# THE PAKISTAN TB JOINT PROGRAM REVIEW MISSION FEBRUARY 11-23, 2019

Review Mission Report

# Contents

# Acknowledgments

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# List of abbreviations/Acronyms

| | |
|---|---|
| ADB | Asian Development Bank |
| aDSM | active Drug Safety Monitoring and Management |
| AE | Adverse Events |
| AKUH | Aga Khan University Hospital |
| ART | Anti- Retroviral Therapy |
| ATMs | Automated Teller Machines |
| BCTB | Bacteriologically Confirmed TB |
| BDQ | Bedaquiline |
| BHU | Basic Health Units |
| BISP | Benazir Income Support Program |
| BMU | Basic Management Unit |
| CAD4TB | Computed Aided Diagnostics for TB |
| CDPTB | Clinically Diagnosed Pulmonary TB |
| CHS | Community Health Solutions |
| CMs | Chief Ministers |
| CMU | Central Management Unit |
| CPT | Co-trimoxazole Preventive Therapy |
| CRS | Corporate Social Responsibility |
| CXR | Chest X-ray |
| DFID | Department for International Development (United Kingdom) |
| DHIS2 | District Health Information System 2 |
| DHQs | District Headquarter Hospitals |
| DLM | Delamanid |
| DNC | Deputy National Coordinator |
| DOT | Directly Observed Therapy |
| DOTS | Directly Observed Therapy – Short Course |
| DRAP | Drug Regulatory Authority of Pakistan |
| DR-TB | Drug Resistant TB |
| DST | Drug Susceptibility Testing |
| DS-TB | Drug Susceptible TB |
| E | Ethambutol |
| EMR | Eastern Mediterranean Region |
| 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 |
| FEFO | First Expiry, First Out |
| FLDs | First Line Drugs |
| FQ | Fluoroquinolone |
| GB | Gilgit Baltistan |
| GDP | Gross Domestic Product |
| GDF | Global Drug Facility |
| GF | Global Fund |
| GLC | Green Light Committee |
| GNI | Gross National Income |
| GoP | Government of Pakistan |
| GPs | General Practitioners |
| GSM | Greenstar Social Marketing |
| Gx | GeneXpert |
| H | Isoniazid |
| HDI | Human Development Index |
| HIV | Human Immunodeficiency Virus |
| HMIS | Health Management Information System |
| HPSIU | Health Planning, System Strengthening and Information Unit |
| HRH | Human Resources for Health |
| HVAC | Heating, Ventilation and Air Conditioning |
| ICT | Islamabad Capital Territory |
| IHN | Indus Health Network |
| IHS | Integrated Health Services |
| IPT | Isoniazid Preventive Therapy |
| ISTC | International Standards of Tuberculosis Care |
| JPRM | Joint TB Program Review Mission |
| KP | Khyber – Pakhtunkhwa |
| LHWs | Lady (Community) Health Workers |
| LMIC | Low- and Middle-Income Countries |
| LPA | Line Probe Assay |
| LTBI | Latent TB Infection |
| LTR | Long Treatment Regimen |
| 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 |
| MoU | Memorandum of Understanding |
| M.tb | Mycobacterium tuberculosis |
| NC | National Coordinator |
| NCDs | Non -Communicable Diseases |
| NEAP | National Emergency Action Plan (for Polio eradication) |
| NGO | Non- Governmental Organization |
| NHV | National Health Vision |
| NIH | National Institute of Health Pakistan |
| N/PTPs | National and Provincial TB Programs |
| NRL | National Reference Laboratory |
| NNS | Number Needed to Screen |
| NTF | National Task Force |
| NTM | Non-Tuberculous Mycobacteria |
| NTP | National TB Program |
| OOP | Out of Pocket |
| OPD | Out Patient Department |
| PAF | Population Attributable Fraction |
| PAS | Para Amino Salicylic Acid |
| PATA | Pakistan Anti- TB Association |
| S | Streptomycin |
| SDGs | Sustainable Development Goals |
| SLDs | Second Line Drugs |
| SLI | Second Line Injectable |
| SOPs | Standard Operation Procedures |
| STAG | Strategic and Technical Advisory Group |
| STR | Short Treatment Regimen |
| TA | Technical Assistance |
| TB | Tuberculosis |
| TC | Treatment Coverage |
| 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 |
| TNF | Tumor Necrosis Factor |
| 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 |
| WRD | World Health Organization Recommended Rapid Test for TB |
| XDRTB | Extensive Drug Resistant TB |
| Z | Pyrazinamide |
| PC | Planning Commission |
| PDHS | Pakistan Demographic and Health Survey |
| PHC | Primary Health Care |
| PLHIV | People Living with HIV |
| PM | Prime Minister |
| PMDT | Programmatic Management of Drug Resistant TB |
| PPHI | People Primary Health Care Initiative |
| PPM | Public Private Mix |
| PPs | Private Providers |
| PR | Principle Recipient |
| PRLs | Provincial Reference Laboratories |
| PSM | Procurement and Supply Chain Management |
| PTPs | Provincial TB Programs |
| PWIDs | People Who Inject Drugs |
| R | Rifampicin |
| RHC | Rural Health Centre |
| RR-TB | Rifampicin Resistant TB |
| Rs | Pakistan Rupees |
| RSSH | Resilient and Sustainable Systems for Health |

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# Executive Summary

The Pakistan Joint TB Program Review Mission, undertaken between February 11-23, 2019, involved all four provinces and the Islamabad Capital Territory. The overall objective of this mission was to assess progress made in the implementation of the TB National Strategic Plan 2017-2020 and Pakistan's readiness to meet the commitments of the United National General Assembly political declaration on TB. The mission sought to determine if Pakistan's TB Program is supported by broader health and development agenda including Sustainable Development Goals, Universal Health Coverage, regulatory frameworks, social protection schemes and linkages with current national/provincial special health initiatives; review programme sustainability factors with a particular emphasis on domestic and international financing; assess the progress in establishing a multi sectoral approach for ending the TB epidemic; assess progress and constraints in reaching the End TB Strategy targets with an emphasis on the 2020 milestones and a focus on finding missing persons with TB; prevention, identification, care and treatment of drug resistant tuberculosis; public private partnership for TB care and prevention and community engagement and partnerships.

The JPRM was composed of both internal and external experts representing a wide range of skills and expertise in various areas of TB care and prevention. The mission carried out its work through document reviews; interviews with key persons at all levels of the health care system in Pakistan; meetings with current and prospective partners of the TB program and visits to more than 28 health facilities in Baluchistan, Khyber – Pakhtunkhwa, Punjab and Sindh provinces. Summarized in the paragraphs below are the key findings and main recommendations of the JPRM.

While significant progress has been made, the burden of TB in Pakistan remains very high. In 2017, it was estimated that over 525, 000 people developed tuberculosis and 54,000 died from it, which placed this country at the 5$^{th}$ position among countries with the highest TB burden in the world. The gains that have been made to keep TB "under control" are threatened by an increasing burden of drug resistant TB. In 2017, it was estimated that Pakistan had more than 27, 000 people who had this form of TB, which placed the country at the 4$^{th}$ position among countries with the highest burden of MDR TB in the world.

In an endeavor to change the time course of the TB epidemic and end this disease as a global public health threat, the global TB community recently organized two high profile meetings. The first was a high-

level Ministerial meeting that was held in Moscow in November 2017 and the second was the first ever United Nations General Assembly High Level Meeting on TB which was held on September 26, 2018 at the United National Headquarters in New York City. At the United Nations General Assembly High Level Meeting on TB, Heads of States and Governments committed to several actions through endorsement of a TB political declaration which is expected to lead to ending the public health menace of TB if comprehensively implemented. Heads of States and Governments committed to, among other things, establish robust multi- sectoral responses to the fight against TB, increase financing for TB, enhance the identification and treatment of TB to narrow and eventually eliminate TB case finding gaps and to increase funding for research to support the discovery of new tools ( diagnostics, medicines and vaccines) and enhance delivery systems for current and future tools through operational and implementation research. Pakistan was represented at both the Moscow Ministerial meeting and the United Nations General Assembly High Level meeting on TB becoming therefore, a signatory to the declarations that were made at both meetings. Following these political declarations, technical units within the Government of Pakistan at both the Federal and Provincial levels have domesticated the targets for Pakistan including specific targets for each province. Despite this, it was apparent to the JPRM that the enormity of the TB health crisis in Pakistan is not familiar to many people who are in positions of influence to make a difference. On the contrary several people thought TB had been “eradicated” in Pakistan. It was also apparent to the JPRM that very limited efforts had been made to establish and nurture the multi- sectoral approach to TB care and prevention including the development of a Pakistan specific Multi – Sectoral Accountability Framework.

Even though Pakistan has increased its effort to identify and place on treatment people who develop TB, it is currently estimated that up to 160, 000 people with TB and 23, 000 people with drug resistant TB are missed every year, either because they are not diagnosed at all or if diagnosed and may be treated, are not reported to the National TB Program. Thus, now the TB situation in Pakistan qualifies to be called a continuing health emergency that requires emergency type of actions to be addressed.

While significant progress has been made to find cases of TB, including expansion of TB diagnostic services and engagement of private health care providers, which has led to a massive increase in TB case notification of about 22% between 2013 and 2017, the number of persons not reached with high quality TB services, including appropriate support remains high. Opportunities have not been taken 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, has a coverage of a meagre 5% or less.

The ultimate measure of political commitment to TB is the mobilization of financial and human resources enough to meet the needs of a comprehensive response to end TB in Pakistan, which is yet to happen. The TB response is financially very constrained. The current TB National Strategic Plan is budgeted at US$ 520 million. Of this only US$ 179 million (35%) is currently available, leaving a funding gap of 65%. Additionally, of the available funding, US$ 144 million or 80% of the available funds is from the Global Fund. The over dependence on external financing projects a sense of lack of ownership of the TB health crisis in Pakistan and does not augur well for a sustainable response. Additionally, at the Federal level, the National TB Program appears to view itself as primarily an implementer of the Global Fund (GF) grant and not as the driver of TB policy and strategy and the national coordinator of multiple partners engaged in the TB response across the country. The funding of the human resources for health (HRH) at the central level is overly dependent on the GF adding to the concerns on the ownership of the TB problem in Pakistan and the development of a sustainable response.

Based on the above findings and considerations the JPRM made the following over- arching recommendations:

1. Pakistan needs to secure and sustain political commitment to the fight against TB as a demonstration of national ownership of the health crisis that is posed by this disease. To this end, the JPRM strongly advises the Islamic Republic of Pakistan through 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 and to establish National / Provincial Steering Committees chaired and under the oversight of the Prime Minister and Chief Ministers. This will not be an entirely new action for Pakistan. The Government of Pakistan provided similar leadership and political push and support to the Polio eradication initiative that has resulted in a great public health response of unprecedented scale. Similar efforts can and should be done for TB.
2. Political commitment to the fight against TB should lead to an increase in financial resources for this disease. While the JPRM recognizes the myriad challenges with fiscal space including the debt burden, it is the belief of the JPRM that even in this situation, additional resources, some in kind, can be mobilized from Government, private citizens, the corporate sector and development partners to collectively increase the financial envelope that is available to comprehensively deal with TB in Pakistan.

3. In line with the Moscow Ministerial meeting on TB and the United Nations General Assembly High Level Meeting on TB political declaration, the JPRM strongly advises Pakistan to take immediate action to adopt a multi-sectoral approach with an accountability framework under the oversight of the Prime Minister at the federal level and the Chief Minister at the provincial levels with active involvement of all concerned ministries, local governments, private sector stakeholders, civil society organizations, affected communities, non – governmental organizations, academia and others to track and reach the End TB and Sustainable Development Goals targets.
4. It is critical that Pakistan takes urgent actions to not only find all persons who have TB disease but also find them as early as possible to interrupt the chain of TB transmission and ensure financial protection to TB patients and their families. This will require expansion of quality TB service provision, 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 is of paramount importance. National and Provincial TB Programs and partners should also methodically expand TB service provision throughout all levels of the Primary Health Care system. Appropriate task mixes should be developed for each level of health service provision. Additionally, Xpert testing should be better targeted, as the rapid expansion of this test in recent years has led to an increase in clinically diagnosed and not bacteriologically confirmed TB which is the form that is infectious, meaning that impact on transmission, a key goal in TB prevention and care, has been very limited. The number of patients diagnosed with RR-TB has not increased either, again raising concerns about targeting.

5. Drug resistant TB continues to pose a major threat to the fight against TB in Pakistan. Not only are the numbers of persons with drug resistant TB high, but also the proportion of patients with this form of TB that are also resistant to critical medicines, especially fluoroquinolones, is alarmingly high. There are also worrying trends that resistance to recently introduced medicines such as bedaquiline has emerged. The continued presence of anti-TB medicines in private pharmacies that are available to people without a prescription is likely to be contributing to the generation and expansion of drug resistance. While capacity to diagnose drug, resistant TB has expanded significantly in recent years, it has not yet reached optimal levels. The provision of care and treatment to patients with drug resistant TB is still too centralized and without enough patient support and observation, which is limiting access and contributes to high rates of loss to follow up. All these problems need to be addressed and the JPRM strongly advises Pakistan through the relevant agencies and partners (National and Provincial TB Programs, local and international partners, the Drug Regulatory Authority of Pakistan, Professional Associations and Societies among many others) to develop

comprehensive decentralized strategies and interventions to prevent, detect (as early possible), treat and care for drug resistant TB.

6. The is a need to engage communities 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.

# About Pakistan

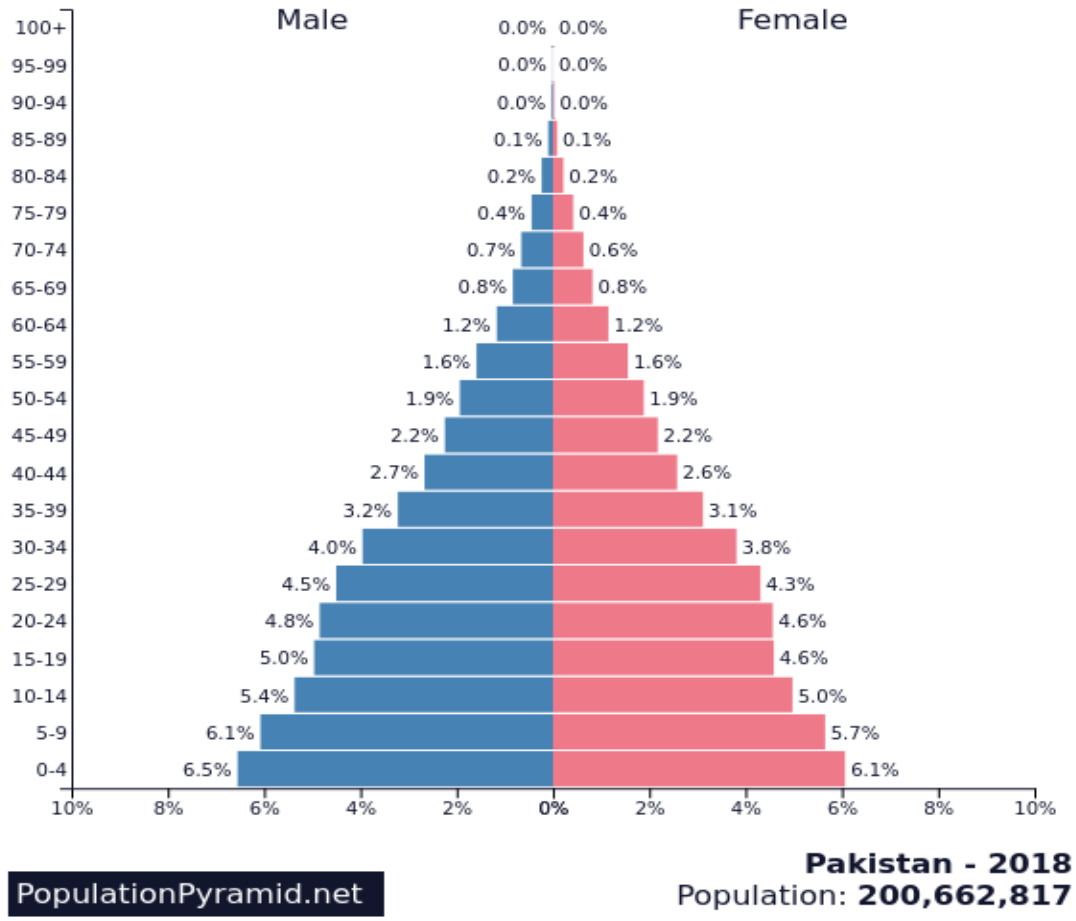
## Geography

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 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 in facilities offering specialized services. The country is administratively divided into the Islamabad Capital Territory ICT); 4 provinces: Baluchistan, Khyber – Pakhtunkhwa (or simply KP), Punjab and Sindh; and two regions (Gilgit Baltistan and Azad Jammu and Kashmir) and the Federally Administered Tribal Areas (FATA).

## Demography

The population of Pakistan is currently estimated at over 212 million people based on the 2017 population census. This places Pakistan in the sixth position among countries with largest populations in the world. As in many Low- and Middle-Income Countries (LMIC) the population of Pakistan is youthful with over 53% of the population being in the age group of 24 years and below while 90% of the population is below the age of 54 years (figure 1 below). There are largely as many males as females with only small difference in the proportions of males versus females in certain age groups such as in persons below the age of 54 years where there are slightly more males and in persons at age 65 and above where there are more females.

Figure1: The Pakistan population pyramid




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

The crude birth rate in Pakistan is estimated to be 21.9 /1,000 population and the annual population growth rate stands at 1.43%. Most of the Pakistan population (60%) lives in rural areas, however, Pakistan is rapidly urbanizing with an annual rate of growth in the urban population of 2.77% (Source: https://www.indexmundi.com.) Most of the Pakistan population lives along the Indus river and its tributaries with Punjab province, which carries about 60% of the country's population, being the most densely populated.

## Economy

The Islamic Republic of Pakistan is classified by the World Bank (WB) as a Low middle-income country. In 2017, Pakistan's Gross Domestic Product (GDP) was estimated to be US $305 billion and the GDP

per capita stood at US$ 1,580. The Gross National Income (GNI) was US$ 1.48 trillion with a GNI per capita of 5, 830 PPP dollars. The GDP has grown at an average of 5.3% over the last 4 years and it is projected that it will increase by 5.1% this year (2019). In 2015, 24.3% of the Pakistan population lived below the national poverty line, however, Pakistan has the fastest growth rate of the middle class in the world (Source: The World Bank). The economy of Pakistan is driven by the service sector which currently contributes over 60% of the GDP followed by manufacturing /industry which contributes about 20% of the country's GDP. The contribution of Agriculture to the Pakistan GDP has been declining from about 53 % at independence to 18.9% currently. Other sectors that are contributing to Pakistan's economy include mining, textiles, housing and energy. The undocumented economy in Pakistan is large and may contribute up to 36% of the country's economy. The country has made great strides in reducing poverty levels in the country. In 2001 the poverty head count ratio at national poverty line was 64.3%, which by 2014 had been reduced to 24.3%. Pakistan, at position 150, is currently placed in the medium human development category with a Human Development Index (HDI) of 0.562 in 2017 which is a 39% change compared to the HDI of 0.404 in 1990. There are proportionately more poor people in rural areas compared to urban areas.

## Health Profile

Pakistan, like other low- and middle-income countries is facing a double burden of disease. While infectious diseases remain a significant public health threat, non- communicable and life style diseases are increasingly threatening the health of the population and have become a major cause of pre-mature deaths.

Table 1 (sourced from[1] [2]below) shows the ten top causes of deaths in Pakistan and clearly highlights the health crisis of preventing, treating and caring for both infectious and non-infectious causes of deaths in this country.

[1] http://www.healthdata.org/pakistan

[2] **https://www.cdc.gov/globalhealth/countries/pakistan/default.htm**

Table 1: Ten commonest causes of death in Pakistan

| Disease | Proportion of deaths (%) |
|---|---|
| Ischemic Heart Disease | 8 |
| Cancer | 8 |
| Stroke | 6 |
| Diarrheal disease | 6 |
| Neonatal encephalopathy | 5 |
| Chronic Obstructive Pulmonary Disease | 5 |
| **Tuberculosis** | **5** |
| Pre-term birth complications | 3 |
| Diabetes Mellitus | 3 |

Between 2007 and 2017, there were significant shifts in the top ten causes of deaths in Pakistan as shown in table 2 below (sourced from[3]). Measles, which was a major cause of deaths in 2007 at number 10 has now become a rare cause of deaths while Diabetes Mellitus has moved up from position 12 to 10. It is important to note that within this ten-year time frame TB has remained among the top ten causes of death in Pakistan.

Table 2: Trends in the ten commonest causes of death in Pakistan, 2007-2017.

| 2007 | | 2017 | |
|---|---|---|---|
| Position | Disease | Position | Disease |
| 1 | Neonatal disorders | 1 | Ischemic Heart Disease |
| 2 | Ischemic Heart Disease | 2 | Neonatal disorders |
| 3 | Stroke | 3 | Stroke |
| 4 | Diarrheal disease | 4 | Diarrheal disease |
| 5 | Lower Respiratory Tract Infections | 5 | Lower Respiratory Tract Infections |
| **6** | **Tuberculosis** | 6 | Road Injuries |
| 7 | Road Injuries | 7 | COPD |
| 8 | COPD | 8 | Cirrhosis |
| 9 | Cirrhosis | **9** | **Tuberculosis** |
| 10 | Measles | 10 | Diabetes |
| 12 | Diabetes | 76 | Measles |

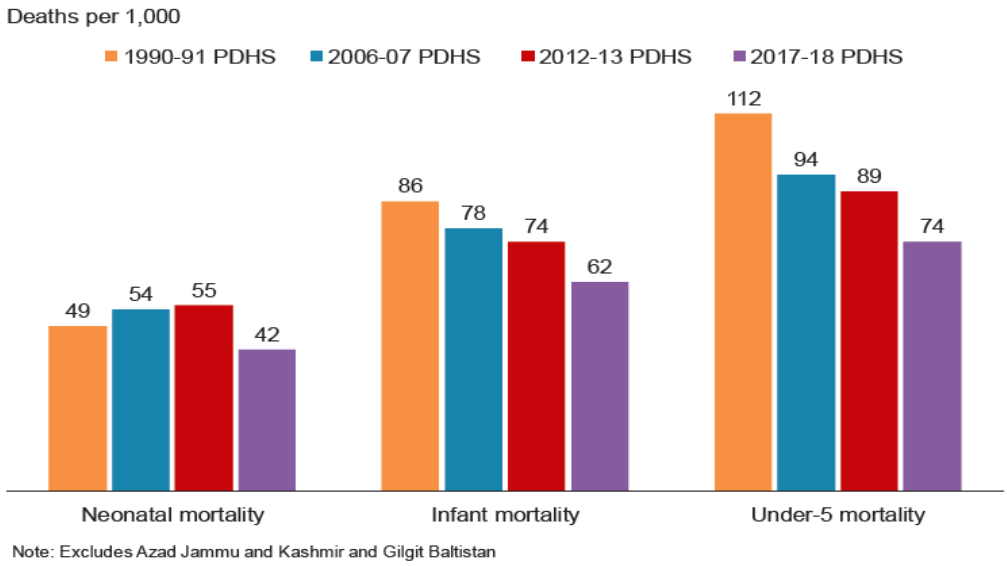
The majority of morbidity is caused by a relatively small set of illnesses which include acute respiratory infections especially in children, diarrheal disease including dysentery, fevers due to a variety of viral and bacterial infections including Dengue, peptic ulcer disease, skin conditions including scabies,

[3] http://www.sbp.org.pk/publications/staff-notes/State-of-Health-Sector-in-Pakistan-(06-04-2018).pdf

hypertension, hepatitis due to hepatitis viruses A, B, C and E, asthma, urinary tract infections, mental health problems and diabetes.

Pakistan has seen steady increase in health indicators in recent years. Thus, infant deaths per 1,000 live births declined from 106.1 in 1990 to 69.0 in 2013. The under-five mortality per 1,000 live births also declined from 138 in 1990 to 86 in 2013, however, for neonatal mortality, there was little change in the number of deaths per 1,000 babies in over 15 years with the rate increasing from 51.4 /1,000 in 1990 to 55.0 /1000 in 2013 before dipping to 46/1,000 in 2017. Although these are positive trends, the current rates still represent an undesirable situation. The deaths among neonates is among the highest in the world. Life expectancy at birth has steadily increased since 1990 and now stands at 66- 67 years. In relation to immunization coverage, Pakistan steadily increased vaccine coverage from 54% in 1990/91 to 66% in 2017/18 (Source*: Pakistan Demographic and Health Survey 2017-18*).

