriologically confirmed New TB cases with DST results for at least rifampicin, divided by	113011	68470	100561	122049	141549	159419
D	Total number of New bacteriologically confirmed TB cases in the same year, expressed as a percentage	253900	100647	144345	174446	249228	218056
17 b	**Drug-susceptibility testing (DST) coverage for previously treated TB patients**	80%	80%	84%	84%	85%	85%
N	Number of previously treated bacteriologically confirmed TB cases with DST results for at least rifampicin, divided by	25172	9311	14424	17452	20148	22079
D	Total number of previously treated bacteriologically confirmed TB cases in the same year, expressed as a percentage	31303	11705	17221	20764	23770	25998
17 c	**Second line Drug-susceptibility testing (DST) coverage for RR/MDR TB**	93%	95%	94%	94%	94%	94%
N	Number of RR/MDR TB patients with DST results for second line drugs	5719	2751	5370	6906	8118	9142
D	Tota Number of RR/MDR TB patients enrolled on second line treatment	6174	2898	5734	7371	8649	9729
18	**Treatment coverage, new TB drugs**	127%	78%	86%	81%	81%	82%

	(incomplete baseline data)r						
N	Number of TB patients treated with regimens that include new (endorsed after 2010) TB drugs, divided by	916	886	3412	4406	5288	5948
D	the number of notified patients eligible for treatment with new TB drugs, expressed as a percentage.	719	1133	3990	5430	6527	7253
19	**Documentation of HIV status among TB patients**	21%	47%	55%	73%	73%	74%
N	Number of new and relapse TB patients with documented HIV status, divided by the	75401	133622	210153	307102	324859	343386
D	The number of new and relapse TB patients notified in the same year, expressed as a percentage.	360023	285761	384669	419835	442059	464039
20	**Case fatality ratio (CFR)***(incomplete data)*	1%	0%	0%	0%	0%	0%
N	Number of TB deaths divided by	687	226	0	0	0	0
D	estimated number of incident cases in the same years, expressed as a percentage.	91657	93384	96301	103359	106180	110836
21	**Domestic fund contribution** *(Incomplete data)*	386%	142%	199%	0%	0%	0%
N	Total domestic commitment (PC1) for same year	255	107	190	0	0	0
D	Total Need expressed in strategic plan (In US$)	66	76	95	133	122	128

22	**Domestic fund releases**	111%	92%	96%	---	---	---
N	Amount (PKR) released	493	550	593	---	---	---
D	Total domestic commitment (fund allocated) for fiscal year	445	595	615	---	---	---
23	**Domestic fund contribution**	40%	33%	10%	10%	10%	11%
N	Number of FLD courses procured through domestic funds	127800	83600	35938	39399	42973	46663
D	Total First line courses acquired in fiscal year	318749	254547	365953	398874	414923	432288
24	**Change in Control strategies resulting from research**	---	---	88%	70%	70%	70%
	Number of research conducted leading to policy change	---	---	7	7	7	7
	Total number Operation research conducted	---	---	8	10	10	10

4. Surveys planned for 2020 – 23

The M&E Unit, research unit and provinces will collaborate for the **4th National TB Prevalence survey,** which aims to measure the national TB prevalence and also, by enlarging the study size, have sufficient power to provide prevalence estimates for the provinces. Most provinces and regional have included a prevalence survey in their plans as the most practical and precise way of estimating the current true burden of TB in Pakistan. Not all have mentioned collaboration with the national level on a national survey, but this is the only practicable and cost-efficient approach. A national consultation workshop is planned to finalize the methodology for this TB prevalence survey with sub-national estimates with NTP, WHO and provincial representatives, and the support of WHO TME in early 2020. An outline budget of about US$6.7 million has already been developed.

The patient cost survey is required by WHO to assess progress against the important indicator of the number of families experiencing catastrophic expenditures as a result of TB. It will provide evidence for changes to policy and practice, and priority actions to mitigate/eliminate TB patient costs through enhancing social protection and improving TB service delivery and financing.

The estimates of childhood tuberculosis cases remain weak in Pakistan – the previous prevalence surveys have not included children, and the proposed survey will not do so either. It is suspected that children living in orphanages, public and private primary schools and Islamic Madaris are more prone to develop TB because of congested/crowded homes, and low nutritional status. **A pilot study to screen for TB among children** living in such institutions in Rawalpindi is therefore planned.

10. Operational Plan

The provinces and regions are at different stages in the preparation of operational plans: Punjab has a detailed Operational Plan, but, not surprisingly has not yet identified sources of funding (and costs are not stated in the Operational Plan but are very clear in the Budget Plan). Sindh and KP have simply listed their proposed activities and sub-activities, with none of the detail required in an operational plan – see below. Balochistan's Operational Plan is detailed and clear, missing only the sourceof funding. AJK, FATA, GB and ICT have operational plans that clearly link the activities and sub-activities under the appropriate strategic interventions and objectives (as suggested by WHO), but they are vague on the timing and the source of funding – and their costs are in the Budget Plans only.