Figure 2: Trends in childhood mortality 1990-2018




Source: Pakistan Demographic and Health Survey 2017-2018

Table 3: Health Indicators, Pakistan

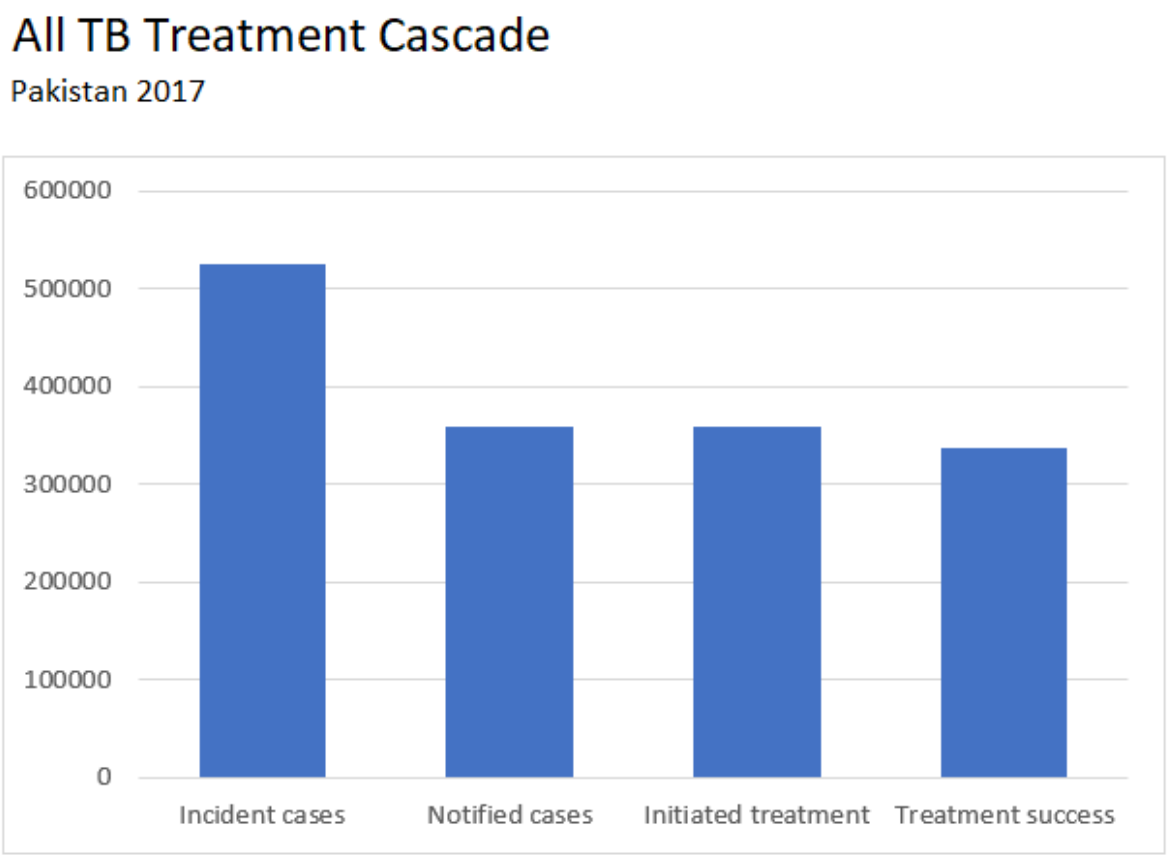
| Health Indicator | Value in 1990 | Most recent value | Year |
|---|---|---|---|
| Under 5 mortality rate/1,000 live births | 139 | 74.9 | 2015 |
| Infant mortality rate /1,000 live births | 64 | 62.9 | 2015 |
| Neonatal mortality rate/1,000 live births | 54 | 44 | 2015 |

| | | | |
|---|---|---|---|
| Maternal Mortality Ratio | 431 (288-656) | 178(11-283) | 2015 |
| Stunting (height for age in children under 5) | 55% | 38% | 2017-18 |
| Underweight (weight for height in children under 5) | 32% | 23% | 2017-2018 |
| Average Life expectancy at birth | 60.5 | 66-67 | 2016 |

## Tuberculosis in Pakistan

Tuberculosis remains a major public health threat in Pakistan. In the last ten years (see table 2 above) this disease has remained in the list of the top ten causes of death in Pakistan. In 2017, the World Health Organization (WHO) estimated that there were 525,000 (95% confidence interval 373,000 -704,000) people who developed TB in Pakistan and the disease caused a total of 54, 000 (95% confidence interval 42, 000 -67,000) deaths, making this disease the most common cause of death from a single infectious agent in Pakistan. The WHO also estimated that in the same year (2017), there were 27, 000 (95% confidence interval 17,000 – 39,000) people who developed Multi – Drug Resistant TB (MDRTB) in Pakistan. These figures place Pakistan in the 5$^{th}$ position for total burden of TB and 4$^{th}$ position for the burden of MDRTB in the world, which is certainly not an enviable position. There has been a wide gap between the estimated number of incident cases of TB and the number that is actually identified, notified and treated. In 2017, for example, only 359, 244 TB cases out of the estimated 525, 000 people who developed the disease were notified and placed on treatment, leading to a Treatment Coverage (TC) of 68% (see figure 3 below). The situation was even worse for MDRTB. Of the estimated 27, 000 cases of MDRTB that were present in 2017, only 3,081 (11%) were identified and treated. Thus, a huge number of people (in excess of 165, 000), with TB including MDRTB were either not diagnosed and thus not treated for TB or were diagnosed and may have been treated for the disease but were not notified. This is a major challenge for TB prevention, care and treatment efforts in Pakistan.

Figure 3: The TB Care Cascade

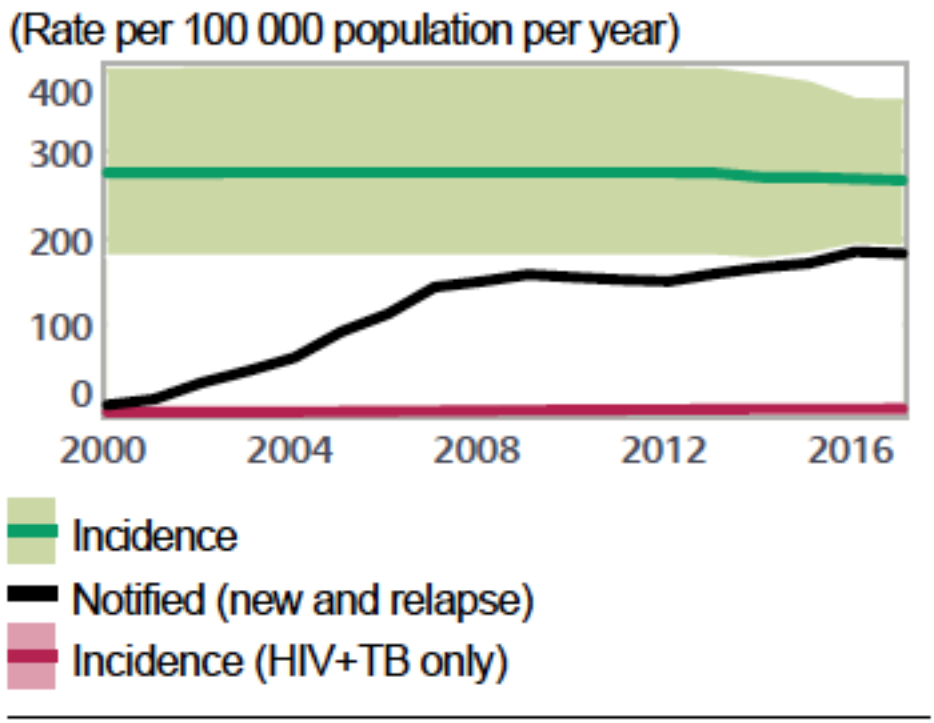



There are more males than females among notified TB cases in a ratio of 1.3:1. Children under the age of 14 form about 11% of all notified TB cases. Pakistan is a low HIV prevalence setting with the epidemic of HIV concentrated mainly among intravenous drug users. Consequently, the number of TB and HIV co-infected people are small with the WHO estimating that in 2017 there were only 7, 300 HIV infected persons who developed TB. Even then the TB program in Pakistan was only able to identify 121 (1.6%) of them, of whom 80% were placed on anti-retroviral treatment (ART).

As in the rest of the world Pakistan adopted the End TB Strategy with its ambitious targets to end TB as a public health threat by 2030/35. The commitment to pursue the End TB Strategy is reflected in Pakistan's National TB Strategic Plan 2017-2020 and was re-iterated at the Moscow Ministerial meeting on TB that was held in November 2017 and at the first ever United Nations General Assembly High Level Meeting on TB (UNGA -TB -HLM) held in New York on September 26, 2018. To be able to achieve the End TB targets the incidence of TB in Pakistan needs to fall by more than 10% annually as opposed to the 1-2% that is the current trajectory of the decline in TB incidence in Pakistan (see figure 4 below).

Current efforts at fighting TB are based on identifying people with the disease and placing them on effective treatment. As seen in figure 4 below TB case finding and notification has been rising over the last 15 or so years, yet this has had relatively little impact on the estimated TB incidence, suggesting that new ways of confronting TB, such as large scale TB preventive therapy combined with enhance search and treatment of TB cases to influence TB transmission and risk factor modification, need to be aggressively explored in Pakistan.

Figure 4: Trends in Tuberculosis incidence and case notification in Pakistan 2000-2016.




Source: WHO Global TB Report, 2018

**Tuberculosis at risk populations in Pakistan**

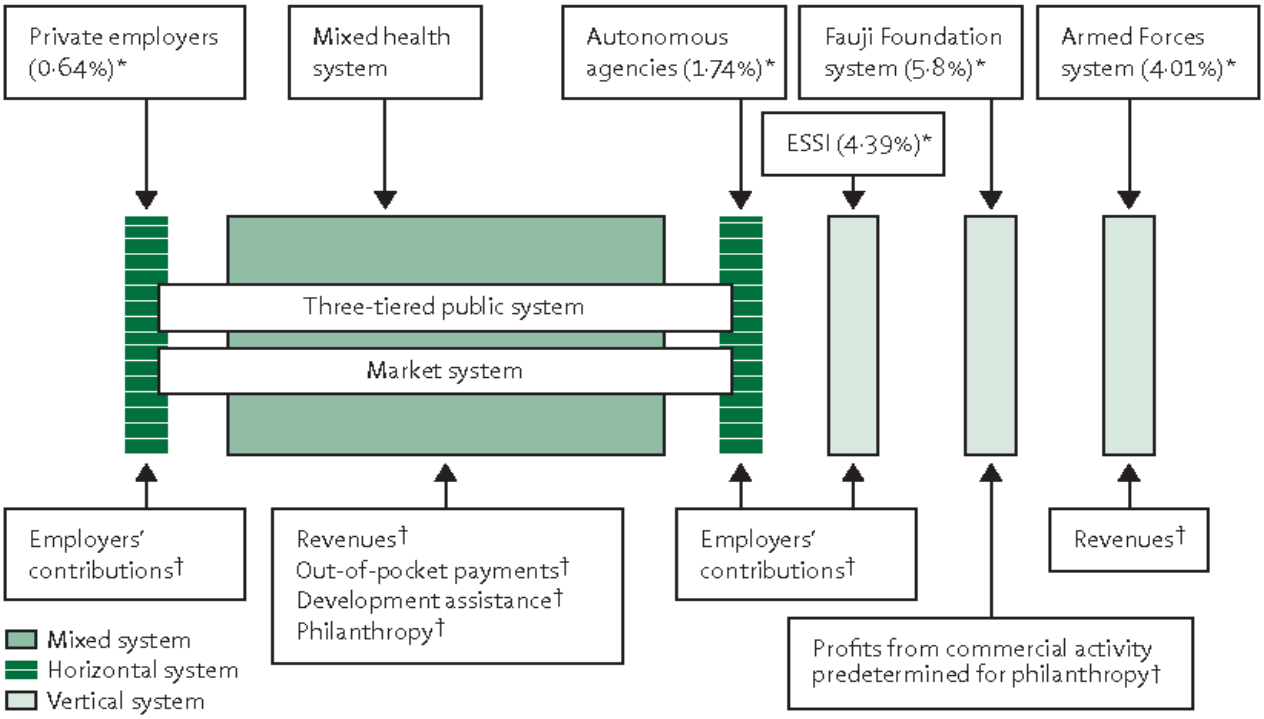
The TB-NSP 2017- 2020 identifies the following population groups as the vulnerable or at-risk populations for TB: adult men in general, older people above the age of 65 years, persons in contact with TB, tobacco users, diabetics, people living with HIV and prisoners. In order to obtain size estimates of all these at-risk populations relevant data bases were accessed and reviewed. The prevalence of diabetes among the adult population in Pakistan is about 9.8% suggesting that up to 10 million people in this country have diabetes (International Federation of Diabetes) and thus have an elevated risk of TB. As for tobacco smoking, it is currently estimated that 41.9% of the adult male population over the age of 15 years in

Pakistan smokes tobacco. Only 3% of females smoke tobacco regularly in Pakistan. Additionally, 0.86% of 10-14-year-old children smoke tobacco regularly. Thus, an estimated 14, 737,000 adults and 125,000 children 10-14 years old smoke tobacco daily in Pakistan and can be considered at risk of TB. Based on the 2017-18 population census, the average family size in Pakistan is 6.4 persons. Recent scientific evidence suggests that the risk of progression to active TB is highest among persons infected with TB in the recent past (within two years). If every case of pulmonary TB will infect all his or her household contacts (an exaggeration) and 85% of all cases of TB have pulmonary disease, then not less than 2.6 million people will be newly infected with TB each year and become vulnerable to TB disease.

## The Pakistan Health Care System

The Pakistan Health Care system is mixed in that a publicly financed health service delivery system co-exists with a privately financed health market delivery system. In addition to state sector related health care providers such as the armed forces health delivery system and health services provided by state corporations, the private health care sector is a major source of health services in Pakistan.

Figure 5: The Pakistan Health Care System




Source : *Sania Nishtar et al. Lancet 2013 ; http://dx.doi.org/10.1016/S0140-6736(13)60019-7*

## The Public Health Care System

To respond to the myriad public health challenges and ensure a healthy Pakistan population, this country has developed and continues to evolve it health care system. The provision of health services was devolved to the provinces in 2011 following the 18th amendment with the Centre or the federal level remaining with a few but essential functions including policy formulation, disease surveillance and coordination.

The public provision of health services in Pakistan occurs through health service delivery units that are organized in a hierarchical fashion from specialized units at the tertiary level to basic health units at the community level. A Basic Health Unit (BHU) serves a population of about 25, 000 people and offers preventive and referral services including maternal and child health services. The BHUs are linked with the community through Lady Health Care Workers (LHWs). The Rural Health Centre (RHC) is a much larger facility that serves a population of up to 100,000 people and offers a wider range of health services compared to the BHU. The RHC is meant to provide support to the BHU. The BHUs and RHCs collectively form the public Primary Health Care System (PHC) of Pakistan. At the secondary health care level are Tehsil Headquarter Hospitals or THQs (Tehsils are administrative units below the district level) and the District Head Quarter Hospitals (DHQs). A THQ serves a population of about 0.5 to 1 million persons while a DHQ serves a larger population of between 1-3 million people. Tertiary care facilities are specialized health units that offer specialized services. By the time of the review there were a total of 13,029 public health facilities distributed as shown in table 4 below.

Table 4: Number and type of public health facilities in Pakistan

| Facility Type | Number |
|---|---|
| Dispensaries | 5, 695 |
| BHUs | 5, 478 |
| RHCs | 684 |
| Hospitals | 1, 172 |
| Total | 13, 029 |

## The private health care system in Pakistan

This subject will be dealt with in more details in the relevant thematic area of this report. Suffice it to say that the private health care sector in Pakistan is a very large and vibrant market place. It is an extremely heterogenous sector that includes state of the art health institutions (Hospitals), qualified medical practitioners, homeopath practitioners, Hakeem, spiritual healers, Unani (Greco-Arabs) healers,

herbalists, bonesetters and quacks. In terms of service provision, the private health sector is the main provider of health services with at least 85% of initial outpatient visit for illness taking place in this sector. The general perception is that the private health sector outperforms the public sector in terms of service quality and patient satisfaction or convenience.

### Health System Governance and Coordination

With the advent of devolution in 2011, all health functions shifted to the provincial level with nothing left for the Centre, however, this situation did not last too long and in May 2013, the Ministry of National Health Services, Regulation and Coordination (MoNHSRC) was created. The Ministry is mandated to carry out critical functions for health including developing and managing the health information system, trade in health, formulation of overarching policy norms, federal fiscalism , external resource mobilization for health, interprovincial coordination, regulation and provision of technical support to the provinces in addition to being involved in the delivery of health services for the population that lives within the Islamabad Capital Territory (ICT). On the other hand, the core business of the provincial level is health service delivery supported by other critical elements of a functional health care system. The MoNHSRC in partnership with the provinces developed the National Health Vision 2016-25 (NHV 2016-25) which is aligned to Pakistan's Vision 2025, poverty reduction strategy and pro-poor social protection initiatives. Among the thematic pillars of NHV 2016-25 is governance of the health sector which is recognized as a major challenge facing the health sector in Pakistan. The weak regulatory capacity and the dual role of the regulators (MoNHSRC, Provincial MoHs) also being service providers are highlighted as major constraints in health governance in Pakistan. The NHV 2016-25 indicates that these issues will be addressed as the health vision is pursued. The stewardship of the health system is in the hands of the Minister for National Health Services, Regulation and Coordination and the Ministers of Health at the federal and provincial levels respectively.

### Human Resources for Health

The Islamic Republic of Pakistan has made tremendous progress in the development of its health work force since it gained independence in 1947. At independence, it is reported that there were only 2, 298 medical doctors, 418 nurses and no dentists. By 2014 there were 160, 289 registered doctors, 12, 544 dentists, 82, 119 nurses, 32, 511 pharmacists, 13, 678 lady health visitors, 29, 000 registered midwifes and 100,000 lady health workers (Source*: Muhammad Ahmed Abdalla et al. World Health & Population. vol 15. No 3. 2014*). This was achieved through expansion of training capacity. From two medical colleges at independence Pakistan now has in excess of 100 medical colleges, 60% of which are in the

private sector. Despite the huge increase in the numbers of trained health care workers, Pakistan still suffers a large deficit in its health work force and continues to be in the group of countries classified to have a Human Resource for Health (HRH) crisis. For example, while the recommended international standard is to have about 2 doctors per 1,000 population, Pakistan only has 0.29 of this cadre of health care worker per 1,000 population. The HRH gaps run across all cadres of the health care workforce. In addition, official documents of government such as the National Health Vision 2016 -2025 highlight the need to improve job satisfaction and the work environment. It is important to highlight that the HRH gaps are also contributed by a significant brain drain to other countries, especially of doctors. The MoNHSRC working with the provincial governments recently launched the first Human Resources for Health Vision 2018-30 to address the HRH challenges facing the country which include rural urban maldistribution of the health care workforce in favor of urban areas and weak HRH management systems.

### Th Pakistan Health Information System

The Health Information Management System (HMIS) in Pakistan is to date still fragmented. There are numerous health information and disease surveillance systems that are currently not communicating with each other, even though 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 Maternal, Neonatal and Child Health (MNCH), HIV/AIDS, TB, Expanded Program of Immunization (EPI), Malaria, Dengue, Service statistics, 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 system and the verticalization of these systems, the MoNHSRC recently established a technical unit, called the Health Planning, Systems Strengthening and Information Unit (HPSIU) 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 Goal (SDG). It is worth noting that the Provinces have been using DHIS since 2007 or thereabout and recently this system has been digitized.

## The Review

The Pakistan TB Joint Program Review Mission (JPRM) was undertaken between February 11- 23, 2019 with the following objectives:

## Overall Objective

The overall objective was to make an independent and comprehensive review of the TB situation in Pakistan and carry out an in-depth analysis of progress being made towards the realization of the commitments made at the Global Ministerial Meeting in Moscow and the United Nations General Assembly's Political Declaration on TB ( the UNGA- TB High Level Meeting or UNGA- TB HLM) to which Pakistan is a signatory, and the END TB Strategy targets which are in line with the Sustainable Development Goals (SDGs) and targets. As a secondary objective the mission was also requested to review policies, strategies and plans intended to support the TB response and to identify challenges that Pakistan is currently facing in the implementation of these policies, strategies and plans in order to support Pakistan's TB program and partners to identify feasible solutions to mitigate against existing constraints.

## Specific Objectives:

The specific objectives of the mission were the following:

1. Assess whether the National TB Program (NTP) is supported by the broader health and development agenda including the Sustainable Development Goals (SDGs), Universal Health Coverage (UHC), regulatory frameworks, social protection schemes and linkages with current national/provincial special health initiatives such as the Lady Health Care Worker (LHW) program, health insurance schemes, nutrition programs and improved housing.

2. Review Programme sustainability factors with a focus on domestic and international financing.

3. Assess the progress in establishing a multi sectoral approach for ending the TB epidemic in Pakistan.

4. Assess progress, challenges and constraints in reaching the targets of the TB National Strategic Plan (TB-NSP) for the period 2017-2020 and of the End TB Strategy with an emphasis on reaching the 2020 milestones. Attention was to be focused on reviewing efforts being made to find missing persons with TB; prevention, identification, care and treatment of drug resistant tuberculosis; public private partnerships for TB care and prevention; community responses

including engagement in the design, implementation and monitoring of TB responses at the community level.

5. Review progress made on the implementation of the 2015 JPRM recommendations.

The expectation was that the JPRM would contribute to

- Improving the effectiveness of the TB program to meet the End TB Strategy targets.
- Advocacy efforts for TB at all tiers of Government and the non-state sector to accelerate progress towards the development of an integrated and multi-sectoral approach to TB care and prevention.
- Strengthening political commitment for TB at both the national and provincial levels and thus, enhance and sustainably finance the TB response.
- Providing useful insights to improve and strengthen strategic planning for TB care and prevention in the next strategic planning period.
- Promoting and enhancing coalitions and partnerships for TB care and prevention between the state through the TB program with NGOs, the private sector and both domestic and external donors.
- Identification of key challenges with focused recommendations related to the prevention, care and treatment of Drug Susceptible (DS) and Drug Resistant (DR) TB.
- Providing guidance to the TB Program to achieve its NSP and End TB targets

## The JPRM Methodology

In partnership with WHO, the Global Fund and local partners, the NTP identified and invited both external and internal experts (see annex 1 for a list of mission participants) in various areas of TB care and prevention to participate in the mission. Individually and collectively the team of mission participants undertook the activities highlighted below to respond to the objectives and Terms of Reference (ToRs) of the JPRM:

### Documents Review

The principal documents that were reviewed include

- The National TB Strategic Plan 2017- 2020.
- Tuberculosis strategic plans of the provinces that were visited by field teams.
- The Funding Request to the Global Fund for the funding period 2018-2020.
- Previous Mission reports including the 2017 Green Light Committee (GLC) Mission report.
- Annual reports of the NTP.

- WHO 2018 Global TB Report with a focus on Pakistan's TB Country Profile.
- National Health Vision 2016-25.
- Pakistan's Vision 2025.
- Published and grey literature relevant to Pakistan's health system and TB
- Pakistan's Demographic and Health Survey 2017 -2018
- Pakistan's National Health Accounts 2015/2016
- Pakistan TB Patient Pathway Analysis
- Pakistan's TB disease prevalence survey report
- National TB Programme guidelines
- Pakistan TB epidemiology review slide deck
- Patient Centered Care Workshop slide deck
- And others

### Meetings with Stakeholders

The mission participants were divided into 4 teams (see annex 1 for team composition) that visited the provinces and the Islamabad Capital Territory (ICT). All the 4 provinces: Baluchistan, Khyber Pakhtunkhwa, Punjab and Sindh were visited. In each of these provinces and the ICT, mission participants held intensive but collegial discussions with the NTP, Provincial TB Programmes, state officers, officers from partner organizations, and health care workers at health care facilities among other persons (see separate document on provincial field reports). The purpose of these discussions was for mission participants to gain a deep understanding and receive perspectives from a wide array of stakeholders on the TB situation in Pakistan, the progress being made, the challenges/constraints being faced, and the solutions being pursued to address these challenges from political, social, governmental, non -governmental and community perspectives.

### Facility visits

Other than for the team that remained at the ICT, which did not visit any health care facilities, the other three teams visited various health care facilities including THQs, DHQs, RHCs, BHUs, and tertiary health facilities in the public sector and in the private sector in addition to visiting offices or clinics of private General Practitioners (GPs), chemists, private medical laboratories and hospitals. The purpose was to observe practices in the care and treatment of presumptive and confirmed cases of both DS and DR TB and to assess how these practices conform to laid down policies and practice recommendations including conformity with the International Standards of Tuberculosis Care (ISTC). In addition to observing practice,

the mission also held discussions with front line health care workers to understand perceptions on recommended policies and practices, workload, work environments and other relevant issues.

### Review of findings and formulation of recommendations

After the fields visits, mission participants spent time to review the findings of the mission and to formulate recommendations in each thematic area. For each thematic area, programmatic strengths, weaknesses and constraints were identified and recommendations (see below) elaborated with the primary aim of supporting Pakistan to address identified bottlenecks to the achievement of the UNGA-TB- HLM, and the End TB Strategy targets. On Thursday February 21, 2019 a debriefing was held at the National Institute of Health (NIH) of Pakistan. Invitees to this debrief included the leaders of the PTPs and partners of the NTP among others. This debrief was graced by the Minister and the Parliamentary Secretary, MoNHSRC.

## Review Findings and Recommendations

### Thematic area 1A: Political commitment

Strengths

1.0. Pakistan was represented at the Moscow Ministerial meeting on TB that was held in November 2017 and was a signatory to the Ministerial Declaration that came out of this meeting in which countries committed to accelerate action to end TB and to meet the milestones towards achieving the SDGs. An important outcome of this meeting was the commitment by countries to pursue a multi – sectoral approach to the fight against TB. The Islamic Republic of Pakistan was also represented at the first ever United Nations General Assembly Meeting on TB ( UNGA TB-UNHLM) in which a number of commitments were made by Heads of States and Governments to fight TB including the adoption of very ambitious targets such as the identification and treatment of 40 million people with TB disease and the provision of TB preventive therapy to 30 million people with latent TB infection (LTBI) by 2022 and closing the TB financial gap to reach the END TB Strategy and SDGs goals and targets.

2.0. Following devolution of health in 2011, only the three national disease programs supported by the Global Fund (TB, HIV and Malaria) and the national Expanded Program of Immunization (EPI) remained. This was considered by the mission to be a demonstration of the importance that the Government of Pakistan places on TB.

3.0. There is a National Stop TB Partnership in Pakistan that is led by a former National TB Program Manager and which has direct links with the leadership of the MoNHSRC at the Federal level and linkages with the Ministries of Health at the Provincial level.

4.0. The Provincial Government of Sindh held an event on February 19, 2019 when the JPRM was going on to announce an initiative to End TB in Sindh, which was also considered to be a good measure of increasing political commitment to TB in this province.

Weaknesses

1. Even though TB is such a major public health threat in Pakistan, many people in leadership positions within both the Federal and Provincial Government levels were not aware of the enormity of the TB problem in Pakistan. In fact, a significant proportion of people that were engaged in discussions with the mission, thought that TB had long been "eradicated" in Pakistan. This lack of awareness in high levels of Government in Pakistan, if not addressed, will be a major barrier to the cultivation of political commitment to TB in this country.
2. By the time of the mission, there was limited evidence that the commitments that had been made at the Ministerial Meeting in Moscow in 2017 and at the UNGA-TB-UNHLM were being pursued. Specifically, there was limited evidence that a whole government approach to TB care and prevention intended to lead the multi- sectoral approach to the fight against TB was in place.
3. The ultimate measure of political commitment to the fight against TB is the mobilization of adequate financial, human and other resources for this disease with the larger proportion of the realized financial envelope coming from domestic sources. In Pakistan however, by the time of the mission there was little evidence that a commitment to increase domestic financing for the TB response had been made.

Recommendations

1. To demonstrate political commitment to TB care and prevention and to begin to vigorously pursue the UNGA -TB-UNHLM and the END TB Strategy targets, the JPRM strongly advises the Islamic Republic of Pakistan to declare a National End TB Initiative by or on World TB Day, March 24, 2019. The declaration of this initiative should, as much as feasible, be made by the highest political leadership in the country (the Prime Minister and or the President of the Islamic Republic of Pakistan).
2. The JPRM also strongly advises that Provincial END TB Initiatives be announced on or before March 24, 2019 by none other than the Chief Ministers at the Provincial levels.
3. To ensure that the political declarations to initiate National and Provincial End TB Initiatives do not become mere rhetoric and are followed by concrete actions that would truly provide an

opportunity to bend the TB curve in Pakistan, the JPRM advises that National and Provincial Level End TB Steering Committees be formed under the leadership or with direct oversight of the Prime Minister at the Federal level and the Chief Minister at the Provincial Level to track progress that is being made.

4. The JPRM acknowledges the special attention and actions for the Polio eradication campaign in Pakistan. The effort to eradicate polio in Pakistan is based on an elaborate National Emergency Action Plan (NEAP) that has specific objectives, targets, milestones and indicators that guide the program to its goal of zero -polio in Pakistan. The NEAP was endorsed by the National Task Force (NTS) for polio eradication chaired by the Prime Minister of Pakistan and which includes Chief Ministers and heads of partner agencies. The emergency mode that has been pursued to eradicate polio from Pakistan has seen great strides made against this infectious disease. Between 2014 and 2018, there was a 97% reduction (from 306 cases in 2014 to 3 in 2018) in polio cases in Pakistan (*Source: Global Polio Eradication Initiative*). The JPRM strongly implores the Islamic Republic of Pakistan to follow similar approaches for ending TB in Pakistan.

## Thematic area 1B: Financing the TB Response in Pakistan

Strengths

1. There is a TB National Strategic Plan TB that covers the period 2017 -2020. This TB-NSP was costed at US$ 520 million. Thus, the financial need to comprehensively address TB in Pakistan is known.
2. At the Provincial level, Provincial TB Strategic Plans have been developed and have also been costed. Therefore, the financial need to comprehensively address TB at the provincial level is also known.
3. The Global Fund has been providing predictable financing to support the TB response in Pakistan since the inception of the New Funding Model (now called the Funding Model) in 2014. In the current grant cycle (2018-2020), the Global Fund is providing US$ 144 million distributed among three Principal Recipients (PRs) to cover the modules: TB care and prevention, MDRTB, TB/HIV, Building Resilient and Sustainable Systems for Health (RSSH) and program management. Of the 144 million US$, the GoP through the Central Management Unit and the National TB Program as the Government PR was allocated US$ 89 million (61% of the available GF financial resources for TB in Pakistan) , Indus Hospital Health Network (IHN) US$ 40 million (27% of the available GF financial resources for TB in Pakistan ) and Mercy Corps USD$ 15million (10% the available

GF financial resources for TB in Pakistan). Overall the TB Global Fund grant in Pakistan is running well and is achieving the intended results with a rating of B1.

4. The Federal and provincial levels have been providing funding, mainly to support staff positions at the TB program but also for other activities at the provincial level including procurement of first line drugs.
5. 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.

Weaknesses

1. Pakistan is overall spending very little money on health. Based on the National Health Accounts 2015-2016, only 3.1% of the Gross Domestic Product is spent on health. Of the proportion of the GDP that is spent on health, Government expenditure represents 0.91%[4]. Of the total Government Fiscal Consumption Expenditure (including Provincial Governments) only 9.7% was spent on health. The per capita Total Health Expenditure (THE) was US$ 45. Of THE 34% was from the public sector, of which 21.8% was from the Federal level, with 34% of this coming from civilian sector and 42% from the military. Over 64% of THE is funded through the private sector with 89% of this being household Out of Pocket (OOP) expenditure[5].

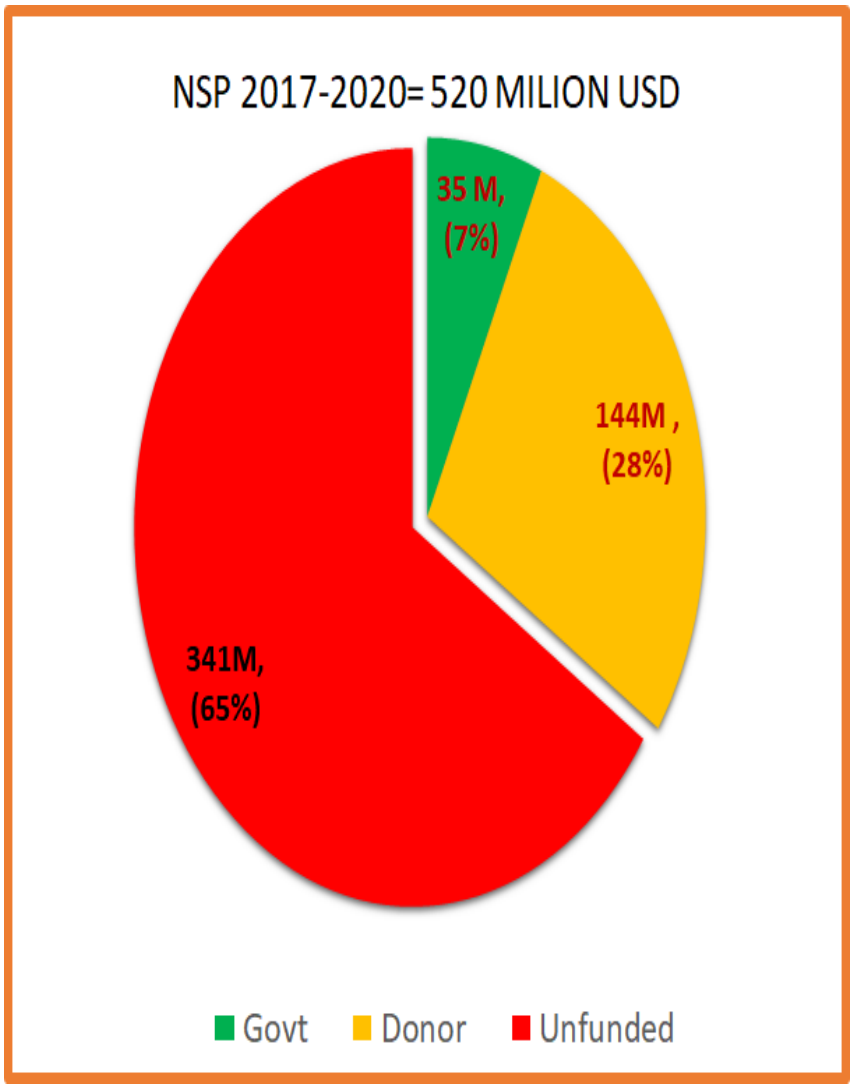
2. There is a very large funding gap for the TB-NSP 2017-2020. Of the costed budget of US$ 520 million, only USD 179 million is available through either the Government (US$ 34 million or 7%) or the Global Fund (US$144 million or 28%) leaving a financing gap of US$ 341million or 65% (see figure 6 below). At the federal level, there were plans to increase federal level funding for health from less than 1% to about 3%, which though a significant proportionate increase, would still constitute a small Governmental financial envelope for health. At the provincial level, funding for TB has been small (see figure 7 below) and often based on project type of funding through a mechanism called Planning Commission 1 (PC1).

3. There is over- dependence on external financing for TB, especially from the GF, which does not augur well for country ownership of the program and long-term sustainability of the TB response.

[4] http://www.finance.gov.pk/survey/chapters_18/Economic_Survey_2017_18.pdf
[5] National Health Accounts 2015-2016

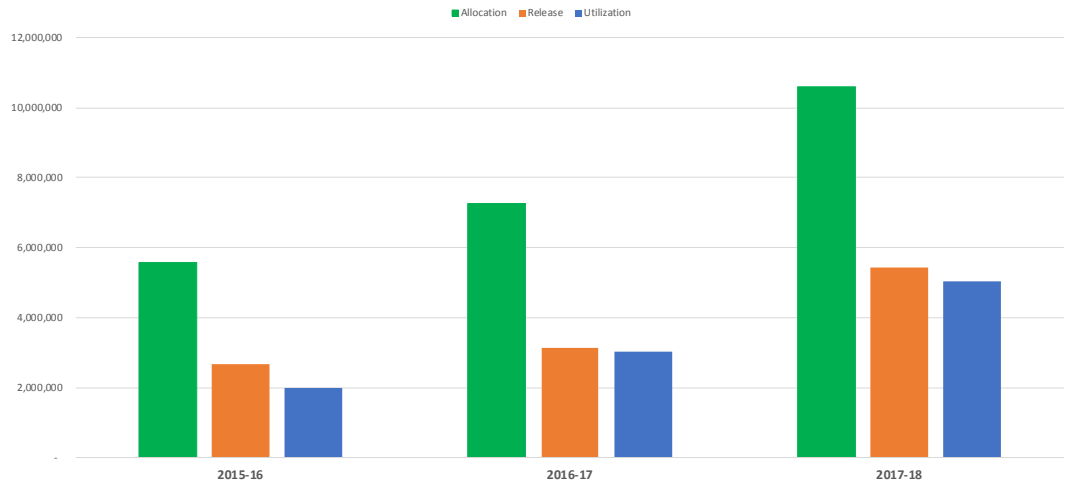
4. For domestic funding, the Annual Development Program (ADP), managed by the Planning Commission (PC), is the main mode of mobilizing resources from the Government for TB in the visited provinces. It is a project-based mechanism in which funds are approved in principle but released subject to availability, 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 7).

Figure 6: Funding Status for the TB-NSP 2017-2020




Source: The NTP

Figure 7: Funding for TB (US$ equivalent) from the Pakistan Provincial Governments




Recommendations

1. Even though the JPRM is fully aware of the challenges with fiscal space, the Pakistan debt burden and other financial challenges, the mission urges the GoP and Provincial Governments to demonstrate its stated commitment to health by significantly increasing allocation to health and after mobilizing more resources for health to allocate needed resources to eliminate the funding gap in the TB response and thus increase the potential of the country to reach the UNGA -TB UNHLM and END TB Strategy targets.
2. The JPRM also advises that the mobilization of resources from domestic sources, principally Federal and Provincial Government sources, not be based on the ADP/PC1 mechanism but be incorporated into the regular budget of the Government at all levels. A project-based mode of funding the TB response is unlikely to lead to sustained efforts.
3. The JPRM advises the NTP/ PTPs to identify and work with local partners that could be a source of domestic financing for TB through, for example, through social responsibility programs.
4. In the development of the next TB-NSP, the NTP and the PTPs are advised to prioritize interventions and to apply a scenario-based approach to the prioritization and budgeting process to make best use of available resources.
5. Even though the JPRM would like to emphasize the importance of domestic financial resources to support and sustain the TB response, the mission appreciates that Pakistan may not be able in the near term to fully fund the TB response with domestic resources. Thus, the JPRM strongly

requests external donors to continue and to increase their support to Pakistan in its fight against TB. On the other hand, Pakistan is strongly advised to contribute to advocacy efforts that will ensure that the Global Fund is fully funded in its next replenishment. In this way the financial support the Global Fund provides to Pakistan for TB care and prevention will be maintained or even enhanced.

## Thematic area 1C: Implementation of the TB- NSP 2017-2020

Strengths

1. The recommendations of the JPRM that was conducted in 2015 were used to develop the TB-NSP 2017-2020.
2. The 2017-2020 TB- NSP is ambitious and has targets that are aligned with the End TB Strategy targets.
3. The current TB- NSP (2017-2020) was used as the basis for the funding request to the GF and thus by implementing the current GF grant, Pakistan is implementing its 2017-2020 TB-NSP.

Weaknesses

1. As seen in table 5 below, most of the TB-NSP 2017-2020 targets are not on course to be achieved. Tuberculosis Treatment Coverage(TC) for DS-TB and DR - TB should, at the moment be at or beyond 90% and 50% respectively but, while there has been a small improvement from 63% in TC for DS-TB in 2015, the baseline year, to 68% in 2017, TC for DR-TB has actually declined from 20% in 2015 to 12% in 2017. Only a minor proportion (3%) of persons with TB were tested with a World Health Organization Recommended Rapid Test (WRD) in 2017 against a target of 20%. There is no data on coverage of treatment for Latent TB Infection (LTBI), and a patient cost survey has not yet been conducted implying that Pakistan may not be able to report on the proportion of TB patients who experience catastrophic costs as a result of TB, who's reporting to WHO is expected to begin in 2020.

Table 5: The TB-NSP 2017-2020 Targets and Achievements by 2017

| Indicator | Baseline (2015) | Target by Year | | | | | **Achieved by 2017** |
|---|---|---|---|---|---|---|---|
| | | 2016 | 2017 | 2018 | 2019 | 2020 | |
| TC: DS- TB | 63% | 72% | 80% | 85% | 88% | 90% | **68%** |
| TC: DR-TB | 20% | 21% | 30% | 40% | 50% | 60% | **12%** |
| TS: DS-TB | 93% | 93% | 93% | 93% | 93% | 93% | **94%** |
| TS: DR-TB | 69% | 72% | 72% | 73% | 74% | 75% | **64%** |
| % of HH experiencing | NA | Awaiting a patient cost survey | | | | | **Survey not done** |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Catastrophic costs | | | | | | | |
| % if new and relapse cases tested with WRD | NA | 20% | 30% | 40% | 50% | 60% | **3%** |
| LTBI Coverage | NA | - | 10% | 20% | 35% | 50% | **No data** |
| Contact Investigation Coverage | NA | 15% | 20% | 30% | 45% | 60% | **No data** |
| DST coverage (new) | 1% | 8% | 10% | 25% | 35% | 50% | **11%** |
| DST coverage previously treated | 84% | 86% | 88% | 90% | 90% | 90% | **47%** |
| TC: New drugs | NA | 5% | 10% | 20% | 40% | 80% | **No data** |
| Documentation of HIV Status among TB patients | 4% | 3.4% | 10% | 30% | 40% | 60% | **7%** |
| Case fatality ratio | 9% | <8% | <7% | <6% | <5% | <5% | **0.11** |

Recommendations

1. Specific recommendations related to these indicators and targets are provided in the relevant thematic areas of this reports. The NTP and PTPs are strongly advised to vigorously pursue these recommendations in order to begin to turn the tide against TB in Pakistan.

## Thematic area 1D: Program Structure, capacity and function

Background

The TB program has a presence at the Federal, Provincial, District and the facility levels. At the Federal level the program is embedded into the Central Management Unit, an entity created in 2018 for integrated management of the currently running GF grants to Pakistan (HIV, TB and Malaria grants). The NTP manager is one of three Deputy National Coordinators (DNC), the other two being the manager of the HIV and Malaria control programs in the CMU. The NTP manager reports to the National Coordinator (NC) of the CMU who in turn reports to the Director General at the MoNHSRC. Current staffing levels at the federal level of the NTP includes: 1 DNC/NTP manager; 1 PPM focal person; 2 MDRTB specialists; 1 M&E focal person; 1TB advisor; 1 laboratory advisor and 1 partnership and communication manager assisted by 2 officers. The CMU includes cross cutting supporting units which include Procurement and Supply Management, Finance management, an Audit unit and a Research unit

Strengths

1. The wide reach of the TB program was considered by the JPRM to be a major strength

2. 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. There was information to the effect that inter-provincial level meetings at the national level were no longer supported which is a cause for concern in relation to national coordination of the TB response.

3. 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.

4. At the district level a multipurpose staff is the focal person for TB, but the post is not a regular position of the Ministry of Health (Province) at that level.

5. 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.

Weaknesses

1. As the PJRM begun its work, the perception among staff at the NTP was that the main function of this unit was to manage the TB Global Fund grant. It initially appeared that the NTP did not consider the other critical functions of a national program such as policy and strategy formulation, resource mobilization, development of standards of practice and their dissemination among implementers, partner coordination and TB surveillance among other national level type of activities as part of the mandate of the NTP. The mission surmised that the devolution of health in Pakistan may have contributed to this perception. It was gratifying however, that towards the end of the mission this perception seemed to have dissipated.

2. By the time of the mission, most if not all positions at the NTP, except for the NTP manager, were funded by the Global Fund which raises major concerns about program ownership and by extension ownership of the TB problem itself in Pakistan. Additionally, even though the current NTP manager has been in place for about 4 years, his position as DNC/NTP manager had not been confirmed, was officially open and has been advertised.

3. At the provincial level, while technical experts are available, there has been a rapid turnover of program leadership in some provinces, affecting programme performance, accountability and sustainability.

4. 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.

Recommendations

1. In order to deliver on the commitments of the UNGA-TB-UNHLM and the END TB Targets, the JPRM strongly advises the Islamic Republic of Pakistan to strengthen the National and Provincial TB programmes to provide effective leadership in the arduous journey to reach the END TB targets. The Government of Pakistan at all level needs to provide and demonstrate strong leadership to the TB response, so that all national and provincial players in the TB response become fully aligned and harmonized, policies, strategies and technical interventions are collaboratively developed under the firm leadership of the NTP and PTPs and platforms are created by the NTP and PTPs for information sharing and informed public discourse on the appropriate pathways to achieve a common purpose, a TB Free Pakistan. Creating a unity of purpose is critical for the NTP and PTPs. To be able to achieve these objectives the PJRM recommends that:

    a. Pakistan works to enhance the NTP and PTP's to become the leaders of the TB response across Pakistan by enhancing skills and increasing capacity to make the NTP and the PTPs technically strong.

    b. The dependency on external financing for critical human resources needed for policy formulation, guidance, technical support and coordination of the TB response in Pakistan be abolished on a priority basis in order to ensure ownership and a sustainable response for ending TB in Pakistan.

### Thematic area 1E: Building a robust multi- sectoral response

Strengths

1. The NTP used the opportunity presented by the JPRM to begin to establish or strengthen linkages with both Governmental and non-Governmental partners in an effort to kick start the

development of a multi- sectoral approach to TB care and prevention and to accelerate effort towards achieving the UNGA-TB-UNHLM and END TB Strategy targets and milestones.

2. Most people and organizations that interacted with the JPRM appeared eager to partner with the NTP and PTPs to support efforts to End TB in Pakistan.

3. Pakistan has an inter- ministerial coordinating task force that has been briefed about TB and which had placed TB in the agenda of its next meeting by the time the PJRM was being conducted.
4. In Sindh, the Health Minister chaired a multi-sectoral meeting on TB on February 19, leading to the establishment of a high-level Provincial TB Task Force.

Weaknesses

1. While the general sense of the JPRM was positive for the development of a robust multi- sectoral response with an associated multi- sectoral accountability framework, the work is just beginning, and it is unclear how this work will pan out in the future. It is especially critical to monitor how the political class, the corporate sector, line ministries and other organizations will respond to the invitation to participate in the fight against TB and the zeal with which the lead ministry at the national level and the MoHs at the provincial will pursue this agenda in an environment of limited financial resources to fund the related activities.

Recommendations

1. The JPRM advises Pakistan under the oversight of the Prime Minister at the Federal level and the Chief Minister at the Provincial Level, through the proposed National and Provincial Multi - Sectoral End TB Steering Committees and supported by the MoNHSRC and the MoHs and to develop a Pakistan specific Multi- Sectoral Accountability Framework with a mechanism for timely reporting.

2. Under the auspices of the MoNHSRC, the NTP is advised to develop a prioritized list of sectors/partners to be engaged in the TB response, considering core activities of these sectors and organizations and outlining their potential responsibilities, commitments, targets for each partner with a system for monitoring and review to make each sector/partner accountable.

3. The MoNHSRC and the provincial MoHs are advised to rapidly work towards establishing a National and Provincial multi- sectoral technical committee to steward and support the Multi-Sectoral Response and Accountability Framework.
4. At the NTP, the JPRM advises that a unit be designated and or strengthened to become the coordinating unit to support the National Multi-Sectoral Steering Committee and to regularly monitor and follow up on agreed actions.

## Thematic area 1F: Linkages with UHC, poverty reduction strategies and social protection schemes

Strengths

1. Pakistan is committed to Universal Health Coverage (UHC) and has been commended for the progress it has made towards achieving this. The National Health Vision 2016- 25, highlights UHC as a major goal of this vision. While the notion of UHC may vary from one setting to another, in general UHC is defined by the package of services that should or are offered, the delivery system for this package of health services and the system for payment for these services. The package of health services that Pakistan has included under the UHC realm include inpatient care services (indoor health services), the package of medicines that ill persons should take home depending on the illness, rehabilitation services such physiotherapy and home-based care services. Pakistan has made good progress in all these areas.
2. There have been commendable efforts to roll out a social health insurance program (Prime Minister's National Health Program) that targets the poor. By the time of the JPRM this program was covering 38 districts and had contracted 154 public and private hospitals. The social health program initiated in 2016 currently covers about 3.8 million families (Husbands, wives and unmarried children). When fully rolled out the program will cover over 50% of the Pakistan population. The program now provides cover for indoor health services (hospitalization related costs) with each family entitled to 7.7 million Pakistan Rupees (Rs). 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 on-going. There are on-going discussions to include preventive programs (Malaria, TB and others) in this initiative.
3. Pakistan is implementing social support programs financed by the state such as Bait – ul- mal and the Benazir Income Support Program that provide safety nets for the poor. The Bait -ul mal

program is a government supported program that provides health financial assistance to the poorest people. 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. Initiated in 2008, the Benazir Income Support Program (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 Bait – ul -mal 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 his or her child to school. There is talk about developing a poverty alleviation commission.

Weaknesses

There is currently very limited coverage of the population by health insurance schemes. Only about 2% of the Pakistan population is covered by corporate health insurance with another 7-8% of the Pakistan population having private health insurance. Over 60% of health care in Pakistan is accessed through out of pocket expenditure. This situation suggests that persons who suffer TB are at a high risk of experiencing catastrophic health expenditure. Thus, Pakistan still has a long way to go before UHC and financial protection for the poor is fully realized.

It is notable that all existing social support programs in Pakistan do not benefit TB families directly now.

Recommendations

1. The NTP is advised to urgently follow up with the relevant organizations ( for example Bait -ul mal, BISP and the Prime Minister's National Health Program) to ensure inclusion of TB patients in on–going social support programs so as to cushion TB patients from catastrophic health

expenditures and to evolve sustainable support programs for these patients that will outlast donor funded programs.

2. The NTP should work with Prime Minister's Health Insurance Program to include TB in the benefit package, ensuring access to program-procured drugs and diagnostics but capitalizing on social health insurance to pay the hospital fees and channel social support to DR patients. Payments should be designed to incentivize case finding from OPDs, case management only of complex cases, and down-referral of simple cases to the primary care level.[6]

[6] See Wells W et al (2019) How TB programs can navigate the works of social health insurance. *Int. Journal Tuberc Lung Dis 23(1):26-37*

## Thematic area 2A: Drug susceptible TB case-finding and management

Findings

The number of new tuberculosis (TB) episodes notified every year (including relapse cases) increased by 22%, from 293,860 cases in 2013 to 359,224 in 2017; the rate of increase was approximately 5% per year. The distribution of the number of notified TB cases among the provinces did not vary between 2013 and 2017. On average, slightly more than 93% of notified TB cases were identified in the Provinces of Punjab (nearly 62%), Sindh (19%) and Khyber Pakhtunkhwa (13%). The increase in notification was observed in all the provinces except in the Federally Administered Tribal Areas (FATA), but it was not steady across the years in all the provinces. The highest increase occurred between 2015 and 2016 in all the provinces, even in FATA, with an overall increase in TB case notification of 10% across Pakistan. The lowest annual increase was observed in most of the provinces between 2016 and 2017 and across Pakistan the increase in TB case notification was less than 1% over this period.

Among notified cases of a new TB episode, the average proportions of bacteriologically confirmed pulmonary TB (BCPTB) cases, clinically diagnosed pulmonary TB (CDPTB) and extra-pulmonary TB (EPTB) were 40, 41 and 19% respectively between 2013 and 2017. The number of BCPTB cases, CDPTB cases and EPTB cases notified during the period covered by these years increased respectively by 4, 6 and 8% per year.

The number of notified previously treated TB cases (including patients with TB relapse) in a year increased by nearly 55%, from 15,839 in 2013 to 24,484 in 2017 with an average annual rate of increase of nearly 12% per year for all Pakistan. This increase was observed in all the provinces except in Gilgit Baltistan. Like the distribution of new TB cases, that of previously treated TB cases was stable and reproducible among the provinces and across the years between 2013 and 2017. Nearly 93% of these cases were notified in Punjab (47%), Sindh (37%) and Khyber Pakhtunkhwa (8%) with each of the other provinces accounting for hardly 2% or less. The proportion of previously treated TB cases accounted for 5 to 6% of the total number of identified TB cases with the highest proportion at approximately 11% observed in Sindh Province.

The NTP developed and issued national guidelines for the management of TB cases within the health system of Pakistan, including in the private health sector. Significant actions have been taken to involve health professionals in the private sector in the efforts to provide TB prevention, care and treatment

services for the persons who seek care in this sector. Tuberculosis diagnosis and treatment services are provided to patients through a network of 1,571 BMUs of which 1,140 (73%) are in the public sector and the remaining 431 (27%) in the private health sector. Most of the BMUs within the public sector network of care providers are at the level of first referral health facility and above, namely in RHCs, THQs, DHQs (Sindh) and tertiary hospitals. In addition, 36 BMUs have been implemented in the penitentiary system. However, most PHC facilities (BHUs, dispensaries and maternal, neo-natal and child health (MNCH) centers) are not engaged in the provision of TB services and child TB services are absent beyond the DHQ/BMU level.

Tuberculosis microscopy services are provided in all the 1,571 BMUs, of which 280 also carry out Xpert testing (82% in the public sector and 18% in private sector). Even though there is a lack of consistency in some provinces, the data collected on routine basis by the NTP show that the number of presumed TB patients whose sputa were examined in TB laboratories increased from 731,000 in 2013 to 1,090,000 in 2017. In 2017, approximately 1.4 million microscopy examinations and 280,000 Xpert tests were performed in the network of TB laboratories. The number of Xpert tests carried out increased from 914 in 2011 to 280,000 in 2017, at the rate of nearly 50% per year. Patients with presumptive TB who attend BMUs are usually assessed for TB by the physician in charge. Those who are found to have active TB are registered in the treatment register available in each BMU and prescribed TB treatment in line with the NTP policy. Each patient who is prescribed TB treatment will have a facility-based patient treatment card, a patient identity card and will be provided her/his treatment in the BMU on monthly basis. Each BMU provides TB treatment and follow-up of about 50 TB patients each year, however, in some settings this number may reach more 100.

Strengths

1. In comparison to the late 1990s, the NTP has developed strong capacities to train health workers and implement TB diagnosis and treatment in public health facilities and, through relevant partners, in the private health sector. This has resulted in a major increase in TB case-finding at national level. Former NTP data show that only 20,707 incident TB cases were notified in 2001 which is 17-fold less than the number of TB cases registered in 2017.
2. Significant efforts have been made to improve the identification of presumed TB patients in the health facilities visited during the review. A standardized working definition of “patient with presumed TB” is widely used and understood by the health workers trained by the NTP. The

definition of a presumptive case of TB is in general well accepted and utilized by the health staff of the health facilities visited.

3. The principle of using a register for presumed TB patients in health facilities has been adopted by the NTP. Indeed, the NTP has developed a register to capture relevant details on each patient identified by health workers as presumed TB cases at the first contact in the health facility before being referred to the TB laboratory. This register aims at monitoring the identification and management of presumed TB patients among whom definite TB cases will be identified. The physician in charge of the TB services is responsible for the registration of presumed TB patients in the presumptive TB patients' register. Following referral to the TB laboratory, presumptive cases of TB who reach the laboratory are then registered in the TB microscopy and Xpert register. By matching the 2 registers the NTP can identify presumed TB patients who were referred but did not reach the laboratory and probably were not tested for TB.
4. The number of presumed TB cases who were identified and referred to TB laboratories significantly increased over time. The NTP data from laboratory registers show that the number of presumed TB patients whose sputa were examined increased by 49% between 2013 and 2017 which is an average increase of 11% per year.
5. The visits to TB laboratories during the review showed that a significant number of sputa were examined every day, averaging about 15 to 25 sputa examined by a laboratory technician per day. In some laboratories, for example at the TB laboratory at Karachi Civil Hospital, the number of sputa examined per day was observed to be as high as 45. In general, the positivity rate of sputa examined was relatively low (1 to 6% per day) in the TB laboratories visited during the field visits. This suggests that there is an appropriate index of suspicion at least among the referring staff of the health facilities visited.
6. In Pakistan there are more than 11,500 PHC facilities (BHUs, dispensaries and MNCH centers)[7]; most of which are not involved in the provision of any TB service including identification and referral of presumptive cases. 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.