According to WHO, the operational plan is an important component of the NSP and should focus on the activities to be implemented. It must be fully consistent with the core plan, budget plan, monitoring and evaluation plan, and technical assistance plan. However, at this point in the preparation of P and RSPs in Pakistan, it makes sense to hold off on detailed operational planning until the budget envelope in each province and region is clearer since the total budgets significantly exceed the anticipated overall funding.

WHO further recommends that the operational plans should specify detailed information, by quarter, on the activities and sub-activities that need to be implemented at least for the first year of the period covered by the NSP. "The implementation of the activities for the remaining years of the NSP can be detailed subsequently.

For the first year, on a quarterly basis and for each activity or sub-activity clearly specified, the following information should be identified:

- the dates or the period when it will be implemented;
- the setting where it will be implemented;
- the person/institution that will be responsible for its implementation;
- the cost inherent in the implementation of this activity or sub-activity as calculated in the budget plan;
- the source of funding that will cover this cost;
- the process indicator that will be used to monitor the implementation of the activity or sub-activity."

Technical assistance components listed in the operational plans should be further developed in a specific TA Plan, again, under the relevant objective, intervention or activity or sub-activity.

Consistency should be assured with the operational plans of other programmes such as HIV/AIDS programmes, maternal and child health programmes or noncommunicable disease programmes.

11. Technical assistance (TA) plan

1. Introduction

The NTP and P/RSPs may wish to engage providers of technical assistance (TA) to support the adoption and implementation of interventions. TA at regional or provincial level should be coordinated nationally to avoid ineffeiciencies, since needs are similar across provinces and regions. TA activities should be closely linked to the Operational Plan on which they should be based. According to WHO, the TA Plan provides detailed information on the technical assistance required for the strategic interventions and activities, as identified in the operational plan.

Like the operational plan therefore, the TA Plan should be established for the first two years of the NSP, and should be based on provincial and regional needs. For the remaining years, the technical assistance needs to be identified as far as possible. Technical assistance can be provided by national as well as international experts.

2. Areas indicated for TA by the JPRM

The JPRM suggested the following areas for TA at the national level:

1. Data driven supervision to support the use of data to drive interventions at the local level.

This is intended to support the need for district and tehsil level staff to understand, analyse and use their own data for local decision-making. The International Union against TB and Lung Disease runs international courses on "Principles of Tuberculosis Care and Prevention: Translating Knowledge to Action" which can be tailored for individual countries[74]. Pakistan may wish to coordinate such TA from the central level for the provinces

2. DR-TB decentralization and adoption of new regimens

The management of DR-TB is complex, and will very probably undergo significant advances in the coming years especially in treatment[75]. International TA may well be desirable.

3. The development of operational guidelines for sputum transport

The expansion of properly organised and effective sputum transport is a major priority and mentioned in almost all P/RSPs (see below), however, none of these has a convincing solution. Yet, the Global Fund is prepared to invest in radical solutions. At the same time, local staff correctly point out that the variation in local conditions in Pakistan is immense and therefore "one-size-fits-all" is not going to be a solution. However, analysis and organisation of effective approaches can be addressed centrally and different approaches tried in different places, until sufficient successful examples are found that will solve the problem.

4. Further development of TB laboratory capacity, especially the introduction of genome sequencing procedures.

1. Development of operational guidelines for preventive treatment of TB

[74] Heldal E, Dlodlo RA, Mlilo N, Nyathi BB, Zishiri C, Ncube RT, Siziba N, Sandy C. Local staff making sense of their tuberculosis data: key to quality care and ending tuberculosis. Int J Tuberc Lung Dis. 2019 May 1;23(5):612-618. doi: 10.5588/ijtld.18.0549

[75] WHO. December 2019. Rapid Communication: Key changes to the treatment of drug-resistant tuberculosis. WHO, Geneva.

Work on this issue is already under way.

3. Areas for TA indicated in the provincial/regional plans

The four regions/territories have developed sketchy TA Plans, while Baluchistan a has a more considered and detailed Plan. Punjab, Sindh and KP have yet to prepare a TA Plan, although Punjab, in its Operational Plan, has declared a need for TA to support the Prevalence Survey, and to help drafting a law to prevent the sale of over-the-counter (OTC)anti-TB drugs.

Understanding of what needs to be in a TA Plan is still basic. The TA Plans at present include problematic areas which could relatively easily be addressed by central discussion and coordination. What should be included will be addressed below using WHO guidance[76]. However, some important common needs are emerging:

3.1 Procurement of purified protein derivative PPD.

This is common to AJK, GB and ICT and represents a problematic area which is caused by low stocks internationally, but a coordinated national approach could be organised centrally, in collaboration with the Global Drug Facility (GDF). Specific TA beyond routine GDF support probably not required.

3.2 Procurement of digital XR machines

This is common to AJK, FATA and ICT and may be a challenge for the smaller regions, but a coordinated national approach could be organised centrally, with support from WHO.

3.3 Procurement of Xpert machines

Common to AJK and ICT. Similar to 3.2 above, and in any case there is considerable experience in Pakistan already in procurement of these machines. Perhaps acase for inter-regional/provincial TA.

3.4 Mobile applications for case notification and contact tracing

Common to AJK, Balochistan and ICT. Mention is also made of "case based android TB case notification applications …for reporting GPs" in the Core Plan of Punjab and a similar mention in Sindh. This may be another area for inter provincial/regional TA.

3.5 Legal drafting of Bills

Punjab's Core Plan mentions the need for TA to draft a Bill against OTC sales of ATT medicines, while GB needs help for a Bill on Mandatory Notification. The latter has already been achieved in a number of provinces and regions and hence perhaps is another area for inter provincial/regional TA.

3.6 Mapping of private providers

The need was expressed by FATA and ICT. Again, this has already been achieved in some provinces/regions and could thus be another area for inter provincial/regional TA.

4. Recommendations for finalising TA needs

Identification of TA needs is clearly a provincial/regional responsibility. KP, Punjab and Sindh need to develop their TA Plans, while the regions may wish to revise theirs. It is most sensible to start defining those needs in the process of preparing the operational plans. Then, national level review and coordination of the final listing of TA needs is essential to avoid repetition and inefficient organisation of support, especially for the regions.

[76] WHO, 2015. Toolkit to develop a national strategic plan for TB prevention, care and control: methodology on how to develop a national strategic plan. WHO, Geneva.

As recommended by WHO, the following information must be specified for each strategic intervention or activity that needs technical assistance:

- a brief description of the terms of reference for the technical assistance required, including the specification of deliverables;
- a brief description of the profile/expertise of the consultant who will ensure the technical assistance;
- the identification of the entity responsible for the implementation of the intervention or activity;
- the timeframe to carry out the technical assistance;
- the estimated cost of technical assistance (including consultancy fee, travel, per diem) as
- calculated in the budget plan;
- identification of the source of funding, if available;
- identification of the funding gap that needs to be closed in the event that there is no financial
- source to cover the cost of the technical assistance.

12. Contingency Plan for Emergencies, Natural Disasters etc.

Background

Pakistan is prone to earthquakes, floods and droughts, as well as man-made, military interventions by State, or Non-State actors that threaten the security of the general population, within or just outside the national borders, and therefore can give rise to mass displacement of populations within the country. Such displacement will obviously affect patients, their families, and indeed, health staff, including those responsible for TB care and prevention. An Emergency Plan therefore initiates contingency planning for such events. It should address the issues relating to the care of patients with tuberculosis (TB) and controlling the spread of the disease in refugee and displaced populations.

A major problem with IDPs and refugees, whether they are in a formal camp or not, is that they may not be able to access national or NGO health services. Mechanisms providing services for the stable population may not apply. IDPs, unlike refugees, may not have the same level of protection from the international community and national authorities may not address their needs. It is therefore vital that efforts are made to reach this vulnerable population and include them in health care services. Increased collaboration between the NTP and NGOs can increase population coverage and improve the efficiency with which TB care and control activities are implemented in displaced populations. Proactive measures should be taken, including the use of community health workers and mobile clinics.

A patient suspected of TB must be managed according to the International Standards for Tuberculosis Care.

At present, the only RSP to address this emergency situation is FATA's. Even there, however, the details are sketchy. Planning for such emergencies needs to take place at both the Central and Provincial/Regional levels. It should address internally displaced populations, refugees, and asylum seekers, whether in camps or not.

A logical approach to the development of an Emergency Plan would be for the central level to develop a template that addresses actions required at central level and provides a format for the provinces and regions to follow. This then needs to be coordinated with the national, provincial and regional stakeholders likely to be involved in any emergency, namely the military, Red Cross, UNICEF, World Food Programme, national and international NGOs and CBOs involved in this type of work, such as MSF, as well as the NTP and WHO/WCO. The best available international guidance is Chapter 7 of the 2007 *Tuberculosis care and control in refugee and displaced populations: an interagency field manual.*

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[i] Zignol M, Dean AS, Alikhanova N, Andres S, Cabibbe AM, Cirillo DM, Dadu A, Dreyer A, Driesen M, Gilpin C, Hasan R, Hasan Z, Hoffner S, Husain A, Hussain A, Ismail N, Kamal M, Mansjö M, Mvusi L, Niemann S, Omar SV, Qadeer E, Rigouts L, Ruesch-Gerdes S, Schito M, Seyfaddinova M, Skrahina A, Tahseen S, Wells WA, Mukadi YD, Kimerling M, Floyd K, Weyer K, Raviglione MC. Population-based resistance of Mycobacterium tuberculosis isolates to pyrazinamide and fluoroquinolones: results from a multicountry surveillance project. Lancet Infect Dis. 2016 Oct;16(10):1185-1192. doi: 10.1016/S1473-3099(16)30190-6. Epub 2016 Jul 7. PubMed PMID: 27397590; PubMed Central PMCID: PMC5030278

[ii] Ghodousi, A., Rizvi, A. H., Baloch, A. Q., Ghafoor, A., Khanzada, F. M., Qadir, M., … Cirillo, D. M. (2019). Acquisition of cross-resistance to Bedaquiline and Clofazimine following treatment for Tuberculosis in Pakistan. *Antimicrobial Agents and Chemotherapy*, (July). https://doi.org/10.1128/AAC.00915-19