[7] Pakistan Statistical Year Book 2015.

7. The NTP has developed a successful strategy to involve the non-state health sector in the provision of TB services, especially the private medical sector through major NGOs such as Mercy Corp, GreenStar Social Marketing or Bridge Consultants Foundation. This includes efforts that have been made to expand TB laboratories in the private health sector. The number of TB cases identified through the non-state health sector increased by 68% from 68,177 in 2013 to 114,835 in 2017 with an average annual increase of 16.2% per year. This strongly indicates that the contribution of the non-state health sector to overall TB notification has significantly progressed. The proportion of TB cases identified through the non-state health sector among the total number of notified TB cases increased from 23% in 2013 to 31% in 2017. Within the same period, the notification of TB cases in the public health sector increased by 10% between 2013 and 2017, at the rate of 2.6% per year compared to 16.2% in the non-state health sector as highlighted above.
8. Moreover, the diagnosis of TB in children and adolescents, below 15 years, has increased 11 times, from 3947 in 2012 to 44,669 in 2017. The NTP has recently prepared and issued national guidelines and training modules on childhood TB. Many training sessions have been organized in all the provinces of Pakistan.
9. Patients who are diagnosed with active TB, either bacteriologically confirmed TB or clinically diagnosed TB, are registered in the treatment register of the BMU and prescribed TB treatment in line with the NTP policy. Presumptive cases of previously treated TB patients are tested with the Xpert MTB/Rif assay and if the Xpert test shows rifampicin resistance they are referred to the relevant PMDT sites. If the Xpert test does not show any rifampicin resistance, sputum is collected and submitted to the laboratory for culture and drug susceptibility tests (DST) as the patient is initiated on treatment with first line TB drugs, including Category II regimen (2SHRZE/1HRZE/5RHE). The treatment of these patients is then readjusted according to the results of DST.
10. The examination of TB treatment registers in the BMUs visited during the review showed that most of the patients diagnosed with BCPTB have sputum smear microscopy at the 2$^{nd}$, 5$^{th}$ and 6$^{th}$ months of treatment. In some BMUs, even patients with CDPTB have smear examination at the 2$^{nd}$ month of treatment. In general, the facility-based patient treatment cards examined in the BMUs are correctly filled and most of the relevant information needed is included in the cards. All the patients receive their TB treatment at the BMUs on monthly basis. Direct supervision of TB treatment is largely not carried out by the health workers of BMUs' TB units but by the family members.

11. Health workers in charge of TB case management and follow-up have appropriate knowledge on the required definitions of TB treatment outcomes. BMUs are supplied with first line TB drugs on a quarterly basis by the district TB coordination unit. During the review, it was observed that TB drugs provided to patients were in the required fixed-dosed combination presentations. In the BMUs visited, the TB drugs were in appropriate quantities in relation to the TB patients registered and there were no TB drugs that had exceeded the expiry date. Health staff in charge of TB treatment services reported no major TB drugs stock outs in the preceding 12 months.
12. The DS-TB treatment success rate, overall for Pakistan, is above 90% since 2013 onwards.

Weaknesses

1. In Pakistan, there are approximately 5,700 dispensaries, 5,480 BHUs and 730 MNCH centres[8]. These health facilities are the most peripheral and the closest to the population to whom they provide PHC services. For example, in Sargodha District, Punjab, approximately 45% of all health care visits are taking place in the BHUs of this district. Most of them, except 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 nor are they engaged in the management of the TB patients, living in their catchment areas, who are treated and followed by the BMUs.
2. Moreover, within the BMUs many health workers, especially physicians practicing in outpatient settings, have not yet been trained by the NTP on the basics of TB care and prevention and are not engaged in routine TB activities already taking place in the BMUs. For instance, in Kotri Institute of Chest Disease (Jamshoro, Sindh Province) which was visited during the review, only five out of ten OPD physicians were trained on basic DOTS a few years ago. At the Rural Health Center of Gharo, only 1 physician out of five was trained by NTP while at the Civil Hospital Karachi, only 2 out of 4 physicians who work in the TB unit were trained by NTP and none of the eight physicians practicing in the medical OPD for

[8] Ibid.

women have been trained on the basics of TB care and prevention. Therefore, there is no clear involvement of OPD staff in TB activities, especially in the identification and referral of patients with presumed TB. The reported high yield of screening with chest x-ray and Xpert testing in hospital general OPDs supports the need for a more systematic and sustained engagement of OPD clinicians. Furthermore, because of the lack of funds no training has been undertaken in any province of Pakistan since 2016, except recently for childhood TB.

3. The standardized register for presumed TB patients that was established and issued by the NTP, has not yet been implemented in most of the health facilities visited during the review. In addition, there is no guidance from the NTP on how this register should be used to ensure its links with: i) the OPD register in order to assess the proportion of presumed TB patients identified among those who seek care for respiratory signs and symptoms ii) the TB microscopy/Xpert laboratory register to track the presumed TB cases who are referred to the TB laboratory and iii) the Quarterly report on case finding (TB 07) introduced in 2018 and which is filled at each BMU on presumptive TB (new OPD patients, presumptives identified, presumptives tested with smear/Xpert, confirmed with TB, confirmed with Xpert).
4. Even though the TB laboratory network has significantly expanded, it still does not cover the needs in many districts. Overall, there is still only 1 microscopy laboratory for 135,000 population in Pakistan which appears to be grossly inadequate. In some districts, like the urban districts of Karachi the ratio is 1 laboratory for more than 200,000 population. In addition, the Xpert machines that have been deployed to date are not fully used.
5. Although, the visits to TB microscopy laboratories during the review showed that the bacteriological positivity rate of sputa examined was relatively low, the data generated by the NTP information system report that this rate progressively declined from nearly 17% in 2010 to 12% in 2017. At 12% this positivity rate is still relatively high. In addition, the NTP data show that the positivity rate among patients with presumed TB (not sputa) remained somehow stable at 14% between 2013 and 2017. These 2 types of data suggest that the index of TB suspicion among health workers might not be as high as highlighted above (in "Strengths"). These relatively high percentages tend to suggest that maybe not all patients, who seek care in the health facilities and need to be assessed for TB, are really evaluated for this disease. Another explanation may be, that, given that the PHC network and a significant number OPDs are not involved in TB case detection, only patients with signs and symptoms highly suggestive of TB are identified and assessed for TB.

6. Furthermore, there is no sample transportation system established between PHC facilities (BHUs, dispensaries, MNCH centres) and BMUs while the existing transportation system between the BMUs and Xpert sites is irregular and weak.
7. The procedures used to manage presumed TB patients who are identified varies among the clinicians met during the review. It was observed that a large proportion of clinicians do not follow clear and standardized steps in the management of presumptive cases of TB until the TB diagnosis is made. Among the health facilities visited during the review, very few of them had NTP guidelines, algorithms, desk aids or wall charts, available to the clinicians. There is no clear stepwise process specified in the NTP guidelines to establish the diagnosis of CDPTB, even in the new guidelines which have recently been revised and updated. Some of the key steps to reach this diagnosis are omitted. As a result, hardly 50% of PTB cases have on average been bacteriologically confirmed in Pakistan since DOTS was initiated in 2001. The NTP data show that, between 2013 to 2017, the highest bacteriological confirmation (around 55%) was in Baluchistan, Khyber Pakhtunkhwa and Sindh Provinces and the lowest in Gilgit Baltistan Province (15% on average).
8. Unlike many Eastern Mediterranean Region (EMR) countries, the proportion of patients with EPTB among notified cases of new TB episodes remained stable at 19% between 2013 to 2017. The guidelines strongly stress the need for Xpert testing on appropriate specimens to arrive at a bacteriologically confirmed diagnosis of EPTB, however, they do not specify which clinical criteria would be the most appropriate to establish this diagnosis if Xpert testing is not conclusive.
9. As highlighted above, the proportion of previously treated TB patients (including relapse cases) represented 5 to 6% of the total number of TB cases identified from 2013 to 2017. In contrast to Sindh Province where previously treated TB cases accounted for 11%, this proportion was most often less than 5 and 4% and even 3% in Baluchistan, Khyber Pakhtunkhwa and Punjab Provinces. These proportions are too low and suggest that some of the TB patients considered as new cases might have been treated for TB before. These wrongly categorized patients, who have a risk of drug resistant TB, are probably not appropriately tested for TB drug resistance.
10. Among previously treated TB patients (including relapse cases), the proportion of those labelled “other previously treated TB patients” is quite high, even though it has declined from 48% in 2013 to 28% in 2017. This percentage may be much higher in some settings, for instance “other previously treated TB patients” accounted for nearly 70% among all retreatment TB case identified in Kotri Institute of Chest Disease (Jamshoro, Sindh

Province). Furthermore, there are significant variations among the provinces. For instance, the proportion of "other previously treated TB patients" was on average 11% in Khyber Pakhtunkhwa Province between 2013 and 2017, but it reached nearly 50% in Sindh Province and even more than 90% in Gilgit Baltistan. It is not clear why the proportion of this category of patients is so high among retreatment TB cases. It might be related to issues in the patients' assessment procedures used by the health workers in charge.

11. Only 68% of the estimated TB cases were identified and notified in 2017. This percentage is still below the 80% target established for that year in the NSP.
12. First line TB drugs in loose tablets are not at all available in the health facilities visited during the review. Loose formulations of single anti-TB drugs are very useful in the management of patients who experience adverse effects and when they are not available, as was apparent in the visited facilities, it is not clear how patients with TB drugs' adverse reactions are managed.
13. The lady health workers (LHW), who are usually linked to PHC facilities and were previously involved in TB activities, are no longer engaged in TB-related activities such presumptive case identification and referral, treatment provision or contribution to contact investigation.

Recommendations

To enhance TB case finding and management the JPRM recommends that the NTP and PTPs undertake the following interventions and activities:

1. Progressively involve lower levels of the health care system including BHUs, dispensaries and MNCH centres, and the Lady Health Care workers (LHWs) who are linked to these levels, in the provision of TB services with the aim of reaching universal coverage:
    - the process of identification and registration of presumed TB patients,
    - sample collection and transportation to BMUs,
    - contact investigation activities and
    - the provision of: i) treatment to patients with active TB and ii) preventive treatment to eligible persons identified with latent TB infection (LTBI).
    - tracing and retrieving people with TB who interrupt treatment
    - Provision of health education
    - Community engagement initiatives

    The implementation of these TB activities in the PHC network must be developed according to a sound operational plan and included as a top priority in the coming NSP. This plan should include training activities, provision of recording and reporting tools, the development of an

efficient specimen transport system and clear referral mechanisms with feedback loops. The cost, including cost effectiveness (cost per TB case identified and or successfully treated) of engaging the lower levels of the health care system will need to be carefully analyzed. Partners of the N/PTPs are strongly advised to support these efforts.

2. The identification of persons with TB at health care settings needs to involve all clinicians and especially those at the front-line. Therefore, in OPD settings, the JPRM advises that all clinicians should be trained and involved in TB services' provision in their respective health facilities and should closely collaborate with the TB focal points of these facilities. To reach the large number of clinicians that need to be trained, the N/PTPs are advised to explore innovations such as digital technologies (m or e -health) to deliver this training.
3. Facilities engaged in presumptive TB case identification should be provided with the existing presumptive TB register established by the NTP. With the broad engagement of all levels of the health care system in TB services provision, such facilities will include dispensaries, MNCH centres, BHUs, BMUs/RHCs, OPDs of tehsil/taluka hospitals, district headquarter hospitals and tertiary hospitals. The relevant information needed on the presumptive TB patients who are identified by the health workers must be specified in the presumed TB registers implemented in health care facilities. The NTP staff in charge of the supervision of TB activities in the districts and the TB focal persons of the health facilities are encouraged to assess the routine data in the OPD and presumptive TB register and the quarterly TB07 form to:
    - check whether all the presumed TB cases specified in the presumed TB patient registers have been assessed in the TB laboratories and been appropriately followed up.
    - compare the number of presumed cases of TB in the presumptive TB register with the number of patients with persistent respiratory symptoms who are identified in the OPDs' registers[9] and
    - assess on routine basis the bacteriological positivity rate among presumed TB patients examined in TB laboratories as well as the positivity rate of the samples tested.

    Supervision must monitor and assess more frequently the quality of TB services in the health facilities with high bacteriological positivity rate among presumed TB patients identified.

[9] PAL surveys, carried out from late 1990s to mid 2000s, showed that among patients > 5 years of age who seek care for any reason in PHC facilities, the proportion of those with respiratory symptoms represents 20 to 35%; among these respiratory patients 20% on average seek care for persistent symptoms (> 2 weeks). It is important to highlight that among these patients with persistent symptoms there are patients with known chronic respiratory diseases who are using to attend health facilities every now and then and therefore they would not be identified systematically at each contact as presumed TB cases.

4. Initiate, implement and evaluate strategic approaches to identify presumed TB and TB cases in OPD settings. For example, designing and testing systematic verbal screening, followed by further assessment if required, of patients who attend OPDs for any reason (universal TB screening). Such interventions need to be appropriately evaluated before further expansion or being included in the NTP policy.
5. The TB laboratory network needs to be expanded further to cover the needs, especially in areas with a low number of TB laboratories per population or hard to reach geographical areas.
6. The sample transportation system between BHUs and BMUs should be established and that between BMUs and Xpert sites needs to be strengthened.
7. The NTP is urged to finalize the new NTP guidelines for TB case management , to be aligned with WHO guidelines, which will have a clearly detailed stepwise process of: i) identifying and managing presumed TB cases and ii) establishing the diagnosis of TB, especially that of CDPTB and the steps that lead to the diagnosis are highlighted in the algorithms. In addition, the guidelines need to provide the most appropriate guidance to establish the diagnosis of EPTB if there is no bacteriological evidence.
8. The new NTP guidelines should be widely available in all the health facilities irrespective of the health sector. Furthermore, the NTP should make available, for all health workers, clear standard operating procedures (SOPs), algorithms, desk aids and, if possible, wall charts to help clinicians at these facilities to quickly arrive at key decisions in the TB diagnostic and management pathway.
9. The bacteriological confirmation rate of pulmonary TB must be closely monitored. Health facilities with a low rate should be prioritized for support supervision by the districts' TB units in order to assess the quality of the procedures used to establish the diagnosis of TB. It is highly advised that the diagnostic pathway be assessed to understand the reasons for the high rate of CDTB in both the public and private health sectors and address gaps.

10. Evaluate and monitor the procedures to identify previously treated cases while prioritizing:
    a. the provinces where the proportion of previously treated cases among all diagnosed cases is low and
    b. the provinces where the proportion of "other previously treated TB cases" is significantly high among the total number of retreatment cases of TB identified.
11. The existing system of TB drug supply to health facilities must be maintained and strengthened. First line TB medicines in loose formulations need to be available for the health workers who

provide TB treatment to patients. The training of health staff should include sessions on the management of adverse events of TB medicines.

12. Progressively integrate TB services (identification and referral of presumed TB patients, treatment provision and identification of contacts and their preliminary screening) in the health care package delivered by LHW in the communities.
13. Reconsider the issue of abolishing Cat II treatment in the light of the most recent WHO guidelines on the management of drug-susceptible TB (2017 WHO Guidelines' Document). This recommendation is targeted primarily at the Pakistan Strategic and Technical Advisory Group for TB (STAG).

## Thematic area 2B: Contact investigation

### Findings

Contact investigation is included in the national strategy to end TB in Pakistan and most of the health professionals met during the review are aware of the need to appropriately implement this intervention. Contact investigation has been initiated through the BMU network, however, it is poorly developed, and its implementation is not consistent in most of the provinces visited during the review. There are, however, examples of successful implementation of contact investigation that have been undertaken on a small scale by NGOs such as Bridge Consultants Foundation, Mercy Corps and Indus Health Network.

### Strengths

1. Guidelines to implement contact investigation activities have been developed and are included in the new NTP guide which is still in the process of revision. In line with the WHO recommendations, they clearly specify:
    - the index TB cases around whom contact investigation should be triggered,
    - household contacts as the key individuals that must be screened and, if needed, further assessed and
    - the categories of household contacts that need to be evaluated as a priority.
2. Isoniazid preventive treatment (IPT) in children who were exposed to an index TB case but who do not have active TB has been recommended in NTP guidelines for over ten years.
3. The NTP has included a component on TB contact investigation in the Facility-based Patient Treatment Card and in the quarterly TB 07 form on case finding (Bacteriologically positive index patients whose contacts were screened, number of contacts screened, confirmed TB detected, contacts under 5 placed on TB preventive treatment ) in order to collect, on routine basis, the data inherent to this intervention. As a result, a process of data collection on contact investigation has been initiated for the last few years in most of the provinces.
4. Bridge Consultants Foundation, Mercy Corps and IHN have shown that contact investigation can be successfully implemented. In general, they reported that the households of approximately 65% of the index cases (usually BCPTB patients) can be investigated and the prevalence of

active TB among contacts screened was around 1%. Indus Health Network reported that the prevalence of TB was 2.5% among children who were household contacts in 2018.

5. Sites for the Programmatic Management of Drug Resistant TB (PMDT) usually screen and assess the household contacts of their patients who are diagnosed with MDR/XDR/RR-TB.
6. Furthermore, it is important to highlight that significant operational research studies are being carried out by the Indus Health Network on:
    - the outcomes of contact investigation in which all forms of TB, including EPTB, are index cases,
    - the use of rifapentine and isoniazid in the preventive treatment of contacts with no active TB, including adults and
    - the use of levofloxacin and ethambutol in the preventive treatment of contacts, with no active TB, who were exposed to index MDRTB cases.

Weaknesses

1. Even though many elements of contact investigation guidelines are in line with the WHO recommendations, these guidelines do not clearly describe the process of screening and evaluating the household contacts nor specify the roles of the various categories of health facilities and health staff including the possible role of community workers, like LHWs. In addition, they do not include any algorithm on the process of screening and assessing household contacts. The guidelines do not specify that persons living with HIV (PLHIV) who have been exposed to index TB cases must receive IPT for 6 months (6 months is the duration required for IPT by the National HIV/AIDS Program of Pakistan).
2. While the child TB guidelines have a chapter on contact evaluation and IPT provision the national TB management guidelines do not provide guidance on contact investigation and no algorithms and job aids to carry out screening and assessment of contacts are available in the health facilities visited during the review. In general, health staff are aware of the need to undertake contact investigation. Most of them consider BCPTB cases as the only index case around whom contact investigation should be carried out, very few of them consider the need for reverse contact investigation to identify the source or index case of a child with TB and none of them include the cases of TB/HIV and MDR/RR TB as index TB cases.
3. In most health facilities visited, the BCPTB patients are clearly identified as index TB cases in the Facility-based Patient Treatment Cards with even the names of the household contacts reported by the index cases, however, contact screening and assessment is carried out irregularly or not at all.

The health workers rely on the index cases to refer the household contacts who have symptoms (passive contact invitation) but most of them do not come to the health facilities.

4. There is no information on the provision of IPT for the eligible contacts. It seems that IPT is mostly not provided to PLHIV who are exposed to index TB cases and it is provided, at a limited scale, when pediatricians are involved in the management of childhood TB cases
5. The component on TB contact investigation included in the Facility-based Patient Treatment Card does not allow to capture all the required information on TB contact investigation and to create a linkage with a TB prevention treatment registration system.
6. Despite the limited quality, the available NTP data collected on routine basis 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 notification.

7. It is important to highlight that the NTP has not yet defined clear indicators to monitor the implementation of contact investigation activities and to evaluate their outcomes.

Recommendations

1. The momentum, existing within the NTP network, to develop and implement contact investigation needs to be strengthened and further accelerated. The data collected through the quarterly TB reporting form TB 07 on contacts should be assessed during supervision and used for program management and enhancement.
2. The new NTP guidelines which are in the process of revision need to be completed and should:
    - clearly describe how the screening and assessment of household contacts will be carried out, which categories of health facility will be involved and what will be the role of health staff and community workers (such as LHWs),
    - include a clear algorithm describing the stepwise process to perform the screening and the assessment of household contacts,
    - specify that PLHIV, irrespective of their age, who are household contacts and in whom active TB has been excluded following evaluation should receive IPT for 6 months,

- clarify whether household contacts with no active TB and no HIV infection who are aged more than 5 years need to be managed for LTBI or not in Pakistan (this is a conditional WHO recommendation for high TB incidence countries[10]).

3. Clear SOPs and algorithm on the process of contact investigation should be made available by N/PTPs in all the health facilities involved in the provision of TB services.
4. Training on contact investigation should be included in the training of health staff on basic TB. The training should focus on the definitions of the index TB cases and contacts, the process of screening and assessment of contacts and the use of the relevant information system for the monitoring and evaluation of contact investigation activities.
5. The N/PTPs should design and implement an Index TB Case Form which captures all the information needed to ensure the monitoring of the implementation of TB contact investigation and the evaluation of its outcomes. This form should be linked to the TB treatment register and to the TB preventive treatment registration system (see example in Annex 5).
6. The PHC network (dispensaries, BHUs, MNCH centres) and LHWs should be involved in the process of identification, screening and assessment of household contact as well as in the provision of IPT to eligible contacts with no active TB.
7. Household contacts who are prescribed IPT should be included in a TB preventive treatment registration system when it is established.
8. The N/PTPs should establish clear indicators to monitor the implementation of TB contact investigation and to evaluate its outcomes.
9. Contact investigation should be included in the process of supportive supervision carried out at district level.
10. The N/PTP and partners, especially IHN, should assess and discuss the outcomes of the operational research studies, undertaken by IHN, on contact investigation and preventive treatment of contacts with no active TB and identify what potential actions can be taken to improve and strengthen the implementation of contact investigation activities in Pakistan.

[10] See section 2.3, page 11 in https://www.who.int/tb/publications/2018/latent-tuberculosis-infection/en/

## Thematic area 2C: Latent TB infection management

Findings

1. Latent TB Infection management is included in the NSP and the new NTP guidelines which are in the process of revision. In line with the last WHO recommendations[11], the guidelines specify clearly that LTBI management should be carried out for PLHIV in general, child TB contacts less than 5 years with no active TB and no HIV infection and HIV-negative patients who are initiating anti-TNF treatment, or receiving dialysis treatment, or preparing for an organ or hematological transplant or having silicosis. However, contacts aged more than 5 years with no HIV infection and no active TB are not included. The guidelines do not describe the steps to carry out LTBI management nor include any algorithm. Also, they do not specify how the implementation of LTBI management will be monitored nor how its outcomes will be evaluated. The section on preventive treatment in the guidelines (pages 63 and 64) is in general not straight forward and quite confusing. The IPT provision is clearly described only for contacts less than 5 years of age.
2. As highlighted above, IPT in child household contacts less than 5 years with no active TB is somehow ensured in health settings where pediatricians are involved in childhood TB case management. The visit to two HIV care sites during the review observed that IPT is included in the HIV care package and is provided to registered PLHIV.
3. Except for IPT in child TB contacts and PLHIV who are registered in HIV sites, LTBI management is not implemented in the health facilities visited.
4. According to the UNGA -TB -HLM target for TB preventive treatment, a total of 30 million people should be treated for LTBI by 2022 at the global level and of these Pakistan's share has been estimated at 1.6 million people. However, no information on TB preventive treatment in PLHIV and contacts < 5 years with no active TB was reported to WHO in 2017 (Source: *Country profile, WHO Global TB Report 2018*).

Recommendations

1. The section on LTBI management included in the new guidelines needs to be correctly completed. It should clarify whether contacts aged more than 5 years with no active TB need to

[11] https://www.who.int/tb/publications/2018/latent-tuberculosis-infection/en/

be considered for LTBI management. This section should clearly describe the stepwise process to carry out LTBI management and include an appropriate algorithm. The preventive treatment to be used in LTBI management should be clearly identified and not be confusing.

2. The N/PTPs should establish a registration system for preventive treatment and define clear indicators to monitor the implementation of LTBI management and to evaluate its outcomes.
3. The management of LTBI must be included be in the training of health workers on basic TB services as well as in supervision activities.

## Thematic area 2D: Population TB mass-screening

Findings

With the financial support from the Global Funds, the NGOs Community Health Solutions (CHS), IHN, Bridge Consultants Foundation and Mercy Corps (MC) organize TB mass-screening, using chest X-ray, in selected districts, with a focus on socially disadvantaged settings. According to the few data reported the prevalence is often less than 1% among the screened groups. For example, the mass-chest X-ray screening undertaken, in 2018, in the Provinces of Sindh, Punjab and Khyber Pakhtunkhwa by CHS /IHN involved 304,672 persons. Among them 1,994 were identified as having active TB for a prevalence of active TB among all the screened persons of only 0.65% and with a number needed to be screened (NNS) of 153 to identify 1 active TB case. Among the 1,994 patients diagnosed with active TB, 845 had BCPTB (42%), therefore, the prevalence of BCPTB among the 304,672 persons was 0.28% with an NNS of 361 to detect 1 BCPTB case. However, through these experiences in population mass-screening, specific areas with more than 1% prevalence were identified in some urban settings for example in the Karachi metropolitan area. Another experience involving transgenders and male sex-workers in urban areas reported a prevalence of TB of more than 1%. Projects involving screening of OPD attendees using Chest X-Ray (CXR) and Xpert have also resulted in high yields.

Recommendations

1. The yield and cost-effectiveness of TB mass-screening undertaken by the NGOs needs to be evaluated in order to define its use and contribution to TB case-finding policy in Pakistan, and to inform the upcoming NSP.
2. 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 TB prevention, care and control in these areas.

## Thematic area 3: Drug resistant TB

The following report is a short version of a more detailed separate Green Light Committee (GLC) report. The previous GLC mission took place in May 2018. Of the 49 recommendations made during the previous GLC mission, 7 had been done, 14 partly done and 18 not done by the time of the JPRM. Of the 18 recommendations that had not been done, there was not enough information, yet, to classify 9 of them (as done or not done) and one was no longer relevant (annex 4). Progress had therefore been moderate.

Strengths

1. Multi – Drug Resistant TB (MDRTB) treatment is provided in 33 operational PMDT sites, each with 8 staff, operational in all provinces of the country, and fully supported by the GF. Most of these sites are managed by a partner NGO. A high number (around 3,000) of Rifampicin Resistant (RR) patients were enrolled each year between 2016-2018 (figure 8).
2. In 2018, access to Line Probe Assays and Drug Susceptibility Testing (DST) stood at over 60% (figure 9) with variations among provinces from less than 40% in FATA and KP to more than 80% in GB.
3. The use of Short Treatment Regimens (STR) of 9-12 months has expanded rapidly to 40% of MDR/RR patients with strains sensitive to Fluoroquinolone (FQ) and Second Line Injectable (SLI) varying from 63% in Punjab to 9% in Sindh (figure 10). The STR was provided to 38% of all RR-TB patients enrolled in 2018, increasing from 20% in quarter 1 to 35% in quarter 4. Preliminary data suggests that outcomes are like those obtained with Long Treatment Regimen (LTR).
4. Funding has been allocated to support patients on treatment for RR/MDR-TB with transport and food and to treatment supporters for transport.
5. The Provinces have developed innovations such as WhatsApp groups to link X/pert sites, DS-TB and MDR -TB treatment sites, strengthening follow-up of patients and reducing losses to follow-up.
6. New drugs (Bedaquiline (BDQ) and Delamanid (DLM)) have been introduced and used for selected patients.
7. In the PMDT sites visited, routine audiometry was in place to detect and prevent hearing loss caused by Amikacin and house visits were made routinely for contact tracing and management.
8. Drug supply was found to be regular with no reported stock outs.

Challenges

1. The number of confirmed RR patients (by Xpert and/or DST) is not accurately known since not all Xpert results are entered in a BMU register which is the source for the TB 07 form, the tool for quarterly reporting of case finding from BMUs. The new TB 07 form introduced in 2018 provides numbers of TB patients by disease category (pulmonary, extrapulmonary, new, previously treated, bacteriologically confirmed/not confirmed) but does not specify how the diagnosis was confirmed, for example, if by smear and/or Xpert (block 1). Block 4 of this form includes number of bacteriologically confirmed TB patients tested with DST results for Rifampicin among new, relapse and previously treated patients and the number who have RR-TB but does not specify if the disease is pulmonary or extrapulmonary. Additionally, the proportion of diagnosed RR patients started on MDR treatment and the delay from diagnosis to treatment start cannot be monitored.
2. The number of RR cases enrolled onto treatment has stagnated since 2016 (figure 8) despite rapid increase in Xpert testing. The treatment success rate among RR-TB patients has on the other hand declined gradually from over 70% in the early years of the program to 62% in 2016, mainly because of increasing deaths and patients lost to follow-up (figure 11). The deaths are probably mainly caused by patients being diagnosed with TB very late, after having spent many months in the health services before being diagnosed, and less in delay in diagnosis of DR-TB or initiation of treatment for it.
3. Most PMDT sites are separate units inside public tertiary hospitals, administered by partners and fully funded by the GF. This raises sustainability concerns and appears to diminish the role of N/PTPs in coordination of the PMDT response and the integration of these services into routine public health services.
4. The number of PMDT treatment sites has not increased in recent years and are centralized to one per 4-5 districts: 33 PMDT sites for 155 districts in a country with a population of over 200 million population. 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.
5. Treatment supporters are mainly family members.
6. The rate of resistance to the most important SLD, FQs, at around 40% in RR -TB patients in Pakistan, is very high compared to other countries. It is of great concern that resistance to the

new drug BDQ is increasing around the world, including Pakistan. Among 98 RR patients started on BDQ-containing regimens, 9 have failed, and 7 developed BDQ resistance.

7. In Sindh province there has been a reluctance to use the STR for RR/MDR-TB, with a preference for LTR even in patients with disease caused by FQ sensitive bacilli, even although there is a fair amount of openness to increase the use of these regimens. The NTP guidance document on the use of STR still includes extensive disease as an exclusion criterion although the WHO pre-final guideline does not mention it.
8. The Pakistan NTP needs to update the MDR-TB treatment guidelines in view of the new WHO prefinal guidelines that were released in the latter part of 2018 that promote long oral regimens with new drugs but still also recommends the same STR including Amikacin in patients without strains resistant to drugs in the current STRs. The following bullet points list arguments that the review team considered when making its recommendations:
    a. The STR is not inferior to the LTR in patients with strains susceptible to FQ and SLI, according to the only clinical trial of MDR-TB treatment regimens (STREAM1). Individual patient data collected from 15 countries showed a higher risk of treatment interruption with LTR than STR. There is not yet enough evidence for WHO to recommend oral STR with new drugs, but countries may use such regimens under operational research conditions.
    b. The pro-arguments for using STR (instead of LTR) for patients with strains susceptible to FQ and SLI in Pakistan include: (1) shorter duration of treatment (9-12 versus 18-20 months) reducing cost and workload for patients and health staff and making DOT more feasible (not only by family member), (2) lower cost (approximately 700 USD vs approximately 1500 USD for the drugs if procured through GDF (400 USD for BDQ only) making treatment more affordable and sustainable on national health budgets, (3) no exposure of Bedaquiline which is a lifesaving drug in case of FQ/SLI-resistance and failures of STR, (4) much easier drug management since the regimen is standardized, (5) proven effectiveness in the randomized clinical trial (STREAM1) and several cohort studies in numerous countries in Africa, Asia and Europe , (6) STR has been rapidly expanded in Pakistan and preliminary data suggest similar outcomes to those obtained with LTR.
    c. Counter-arguments against STR include: (1) hearing loss because of Amikacin (but most cases can be prevented by audiometry and should be less as fewer patients are receiving retreatment with another injectable drug Streptomycin), (2) injections are more difficult to organize than oral treatment.

d. Pro-arguments for oral LTR with BDQ in RR patients with strains susceptible to FQ and SLI include: (1) no injections, although, from a health system perspective, injections did not seem to be problem to organize in sites visited, (2) supposedly higher rate of relapse-free cure (although no clinical trial data is available yet). Counter-argument for oral LTR with BDQ include: (1) high cost, more dependence on external support, (2) exposure of BDQ leaving few effective drugs for a salvage regimen in case of failure, (3) adverse reactions especially to linezolid (peripheral neuropathy, optic neuritis, hematological abnormalities), BDQ (QT-prolongation) and cyloserine (seizures, depression, psychosis).
e. The WHO guideline emphasizes that It is important to inform the patient about the treatment options. In the sites visited in Punjab, the MDR doctor explained that most patients preferred the STR because shorter duration was more important than replacing injections with oral drugs.
f. The high level of resistance in Pakistan, especially to FQ, makes it a race against time to prevent further development of resistance. Weak family-based or no DOT in the TB program in Pakistan both for DS-TB and DR-TB and large-scale TB treatment in an uncontrolled private sector including over the counter sale of TB drugs increase greatly the risk of further expansion of drug resistance to both First Line Drugs (FLDs) and Second Line Drugs (SLDs).

Recommendations

To enhance PMDT in Pakistan the JPRM advises the NTP and or PTPs to undertake the following:

1. Further decentralize management of DRTB from PMDT sites to the district level, under close supervision, ensuring proper clinical management, including active Drug Safety Monitoring and Management (aDSM), provision of ancillary drugs, patient centered support and linkage with BMUs.
2. Work towards ensuring that national funding for the DR-TB response becomes progressively available.
3. Finalize, disseminate and implement the new TB diagnostic algorithm.
4. Strengthen regular sample transportation from microscopy centers to Xpert sites to ensure full coverage in previously treated TB cases and a rapidly increasing proportion of new TB cases, in line with the NTP algorithm.

5. Revise the TB-07-reporting form column 4 to monitor also how many BCTB patients by disease site (pulmonary and extrapulmonary) have result of DST for Rifampicin. Given the importance of increasing the coverage of Xpert testing in pulmonary TB patients with positive sputum smears, ideally form TB07 should include both results: confirmed by smear only, Xpert only or both.
6. Strengthen the transmission system of Xpert results to ensure regular flow of Xpert results from Xpert laboratories to PMDT sites so that all RR patients are started on treatment promptly.
7. Immediate actions should be taken by NTP and PTPs to improve access to PMDT services through establishment of PMDT sites managed by the public sector with support of partners. Current PMDT sites managed by partners may continue as an alternate model.
8. Strengthen daily Direct Observation of Treatment (DOT) by agreeing with the patient the best way to organize it, either facility-based if patient lives near a facility, by a community supporter such as LHW, and only if none of these are possible, use family members. (copy of recommendation from 2018)
9. Update national guidelines on RR-TB treatment regimens to the new WHO recommendations adapting to the national characteristics: (1) continue STR with a SLI ( amikacin ) in patients with strains sensitive to FQ and/or SLI, removing extensive disease as exclusion criterion, (2) 20 months all oral LTR containing new drugs in patients with strains resistant to FQ and/or SLI. Failure cases of LTR should receive individualized regimens.

Figure 8. Number of patients with tuberculosis resistant to rifampicin (RR-TB) by year enrolled on treatment in Pakistan, 2010-2018

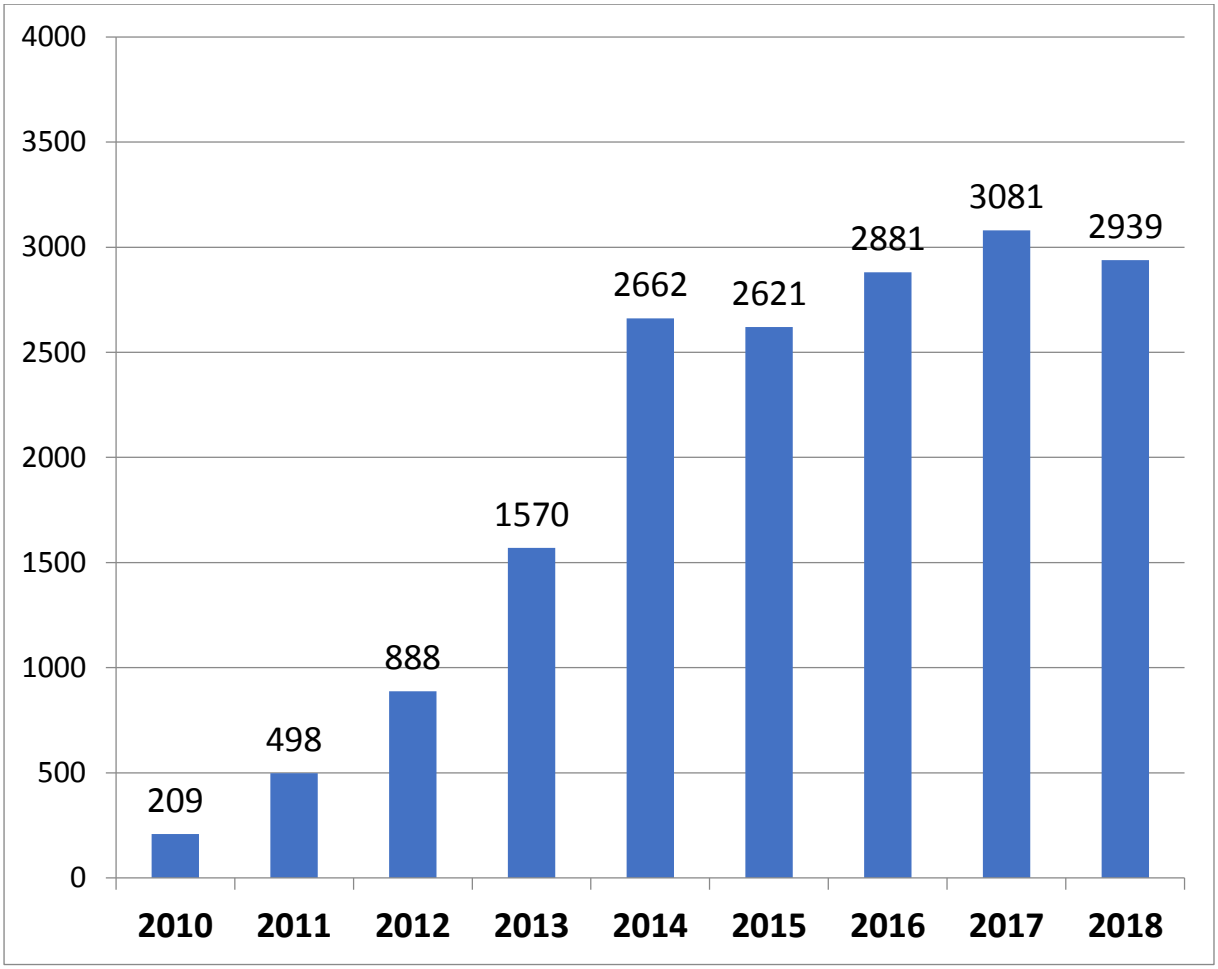


Figure 9: Percentage of patients with confirmed drug-resistant tuberculosis with result of line probe assay test for resistance to first- and second-line drugs 2018 by province (very preliminary data)

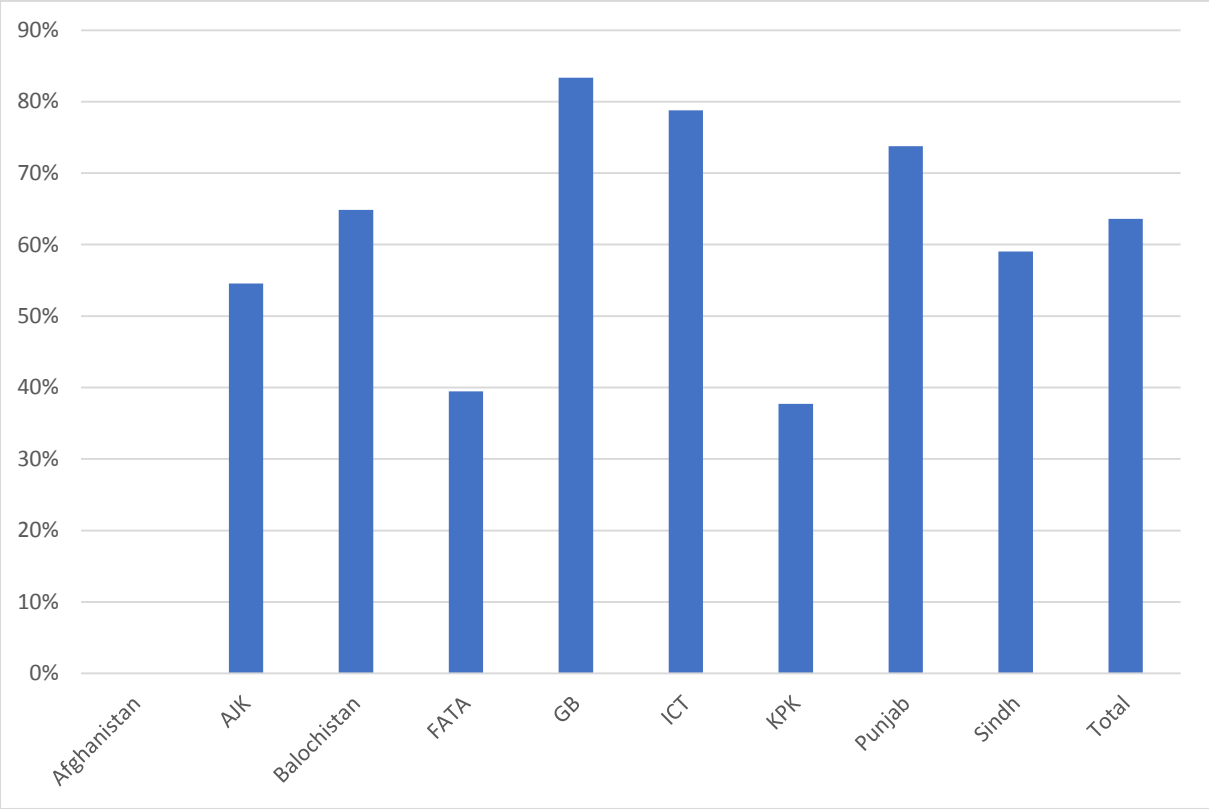


Figure 10: Percentage of all patients with tuberculosis resistant to rifampicin (RR-TB) and sensitive to fluoroquinolones treated with short MDR-TB regimen (9-12 months) enrolled in 2018 in Pakistan

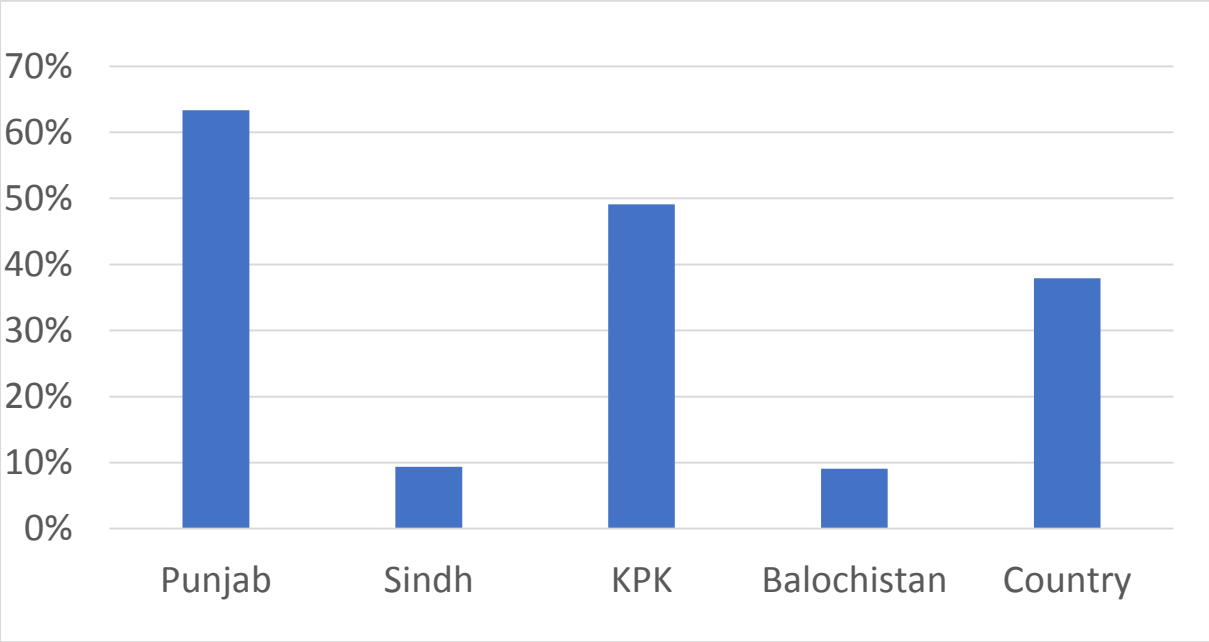
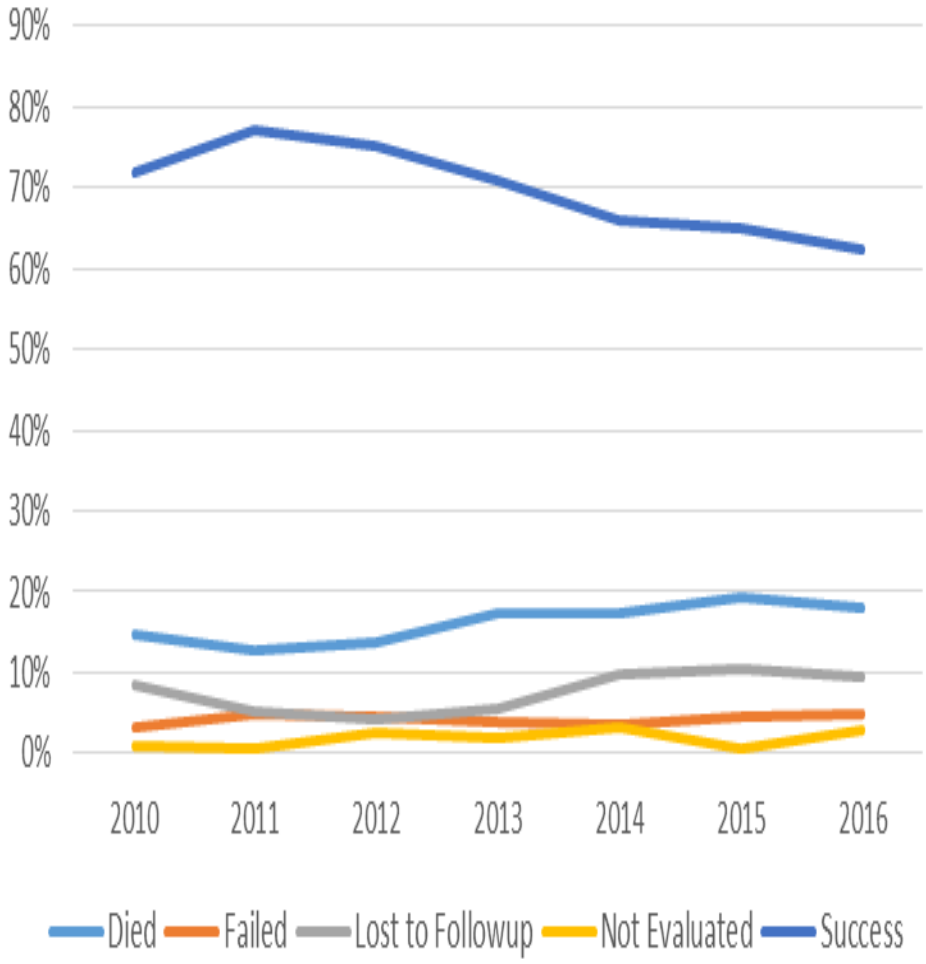


Figure 11: Treatment result (%) of all patients with tuberculosis resistant to rifampicin (RR/MDR/XDR-TB) enrolled on MDR treatment in Pakistan 2010-2018

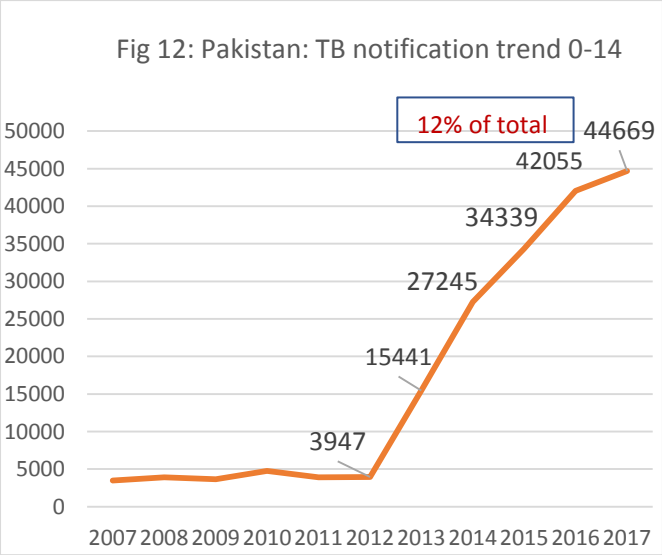


## Thematic area 4: Child and Adolescent TB

Background

Children 0-14 years comprise 35% of Pakistan's population. Of the estimated 55,000 TB deaths that occurred in Pakistan in 2017, 20% were in children, a majority of whom were likely less than 5 years of age and did not reach diagnosis and treatment. The Pakistan NTP has been working towards raising the profile of child TB starting with the publication of the first National Child TB guidance more than a decade ago.

There has been a marked and steady increase in TB case notifications among children that began around 2012, following private sector engagement and the development and dissemination of national child TB guidelines development, with health care worker training based on the guidelines. Pakistan reported 44,669 cases of TB in children in 2017 which comprised 12.3% of the total burden of TB in the country, which is consistent with what is expected (10-20%) of a high TB burden country (Fig 12). Children 0-4 years comprised 38% of the cohort of child TB which is lower than expected. Child TB notifications in 2017 showed marked variability among different provinces. Baluchistan reported the lowest number of children followed by Punjab, which is surprising considering that this province is home to 60% of Pakistan's population. This indicates a large detection gap in Punjab, estimated at over 68% of children with TB that are missed. On the other extreme Gilgit-Baltistan stood out as the highest child TB reporting region in 2017 (fig 13) with nearly half the detected cases of child TB, which, based on projected estimates, is likely to represent over-diagnosis. However, Gilgit has the highest rates of bacteriologic positivity (34%) among samples tested which may represent higher transmission rates, a situation that requires a deeper evaluation.



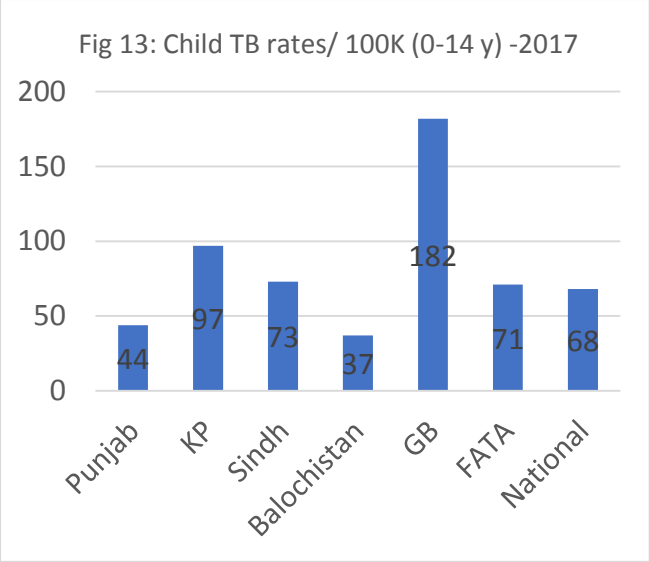



Table 6: National and Provincial targets for TB case finding among children, 2018 - 2022, in Pakistan

| | | 2018 | 2019 | 2020 | 2021 | 2022 | 2018-22 |
|---|---|---|---|---|---|---|---|
| | | | | | | | |
| PAKISTAN | | 48,594 | 57,063 | 60,199 | 56,473 | 52,723 | 275,053 |
| Punjab | | 29,199 | 33,599 | 35,285 | 33,477 | 31,660 | 163,219 |
| Sindh | | 10,376 | 12,793 | 13,638 | 12,461 | 11,275 | 60,543 |
| Khyber-Pakhtunkhwa | | 5,616 | 6,488 | 6,819 | 6,456 | 6,090 | 31,470 |
| Baluchistan | | 1,419 | 1,739 | 1,852 | 1,697 | 1,542 | 8,250 |
| Azad Kashmir | | 744 | 876 | 925 | 866 | 807 | 4,219 |
| Gilgit Baltistan | | 348 | 390 | 407 | 392 | 377 | 1,915 |
| FATA | | 591 | 790 | 856 | 750 | 644 | 3,631 |
| Islamabad | | 301 | 388 | 417 | 373 | 327 | 1,806 |

Strengths

1. There is political commitment for child and adolescent TB in Pakistan as evidenced by Pakistan's participation, at a high level, in the UNGA -TB -HLM and national and provincial acceptance of child TB specific targets for the country that form part of the political declaration that was made at the UNGA -TB -UNHLM. The specific child TB targets have been further broken down to the provincial level based on population density (table 6).
2. A Memorandum of Understanding (MoU) was signed between the NTP and the Pakistan Pediatric Association which has a network of over 5,000 pediatricians nationwide and which resulted in the participation of senior pediatricians in the child TB guideline update process in 2016.
3. There is a national child TB working group, however, it is somewhat inactive and has unclear membership and terms of reference.

4. Provision of BCG vaccination at birth is part of the national immunization schedule with 93% coverage by 2016, with however, variable coverage in provinces ranging from 74-99%.

Weaknesses

1. Children and adolescents with TB present to primary care facilities (public and private) with symptoms that mimic common childhood illnesses such as respiratory infection/pneumonia and malnutrition. The review teams observed that tuberculosis in children is diagnosed by overworked pediatricians at DHQ (secondary and tertiary level) hospitals serving entire districts, despite in some cases, existing capacity at lower health levels.
2. Data from three DHQ/BMU registers revealed high prevalence of TB among adolescents 15-18 years age (13-15% of total TB caseload) and a rate of 13% was found in the 2013 national TB cohort. The current reporting framework, however, does not allow quantification of this hidden epidemic.
3. Pediatric FDCs are available but not always used due to low awareness and poor pediatrician buy in.
4. The review found poor Tuberculin Skin Test (TST) and Xpert utilization among health providers for TB diagnosis in children.
5. Contact evaluation and IPT provision in children less than 5 years (with no disease) has been part of National guidance for over a decade but implementation is very low particularly in Punjab.
6. Recording and reporting materials for preventive therapy are lacking.
7. There is poor integration of TB and child health platforms including MNCH and nutrition.
8. The Punjab review team found several adolescents, 10-18 years old, diagnosed with DR-TB in PMDT registers, however, DR-TB rug resistant TB in children is generally underdiagnosed and managed at tertiary facilities only.
9. Bacteriologic positivity and outcomes data in children are mostly not reported.

Recommendations:

There is an urgent need to enhance prevention, care and treatment of TB in children in Pakistan as a core component of interventions to End TB in the country. The JPRM therefore advises that:

**1.** The Politicians/ MoH (2019) should rapidly work towards declaring child TB a national priority and close funding gaps to facilitate early diagnosis of TB in children and adolescents and the provision of TB preventive therapy so that not a single child dies from this curable and preventable disease.

2. The CMU/NTP should include child TB specific detection and prevention targets in the new TB-NSP and also develop a national child and adolescent TB roadmap, using the Child and adolescent TB roadmap 2018 as guidance http://www.who.int/tb/publications/2018/tb-childhoodroadmap/en/
3. The CMU/NTP (2019) should designate at least 50% of the Rural health centers as "child TB sites" with clinical and diagnostic capacity for diagnosis, treatment, prevention and follow-up of TB in children. Referral mechanisms and pediatric sample delivery systems to higher level facilities should be available when needed. Efforts should be made to enhance capacity to suspect and diagnose TB in children including DR-TB, implement HIV testing in children with TB and TB screening in Children Living with HIV (CLHIV).
4. The CMU/NTP (2019) should recruit a child TB champion to a) lead focused efforts on child and adolescent TB, b) serve as a point person for technical issues, c) liaise with pediatricians and other health providers caring for children and adolescents and d) perform thoughtful national and provincial programmatic data analysis.
5. The CMU/ PTP/ child TB champion (2019) should provide repeated guidance for use of TST, Xpert, use of pediatric Fixed Dose Combination (FDC) anti-TB medicines and IPT provision at monthly meetings with providers and strengthen utilization of non- sputum based pediatric samples, including lymph node tissue and stool, for Xpert testing. The CMU/NTP/PTP should also collect age disaggregated data (0-4, 5-9, 10-14, 15-20) on bacteriologic positivity and treatment outcomes in children and adolescents.
6. The CMU/NTP (2019-2020) should conduct operational research to quantify TB prevalence among vulnerable adolescents 15-18 years who require additional support mechanisms for better treatment outcomes. This will inform the Global TB program as well as national policy.
7. Public Private Mix and Partners (2019-20) should train partner providers in child TB algorithms and contact management to enhance TB diagnosis and preventive therapy in children. The IHN's enhanced child TB model should be scaled-up in busy health facilities until government funded efforts are able to provide quality integrated TB care.
8. NGOs/Civil society (2019) should raise awareness about childhood TB in communities to remove stigma and support existing community program activities to enable a family centered approach that ensures that children are linked to early care and prevention.
9. The N/PTPs are advised to include the childhood TB specific targets as interim 2022 targets in Pakistan's National Strategic plan for TB, in addition to these targets being a major component of the national multi-sectoral accountability framework.

## Thematic area 5: TB HIV and other comorbid conditions

## Thematic area 5A: TB/HIV

With an estimated prevalence of less than 0.1% [i] Pakistan has a low-level HIV epidemic among the general population, however, serial surveillance indicates concentrated epidemics among key populations such as People Who Inject Drugs (PWIDs) who had an average HIV prevalence of 37.8% in 2017. In the same population rates of HIV prevalence as high as 50% were found in Kasur district in Punjab and 49% in Karachi, respectively (table 1).

Table 7: HIV Prevalence in PWIDs in Selected Cities in Pakistan, 2016- 2017.

| | Tested | Positive | Prevalence % | Prevalence 95% CI |
|---|---|---|---|---|
| Rawalpindi | 302 | 65 | 21.5 | 17.3, 26.5 |
| Bahawalpur | 292 | 73 | 25.1 | 20.5, 30.4 |
| Kasur | 302 | 153 | 50.8 | 45.2, 56.5 |
| Jhelum | 302 | 54 | 17.9 | 13.1, 21.9 |
| Karachi | 302 | 147 | 48.7 | 43.1, 54.3 |
| Hyderabad | 302 | 40 | 13.2 | 9.9, 17.5 |
| Sukkur | 302 | 50 | 16.7 | 13.0, 21.5 |
| Larkana | 302 | 49 | 16.2 | 12.5, 20.8 |
| Nawabshah | 302 | 40 | 13.2 | 9.9, 17.5 |
| Mirpurkhas | 302 | 70 | 23.2 | 18.8, 28.3 |
| Peshawar | 302 | 30 | 9.9 | 7.0, 13.8 |
| Bannu | 146 | 5 | 3.4 | 1.5, 7.8 |
| Quetta | 302 | 25 | 8.3 | 5.7, 11.9 |
| Turbat | 302 | 50 | 16.6 | 12.8, 21.2 |

Source: Integrated biological and behavioral surveillance in Pakistan

In general, the implementation of TB/HIV collaborative activities in Pakistan remains low. The status of implementation of these activities, especially bi-directional testing and provision of TB preventive therapy is summarized below:

- There has been limited testing of TB patients for HIV in Pakistan. In 2016, only 4% of TB patients were tested for HIV. This increased to 7% in 2017. Of the patients tested for HIV in 2017, 0.5% were positive. The NTP in collaboration with the National AIDS Program has established a

National TB/HIV Collaborating Board, and provincial level TB/HIV coordination committees. There are currently 41 sentinel sites, which focus on the surveillance of HIV infection in TB patients.

- The Punjab PTP has scaled up HIV screening of TB patients to all BMUS as of October 2018. A review of the TB/HIV data in this province by the JPRM revealed that in 2018, the TB/HIV co-infection rate was 8.2% (90 HIV positive out of 1,089 TB patients tested) at the Sargodha DHQ hospital. This district is a high HIV prevalence area in Punjab. Mortality in the TB/HIV co-infected patients was high with 28(31%) deaths.

- Persons Living with HIV are tested for TB using Xpert at the Sentinel sites and are provided IPT if no disease is detected, however, this is not always done. Review of the data in visited sentinel sites revealed a 5% TB prevalence in PLHIV (2018) in one site in Lahore and 21% in one sentinel site in Baluchistan. Tuberculosis registers lack a recording format for results of HIV screening and HIV management status. In other provinces there was minimal coordination between TB and HIV clinics and distinct verticality. HIV testing is done erratically at PMDT sites and not done at DS-TB management sites or among child TB patients. Pretest counseling is not always done and if done then Voluntary Counseling and Testing (VCT) standards are not always followed.

### Thematic area 5B: Diabetes/TB

The prevalence of Diabetes in Pakistan is estimated to be 9.8% placing this country at position 7 among countries with the highest rates of diabetes in the world (Meo, 2016). It has been established that diabetes increases the risk of TB several fold (up to 3 times) and adversely affects TB treatment outcomes. Thus, it has been recommended that diabetic patients be routinely screened for TB and vice versa. This requires coordination and collaboration between diabetic prevention and care programs and the TB program. This type of collaboration was not evident during the JPRM apart from 2 pilot projects.

Recommendations:

TB/HIV

There is an urgent need to enhance the implementation of TB/HIV collaborative activities in Pakistan. The low rate of HIV testing among TB patients implies that a large proportion of the over 7,000 HIV infected TB patients are not identified and provided with appropriate treatment that is usually lifesaving

and prolonging. Under this situation most TB/HIV co-infected patients will die. This situation needs to be addressed and therefore the JPRM recommends that

1. To conform to current international standards of TB care, the N/PTPs, in collaboration with the National HIV/AIDS Control Program and partners, are urged to develop strategies and interventions that ensure all patients with presumptive TB and those who have been diagnosed with TB are tested for HIV. These strategies and interventions for a national scale up of HIV testing in TB patients can be informed by the Punjab province experience where HIV testing rates in the 2018 TB cohort reached 30%.
2. Like HIV screening in TB patients, all PLHIV should routinely be screened for TB using a clinical algorithm and started on IPT if results of the TB screening and or testing reveal no evidence of TB disease. As currently recommended Anti-Retroviral Treatment (ART) and Co-trimoxazole Preventive Therapy (CPT) should be initiated among all TB patients with HIV, as soon as possible, regardless of CD4 counts.
3. In the update of the TB management guidelines the implementation of TB/HIV collaborative activities should be strengthened.
4. The TB recording and reporting tools and the HIV program recording, and reporting tools should be updated to include essential data on TB/HIV collaborative activities.

Diabetes and other co-morbid conditions

With the large burden of diabetes in Pakistan, it is highly likely that a significant proportion of the TB disease burden is driven by this condition. The Population Attributable Fraction (PAF) of diabetes as a driver of TB needs to be known through relevant approaches including research. Appropriate care needs to be provided to TB patients who are living with diabetes while early detection of TB and prevention of TB in diabetics is an essential intervention where the incidence of TB in diabetics is significantly high. Based on these considerations the JPRM recommends that the N/PTPs in partnership with the Non-Communicable Diseases (NCD) program and partners undertake the following activities:

1. Obtain estimates of the prevalence of diabetes among TB patients and TB among diabetic patients through relevant program-based operations.
2. Implement in a sustainable way, bi-directional screening of TB and diabetes following documentation of the contribution to the morbidity and or mortality of one disease to the other.
3. Develop national guidance that will strengthen bi-directional screening, recording and reporting for diabetes and TB and increase linkages between TB services and NCDs.

4. Use the lessons learnt from the experiences of the TB and diabetes bi-directional screening pilot projects that are on -going in 5 districts of KP to plan the expansion of these programs.
5. Collect appropriate programmatic data in relation to other co-morbid states, to inform strategies for a public health approach to the prevention, care and treatment of TB in the identified co-morbid states. To obtain this data, routine program recording, and reporting tools will need to be appropriately modified.
6. Obtain estimates of the proportion of pulmonary TB patients who suffer significant lung damage post TB treatment (post TB chronic lung disease) and who therefore require long term respiratory care. Working with relevant units in the MoHs, the N/PTPs, should work towards developing appropriate public health programs to provide care to such patients.
5. Continue efforts to provide appropriate care to TB patients who smoke to help them quit smoking and to work with the tobacco control program to support efforts to control use of tobacco in Pakistan, in recognition of the influence of tobacco smoking on TB incidence and treatment outcomes.

## Thematic area 6: The TB Laboratory network

Findings

The diagnosis of tuberculosis is still mainly based on Acid Fast Bacilli (AFB) smear microscopy. Two smears are performed for diagnosis and one is requested for therapy follow up at months 2, 5 and 6. Unfortunately, not in all centers is the algorithm strictly followed and we observed that some centers only request one sample for diagnosis.

### Microscopy coverage

The network has been expanded consistently in the past years with a consistent PPM engagement. In 2017 there were 1,602 laboratories equipped with either light or LED microscopes. The entire network of laboratories is quality assured with slide rechecking and regular monitoring by a supervisor. Performance records are regularly collected and evaluated at provincial and national level.

The average population coverage per center is variable and although higher in ICT, Punjab and Sindh, accessibility is lower in less populated regions where road conditions and remote areas may challenge accessibility of people to diagnostic centers.

Smear positivity rate has been declining constantly from 2010 when it was 16.6%, to 12.2% currently. This is linked to the increased efforts to find cases with a higher number of presumptive TB persons referred for smear microscopy.

Smear microscopy registers are present in all laboratories; however, they are not always properly filled.

### The Xpert network

With the support of the GF a massive Xpert scale up occurred between 2011 and 2019. In 2016 it was agreed to install Xpert machines in all tertiary care hospitals, all DHQ hospitals and in THQ hospitals in Punjab, Sindh and KP.

A total of 74 machines with 16 modules and 406 with 4 modules have been deployed for public and private circuits. Five hundred and forty-eight modules still need to be installed. Many machines are linked to GX alert system. Module failure have been observed and reported in several centers in different regions with one region reporting up to 10% of the modules failing runs. Maintenance is paid as a percentage on each test and assistance is provided by a local contractor. The efficiency of the process should be monitored and discussed with Cepheid as well.

According to the diagnostic algorithm, use of Xpert should prioritize detection of rifampicin resistant cases and diagnosis of tuberculosis in children and paucibacillary samples including extrapulmonary TB cases. The algorithm is to a great extent not applied and very few EPTB and pediatric samples are tested by Xpert.

Underutilization of Xpert machines

It was observed that very few centers run more than one full run per day with this suboptimal use observed in almost all centers visited. As observed during the GLC visit in 2018 the total number of tests carried out is higher in Sindh compared to Punjab but the number of positive tests for MTB and or RR is higher in Punjab, due to the use of the test as primary screening tool in some settings.

The ULTRA assay was validated in the last quarter of 2017 and it is gradually being introduced as replacement of G4. Evaluation of the “trace” calls in the different categories is needed.

## Line Probe Assays (LPA)

Triaging of DR-TB patients for the short versus longer regimen is performed by LPA for first and second line anti-TB medicines. The test is offered at national and provincial level (Punjab, Sindh, KP, Quetta) and large private hospitals in Sindh. External Quality Assurance (EQA) is regularly provided by the National Reference Laboratory (NRL) but not all the centers have been validated yet. The overall capacity to provide timely results is limited (but above 60% in 2018, see figure 9) and still the most efficient center is probably the NRL that is supporting the high workload of Punjab.

## Culture and DST laboratories

The number of facilities performing culture and DST is gradually increasing but is still highly insufficient for the need of the country. Fifteen culture laboratories have been established, but fewer are active.

Performance of the culture laboratories will need to be constantly monitored and not all existing facilities are compliant with the minimum biosafety standard required. National guidelines recommend culture for the initial assessment of anti-TB drug sensitivity profile of new MDR-TB patients and for treatment monitoring. In 2017 a total of 60,456 cultures were performed in 14 laboratories, 20% of them were performed by the NRL.

Drug Susceptibility Testing (DST) services are provided by NRL for PMDT sites in ICT, Punjab, AJK and FATA while Indus hospital provides services for Sindh and Baluchistan. The Aga Khan University Hospital (AKUH) also provides culture and DST. Overall, with the increasing request for bedaquiline susceptibility surveillance and the needs to start testing for group A and B MDR-TB drugs, the capacity of NRL will be highly challenged in the future if the Provincial Reference Laboratories (PRLs) don't start providing DST. The PRL in Lahore has started liquid culture DST, but the process of validation is taking too long, and it needs to be concluded as soon as possible with a validation panel provided by the NRL. The same process should be started by all PRLs after verification of biosafety level.

### Recording, reporting and data analysis

Laboratory registers are present in all microscopy and Xpert laboratories but are not always properly filled and in some laboratories a redundancy in the use of additional notebooks has been observed. Microscopy data are reported quarterly at provincial level. Provinces should then report data to National level for annual analysis. Training on data recording and reporting is performed by supervisors. Based on observation in some sites in Sindh and Punjab, training of trainers may be needed.

### The NRL at ICT

The NRL is the heartbeat of the laboratory network. In 2018 the laboratory performed 11,193 XpertMTB/Rif assays, 9,433 cultures, 2,862 LPA and 1,763 DST. The laboratory has recently moved into a proper space in the National Institute for Public Health (NIPH) with separated areas dedicated to molecular work and BSL3 for TB culture and DST. The laboratory has capacity to support clinical laboratory services for patient management, Technical Assistance (TA) and EQA for DST at provincial level, training for culture and DST, data management, Non-Tuberculous Mycobacteria (NTM) identification, surveillance for bedaquiline and is engaged in several research projects. Next Generation Sequencing for DR surveillance and transmission analysis is planned, training of some staff has already been performed but has been placed on "hold" for the lack of funding to purchase the equipment. The

acquisition of this technology will represent an incredibly important resource for proper managing of the most complex cases, and it is highly recommended. The laboratory has started the surveillance for bedaquiline susceptibility and will soon implement DST for other class A and B drugs and for delamanid. The NRL provides annually comprehensive and very detailed data reports on the activity of the network and on trends in SLD resistance with analysis of genotypic determinants.

## Equipment and infrastructure

The laboratory infrastructure is very variable with high standard, state of the art laboratories at National and provincial level and in the private sector (Punjab /PRL Lahore, NRL, Indus Karachi). In Baluchistan the major issues identified at the Lab is the lack of continuous power supply and the Heating, Ventilation and Air Conditioning (HVAC) is not operational as it should, in a BSL-3 lab. Bio safety cabinet needs calibration and some repair which is pending for many months now. Also, at provincial level the BSL3 was observed not to be up to the required level in term of biosafety. At lower level laboratory infrastructure requires maintenance with several microscopy facilities performing in poor conditions. Air exchange is insufficient and the use of personal protective devices not appropriate. Disposal of infectious waste was observed not to be compliant with good laboratory practices in the laboratories visited.

In PMDT sites where both Xpert laboratory and smear microscopy coexist in the same structure, very often they are in different areas of the facilities, which contributes to delays in the transport of samples and creates additional challenges to correct registration of laboratory data in the different registers.

Recommendations

In order to continue enhancing and sustaining the quality of the TB laboratory network, the JPRM advises that N/PTPs undertake the following activities:

1. Finalize, disseminate and implement the revised diagnostic algorithm. In order to increase the number of microbiologically confirmed cases the N/PTPs are advised to a) increase the categories of patients tested by Xpert (algorithm modification), b) enforce the use of Xpert for diagnosis of TB in children and EPTB and c) improve timely maintenance of Gene Xpert (Gx) machines.

2. Increase accessibility to microscopy and Xpert tests by establishing a functional sample transport and results reporting mechanisms starting from the BHU level.

3. Train the end user (clinicians) on proper interpretation of Xpert and LPA for clinical management of cases and recording of laboratory results in TB registers (DOTs facilitator) and Laboratory registers (Laboratory staff).

4. Increase the capacity for LPA, culture and DST and strengthen the link of PRLs with NRL. The NRL should be actively engaged in creating laboratory leadership at provincial level.

5. Establish capacity at NRL to perform regular molecular and phenotypic surveillance of emerging resistance and consider starting transmission studies

   research

# Thematic area7: Engaging all care providers - Public-Private Mix (PPM)

## Main messages

1. Pakistan has been a global leader in PPM, which now constitutes 32% of total TB case notifications, and has several of the world's leading NGOs in this field.
2. The scope for improvement remains huge: private primary care providers account for 80% of initial care-seeking, yet less than 5% of them are effectively engaged.
3. Pakistan should prioritize a major expansion of PPM, without which it will not achieve the End TB goals and targets.

**Table 8: 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% |

Situation analysis

## Private health sector in Pakistan

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[12]. Private healthcare providers include at least 100,000 GPs, over 67,000 pharmacies, thousands of laboratories, and around 5,000 hospitals (Table 8). While they are concentrated in urban areas, GPs and informal providers also serve small towns in rural areas.

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[13]. The market leader is Myrin-P[14] sold in FDC formats, with a full 6-month standard treatment course costing a total of around Rs 6,000 (US$ 43) for the average adult.

## PPM trends and current status

There are four main models of PPM in Pakistan: PPM1 for GPs, PPM2 for NGOs, PPM3 for private hospitals, and PPM4 for parastatal or other public hospitals. The review focused on interventions supported by the Global Fund under PPM1 and PPM2. The total number of TB case notifications from PPM increased from 58,288 (20% of the total) in 2013 to 114,974 (32% of the total) in 2017. The biggest increases have come from the GPs since 2016 (Figure 14). Final data are not yet available for 2018, but the rate of increase may have levelled off.

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

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

[14] Wyeth/Global Pharmaceuticals Ltd

## Main partner implementers and models

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 is standard: mapping; selection of providers based on client load and willingness; short training for GPs and their paramedical staff; engagement and equipment for private labs (paid Rs 50 per slide); free NTP drugs; $2.86 per case (Rs 200 at registration, Rs 200 at completion) for the GPs; 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 recent published study by staff of Mercy Corps and the NTP demonstrated a 71% increase in case notifications by GPs after the introduction of cash incentives in 2015.[15] Greenstar and Mercy Corps report treatment success rates among patients treated by private providers in excess of 90%, but the NTP is not able to disaggregate treatment success rates for PPM; a published study reported 81% treatment success amongst 883 TB patients treated by private providers in Lahore in 2015.[16] In 2017, GSM engaged 1,963 pharmacies in 3 provinces and encouraged them to refer customers with symptoms of TB to nearby networked GPs, resulting in 13,635 presumptive cases referred (average 7 per pharmacy) and 1,956 cases registered (14%, 1 confirmed case per year per pharmacy); this work continues on a smaller scale. In 2019, GSM proposes to attempt to achieve 100% coverage of GPs and private TB patients in one district (Faisalabad, Punjab), an initiative which would generate important lessons and insights to guide expansion if it is funded.

[15] 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

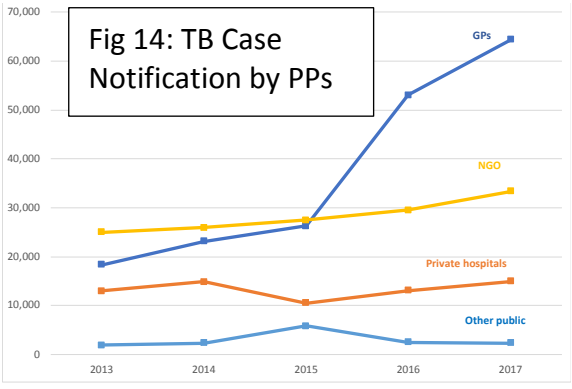
[16] Khan BJ et al (2017) Alarming rates of attrition among tuberculosis patients in public-private facilities in Lahore, Pakistan, *Public Health Action* 7(2): 127-133. The study also reported 64% initial loss to follow-up, but acknowledged that it was not able to account for patients treated at public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

Table 9: Engagement of private primary healthcare providers by major GFATM NGO recipients, 2018

| NGO SR/PR | Districts | Active GPs | Active GPs /District | Total cases notifed | Cases/Active GP/year | Pulmonary B+ | Success rate (2017 cohort) | Labs | Pharmacies | GFATM budget 2018-2020 (US$ m) | GFATM Target 2018-2020 |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Mercy Corps and 8 NGO SRs | 65 | 1,778 | 27 | 36,774 | 21 | 37% | 94% | 288 | | 15.00 | 117,000 |
| Greenstar Social Marketing | 20 | 1,096 | 55 | 29,173 | 27 | 26% | 93% | 146 | 1,500 | 6.50 | 100,000 |
| **Subtotal PPM1** | **85** | **2,874** | **34** | **65,947** | **23** | **32%** | **94%** | **434** | **1,500** | **21.50** | **217,000** |
| Community Health Solutions | | | | | | | | | | | |
| PP referrals | 27 | 1,316 | 49 | 8,347 | 6 | | | | | | |
| Camps, walk-ins | 27 | | | 5,570 | n/a | | | | | | |
| **CHS total** | **27** | | | **13,917** | **n/a** | **52%** | **76%** | **-** | **-** | **7.30** | **110,000** |
| **Total** | **107** | **4,190** | **39** | **79,864** | **19** | **36%** | **91%** | **434** | **1,500** | **28.80** | **327,000** |

Notes: CHS operates 61 Sehatmand Zindagi centers; CHS notifications classified as PPM2 (NGO) include referrals from GPs, some of whom manage treatment, and informal private providers; Total number of districts with GF-funded private provider engagement includes 5 with both CHS and PPM1; Active GPs defined as those referring at least one notified TB case during the year; GFATM budgets subject to revision.

In the last three years, an innovative model of private primary care for TB has been developed by Community Health Solutions (CHS), which now operates 61 Sehatmand Zindagi TB diagnostic and treatment centers, supported by 20 vans equipped with digital x-ray and the software for x-ray interpretation (Computer Aided Diagnostic for TB or CAD4TB) for mass screening, in 27 districts. In 2018, the centres that had been in operation for the full year detected an average of 22 cases per center per month. Each center drew presumptive cases from an average of 58 GPs and diagnosed cases from an average of 24 GPs over the year. In 2018, 54% of their cases were referred from providers, 25% came from screening camps, and 21% were walk-ins. This is a distinctive and innovative model, piloted in Bangladesh and Pakistan in 2015-17 and scaled up under the current Global Fund grant. Unlike the GSM and MC models, it offers ready access to digital chest x-ray and Xpert, and Private Providers (PPs) who cannot or prefer not to manage TB cases are believed more likely to be willing to refer to an NGO than to another PP. Their motivation to disrupt any existing relationships with private labs is believed to be related to an assumption that the majority of presumptive referrals will not have TB and will return to them, happy to have been availed free diagnostics, and the fact that the PPs receive the standard incentive for those presumptive cases who are confirmed to have TB even if they are



managed by the Centre.[17] While this model is falling short of targets, for various reasons, it is likely to continue to grow and to complement the other approaches.

These two models of engaging private providers are potentially complementary, given that GPs who prefer to retain their TB patients may prefer the GSM/MC model while informal providers and GPs who prefer to refer them out may prefer the CHS model. MC has a lower number of active GPs per district because it tends to work in more rural districts. CHS has a lower yield per active referring provider because the engagement is less intense than the other models and they include informal providers (Table 9). However, the models are mainly in different districts at present.

The leading NGO provider of TB services is the Pakistan Anti-TB Association (PATA), which has been active since 1955, operates 42 centers, and contributed 18,000 cases in 2017. PATA has a Global Fund budget of $0.6m/3 years via Punjab PTP, but the contract is reportedly not yet signed.

As Figure 14 shows, 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 GF to use the Find cases Actively, separate safely and Treat Effectively (FAST) approach 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 (see MDR section). 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[18]) and 15 major Military Hospitals. Both partnerships seem to have the potential to contribute substantially to TB case notification from 2019, if properly managed.

**Table 10: Number and outcomes of Screening camps by 3 major NGOs in 2018**

| NGO | Vans | Camps | Cases per camp | Cases |
|---|---|---|---|---|
| GSM | | 607 | 2.06 | 1,248 |
| MC | 7 | 965 | 2.22 | 2,147 |
| CHS | 20 | 3,095 | 0.79 | 2,443 |
| **Total** | **27** | **4,667** | 1.25 | **5,838** |
| **Analysis** | | | | **Number** |
| No. GPs required to find camp cases at 15 cases/GP/year | | | | 389 |
| No. Field Officers needed to engage GPs at 15 GPs/FO: | | | | 26 |

IHN, CHS, GSM and MC 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 (Table 10).

[17] The model is described as potentially "sustainable" because of revenue from non-TB-related laboratory tests, but such revenues are currently reported to cover only 10% of costs (not verified) and it seems likely that these centers will continue to require grant or contract funding.

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

While the results from passive case finding may not be directly comparable to those generated by active case finding camps, this analysis at least suggests that the cost-effectiveness of this activity should be carefully reviewed, given the low coverage of TB services among primary care providers.

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). These NGOs appear to have adequate funding and the ability to hire and fire staff; the few facilities visited by the JPRM appeared to be well managed. Although under government contract in publicly-owned facilities, PPHI case notifications are recorded under PPM2 (NGOs) in the NTP data. The draft MOU between Sindh PTP and PPHI proposes to establish TB services in only 121 of PPHI's 971 primary care facilities in the province.

Most provinces and the Federal Government have passed Mandatory Notification Acts, providing for jail terms of up to two years for healthcare providers who fail to notify TB cases, but implementing regulations have not been issued. The NTP plans a "mandatory notification pilot project" in 5 districts from April 2019. Two Field Officers will be appointed per district to work with 20 GPs each, using a mobile phone app to register cases. Rather than testing any innovation for mandatory notification, this will simply show that the PTP can implement the already well-proved PPM1 model of GSM and MC.

## Strengths

1. Pakistan has several very strong NGO partners with many years of experience engaging private providers. They include Greenstar Social Marketing, Mercy Corps (and its 6 NGO SRs), Community Health Solutions, PPHI, the Pakistan Anti-TB Association, and the Indus Health Network.
2. There are strong precedents for government contracting of NGOs in health, and since 2015 there has been provision for TB strategic purchasing from private providers: Rs 200 per case notification to GPs, a further Rs 200 per treatment success to GPs, and Rs 50 per slide to private labs. These incentives appear to have contributed to the significant increase on PPM1 case notifications.
3. There is considerable innovation within the PPM field in Pakistan. Examples include the Sehatmand Zindagi centers, MC's demonstration of the impact of re-engaging Lady Health Workers, GSM's work with pharmacies and a plan to explore 100% coverage in one district, the introduction of incentives in 2015, and various modes of active case finding.
4. Implementing organizations have demonstrated the capacity to analyze data, generate ideas for improvement, and test them.
5. Mandatory Notification Acts have strengthened the legal foundations of PPM and the NTP is motivated to explore ways of effectively implementing them.
6. 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 (see UHC section). 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.[19]

## Challenges/Weaknesses

1. PPM initiatives have not reached a scale that is commensurate with the magnitude of the TB epidemic or the role of the private sector, especially at the primary care level. They notify 22% of estimated incidence, in contrast to the 80% private share of primary care. Less than 5% of private primary care providers are actively engaged.
2. Given its importance for TB prevention and care in Pakistan, PPM is relatively neglected in the National Strategic Plan. It is one of 24 intervention areas but does not feature in the top 10 monitoring and evaluation targets.[20]

**Table 11: GFATM budgets for main NGO PRs and SRs, 2018-2020, by broad level of intervention, US$m**

| Recipient | Primary care | Hospital and MDR | Total |
|---|---|---|---|
| Indus Health Network | | 26.3 | 26.3 |
| CHS | 7.2 | | 7.2 |
| Greenstar SM | 6.5 | | 6.5 |
| Mercy Corps | 15.0 | | 15.0 |
| **Total** | **28.7** | **26.3** | **55.0** |

CHS and GSM are SRs to IHN; Mercy Corps has 8 NGO SRs

3. Funding for PPM remains insufficient and has been almost entirely dependent on external donors, mainly the Global Fund (Table 11). In the NSP, the proposed budget for engaging all providers is 12% of the total (even excluding from the total the costs of first- and second-line drugs, patient support and programme management and supervision). The current level of Global Fund support for engaging private primary care providers averages just $9.5m per year, or 34% of the GF total excluding drugs and social support. While the Sindh provincial government seems ready to substantially increase its funding for TB care and prevention, the proposed budget includes no funding for PPM partners.
4. PPM partners have been trying to use the same registers and forms as are used in the public sector. This is always a major constraint to PPM, especially for small private providers. GSM, MC and CHS have all developed their own case-wise databases, but data collection remains paper-based and the NTP forms are used in parallel. MC and the NTP have developed apps for case registration, but they are not deployed. GSM has a call center for family planning, but it is not used to support the TB work. Recent experience in India suggests that a combination of Call Centers and apps or tablets for field workers may work well, and that the resulting digital system not only enables more efficient operations[21] but also permits patient tracking through the care continuum, linkages to supply chain systems, adherence monitoring and digital payment of social supports and incentives.

[19] Social health insurance is important for TB control and engagement of the private sector in Taiwan, Korea, Indonesia and Philippines.
[20] Appendix 2 (p. 135) lists 127 "epidemiological projections" that include 19 targets for PPM; a target for PPM notifications (152,740 by 2020) and various quality measures. The narrative (p. 115) proposes targets for engaging different kinds of providers, notably 6,000 GPs by 2020.
[21] World Health Partners (in Patna, India) manages around 19,000 cases per year with private providers by deploying one Field Officer for every 25-30 GPs (compared with 1:15 for GSM and MC) backed up by a 12-person Call Centre and extensive use of digital technologies

5. The proposed pilot project to implement mandatory notification seems ill-conceived. In principle it is good for NTPs to also directly engage PPs, but the major PPM NGOs have a clear comparative advantage in this area, while PTPs are better-equipped to focus in the near term on the equally important challenge of extending TB services in the public primary care sector.
6. While the JPRM came across many instances of excellent collaboration between NGO partners and the NTP/PTPs, instances of rivalry, competition and mistrust were also observed. There is competition for limited Global Fund resources, and even for patients in some places. Key implementing partners did not participate fully in the JPRM process. Briefings at national and provincial levels were organized separately, rather than as an integrated partnership. Responsibility for poor relationships, where they exist, seems to be shared: some partners do not seem to show sufficient respect for the NTP/PTP leadership role as they plan activities, analyze data and adjust strategies; some PTP managers seem not to respect or welcome partner contributions and to focus on the number of public patients rather than the total, as if they were in competition with NGOs.
7. Some large public and private hospitals are not screening for TB in OPD or effectively linked with N/PTPs. PTPs should be able to work with these large facilities to establish TB screening teams and DOTS centers, although it will be important to strengthen down-referral for simple cases in order to ensure follow-up and treatment adherence.
8. The proportion of pulmonary TB cases that is bacteriologically confirmed is particularly low in PPM: 42% overall, and just 37% for GPs, in 2017.

## Recommendations

To re -iterate Pakistan needs to prioritize a major expansion of PPM, without which it will not achieve the End TB goals and targets. To this end the JPRM recommends the following:

1. N/PTPs and partners should increase the proportion of private primary care providers (GPs, pharmacies, labs) actively engaged in the TB program from <5% to >20%, and double quality-assured private case management, within 3 years. Practical ideas for scaling up that were discussed with PPM partners include: increasing private patients' access to Xpert; engaging more providers, especially using digital technologies (see below); adapting recording and reporting procedures for the private context; offering small incentives for the paramedics who are responsible for paperwork in private clinics; strengthening pubic recognition of high-performing providers; increasing engagement of private labs and pharmacies to identify and reach out to all private TB patients; engaging and incentivizing more informal providers to increase early case referral; etc.
2. Funding for PPM should be increased, especially for engaging the private primary care sector. Near-term options include increasing the share of the current and future Global Fund budgets allocated to this priority, accessing the new USAID funding mechanism for local organizations, persuading other bilateral funders to prioritize PPM in Pakistan, and accessing Pakistani philanthropic and CSR resources. For long-term

sustainability, Pakistani provincial governments must develop contracting mechanisms to support PPM as an integral component of their commitment to ending TB.

3. PPM partners should develop digital technologies to facilitate PP engagement at scale, not just for registration but also for patient tracking, adherence support and digital funds transfers. A common system should be jointly developed by GSM, MC and CHS, designed from the beginning to connect with DHIS2. A call center could play a key role. Digital systems will enable implementers to increase scale and coverage without proportionately increasing human resources.
4. The N/PTPs and all partner NGOs should more consistently demonstrate a spirit of genuine partnership. NGOs should respect the leadership role of the N/PTP, take time to nurture productive relationships at all levels, consult in developing and revising plans, and share detailed data analyses. The N/PTPs should welcome strong partner contributions and understand the differences between leadership/partnership and management/control. Collaboration should focus on joint problem-solving towards a common goal. It shouldn't matter who provides services, if every Pakistani with TB receives prompt, high-quality care with financial protection.
5. The NTP should include one or more PPM-specific targets amongst the priority indicators in the next NSP. Targets should include: the number of cases notified and managed under PPM; the proportion of pulmonary cases that are bacteriologically confirmed; treatment success by scheme; numbers of GPs, labs, pharmacies and hospitals notifying or referring at least one TB case; the amount of funding for PPM; and the amount of GoP funding for PPM.
6. The WHO STOP TB Partnership – Pakistan (supported by the Global Stop TB Partnership), and the NTP should ensure that multi-sectoral TB Task Forces at national and provincial levels include strong participation from the private medical sector, NGOs and CBOs. Task Force Chairs should be oriented on the importance of engaging all providers and of using their authority to encourage partnership rather than competition between PTPs and non-state actors of all kinds.
7. PPM NGOs should review the incremental cost-effectiveness of mass screening camps relative to engagement of GPs, labs and pharmacies, and allocate resources accordingly.
8. NTP and PTPs should invest time and resources to nurture the nascent partnerships with AKDN and military hospitals in order to capitalize fully on their potential contributions.
9. The NTP should reconsider objectives and plans for the mandatory notification pilot project. Rather than replicate PPM1, it may be more useful to support and learn from GSM's proposal to implement 100% coverage in one district, to experiment with the use of a Call Centre, and to test the impact of small incentives for pharmacies and labs.
10. The MoNHSRC should encourage Provincial Health Secretaries to instruct all public tertiary care hospitals to appoint dedicated TB teams, under the oversight of a senior manager, to improve referrals from the various OPDs to a TB unit and ensure reporting to the PTP.

11. PPM NGOs should address the low proportion of bacteriologically confirmed pulmonary TB patients by reviewing diagnostic and treatment algorithms, retraining clinicians and systematically monitoring care processes for clinically diagnosed patients.
12. The NTP should negotiate with IMS/IQVIA for access to quarterly information on private sales of anti-TB drugs, by Province, district and/or city, and use this data to monitor progress in PPM.

## Thematic area 8: Community TB Care and Prevention Responses

Context and status

Pakistan's TB – NSP 2017-2020 identifies engagement of lady health workers as an opportunity to improve TB outcomes, find missing persons with TB and find them earlier in the course of their illness. The TB-NSP highlights high levels of stigma, especially among high risk, low income groups, and includes strengthening meaningful partnerships with the Lady Health Worker (LHW) programme as one of the key actions to boost community engagement in TB.

The LHW community-based health programme covers between 50 and 70% of the overall Pakistan population. In order to operationalize and implement activities and strategies laid out in the TB-NSP 2017-2020, two pilots integrating TB into the LHW programme were started in 2017: one in Sindh and the other in Punjab. Both pilots have been yielding promising results and documented increase in case notifications. In Sindh, Mercy Corps, as one of the implementers of the current GF grant, reported up to a 17% increase in TB case notification in the implementation periods as compared to the same period in the previous year, prior to LHW engagement.

Pakistan has a strong civil society and community voice beyond TB and health. Stakeholder interviews during the review confirmed existence of a high number of national and local nongovernmental organizations (NGOs) working in health, poverty reduction and other topics relevant for Ending TB. Such NGOs could engage in community-based TB activities. Similarly, powerful private philanthropy in the country can be an opportunity for mobilizing partnerships for a suitable action to end TB, including at community level.

Challenges

Engagement of affected communities and civil society in planning, service delivery and monitoring and evaluation is very low outside of the two pilots. Where community actors are involved, this involvement is often poorly documented and largely remains unsupervised.

Programmatic attention to community-based activities is overall poor. Potential of community-based activities to boost notifications is largely underutilized. Large scale programmes such as Lady Health Worker programme sometimes have TB as part of their initial training and guidelines, however the linkages between the LHW and Provincial TB Programmes remain weak and haphazard. The national

TB recording and reporting tools include data fields for capturing community contributions to treatment adherence and referral of persons with TB symptoms, however these fields are not utilized nor reported to the central level. It is worth mentioning that Pakistan in the only TB high burden country with coverage of community health programme of more than 50% which does not report to WHO on contributions of community-based TB activities in line with WHO-recommended indicators.

Where good practices in community-based activities do exist, they remain largely unanalyzed and not promoted. Related bottlenecks go beyond the scope of this section and include insufficient horizontal and vertical coordination of activities at different levels. Coordination, reviews and monitoring progress is equally poor between provinces (especially as far as community-based TB activities are concerned) as well as between provinces and the central level. This is a major programmatic gap in the country.
Online search of TB in the media in Pakistan yielded very few results. The current regulatory requirement is for all national media to ensure at least 10% of their coverage (air time or published content) go to target issues of public health interest. Given this regulatory framework, media outreach is a major opportunity for boosting the TB response in the country.

Anecdotal proxies for very high stigma in line with the status at the time of the TB-NSP 2017-2020 writing was evident, including repetitive testimonies of isolation of persons with TB in households; high volume of examples of persons with TB hiding TB in families and communities and extremely low awareness of the TB burden and TB basics in meetings/interviews with less traditional TB partners within the country.

Recommendations

To enhance community engagement in the TB response in Pakistan the JPRM advises the National and Provincial TB programs, in collaboration with local partners to undertake the following activities:

1. Scale up the integration of TB into LHW programmes to support community-based activities such as a) identification of persons with TB symptoms, b) referrals of presumptive TB cases to diagnostic centres and or collection of sputum samples and transportation from the community to TB testing centres; c) systematic household contact tracing and screening and d) treatment support.
2. Standardize monitoring and evaluation using similar indicators and tools across provinces.
3. Develop a functional coordination mechanism among provinces and between the provinces and the central level.

4. Engage with local NGOs working in health and poverty reduction and prioritize engagement of those working among geographic areas with low TB case notifications and/or among TB vulnerable populations.
5. Nurture and promote engagement of affected communities as a powerful strategy to raise TB awareness and reduce stigma in the society.
6. Proactively scale up engagement of media and use of mobile phones and technologies in TB response to raise awareness about availability of free TB services in the public sector.
7. Ensure WHO-recommended community TB indicators are part of the TB module in DHIS-2 adapted to country context
8. Ensure explicit inclusion of persons and families affected by TB in major poverty reduction and philanthropic organizations and initiatives in the country including but not limited to BISP and Bait-ul-Mal.

## Thematic area 9: The TB Procurement and Supply Chain Management System

Review Findings

Procurement and Supply Chain (PSM) management of all three-disease programs i.e. AIDS, Malaria and TB are combined and have unified functions under an integrated common unit, supported by the Global Fund. PSM functions of TB commodities are being managed by a dedicated team of professionals, managing demand generation, quantification, procurement, distribution and storage.

Currently, the PSM Unit is renting a 33,000 square feet warehouse at central level to cater for the storage requirement of all three-disease programs. Considering the geographical spread and presence of storage facilities of the program across the country i.e. 4 Provincial warehouses and more than 140 district stores and quantum of load to feed all these warehouses, the MoNHSRC with the support of GF has proposed the construction of state-of-the-art central warehouse of about 60,000 square feet, which is currently under discussion. Pakistan is a critical country for the fight against TB. An efficient pharmaceutical and health products management is key to ensure access to affordable and efficacious treatments. The context in Pakistan requires close coordination by the NTP with the PTPs as well as the TB treatment sites in each of the regions and provinces. Coordination is also required not only vertically within the TB program but also externally with the Drug Regulatory Authority of Pakistan (DRAP) and with the Ministry of Planning and Finance. Data quality and regular information sharing for forecasting and management of pharmaceutical and health products at all levels are needed for a smooth procurement and efficient supply chain.

Noted that the JPRM also doubled up as Global Drug Facility (GDF) Technical Assistance (TA) mission and a separate GDF - TA Mission Report will be submitted with a more detailed PSM review for Pakistan.

Strengths

1. All medicines and supplies required for TB program management (FLDs, SLDs, new FLD and SLD pediatric formulation, medicines for the therapy of LTBI and laboratory commodities) are available in the country, including new drugs and diagnostics.
2. No major national stock outs were noted.
3. Early warning system at the national level using QuanTB exists to monitor drug stocks situation and supply planning.

4. Since the country has moved to a devolved system of health care including TB drug procurement, provinces are expected to co-finance and procure a portion of the provincial anti-TB medicine requirements. In 2018, 3 (Punjab, Sindh and Baluchistan) out of 4 provinces procured FLDs for adults from local suppliers.
5. Provincial regulations exist to control the sales of TB drugs in private pharmacies by restricting sales without prescription.

Challenges and weaknesses

1. Although there are provincial regulations to control over the counter sale of anti-TB drugs, there is still rampant sale and use of these medicines without prescription. Tuberculosis drugs are available in private pharmacies, which has been a concern in that the private sector that is not linked to the TB Program is probably using these medicines incorrectly thereby contributing to the generation and expansion of the burden of drug resistance in the country. Furthermore, several formulations of TB drugs available in the private pharmacies are not compliant with the WHO or the national TB guidelines, for example the old pediatric formulation, which provides a barrier in administering correct and appropriate doses.
2. Under the current GF grant, the NTP together with the provinces agreed to a phased co-financing and procurement of FLD requirements. The agreed contribution should be 50% in 2018, 70% in 2019, and 80% in 2020. The review found out that contribution and actual release of government funds for TB drug procurement is less than the agreed commitment, standing at about 20% instead of 50% requirement in 2018. Furthermore, these procurements were not fully coordinated and reconciled at the national level. The weak coordination and poor reconciliation of provincial TB Program medicine procurements with that of the National TB Program PSM supply planning resulted in an imbalance in the overall drug supply. The First Expiry First Out (FEFO) principle is being violated in some instances to allow the consumption of provincial government procured medicines first.
3. A standard operating procedure for PSM was developed in 2014. With the change in the TB drug procurement landscape in Pakistan as well as the change in management because of devolution, there is no clear guidance for the proper management of drug supplies and the tools for inventory and reporting are not standardized. During field visits, there were vertical duties and responsibilities of facility staff responsible for FLD for DS-TB and SLD for DR-TB treatment. One-point person is responsible for FLD and another person is responsible for SLD, when these functions could have been harmonized and vested in one person to maximize the use of the pharmacist in the facility. In

addition, there were short-term stock outs and near expiry found during the visits, which clearly indicates that facility staff require capacity building in PSM, including inventory management.

4. Adverse events (AE) experienced by the patients were identified and managed at the facility. There is a patient-based form where AEs are recorded, however this is not linked and reported to DRAP, who have the mandate on pharmacovigilance and patient's safety.

Recommendations

To improve the TB PSM system the JPRM advises the NTP/PTPs and partners to undertake the following activities:

9. Coordinate closely with DRAP to implement the following interventions:
    1. Enforce the regulation to restrict TB drug sales without prescription. The regulation is available and so the NTP and DRAP needs to have a good strategy on how to enforce the regulation.
    2. Ensure TB drugs available in the country, including those in private pharmacies are quality-assured and in formulations that are compliant to WHO guidelines.
    3. Develop the national framework of active Drug Safety Management & Monitoring (aDSM) to ensure patients safety, especially since there are many new TB drugs as well as off-label use of medicines in the TB program.
10. Enhance government financing to procure internationally quality-assured products according to agreed co-financing agreements.
11. Plan the quantification and procurement of TB medicines including the provincial TB drug procurements to harmonize and reconcile quantities for national supply planning.
12. The PSM unit at CMU should update the SOP for the management of drugs and lab supplies; train staff and strengthen monitoring and supervision of PSM. As part of the SOP for the management of drugs and lab supplies, the program needs to agree on a standard format of inventory records and reporting tools. Training including dissemination of the SOP and standard forms need to be disseminated from the national level down to the facility level. Regular and effective monitoring and supervision is required to ensure proper supply management.

## Medicine Quantification and Forecasting

PSM Supply Chain team is well versed and trained on the latest tools being used for quantification and forecasting. There is a PSM Technical Working Group (TWG) that meets bi-annually or on case-to-case basis to update the quantification files, review the consumption of anti TB medicines and take corrective measures to ensure implementation of early warning system of stock outs. In this JPRM/GDF TA mission, two days were dedicated to updating the quantification files to ascertain future demand while considering the domestic procurements and financial situation.

### FLDs Adult

The assumptions made in the quantification exercise include: considering the 6 months of buffer stock / minimum months of stock because the district and health facility stocks are not included as stock on hand; local procurements by PTPs; IPT at 5% of the adult DS-TB cases in 2019; Indus Health Network will provide the weekly dose of Isoniazid and Rifapentine (3HP) for LTBI treatment for 17,000 cases over the next 2 years. Monitoring the consumption of FLD is recommended to consume near expiry stocks first before the consumption of medicines procured at Province that would arrive in the PTP warehouse as fresh supplies.

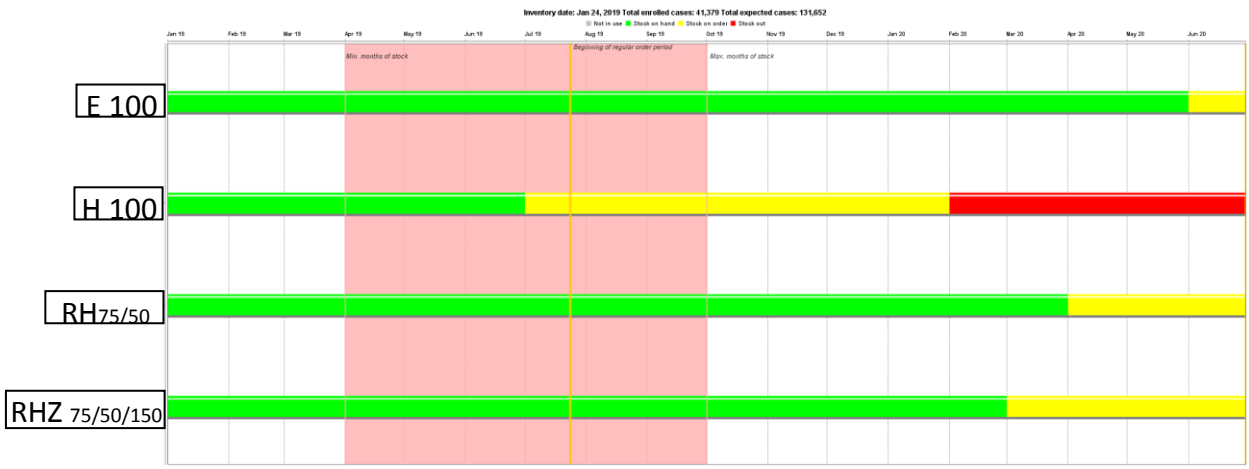
Figure 15: Quantification for adult FLDs


### FLDs Pediatric:

Assumptions for Pediatric FLD have been revised in this quantification and include: 2 and 3 tablets of RHZ and RH for children below 4 years of age and 5 to 10 years of age respectively; children above the age 10 years will receive adult regimens, with the estimate that these children contribute around 25% of

5-14 years age bracket. The dashboard below depicts that the situation has no risk of stock outs, and medicines needed to treat children are available in country and in the pipeline. However, there is a need to monitor the consumption trends and expiries due to shorter shelf lives of available stocks across the supply chain.

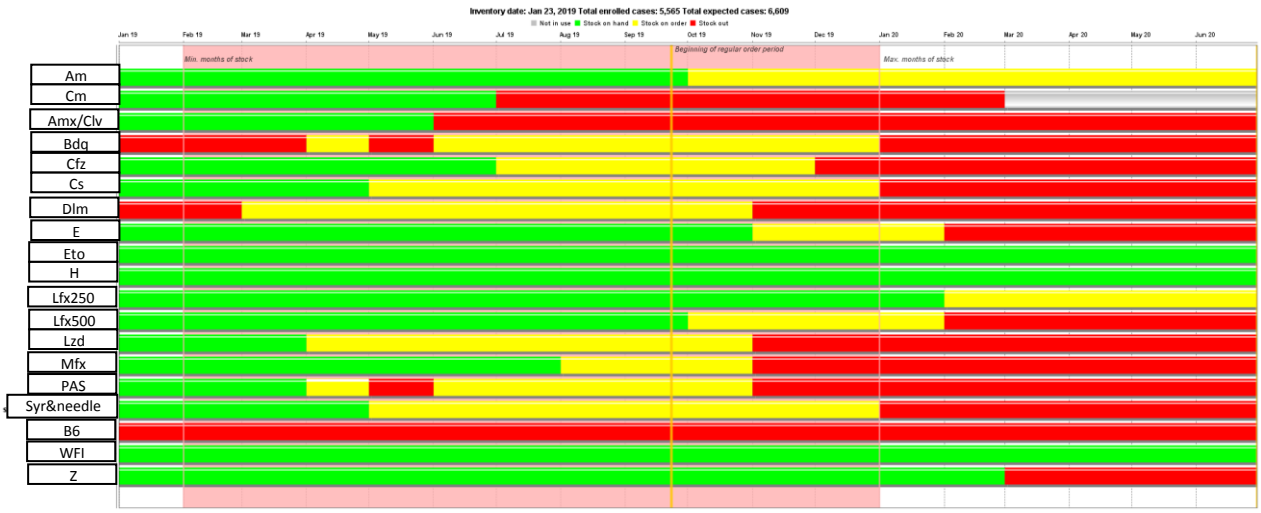
Figure 16: Quantification for paediatric FLDs




## SLDs:

Quantification was done based on the following assumptions: current enrolled patients on old regimens and new enrollments from April 2019 that will shift to the new WHO guidelines, adopting the phase in and phase out approach; enrollments trends on new proposed regimen and the order of 2,016 patient courses that was placed with GDF to avail Bedaquiline through the donation program that ends on 5 March 2019 to determine the requirement of Bedaquiline. There was pressure in supply chain for some of the SLDs like, Bedaquiline, Delamanid, PAS, Clofazimine and shipments in pipeline need to be expedited to avoid stock outs. The other medicines are enough to cater for the need of the Program until June 2020. It was decided that the procurement request will be submitted after updating the quantification files during mid-year supply chain review.

Figure 17: Quantification for SLDs




The following are the new proposed RRTB regimens used in the quantification:

| | |
|---|---|
| LTR1 Regimen: 6 Bdq-Cfz-Cs-Lfx-Lnz-Z / 14 Cfz-Cs-Lfx-Z | 22% |
| LTR2 (FQ Resistant Patients) :6 Bdq-Cfz-Cs-Lnz-Mfx-Z / 6 Cfz-Cs-Lnz-Mfx-Z / 8 Cfz-Cs-Mfx-Z | 40% |
| LTR3: 6Bdq-Cfz-Cs-Dlm-Eto-Lfx-Lnz-Z/6 Cfz-Cs-Eto-Lfx-Lnz-Z /12Cfz-Cs-Eto-Lfx-Z | 8% |
| STR: 4Am-Cfz-E-Eto-H-Mfx-Z /5Cfz-E-Mfx-Z<br>30% | |

## Thematic area 10: The TB Health Management Information System

Findings

The NTP has developed an adequate information system to monitor TB notification and the implementation of TB prevention, care and treatment activities and to evaluate their outcomes. This system includes: i) a presumed TB patients' register, ii) a request form for sputum examination, iii) a TB microscopy and Xpert register, iv) a laboratory culture request form, v) a TB treatment register, vi) a facility-based patient treatment card, vii) a patient identity card, viii) a sputum conversion reporting form, ix) a referral form, x) a quarterly TB registration reporting form, xi) a quarterly treatment outcome reporting form, and xii) a quarterly TB drugs' inventory reporting form.

Most of the components of this information system are implemented and used in all the BMUs visited during the review. 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 program, has been developed and implemented in the PMDT sites.

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

Strengths

1. 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 in general adequately filled, and include, most of the time, the required information. The quarterly reports on TB notification and treatment outcomes are made in all the BMUs visited and include detailed information.
2. In many districts, the data included in the quarterly reports are reviewed and discussed in the district quarterly meetings with the staff of the relevant BMUs.
3. The required data on TB activities undertaken in the private sector are collected through the NGOs and included in the NTP information system.
4. The information system of NTP has succeeded to collect a significant amount of data that are used for advocacy purposes, epidemiologic surveillance and programmatic management

purpose, including supervision activities. The results of data analysis contribute to identify hypothesis for operational research.

5. The NTP prepares and issues every year an annual report on TB notification, interventions developed and implemented and TB services outcomes. This report is widely distributed and forwarded to those who need to be informed.

Weaknesses

1. Even though the NTP has issued a register to identify specifically presumed TB patients, this register is not available in many BMUs visited. The information on patients identified as presumed TB cases is not collected in most of the BMUs. In addition, the NTP has not issued clear guidance on how to use this register, especially how it should be linked to TB laboratory register and OPD register.
2. The request form for bacteriological examination is not uniform. In some health facilities visited, the request forms for sputum examination do not include items to collect information related to a request on Xpert testing; in others, the request forms available include items for both microscopy and 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.
3. Given the low proportion of previously treated patients among all registered TB cases in some districts and provinces (Baluchistan, 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.
4. Different TB treatment registers are used in the BMUs visited during the review. The most recent of them included unnecessary columns for CXR, especially at the 2nd and 5th months of treatment. Regardless of the type of TB treatment registers (old or recent), no columns are included on HIV screening, ARV treatment and co-trimoxazole provision. In some BMUs, there is a separate register on HIV screening and treatment with ARVs and co-trimoxazole.
5. As highlighted above:
    - the component on contact investigation included in the facility-based patient treatment card does not allow to collect all the relevant data on TB contact investigation activities and preventive treatment,
    - 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 and TB preventive treatment and to evaluate their outcomes.

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

Recommendations

1. The presumed TB patients' register should be made available in all the OPDs, BHUs, dispensaries and MNCH centres. The information included in this register needs to be compared with that included in the OPD and TB laboratory registers (see details in "Recommendations" in the section on "Drug susceptible TB case-finding and management"). The NTP should issue guidance on how to use the data collected in the presumed TB patients' register and to compare the data included in this register with that in the OPD and TB laboratory registers.
2. The request form for sputum examination should include a component on Xpert testing. A uniform request form, which includes items to collect information related to both microscopy examination and Xpert testing, should be used everywhere even in the NGO settings.
3. A uniform TB laboratory register needs to be available in all the TB laboratories.
4. The TB treatment register needs to be revised to remove the unnecessary CXR columns and to include columns for HIV information. The revised register should be made available in all the BMUs, including those of the private sector.
5. A focus should be made, in the training on basic TB, on the definitions of TB cases and treatment outcomes, including on the previously TB treated patients and their various categories (see "Recommendations" in section on "Drug-susceptible TB case-finding and management").
6. During their supervision visits in the BMUs, the district supervisors should carefully check the quality of the data collected in the various registers and compiled in the quarterly 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.
7. As highlighted in "Recommendations" in the section on "Contact investigation" an index TB case form need to be designed in such way that it can include all the information on TB contact investigation activities (see example in Annex 5).
8. The NTP should clearly define indicators to monitor the implementation of TB contact investigation and to evaluate its outcomes. The following indicators are proposed:
    - Monitoring indicators
        - 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.

9. As highlighted above (in "Recommendations" of the section on "Latent TB infection management"), a standardized registration system for TB preventive treatment should be designed and established by the NTP. The NTP should also define clear indicators to monitor the implementation of LTBI management and to evaluate its outcomes.
10. The NTP information system needs to be linked to the DHIS2 which is in the process of implementation.
11. The relevant provincial staff need to be further trained on methodology of data analysis using for example the Data for Action Course that has been developed by the IUATLD.

## Thematic area 11: Research for better TB care and prevention in Pakistan

### Situation Analysis

As part of the effort to fully implement the END TB Strategy including pillar 3, the CMU/NTP set up a research unit to undertake operations research for the program. The major goal is to utilize the rich TB data in the country and to link research with surveillance to build the evidence for policy change at the country level. The research unit within the CMU that has been implementing the Structured Operational Research Training Initiative (SORT IT) in Pakistan, encompassing all three modules (module 1: proposal development; module 2: data analysis and module 3: manuscript writing and publication) in collaboration with the WHO, GF, and The UNION, since 2016 when the first course was conducted , with the goal of developing operations research capacity as a sustainable solution to improve program performance. The Global Fund is providing the funding to support Pakistan's SORT IT courses. The plan is to launch a SORT IT course call for applicants in March every year and to select potential course participants using standard competitive criteria set by The Union.

Strengths

- In total 40 manuscript have been published since the research unit was established with 20 of them coming from SORT IT alone. These manuscripts can be assessed at http://www.ntp.gov.pk/resource.php
- About 21 institutions in Pakistan are involved with operational research as a result of the SORT IT initiative.
- There is a diversity of topics and disease programs i.e. event-based surveillance system, effectiveness of e-health intervention on IYCF, malaria surveillance system, hepatitis B &C, burden of HIV in prisons, PPM intervention comparison, retreatment TB cases, treatment outcomes among extra-pulmonary cases of TB, comparison of public and private sector TB case notifications and MDR .
- SORT IT course participants and the research projects that arise from these courses come from and cover all provinces in Pakistan including AJK.
- An expanding pool of trained researchers is available at the National and Provincial level to continue generating useful evidence leading to positive policy changes.

- The success story of the Pakistan SORT IT initiative was duly acknowledged by WHO TDR in the last Joint coordinating board meeting as highlighted in this article available at https://www.who.int/tdr/capacity/alumni/razia-fatima/en/.

Weakness

- There are significant resource constrains. In the current Global Fund grant, only USD 180, 00 per year is allocated to SOTR IT courses for module 1 and 2 with no funding for module 3 (manuscript writing).

Recommendations

- The N/PTPs should continue to strengthen program based operational research as a key component of the END TB strategy to generate evidence to support policy and practice recommendations to End TB in Pakistan.
- As part of the process to strengthen program based operational research, the N/PTPs, should mobilize resources from all possible sources, at both the national and international level through bilateral and multi-lateral cooperation.

## Proposed list of TB research priorities

- The N/PTPs should develop a prioritized list of research topics which may include but not limited to the following:
    1. The patient cost survey as recommended by the most recent TB Epi review.
    2. A clinical audit to assess the proportion of clinically diagnosed TB cases who are true cases of TB and the TB treatment outcomes of clinically diagnosed cases.
    3. Assessment of TB service delivery system at the PHC level including referral systems
    4. An audit/review of child TB notifications to develop a hypothesis for the apparent under-reporting in some provinces (Punjab, Baluchistan) and the over reporting in others (GB, KP).
    5. Assess and monitor amounts of anti-TB medicines sold by private pharmacies and attempt to understand who the clients/beneficiaries are.
    6. Assess and monitor changes in TB case notification that can be attributed to the law on mandatory TB case notification.
    7. Risk factors for drug resistance, with special focus on the informal private sector
    8. Assess models of linkages between Xpert labs, PMDTs and BMUs to improve access to the Xpert test.
    9. Tuberculosis in adolescents 10-18 years age in Pakistan (using existing EMR data)
    10. Tuberculosis in health care workers

11. Evaluation of the NTP diagnostic algorithm on pediatric TB cases notification
12. Assessment of innovative strategies for contact screening.
13. How can joint TB and HIV interventions best be integrated and cost-effectively delivered at community and health sector levels and in settings with different TB and HIV epidemiological status?
14. What is the feasibility and effectiveness of bi-directional TB and diabetes screening in TB and diabetic clinics?
15. Which risk groups and vulnerable populations have highest risk of TB? What is the impact of enhanced and targeted contact investigation in settings with limited resources?
16. Effect of decentralization of treatment services on treatment outcomes of DR-TB.
17. Effect of sputum transportation systems on the promptness of TB diagnosis including DR-TB and treatment outcome MDR-TB.
18. Implementation research for oral short regimens for FQ sensitive patients in selected PMDT sites to follow up and document outcomes.
19. Assessment of the STR for MDR- TB

## Technical Assistance Needs

The NTP may wish to contact providers of technical assistance to support the adoption and implementation of interventions related to:

1. Data driven supervision to support the use of data to drive interventions at the local level.
2. Support in the development of the next TB – NSP with a focus on the choices that need to be made during prioritization of interventions based on cost and effectiveness. A well-developed TB-NSP which includes the prioritization of interventions based on the funding scenario may be better suited to support the next funding request to the GF.
3. DR-TB decentralization and adoption of new regimens
4. Further development of the TB laboratory capacity, especially the introduction of genome sequencing procedures.

# Annexes

## Annex 1: JPRM Participants

**A: Islamabad Capital Territory**

| | |
|---|---|
| Dr. Chakaya Muhwa | External reviewer, overall JPRM team lead |
| Dr. Thomas Chiang | External Reviewer (USAID) |
| Dr. Qadir Khan | External reviewer (USAID) |
| Ms. Lana Syed | External reviewer (WHO), thematic lead, community responses |
| Dr. Aurangzaib Quadir Baloch | Internal reviewer, NTP manager |
| Dr. Razia Fatima | Internal reviewer, research unit, CMU |
| Ms. Amina Mahfooz | Internal reviewer, CMU, partnership and communications unit |
| Ms. Ammara Omer | Internal reviewer, CMU, partnership and communications unit |
| Mr. Zubair Shad | Internal reviewer, CMU, partnership and communications unit |

**B: The Sindh Team**

| | |
|---|---|
| Guy Stallworthy | External reviewer, independent PPM Specialist, Team Lead/ thematic lead PPM |
| Dr Einar Heldal | External reviewer, WHO consultant, thematic lead, DR-TB |
| Dr Salah Ottmani | External reviewer, independent consultant, thematic lead, DS- TB |
| Dr Abdul Ghafoor | External reviewer, MDR TB consultant, USAID |
| Ms. Zaza Munez | External reviewer, PSCM Specialist, GDF, thematic lead, PSM |
| Dr Muhammad Aamir Safdar | Internal reviewer, PPM Specialist, NTP |
| Mr. Naveed Chaudhary | Internal reviewer, PSCM, CMU |
| Mr. Abdullah Latif | Internal reviewer, Data Manager, CMU |

**C: The Baluchistan and Khyber Pakhtunkhwa team**

| | |
|---|---|
| Dr. Muhammad Akhtar | External reviewer, TB Regional Advisor/EMRO-WHO |
| Mr. Choub Sok Chamerun | External reviewer, Executive Director KHANA |
| Dr. Syed Hussain Hadi | Internal reviewer, Advisor Policy & Strategy-NTP |
| Dr. Fakhra Naheed | Internal reviewer, M&E Officer-NTP |

| | |
|---|---|
| Dr Yasir Waheed | Internal reviewer, M&E Officer-NTP |

**D: The Punjab Team**

| | |
|---|---|
| Dr. Christian GUNNEBERG, | External reviewer and Team Lead, WHO, HQ |
| Dr. Daniela Maria Cirillo , | External reviewer, Lab Consultant/thematic lead, lab network |
| Dr. Einar Heldal, | External reviewer, WHO consultant, thematic lead, DR- TB |
| Dr. Farhana Amanullah | External reviewer, WHO consultant, thematic lead, child TB/ TB and HIV and other co-morbidities |
| Dr. Sabira Tahseen, | Internal reviewer, Advisor NRL, NTP |
| Dr. Khawaja Laeeq Ahmad, | External reviewer, TB Consultant, WHO Pakistan country office |
| Dr. Raja Muhammad Ayub, | Internal reviewer, M & E Specialist; CMU, NTP |
| Dr. Zafar Iqbal Toor, | Internal reviewer, MDR-TB Specialist, NTP |
| Mr. Obaidullah Baloch, | Internal reviewer, Deputy Manager Procurement, CMU |

**The Global Fund Team (Joined the discussions to synthesize findings from the field and formulate mission recommendations)**

| | |
|---|---|
| Dr. Mohammed Yassin | Senior TB advisor |
| Dr. Shukhrat Aripov | Senior Program Officer |
| Mr. Werner Buehler | Fund Portfolio Manager |

## Annex 2: Recommendations of the 2019 JPRM

| Thematic Area | Recommendation | Duty Bearer (s) | Time Frame |
|---|---|---|---|
| Political Commitment | Declare a Pakistan END TB initiative at National and Provincial level | Advocacy efforts by MoNHSRC, MoHs, Stop TB Partnership- Pakistan, Stop TB Partnership – Global, WHO, The Union, local partners and others | March 24, 2019 |
| | Establish National / Provincial Steering Committees chaired or with the oversight of PM and CMs | Advocacy efforts by MoNHSRC, MoHs, Stop TB Partnership- Pakistan, Stop TB Partnership – Global, WHO, The Union, local partners and others | Within 3-6 months after the JPRM |
| TB response financing | Increase Government allocation to health and TB. | Advocacy efforts by MoNHSRC, MoHs, Stop TB Partnership- Pakistan, Stop TB Partnership – Global, WHO, The Union, local partners and others | Continuously |
| | Mobilize additional financial and other resources from local partners including in CSR program | N/PTPs and local partners | Continuously |
| | Develop a new TB NSP with sets of prioritized interventions for available funding levels | N/PTPs and local partners | December 2020 |
| | Work with Prime Minister's Health Insurance Program to include TB in the benefit package | NTP | 2021 |
| Multi- Sectoral Approach to TB care and prevention | Establishing a National multi- sectoral technical committee. | N/PTPs and local partners | Within 3 months of the PJRM |
| | Develop a prioritized list of sectors/partners to be engaged in the TB response. | N/PTPs and local partners | Within 3 months of the JPRM |
| | Develop a Pakistan specific Multi- Sectoral Accountability Framework and mechanism for timely reporting | N/PTPs and local partners | Within 3 – 6 months of the JPRM |
| Social Protection | Include TB patients in on–going social support programs to cushion them from catastrophic health expenditures. | N/PTPs | Within 3-9 months |

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| Program structure, function and capacity | Enhance skills and capacity of the N/PTPs to provide leadership to the national/provincial TB response | MoNHSRC/MoHs | Within 3-6 months and continuously |
| | Reduce dependency on external financing for critical human resources at the N/PTPs | MoNHSRC/MoHs | Immediately and continuously |
| Tuberculosis Case Finding and management (DS-TB) | Progressively engage all BHUs in the provision of TB services | MoNHSRC/MoHs though N/PTPs and partners | Immediately and continuously |
| | Enhance identification and management of presumptive cases at OPD settings | MoNHSRC/MoHs though N/PTPs and partners | Immediately and continuously |
| | Finalize the new guidelines on TB case management and make them available for all the health professionals regardless of the health sector they belong to | N/PTPs and partners | Within the 3 months following the JPRM for finalization and 1 year for training |
| Pediatric TB diagnosis and management | Train and support clinicians and other health care workers to correctly manage children with presumed and confirmed TB | N/PTPs and local partners | Immediately and continuously |
| | Designate 50% THQ/RHCs as “Child TB sites” with CXR facility and referral of only complex cases to DHQ level (PTP) | N/PTPs | Immediately and continuously |
| TB/HIV and other co-morbidities | Expand and strengthen HIV testing and pretest counseling in TB patients (learn from Punjab experience) | N/PTPs/NACP | Immediately and continuously |
| | Integrate TB in chronic lung disease, diabetes, malnutrition, MNCH, HCV clinics | N/PTPs and local partners | Immediately and continuously |
| Engaging all care providers (PPM) | Increase proportion of private primary care providers (GPs, pharmacies, labs) actively engaged in TB program from <5% to >20% and double | N/PTPs and local partners | Within 3 years |

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| | quality-assured private case management | | |
| | Increase funding for PPM, especially for engagement of private primary care providers | N/PTPs, Global Fund and other partners | Immediately and continuously |
| | Develop digital technologies to facilitate PP engagement at scale (registration, patient tracking, adherence support, digital transfers) and mandatory notification. | N/PTPs and | Within 3 years |
| | Demonstrate a more consistent spirit of genuine partnership | N/PTPs and NGOs | Immediately and continuously |
| | include PPM-specific targets in next NSP | NTP | December 2020 |
| | Government of Pakistan to begin to assume responsibility for funding PPM and social contracting | MoNHSRC, MoHs, local TB advocacy groups | From 2020 |
| | Ensure strong participation of, and focus on, non-state actors in TB Task Forces and other accountability mechanisms | MoNHSRC, MOHs, N/PTPs, Stop TB Partnership, WHO | Immediately and continuously |
| | Review the incremental cost-effectiveness of mass screening camps relative to engagement of GPs, labs and pharmacies, and allocate resources accordingly | Greenstar Social Marketing, Mercy Corps, Community health Solutions | 2019 |
| | Nurture the nascent partnerships with AKDN and military hospitals to capitalize fully on their potential contributions | N/PTPs | Immediately and continuously |
| | Reconsider objectives and plans for the mandatory notification pilot project | N/PTPs | 2019 |
| | Address the low proportion of bacteriologically | Greenstar Social Marketing, Mercy Corps, | Immediately and continuously |

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| | confirmed pulmonary TB patients | Community health Solutions | |
| | Negotiate with IMS/IQVIA for access to quarterly information on private sales of anti-TB drugs, by Province, district and/or city, and use this data to monitor progress in PPM | NTP | 2019 |
| | Instruct all public tertiary care hospitals to appoint DOTS team for Hospital DOTS Linkage | Health Secretaries at MoHs | Within 3 months of the JPRM |
| Community Engagement | Scale up the integration of TB into LHW programmes | N/PTPs and local partners | Immediately and continuously |
| | Map national, provincial and local NGOs working in health and poverty reduction and strengthen engagement | N/PTPs and local partners | Within 3-9 months of JPRM for the mapping and continuously for the engagement |
| | Nurture and promote engagement of affected community, engagement of media including use of mobile phones and technologies | N/PTPs and local partners | Immediately and continuously |
| The TB Laboratory Network | Finalize, disseminate and implement the revised diagnostic algorithm | N/PTPs, local partners, TA providers | Within 3-6 months |
| | Increasing the categories tested by Xpert (algorithm modification), enforce the use of Xpert for diagnosis of TB in children and EP. | N/PTPs, local partners | Within 3-9 for guideline revision/continuously for implementation |
| | Establishing a functional sample's transport and reporting mechanisms starting from BHU level | N/PTPs, NRL, PRL, local partners | Immediately and continuously |
| | Increase the capacity for LPA, culture and DST and strengthen the link of PRLs with NRL | NTP/PTPs, NRLs, PRLs, local partners, TA providers | Immediately and continuously |
| | Establish capacity at NRL to perform regular molecular and phenotypic surveillance of emerging resistance and consider starting transmission studies | NTP/PTPs, NRLs, PRLs, local partners, TA providers | Immediately and continuously |

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| Drug Resistant TB | Further decentralize management of DRTB to district level | NTP/PTPs, NRLs, PRLs, local partners, TA providers | Immediately and continuously |
| | Strengthen the flow of Xpert results to ensure that all RR patients are started on treatment promptly. | N/PTPs, NRLs, PRLs and local partners | Immediately and continuously |
| | Update national guidelines and align treatment regimens with new WHO recommendations and national characteristics | N/PTPs and providers of TA | Within 6-9 months of the PJRM |
| The TB Procurement and Supply Chain Management System | Enforce the regulation to restrict TB drug sales without prescription | DRAP | Continuously |
| | Ensure TB drugs are quality-assured in formulations that are compliant to WHO guidelines | DRAP | Continuously |
| | Develop the national framework of active Drug Safety Management & Monitoring (aDSM) | DRAP/N/PTPs, local partners | Within 6-9 months of the PJRM |
| | Plan the quantification and procurement of TB medicines with NTP PSM, to harmonize and reconcile quantities for national supply planning | N/PTPs, Procurement unit CMU | Continuously |
| The TB Health Information System | The presumed cases' register should be made available in all the OPDs, BHUs and dispensaries. | N/PTPs | Immediately and continuously |
| | The treatment register needs to be revised with columns for HIV information. | N/PTPs | Immediately and continuously |
| | Design and implement an index TB case form to capture all the relevant information on TB contact investigation activities and establish appropriate monitoring and evaluation indicators | NTP | Within 3 months after the review |
| | A standardized register of TB preventive treatment should be | | |

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| | designed (see example of model. | | |

## Annex 3: Recommendations and Action points of the 2015 JPRM

| | Recommendation Action Point<br>*Pakistan International Review*<br>*3-12 May, 2015* | OUTCOME |
|---|---|---|
| | **Political Commitment & Programme Management** | |
| 1 | Gradually increase the financial support from the domestic resources at both National & Provincial level | Level of commitment increasing only |
| 2 | Coordination with donor and technical agencies such as World Bank, JICA, USAID, KfW, DFID, UNICEF, etc at national and provincial level should be enhanced. This can be done by revitalizing the IACC at federal level and sub-committees at provincial level | Not done. Partners called together ad hoc |
| 3 | Timely initiation of the process of preparing case for the releases of the PC-1 funds | Not done: PC 1 release still problematic |
| | **TB Case Notification& Outcomes** | |
| 4 | More efforts are required to increase case notification by including systematic screening and active case finding in routine TB care | Efforts have increased to do systematic screning |
| 5 | All the specialties in tertiary and district hospitals should be involved in systematic TB screening. In each hospital a "TB control board" may be considered to be formulated to be chaired by the in-charge hospital and participated by representative of all specialties to discuss TB care progress in the hospital on regular basis | Screeners have been employed in PPM 4 which specifically is geared towards tertiary hospital TB engagement |
| | **Laboratory diagnosis of TB** | |
| 6 | Promote mandatory notification of TB laboratory diagnosed cases in all provinces | |
| 7 | Ban the use of serological diagnostic tests for active TB disease | ? |
| 8 | Expedite the upgrade of NRL (currently unsafe) and consider that the new layout should include sufficient space to avoid transfer of hazardous material from different sites | |
| 9 | Evaluate the introduction of an efficient electronic reporting system at least for GeneXpert MTB/RIF reports | |
| 10 | Promote the use of GeneXpert and liquid culture for Childhood and EP TB | |
| | **Drug Resistant TB** | |
| 11 | Regional GLC should ensure one yearly PMDT monitoring mission | Two missions since 2015 |
| 12 | MoH/NTP should continue increasing national funding for TB including DR-TB and use the current GF project period as an opportunity to prepare for an eventual phase-out, gradually bringing PMDT into | |

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| | routine NTP activities so that it gets the place and attention corresponding to its public health importance | |
| 13 | NTP should as soon as possible introduce routine rapid testing of 2. line drugs (quinolones and injectables) of all RR/MDR patients | |
| 14 | NTP should consider increasing the number of GeneXpert sites particularly in Punjab | |
| 15 | NTP should continue their plans to introduce short course MDR regimen in line with WHO guidance | |
| | **Engaging all health care providers** | |
| 16 | The PPM component of the PTPs needs to be strengthened | PPM contributions have increased |
| 17 | Involvement of private sector and community-based organizations such as People's Primary Healthcare Initiative (PPHI) in TB care, under the guidance of NTP, needs to be accelerated | Little progress with community organizations or PPHI |
| 18 | Approval and enforcement of the law on mandatory TB notification should be implemented nationwide | Laws enacted in most provinces but implementing by-laws pending |
| 19 | The role of each partners and stakeholders must be clearly defined for the quality and effective implementation of the PPM | Continued tensions in some relationships with key partners |
| | **Engagement of civil society organizations** | |
| 20 | The program must reconsider to sustain the activity even if there is no provision of grant from the donor side by integrating and strengthening TB into the existing community-based work focusing on issues related to TB (e.g. primary health care, education, livelihoods, other public sector run clinics, agriculture and cooperative groups) | Some pilot activities in community-based care |
| 21 | The NTP must develop community-based M & E tools to monitor and track the contribution made from community side focusing total number of presumptive TB referred from the community, case notification among the referred cases and treatment success rate of those TB patients, who are receiving treatment in community in line with The Engaged TB Approach | Indicators adopted by NTP though not being systematically utilised |
| 22 | User-friendly recording and reporting tools must be developed to measure the contribution of awareness activities in community level | See above |
| 23 | Re-assess the knowledge of LHWs in community-based TB control activities and enhance their capacity based on the findings | Done only in pilot districts in last year. |
| | **Drug Management** | |
| 24 | Ensure that locally produced anti-TB medicines in Pakistan are in line with WHO standard of quality and dosage formulation of fixed dose combinations. Private pharmaceutical companies if accredited by | USAID support is moving the country in this direction |

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| | WHO could play a bigger role at the national and global level for the supply of quality assured ATB drugs | |
| 25 | Promote the up gradation of an institute in the country that can obtain WHO accreditation as a quality control laboratory to perform bioequivalence testing of ATB drugs | |
| 26 | Promote the rational use of antibiotics and ensure legislation on ban of over-the-counter sales of anti-TB medicines | |
| | **TB HIV Data and others** | |
| 27 | Rapid scale of TB-HIV collaborative activities in all sentinel sites across the country | |
| 28 | Consultative process with all stakeholders (National and Provincial Programs to determine their needs and select a tool that will encompass the needs of the program for both DS and DR TB. The tool should also have a module that will allow the entry of laboratory information, Drug management and generate an early warning to avoid stock outs and over stocking | |
| 29 | Training workshops for Trainers and Data entry operators at the District , Provincial and National levels | |
| 30 | A "Research Agenda" at national level to be formulated and provincial TB control programmes should be actively involved in designing and implementing research studies | Focal point in GF grant structure with Sort-it grant funding |
| 31 | National level STOP TB partnership forum should be established at federal level | Stop TB Forum strengthened . (Check if national level organization) |
| | | |

| Key to color code | |
|---|---|
| Achieved | |
| Some progress/ Ongoing | |
| No change | |

## Annex 4: Example of index TB case form

# National Tuberculosis Program of Pakistan

## Index Tuberculosis Case Form

1. Identification number of the index TB case in the TB treatment register: ……..

2. First and last of the index TB case: ……

3. Age: …… 4. Sex: …… 5. Form of index TB case (tick or circle): - BCPTB (or all PTB??)
- Childhood TB
- MDR/XDR-TB
- TB/HIV

6. Identification and screening/assessment of household contacts

| Name of TB contacts | Age in years | Sex (M/F) | HIV status* | Outcome of TB screening and assessment** | TST/IGRA outcome*** | Isoniazid preventive treatment (yes/no) | Identification number in the isoniazid preventive treatment register**** |
|---|---|---|---|---|---|---|---|
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TB: tuberculosis; M: male, F: female; TST: tuberculin skin test; IGRA: Interferon-gamma release assay

*: The HIV status may be: “HIV-positive”, “HIV-negative” or “Unknown HIV status”;

**: The outcome of TB screening and assessment mmay be: “No active TB”, “BCPTB”, “CDPTB” or “EPTB”; if the contact has a BCPTB, CDPTB or EPTB, specify her/his number in the TB treatment register of the MBU;

***: The outcome should be one of the followings: “Not done”, “Positive” or “Negative”, if the contact is aged more than 5 years;

****: This information should be specified only for the contacts who are prescribed IPT.